NATIONAL CHICKEN COUNCIL

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U.S. Department of Agriculture
1400 Independence Ave. SW
Washington, DC 20250

Re: Docket No. FSIS-2023-0028: *Salmonella* Framework for Raw Poultry Products

Dear Ms. Edelstein:

The National Chicken Council (NCC) appreciates the opportunity to comment on the proposed rule and proposed determination "*Salmonella* Framework for Raw Poultry Products," published in the *Federal Register* on August 7, 2024 (the "Proposed Framework") by the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service ("FSIS" or the "Agency").[1] NCC is the national, non-profit trade association that represents vertically integrated broiler companies that produce and process more than 95% of the chicken marketed in the United States. Our members would be directly affected by the proposed regulation and policy interpretation.[2]

NCC's members are committed to providing safe, high-quality, and wholesome products to consumers and have dedicated substantial resources to controlling *Salmonella* risk in raw poultry products. These efforts have included preharvest interventions, vaccine development, processing controls, and various other interventions implemented in the farm to fork continuum. These efforts have had a measurable impact on *Salmonella* prevalence in raw chicken and on public health. Salmonellosis rates attributable to raw chicken on a per-pound-consumption basis have decreased dramatically over time. Our members support science-based, legally sound, and implementable policies that seek to promote public health through *Salmonella* controls. Unfortunately, the Proposed Framework is not such a policy. As will be discussed throughout these comments, the Proposed Framework is based on a mischaracterization of the presence of *Salmonella* in raw poultry, relies on misinterpretations of the science, and is legally unsound. For these reasons, NCC urges FSIS to rescind the Proposed Framework and consider alternative approaches for addressing *Salmonella* in raw poultry products, mainly through the use of quantitative performance standards and statistical and process controls that

[1] For avoidance of doubt, references throughout to "Proposed Framework" or to the proposed regulation include both the proposed regulation and the proposed policy determination.
[2] NCC's comments on the 2022 Proposed Framework, Docket No. FSIS-2022-0029, are incorporated here by reference and attached as Attachment 1.

the Agency could implement almost immediately and would have a direct and significant impact on public health.

The administrative record supports that withdrawing the Proposed Framework is the most appropriate course of action because it fails to demonstrate that the Proposed Framework would have a measurable benefit on public health. The Proposed Framework would result in widespread disruption and significant costs to the supply chain and ultimately the consumer and is estimated to provide only a net benefit of less than $5 million under the best-case scenario. FSIS should not move forward with a proposal that contradicts longstanding enforcement policy and would result in significant changes in poultry processing operations without identifying a clear, substantial benefit in doing so. For these reasons and those articulated throughout these comments, FSIS should rescind this rulemaking until the Agency is able to identify additional data that supports an alternative rulemaking approach focused on continuous improvement in *Salmonella* performance and measurable public health impacts.

In summary, the Proposed Framework:

- Will not adequately address human salmonellosis attributed to raw poultry;
- Will cause significant supply chain disruptions, food waste, food price increases, and environmental challenges, as well as national security concerns stemming from food and supply chain vulnerabilities;
- Is not reasonably implementable based on current technology limitations;
- Is not based on sound science; and
- Lacks legal footing.

To achieve the desired public health goals, efforts to reduce *Salmonella* illnesses must be effective and practicable without stifling the supply chain and leading to other unintended public health concerns. A properly designed food safety management program helps establishments identify process control issues and allows both the industry and the Agency to take appropriate action when hazards are not properly controlled.[3] The Proposed Framework targets neither of these critical components.

I. BACKGROUND ON *SALMONELLA* REDUCTION EFFORTS AND SUCCESSES TO DATE

Over the years, the broiler industry has exhaustively worked to reduce the presence of *Salmonella* in chicken products. These efforts have included both initiatives overseen by FSIS and industry-driven interventions. As acknowledged by FSIS in the preamble to the Proposed Framework, these efforts have successfully decreased the presence of *Salmonella* in poultry products.[4] FSIS also published

[3] *See* Courtney Leone, et. al, *Interventions to reduce Salmonella and Campylobacter during chilling and post-chilling stages of poultry processing: a systematic review and meta-analysis*, 2024 Poultry Science 103:103492 (Jan. 24, 2024) available at https://www.sciencedirect.com/science/article/pii/S0032579124000713. The beef industry provides a good example of this working in practice. Its success in controlling *E. coli* O157:H7 was associated with taking steps to control contamination throughout the production process. The *E. coli* O157:H7 testing serves as a verification tool providing feedback on the implementation of these process controls.

[4] 89 Fed. Reg. 64678, 64683 (Aug. 7, 2024) ("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.").

research in the International Journal of Microbiology indicating reductions in *Salmonella* occurrence was greater than 70%.[5] Further, the science cited in in the Proposed Framework does not demonstrate poultry products are driving salmonellosis illnesses in the U.S. Considering this landscape, it is unclear why the Agency considers the Proposed Framework the most effective means of achieving the Department of Health and Human Services Healthy People Initiative's ("Healthy People") objective of reducing *Salmonella* infections by 25% by 2030.

A. Industry has successfully implemented FSIS's performance standards resulting in the reduced prevalence of *Salmonella* in poultry products.

FSIS premises the Proposed Framework on the contention that current efforts to reduce *Salmonella* in poultry products have not been effective. At the same time, throughout the preamble, FSIS acknowledges that the implementation of the performance standards system has been effective in reducing the presence of *Salmonella* in poultry products.[6] The preamble is quick to qualify these successes by stating there has not been a corresponding reduction in the number of salmonellosis cases since the implementation of the performance standard. FSIS thus concludes that the performance standards have not been effective. As explained in more detail in Section I.C. below, this conclusion is flawed. These statements downplay industry efforts to effectively control *Salmonella* to meet and exceed these performance standards, which is exactly what FSIS asked the industry to do. FSIS indicated at the time performance standards were initiated that regulatory updates would be made based on learnings from the implementation of said standards.

For years, FSIS has overseen a performance standard program for raw chicken, with major expansion and tightening of the standards in 2011, 2016, and 2018. Industry has taken these performance standards seriously and has aggressively implemented measures to meet and exceed these standards. As a result, almost 91% of establishments producing chicken parts are meeting the performance standard[7] and FSIS sampling in whole carcasses and parts shows very low *Salmonella* prevalence rates at 3.4% and 7.1%, respectively.[8] Current industry performance well exceeds the performance standard thresholds of 9.8% prevalence for whole birds and 15.4% for parts and the baseline prevalence rate of 25% noted in 1995 as part of the Hazard Analysis of Critical Control Point ("HACCP") proposed rule, demonstrating that industry has effectively implemented the performance

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[5] Michael Williams et al., *Assessing the effectiveness of performance standards for Salmonella contamination of chicken parts*, 378 Int'l J. of Food Microbiology (Oct. 2, 2022), available at https://doi.org/10.1016/j.ijfoodmicro.2022.109801.

[6] *See e.g.,* 89 Fed. Reg. at 64678 ("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*"); 89 Fed. Reg. at 64683 ("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"); and 89 Fed. Reg. at 64722 ("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*").

[7] *Salmonella Verification Testing: December 03, 2023 through November 30, 2024*, FSIS (Dec. 20, 2024), available at https://www.fsis.usda.gov/sites/default/files/media_file/documents/Dataset_EstablishmentCategoriesAggregate_202412.pdf.

[8] *Sampling Results for FSIS Regulated Products*, FSIS (Oct. 25, 2024), available at https://www.fsis.usda.gov/science-data/sampling-program/sampling-results-fsis-regulated-products. Note this data is based on a product rinse, not direct product samples.

standard system and is keeping *Salmonella* rates low. Indeed, as is described in more detail below, salmonellosis cases have decreased significantly on a per pound basis of chicken consumption over the years. Rather than abandon this successful program, FSIS should use its authority to implement improved, targeted performance standards and enforce these standards consistent with the Agency's current authority to meet its *Salmonella* reduction goals, as discussed further below.

B. In addition to meeting FSIS performance standards, industry has developed and implemented an approach that has proven effective in controlling *Salmonella* in raising and processing poultry.

To support *Salmonella* reduction efforts, the chicken industry has invested considerable sums – tens of millions of dollars or more – in measures to control the presence of *Salmonella* in raw poultry products. In particular, industry has implemented numerous preharvest intervention strategies to reduce *Salmonella* loads before poultry is processed even though this is not a regulatory requirement. These strategies include robust programs in hatcheries, feed mills, and breeder and broiler houses such as biosecurity programs, equipment sanitation, feed and litter treatment, water sanitation programs, use of pre- and probiotics, pest control, cleanout programs, and vaccinations. These types of programs, and especially the use of vaccines, are tools developed and implemented by industry to help reduce *Salmonella* illnesses and demonstrate industry's commitment to achieving the Healthy People 25% reduction goal. In the processing plant, NCC members use carefully calibrated automated evisceration processes, follow sanitary dressing best practices, and implement multi-hurdle approaches, applying multiple validated interventions to raw product as it moves through the production process. Additionally, NCC members are constantly searching for modernized production equipment and more effective interventions based on scientific trials, which can often be costly to pursue but further innovation in the industry. Further, industry has spent millions on research on reducing and eliminating *Salmonella* in poultry. Companies also engage in substantial testing for pathogen and indicator organisms in well-defined, science-based microbial programs, both on a routine basis to verify the on-going process as well as "for cause" activities that may require additional testing as part of root cause analysis and corrective actions. Examples include process control testing, to evaluate whether their processes are working as intended, and biomapping, which lets companies understand how microbial populations exist and change through their processes. Collectively, these efforts along with pre-requisite programs such as good manufacturing practices and environmental testing represent a concerted and voluntary effort to control *Salmonella* throughout the process.

C. The science of *Salmonella* illnesses in the U.S. support that these interventions have been effective and poultry products are not driving illnesses in the U.S.

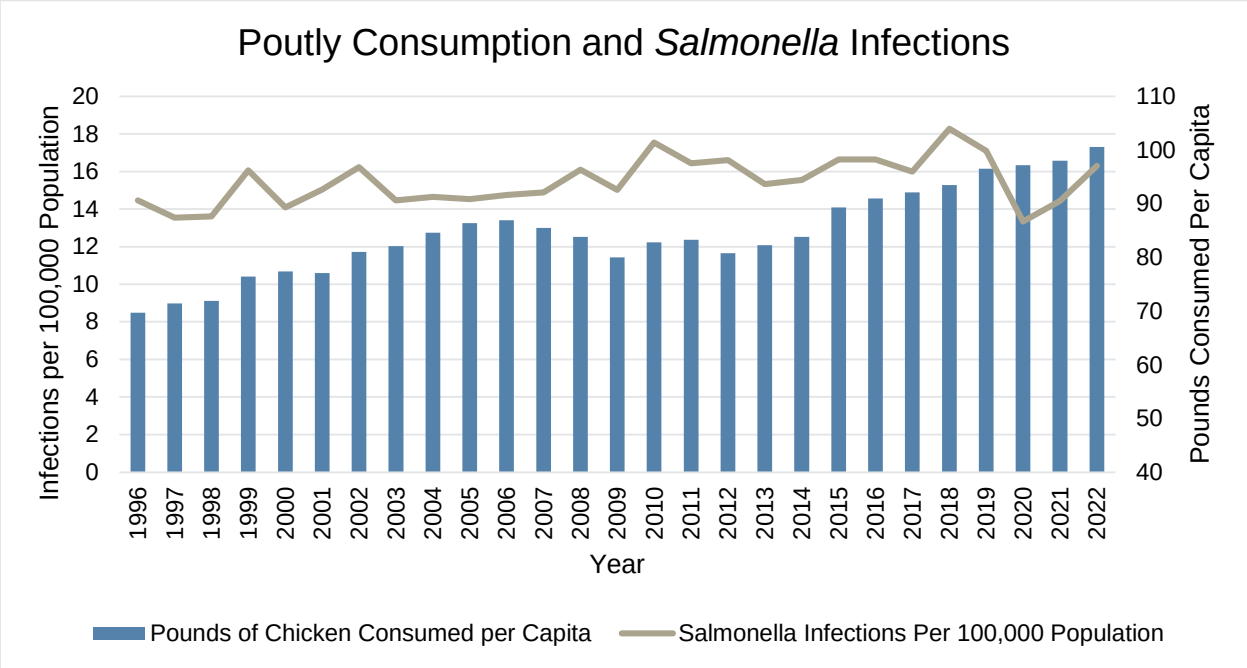
Reading the Proposed Framework, one would think that nearly all cases of salmonellosis originate from raw poultry, although this is not the case. Although recent Center for Disease Control ("CDC") data suggests that chicken products are the greatest source of *Salmonella* illnesses, more than 80% of illness are attributable to other sources.[9] FSIS relies heavily on this attribution data to make the case for the Proposed Framework, however the attribution data is flawed and does not tell the whole story. For example, the attribution data is collected at too broad a level so that it is impossible to understand the number of illnesses attributed to different types of poultry products that go through different types of processing, such as comminuted, parts, and whole carcasses, or different types of

[9] Interagency Food Safety Analytics Collaboration, *Foodborne illness source attribution estimates – United States, 2022*, CDC (Dec. 13, 2023), available at https://www.cdc.gov/ifsac/php/data-research/annual-report-2022.html.

food service or at-home preparations. Further, the data is based on all outbreak illnesses going back to 1998 and cannot be considered an accurate representation of current trends. Even more concerning, this data includes illnesses from both consuming chicken products and handling backyard flocks. Failing to distinguish between these different types of sources, products versus live animals, will prevent resources from being allocated to those products and handling practices that will have the greatest impact on public health.

Throughout the Proposed Framework, FSIS criticizes the efforts taken by industry and the results of the performance standards by asserting there has not been a decrease in the number of illnesses attributed to poultry products. However, this criticism ignores the changes in consumption patterns over the years. In 1996, the CDC created FoodNet Fast to display data for select pathogens transmitted through food, including *Salmonella.*[10] While the incidence of salmonellosis in humans has remained relatively unchanged since 1996, Americans eat significantly more chicken and chicken products today than in 1996. In 1996, chicken consumption in the U.S. was 69.7 pounds per person.[11] In 2024, USDA estimates that Americans will consume 103 pounds of chicken per person.[12] This reflects a 48% increase in chicken consumption over the past 28 years. This trend is shown in Figure 1, below.

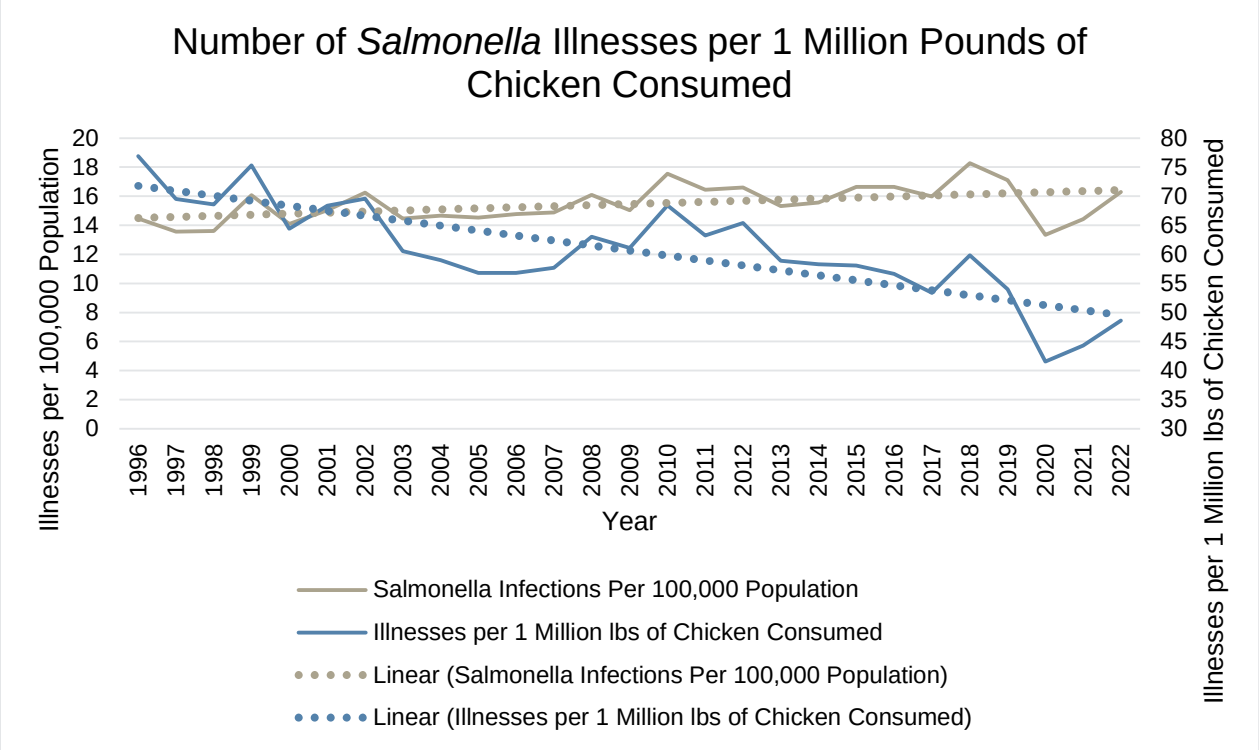
Figure 1: Annual Poultry Consumption and *Salmonella* Infections



[10] CDC, *FoodNet Fast* (accessed: Dec. 17, 2024), available at https://wwwn.cdc.gov/foodnetfast/.
[11] NCC, *Per Capita Consumption of Poultry and Livestock, 1965 to Forecast 2022, in Pounds* (accessed Jan. 14, 2025), available at https://www.nationalchickencouncil.org/about-the-industry/statistics/per-capita-consumption-of-poultry-and-livestock-1965-to-estimated-2012-in-pounds/.
[12] World Agricultural Outlook Board, *World Agricultural Supply and Demand Estimates*, USDA (Dec. 10, 2024), available at https://www.usda.gov/oce/commodity/wasde/wasde1224v2.pdf.

Neither FoodNet Fast nor Interagency Food Safety Analytics Collaboration (IFSAC)[13] takes into account consumption patterns of various food sources, including chicken. When the data from both FoodNet Fast and IFSAC are analyzed based on per-pound consumption of chicken, the rate of salmonellosis in the U.S. has decreased from about 77 illnesses for every 1 million pounds of chicken consumed in 1996, to about 49 illnesses per 1 million pounds of chicken consumed in 2022. This marks a 36% decrease in illness on a per pound basis, which is clear evidence that performance standards alone can and does drive food safety changes when viewed in the proper context. Although over a different time period, this is already highly consistent with FSIS's desired reductions related to the Healthy People goals.[14] As Figure 2 demonstrates, even as CDC data suggests a relatively consistent rate of salmonellosis per 100,000 people over the years, the rate of salmonellosis cases per pound of chicken consumed has been on a distinct downward trend. This is a critical point that cannot be lost in the analysis: each pound of raw chicken is markedly safer today than 25 or 30 years ago.

Figure 2: Salmonellosis Illnesses per One Million Pounds



This data demonstrates that the robust public-health measures implemented by FSIS and the chicken industry over the past decade have been working.

Further, in the Proposed Framework FSIS directly dismisses a credible and peer-reviewed study by a USDA researcher supporting this trend of decreasing *Salmonella* illnesses from serotypes related to poultry. The study suggests that illness rates are remaining steady not because there is no change in the presence of *Salmonella* in poultry products, but because the decreases in poultry illnesses are

[13] IFSAC, *Foodborne Illness Source Attribution Estimates – United States, 2022*, CDC (Dec. 13, 2024), available at https://www.cdc.gov/ifsac/php/data-research/annual-report-2022.html.
[14] 89 Fed. Reg. at 64678.

counteracted by increases in illnesses attributed to other foods.[15] This study highlights the flaws in attribution data. Chicken is a commonly consumed food and associated in the popular narrative with *Salmonella* illness, which causes a natural bias in favor of overestimating the number of illnesses associated with poultry. By looking at the serotypes associated with illnesses and product associations, this study demonstrates that despite the attribution data, illnesses associated with poultry consumption have decreased.

Finally, much of the science noted in the Proposed Framework is underdeveloped, misinterpreted, or flawed, including:

- The Proposed Framework relies on this flawed attribution data to assert the number of illnesses attributed to poultry products in a given year. The Proposed Framework estimates 125,115 illnesses originate from chicken each year, but this is based on a convoluted estimate extrapolated based on the IFSAC attribution report, underdiagnosis multipliers, and other uncertainty factors. The result is an over-engineered number that is difficult to replicate. Even if the Agency's estimate that 125,115 illnesses originate from chicken each year, Americans consume 103 pounds of chicken for year, which equates to about four illnesses for every million pounds of chicken.

- FSIS identified a long list of 37 critical or pivotal questions throughout the Proposed Framework. With 37 open questions, it is unclear why FSIS considers the data well-enough established to warrant issuing a Proposed Framework. This effort should be postponed until all of these numerous questions are answered.

- FSIS's Quantitative Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products[16] ("Risk Assessment") focuses only on load for *Salmonella* spp., entirely ignoring potential effects of including serotype-focused changes.

- FSIS concedes that science in this area "constantly evolves."[17] Because of this, it is inappropriate to issue a finished product standard when performance standards and other metrics would be more effective. Additionally, this statement calls into question FSIS's use of data and reliance on studies that are over 10 years old.

- As discussed below and throughout these comments, the proposal is rife with mischaracterized or misconstrued studies, which fail to support the proposed action and, even more critically, call into question FSIS's broader scientific understanding of *Salmonella* in poultry and salmonellosis risks.

As mentioned, the Proposed Framework does not accurately describe the true landscape of the *Salmonella* illnesses attributed to poultry. Industry has been working diligently for decades to reduce *Salmonella* in raw poultry and these efforts have demonstrated clear successes. In these comments, NCC proposes an alternative approach to addressing *Salmonella* on poultry and subsequent impacts

[15] M.R. Powell, *Trends in reported illnesses due to poultry-and nonpoultry associated Salmonella serotypes; United States 1996-2019*, 44(3) Risk Analysis 641, available at https://onlinelibrary.wiley.com/doi/abs/10.1111/risa.14181 .
[16] FSIS, *Quantitative Risk Assessment for Salmonella in Raw Chicken and Raw Chicken Products*, USDA (July 2024), available at https://www.regulations.gov/document/FSIS-2023-0028-0003.
[17] 89 Fed. Reg. at 64696.

on public health that is grounded in strategies that are proven successful and supported by data and science.

II. PERMEATED THROUGHOUT THE PROPOSED FRAMEWORK ARE THREE KEY CONCEPTS THAT RELY ON MISCHARACTERIZATIONS OF THE ASSOCIATED SCIENCE.

The Proposed Framework relies on three assertions: (1) the Risk Assessment establishes a clear need and public health justification for the Proposed Framework; (2) *Salmonella* is not naturally present in edible portions of chicken; and (3) consumers do not adequately cook chicken to control for the risk of *Salmonella* contamination. However, each of these assertions is incorrect and mischaracterizes the current role *Salmonella* in raw poultry products is playing in public health. As described in more detail in Section III.E below, this mischaracterization renders the Proposed Framework arbitrary and capricious.

A. USDA's characterization of the commissioned Risk Assessment does not accurately reflect the assessment's findings.

FSIS commissioned two risk assessments to evaluate the hazard posed by *Salmonella* in raw poultry products, one for chicken and one for turkey. These risk assessments became the basis of the justification of the design and need for the Proposed Framework; however, the risk assessments are riddled with flaws such that they cannot support the conclusions asserted in the Proposed Framework. As is discussed in more detail below, the chicken Risk Assessment includes key deficiencies that make its conclusions suspect. Moreover, the Risk Assessment fails to put forward a compelling public health case for the Proposed Framework as it does not demonstrate that the various components of the proposal would advance FSIS's mission of achieving the Healthy People 2030 goal of a 25% reduction in salmonellosis cases attributable to poultry.[18] In fact, an independent analysis by a leading veterinary public health expert has identified numerous flaws in the Risk Assessment. The analysis is included as Attachment 2 and is incorporated by reference into these comments. We highlight several key problems below.

1. The risk assessment did not actually evaluate the proposed standard.

Critically, the risk assessments that FSIS points to as a leading justification for the proposed adulteration threshold do not actually evaluate the threshold being proposed. The Risk Assessment model evaluated only the effects of a threshold based on *Salmonella* species, that is, all *Salmonella* serotypes. The risk assessment did not model the effects of targeting specific serotypes at a threshold, nor did it evaluate the serotype-specific effects across the different product categories or variations within product categories. Although FSIS did a limited analysis of serotypes found in chicken carcass samples, there is no evidence that serotype distribution in chicken carcasses correlates to serotype distribution in parts or communicated chicken, nor would it be expected to correlate to turkey. FSIS merely takes the Risk Assessment's output for a *Salmonella* species quantification standard for all product categories and pro-rates that by the frequency with which the targeted serotypes appear in chicken carcasses. This approach is not even a crude approximation; it is just a guess. It provides no scientific support for FSIS's proposed approach.

[18] In addition to these comments, NCC support and incorporates the *Salmonella* Framework Critical Review authored by Randall Singer and attached to these comments as Attachment 2.

2. Flaws in illness attribution estimates.

The Risk Assessment bases its illness attribution estimate on the total number of domestic salmonellosis cases reported through CDC FoodNet per year that are related to food, an under-diagnosis multiplier, and IFSAC attribution estimates. This methodology is complex and flawed. First, this method uses a combination of sporadic and outbreak-related illness measures without controlling for the difference in the two types of illnesses. The IFSAC attribution estimates are based on CDC declared and classified outbreaks, while the total number of illnesses per year include sporadic illnesses. It is not clear whether the attribution information associated with outbreaks is representative of the attribution rates for sporadic illnesses; FSIS certainly has not established that it is. Second, the under-diagnosis factor used is outdated and does not consider serotype-specific characteristics, such as virulence, which is a key component to the Proposed Framework. Finally, the Risk Assessment assumes that all raw chicken products are equally likely to cause illness – which is known to be incorrect – and does not take into account the consumption patterns of higher- and lower-risk poultry products.

***3.* Flaws in serocluster assignment.**

The Proposed Framework and Risk Assessment put a significant emphasis on the importance of categorizing *Salmonella* serotypes by their virulence in an effort to focus on the serotypes that will have the greatest public health benefit. Although the logic behind this exercise is sound, the process for categorizing or clustering the various serotypes did not account for recent facts and knowledge regarding how *Salmonella* appears in raw chicken products. First, the serocluster model is based on hypothetical virulence genes that have not necessarily been shown to influence virulence in *Salmonella* serotypes. Second, different animal species are vulnerable to different strains of *Salmonella* within the same serotype group. This is important because the model developed for the Risk Assessment included genomes from pathogens found in both poultry and beef, so the results could be distorted based on the inclusions of strains that do not present a risk in poultry. Finally, the serocluster model used oversimplifies the science and nuances behind virulence. For example, all serotypes in each cluster were considered equally virulent in the analysis, when in reality one serotype could be driving the overall virulence estimate for the cluster.

4. Flaws in the evaluation of the enumeration-based standard.

Critically, the Risk Assessment assumes perfect accuracy in the testing methods when estimating the potential public health benefits from the Proposed Framework. As is discussed in more detail in Section IV.C, below, the available test methods cannot support this level of accuracy and therefore the estimated public health benefit is flawed. The inaccuracy in test methods is further demonstrated in the FSIS Poultry Exploratory Sampling Program Report accompanying the Proposed Framework.[19]

5. Flaws in the Risk Multiplier estimation.

The Risk Multiplier in the Risk Assessment is designed to be an estimate of the serocluster severity based on documented outbreaks and the frequency with which these serotypes are identified in poultry samples. As a result, serotypes that cause disease sporadically or not as part of an official outbreak

[19] *See* Figure 2 and Table 2 in *See* T. Boynton, et al., *FSIS Poultry Exploratory Sampling Program Report*, USDA FSIS, 8 (Jul. 29, 2024), available at https://www.fsis.usda.gov/sites/default/files/media_file/documents/Exploratory_Salmonella_Sampling_Report_July2024.pdf.

are not considered in the Risk Multiplier and the frequency data is based solely on FSIS sampling in processing plants, which may not be representative of products consumed. In this way the Risk Multiplier represents an oversimplification of the data, which has implications for the Risk Assessment's dose-response model. Specifically, the cluster 2 dose-response model was generated based on the calculated Risk Multiplier rather than direct observation of the outbreak data related to the cluster 2 serotypes.

6. Oversimplification of attenuation distribution.

The Risk Assessment relies on a general and nebulous "attenuation distribution" to account for an exceedingly complex array of factors that might reduce or amplify risk from the time the product leaves the processing facility to the time it is consumed. These factors include temperature control during distribution, subsequent product handling and processing, temperature control at the point of sale, channel of sale, consumer handling after purchase, product preparation, consumption setting, and countless other factors. These factors also are highly likely to vary based on product type. Even factors such as season, climate, and geography play a role. These factors cannot be captured with any sort of accuracy in a single generic variable. Worse, because the factor is multiplicative, even minor inaccuracies in this already inaccurate estimate will be amplified in the final result of the calculations.

7. Significant reliance on outdated data.

The Risk Assessment is grounded in outbreak and prevalence data from before the not-ready-to-eat comminuted chicken and raw chicken parts performance standards were implemented in 2016.[20] This standard drove a significant shift in industry practices and the *Salmonella* populations in farms. In particular, vaccination strategies implemented in the years since 2016 have substantially changed the serotype composition of *Salmonella* in live production. The Risk Assessment is not representative of the realities of today's landscape based on the conclusion of this dated data.

B. USDA mischaracterizes the relationship between *Salmonella* and poultry products by incorrectly asserting *Salmonella* is not naturally present in edible portions of chicken.

FSIS's rationale for proposing to treat *Salmonella* as an added substance in raw poultry products comes down to its assertion that, "*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," and that "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."[21] FSIS in effect presumes that chicken muscle tissue is free of *Salmonella*, and that any *Salmonella* found in raw chicken muscle tissue resulted from cross contamination. There are critical flaws in all aspects of these statements.

First, scientific literature contradicts these statements. *Salmonella* is not an avian pathogen, and it exists naturally as part of the microflora in and on chicken. *Salmonella* can exist in a chicken's skin,

[20] 81 Fed. Reg. 7285 (Feb. 11, 2016).
[21] 89 Fed. Reg. at 64705.

muscle tissue, and gut. Peer-reviewed literature establishes that healthy, asymptomatic birds are known to carry *Salmonella*.[22] To provide but a few examples:

- Testing was completed on six- and eight-week-old birds after defeathering but before processing to determine the rate of naturally occurring *Salmonella* in the liver/gallbladder, spleen, and ceca. *Salmonella* was found in 10% of livers/gallbladders, 15% of spleens, and 8% of cecum for 6-week birds and in 51% of livers/gallbladders, 48% of spleens, and 65% of cecum for 8 week birds.[23]

- A study concluded that the relatively higher presence of *Salmonella* in shoulder joints (0.8%) in comparison to coxofemoral joints (0.4%) and tibiofemoral joints (0.2%) supports the assertion that the presence of *Salmonella* in joints is not the result of a systemic infection.[24]

- Three different studies found that the difference in the rate of *Salmonella* found on skin-off chicken breasts versus skin-on chicken breast was not significant.[25]

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[22] *See, e.g.*, Columb P. Rigney et al., *Salmonella serotypes in selected classes of food animal carcasses and raw ground products, January 1998 through December 2000*, 224(4) J. Am. Vet. Med. Ass'n 524–30 (Feb. 2004), available at https://avmajournals.avma.org/view/journals/javma/224/4/javma.2004.224.524.xml; C.W. Nde et al., *Cross contamination of turkey carcasses by Salmonella species during defeathering*, 86(1) Poult. Sci. 162–67 (2007), available at https://www.sciencedirect.com/science/article/pii/S0032579119423882?via%3Dihub; Irfan Erol et al., *Serotype distribution of Salmonella isolates from turkey ground meat and meat parts*, 3 Biomed Res. Int. (Jul. 2013) available at https://www.hindawi.com/journals/bmri/2013/281591/.

[23] N.A. Cox et al., *Recovery of Campylobacter and Salmonella Serovars From the Spleen, Liver and Gallbladder, and Ceca of Six-and Eight-Week-Old Commercial Broilers*, 16(4) J. Applied Poultry Res. 477-80 (Dec. 2007), available at https://www.sciencedirect.com/science/article/pii/S1056617119316228#cesec30:~:text=CONCLUSIONS%20AND%20APPLICATIONS,final%20food%20product.

[24] Ty Sexton et al., *Salmonella Contamination in Broiler Synovial Fluid: Are We Missing a Potential Reservoir?*, 81(9) J. Food Protection 1425-31 (Sept. 2018), available at https://www.sciencedirect.com/science/article/pii/S0362028X22086781#:~:text=Between%20production%20systems%20(Table,95%25%20CI%2C%200.01%20to%202.75%25).

[25] Angela Cook et al., *Campylobacter, Salmonella, Listeria monocytogenes, Verotoxigenic Escherichia coli, and Escherichia coli Prevalence, Enumeration, and Subtypes on Retail Chicken Breasts with and without Skin*, 75(1) J. Food Protection 34-40 (Jan. 2012) available at https://www.sciencedirect.com/science/article/pii/S0362028X23004337#s0071:~:text=When%20comparing%20the,skin%2Doff%20chicken. FSIS, *The Nationwide Microbiological Baseline Data Collection Program: Raw Chicken Parts Survey*, USDA (2012), available at https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Baseline_Data_Raw_Chicken_Parts.pdf#:~:text=FSIS%20conducted%20the%20Raw%20Chicken%20Parts%20Baseline%20Survey,that%20produce%20raw%20chicken%20parts%20under%20Federal%20Inspection. A. Pointon et al., *A Baseline Survey of the Microbiological Quality of Chicken Portions and Carcasses at Retail in Two Australian States (2005 to 2006)*, 71(6) J. Food Protection 1123-34 (Jun. 2008) available at https://www.sciencedirect.com/science/article/pii/S0362028X22065577.

- The anatomy of chickens is such that the dendritic cells that can move *Salmonella* in the bird's body can transfer *Salmonella* from the gastrointestinal tract through the circulation system to muscle tissue resulting in the *Salmonella* in muscle tissue originating from an internal source.[26]

- In a study focused on examining how *Salmonella* moves through both the host bird and other birds in the processing line, the authors commented that "healthy asymptomatic birds are known to carry *Salmonella.*" *Salmonella* was identified in chicken neck skin, on the outer layer of skin, on feather follicles, connective tissue, and in drumstick muscle.[27]

- A study of chicken breasts and thighs in retail establishments in Atlanta, Georgia found *Salmonella* in skin-off chicken thighs at a rate of 12% of chicken breasts and 22% in chicken thighs.[28]

- An additional three studies identified *Salmonella* in the internal liver, spleens, bone marrow, neck skin, and ceca of chickens.[29]

The Proposed Framework, however, references the established literature showing *Salmonella* presence in chicken muscle tissue only in passing.[30] FSIS has been presented with the above studies in previous comments on the Proposed Framework and the Proposed Rule on Not-Ready-to-Eat Breaded Stuffed Chicken, but the Agency merely notes "the comments stated" with no additional analysis explaining why the Agency blatantly disregards these studies.[31] Despite ignoring this well-established literature, FSIS nonetheless acknowledges that "*Salmonella* exist[s] in poultry skin, livers, bones, and bone marrow" but ignores that these items are routinely consumed as part of a wide variety of chicken products.[32] Chicken skin and livers are consumed directly on a regular basis. Consumers

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[26] A. Leoni Swart & Michael Hensel, *Interactions of Salmonella enterica with dendritic cells*, 3(7) J Virulence 660-67 (Nov. 2012) available at https://www.tandfonline.com/doi/full/10.4161/viru.22761.
[27] Claire-Sophie Rimet et al., *Salmonella Harborage Sites in Infected Poultry That May Contribute to Contamination of Ground Meat*, 3 Front. Sustain. Food Syst. (Feb. 2019), available at https://www.frontiersin.org/articles/10.3389/fsufs.2019.00002/full#:~:text=Chicken%20neck%20skin, days%20of%20age.
[28] Husnu Sahan Guran et al., *Salmonella prevalence associated with chicken parts with and without skin from retail establishments in Atlanta metropolitan area, Georgia*, 73(B) Food Control 462-67 (Mar. 2017), available at https://www.sciencedirect.com/science/article/abs/pii/S0956713516304777?via%3Dihub#:~:text=Salmonella%20prevalence%20in%20the%20skin%20of%20skin%2Don%20breasts,transmission%20to%20consumers%20compared%20to%20skin%2Doff%20chicken%20parts.
[29] I. Kassem et al., *An evaluation of the effect of sodium bisulfate as a feed additive on Salmonella enterica serotype Enteritidis in experimentally infected broilers*, Poultry Sci. (Apr. 2012), available at https://www.semanticscholar.org/paper/An-evaluation-of-the-effect-of-sodium-bisulfate-as-Kassem-Sanad/44b30d0bcce6f9d7d1d339d5f27fee8b4cf8c121. Diezhang Wu et al., *Prevalence of Salmonella in Neck Skin and Bone of Chickens*, 77(7) J. Food Protection 1193-97 (Jul. 2014), available at https://www.sciencedirect.com/science/article/pii/S0362028X23063731#s0005:~:text=Overall%2C%2021.4%25%20(95,undetermined%20Salmonella%20status. Amie M. Jones-Ibarra et al., *Salmonella recovery from chicken bone marrow and cecal counts differ by pathogen challenge method*, 98(9) Poultry Sci. 4104-12 (Sept. 2019), available at https://www.sciencedirect.com/science/article/pii/S0032579119307035?via%3Dihub.
[30] *See* 89 Fed. Reg at 64704-05.
[31] 89 Fed. Reg at 64704.
[32] 88 Fed. Reg. 26249, 26260 (Apr. 28, 2023).

regularly eat skin-on and bone-in whole chickens or chicken parts. Chicken livers are routinely consumed in various applications. Any *Salmonella* that may be present in these products via the skin, bone, or livers is not added; it is inherently part of the product. Likewise, any skin that may be included in a comminuted product is an inherent part of that product – just like all other components of the product. The fact that the skin is distributed more uniformly in a comminuted product does not change this fact.

Second, FSIS's own parts sampling data reinforces that *Salmonella* is ordinarily found in chicken muscle tissue. If most of the *Salmonella* present on a bird resided only on the skin, then there should be significantly lower prevalence of *Salmonella* on skinless parts compared to skin-on parts. In 2012, FSIS published a report on data collected through its Raw Chicken Parts Baseline Survey that addressed the specific question. As part of that survey, FSIS collected hundreds of samples of chicken parts with and without skin. After analyzing the data, FSIS "determined that no significant difference (p-value > 0.05) existed in the percent of *Salmonella* positive samples in parts, whether skin remained intact or was removed."[33] Notably, FSIS collected its samples for this study at the end of the production process, "after all antimicrobial interventions are completed."[34] If *Salmonella* was introduced to a skinless part only through cross contamination (e.g., a knife slicing through a piece of skin and transferring *Salmonella* from that small portion of the skin to the meat), then the transferred organism would likely be present on surface only and at low levels such that it would be eliminated by the subsequent antimicrobial interventions. The data showed the opposite.[35] In other words, *Salmonella* was just as likely to be present on a chicken part regardless of whether the part had skin or not.

Third, FSIS provides no scientific support for the statement that cross contamination during further processing is responsible for the presence of *Salmonella* in the chicken components used to create raw chicken parts and raw comminuted chicken. Tellingly, FSIS cites speculative or inapplicable sources when discussing its cross-contamination theory.[36] First, FSIS relies on a non-peer reviewed white paper published by a chemical manufacturer to support its contention that during processing *Salmonella* is spread to chicken carcasses during picking.[37] Second, the study FSIS cites to support the assertion *Salmonella* is more prevalent in immersion-chilled broilers than air-chilled broilers does

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[33] FSIS, *The Nationwide Microbiological Baseline Data Collection Program: Raw Chicken Parts Baseline Survey (RCPBS)*, USDA, 5 (2012), available at https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Baseline_Data_Raw_Chicken_Parts.pdf.

[34] *Id.* at 6.

[35] Indeed, FSIS can point only to differences between FSIS sampling for whole birds and parts (disregarding the data comparing skin-on and skin-off parts) and speculation that cutting through skin or bones, or incorporating skin into comminuted product, cross contaminates chicken with an added substance that would not otherwise be present.

[36] It is telling that under the Proposed Framework, FSIS only recognizes "*Salmonella* that is present in certain parts of the bird may be added to interior edible muscle where *Salmonella* is not *ordinarily* found." 89 Fed. Reg. at 64705 (emphasis added). This view implicitly recognizes that *Salmonella* is present at some frequency in the muscle tissue of healthy birds (otherwise, FSIS would not have had to qualify its statement with the term "ordinarily").

[37] Further, the study specifically discloses "This white paper is intended to provide general guidance only. The technical information, recommendations and other statements contained in this document are based on experience and information that 3M believes to be reliable, but the accuracy or completeness of such information is not guaranteed." This is not the type of study that should be relied on in a federal rulemaking of this magnitude.

not actually compare the two chilling methods.[38] Third, FSIS relies on two guidance documents, rather than peer-reviewed scientific literature, to assert chicken after processing has a higher incident of *Salmonella* because of cross-contamination between positive and negative parts and carcasses during further processing.[39] Fourth, many of the studies FSIS relies on are dated or based on outdated data collected before the implementation of current performance standards.[40] The implementation of performance standards has had a significant impact on the incidence of *Salmonella* in poultry processing. Data from before the implementation of the performance standards is not indicative of current operations. Finally, FSIS is unable to cite a single scientific source to support its position that muscle tissue would be free of *Salmonella* but for further processing, even though this is an *essential* proposition underpinning its new "added substance" theory for *Salmonella*. FSIS also disregards alternative explanations, such as the fact that breaking carcasses into parts exposes more surface areas (including the interior of the meat) to the sampling rinsate, which would make it more likely to identify the presence of *Salmonella* when sampling parts.

Further, to NCC's knowledge, FSIS has not even attempted to collect data to test its novel cross-contamination theory. However, NCC members have, and industry data demonstrates that *Salmonella* is not an environmental contaminant. NCC is aware that member companies have conducted experimental sampling to assess the potential for *Salmonella* cross-contamination through the environment. Those sampling efforts found virtually no *Salmonella* on processing equipment, reinforcing that *Salmonella* is not being spread through environmental cross-contamination.

In sum, the Proposed Framework would not lead to the desired public health results. FSIS's support for its "added substance" theory is not only highly speculative, but also directly contradicted by the peer-reviewed, published literature. *Salmonella* occurs naturally within chickens and is not an added substance in raw poultry. Because significant evidence shows *Salmonella* does not "ordinarily" render the product injurious to health (see Section III.A), it cannot properly be classified as an adulterant.[41]

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[38] The Proposed Framework states "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." 89 Fed. Reg. at 64705. However the study does not address "air-chilling" or the specific statistics listed.

[39] 89 Fed. Reg. at 64705.

[40] *See* studies published before the implementation of performance standards: D.P. Smith et al., *Effect of Fecal Contamination and Cross Contamination on Numbers of Coliform, Escherichia coli, Campylobacter, and Salmonella on Immersion-Chilled Broiler Carcasses*, 68(7) J. of Food Protection 1340-45 (2005); J–W Kim and MF Slavik, *Cetylpyridinium Chloride (CPC) treatment on poultry skin to reduce attached Salmonella,* 59 J. Food Protection 322–326 (1996).

[41] FSIS recognized that *Salmonella* is not an added substance in its recent 2022 denial of a petition requesting *Salmonella* be declared as an adulterant, noting that "FSIS has traditionally viewed *Salmonella* as 'naturally occurring' in food animals." Letter from Rachel Edelstein to William D. Marler, Esq, at 3 (May 31, 2022). Although FSIS in its petition response noted it was considering reassessing its long-held view, the Agency still has provided no information to explain why *Salmonella*—which comes into plants on chicken skin and inside chickens, including in the muscle tissue—is not a substance naturally occurring in chickens. More established Agency precedent reinforces that *Salmonella* is naturally occurring in raw chicken. *See, e.g.*, Letter from Carmen Rottenberg, Acting Deputy Undersecretary, Office of Food Safety, to Laura MacCleery, Director, Center for Science in the Public Interest, at 1-2 (Feb. 7, 2018) ("We also disagree with your assertion that ABR *Salmonella* is an 'added substance' within the meaning of the adulteration provisions of the FMIA and PPIA.").

C. The cooking studies cited by USDA do not adequately support the need for the Proposed Framework.

In order to support its new position that *Salmonella* can be an adulterant in raw chicken, FSIS relies on its assertion that consumers do not adequately cook poultry to control for the potential occurrence of *Salmonella*. NCC has long supported the use of meat thermometers to ensure chicken products reach an internal temperature of 165°F to control for the risk of *Salmonella* illness and still asserts that it is the most accurate method for determining whether a chicken product is safe to eat. However, we also acknowledge that other methods for determining whether chicken is cooked safely exist, and none of the consumer practice studies cited by FSIS establish that consumers who do not use a meat thermometer prepare unsafe chicken. Instead, these studies focused on measuring the prevalence of thermometer use and by doing so, FSIS inappropriately conflates thermometer use with safe cooking.

FSIS cites a web-enabled panel survey of over 1,500 adults aimed at understanding what methods consumers use to determine poultry products have been adequately cooked.[42] Although the survey was focused on understanding food thermometer usage, the authors also identified several alternative methods consumers use for determining doneness including:

- Relying on cooking time;
- Cutting food and checking it is no longer pink;
- Checking whether the juices run clear;
- Relying on a pop-up thermometer;
- Tasting the food;
- Checking the firmness of the food with a finger; and
- Determining whether the meat fell off the bone.

While NCC's member companies strongly support the use of a food thermometer, the study demonstrates that consumers understand the necessity of determining poultry's "doneness" before eating it and that most consumers use some sort of technique to ensure poultry is cooked. The data cited by FSIS further indicates that most consumers cook chicken through and that this does not vary between thermometer and non-thermometer use.[43] Specifically, the study observed 101 participants preparing chicken breast and other poultry products. 36.6% of participants used a thermometer when cooking the chicken breast, and of those, 78.4% reached the target internal temperature. Of those participants who did not use a thermometer, 75% prepared products that reached the target internal temperature. This data demonstrates that other cooking methods are as effective as a thermometer at determining whether a piece of poultry has been cooked through and that most consumers are able to fully-cook chicken products, regardless of the method used. The authors even highlighted this, stating: "the use of thermometer did not necessarily improve the ability of the participants to reach the

[42] 89 Fed. Reg. at 65699; KM Kosa et al., *Barriers to Using a Food Thermometer When Cooking Poultry at Home: Results from a National Survey*, 37(2) Food Protection Trends 116-125 (2017)., available at https://www.foodprotection.org/files/food-protection-trends/mar-apr-17-kosa.pdf.
[43] 89 Fed. Reg. at 65699; Curtis Maughan et al., *Food Handling Behaviors Observed in Consumers When Cooking Poultry and Eggs. Journal of Food Protection*, 79(6) J. of Food Protection 970-977, (June 1, 2016) available at https://www.sciencedirect.com/science/article/pii/S0362028X22080814?via%3Dihub.

correct end point temperature."[44] In this way, this study demonstrates that thermometer use as a proxy for safe cooking practices is a flawed and inappropriate comparison.

FSIS relies heavily on another study to support the contention that many consumers do not properly cook chicken.[45] The study (based on data that is at least 10 years old) observed 120 households on the west coast and involved a consultant observing the participant cooking a meal they would commonly make for their family.[46] The temperature of the chicken was taken once the participant indicated that they had finished preparing the meal. The study reports that 40% of the prepared chicken had not reached 165°F when the participant indicated the cooking was complete. This study appears to be the crux FSIS's argument that consumers do not properly prepare chicken. However, this study is riddled with flaws that undermine its credibility, including:

1. The study is limited to a single region in the United States and involves a very small sample size, and therefore should not be extrapolated to the whole United States.;
2. The consumers purchased the chicken and other ingredients themselves making it impossible to control for variables related to the product specification;
3. The study did not control for the method of preparation;
4. The study did not control how long after cooking was completed before the temperature was taken;
5. The study did not determine the dwell time for chicken cooked to a temperature below 165°F; and
6. The study did not determine whether, if cooking stopped before 165°F was reached, the center of the meat continued to increase in temperature as the meat rested and thermal load from the outer portions dissipated into the interior.

Additionally, by relying primarily on this study, FSIS neglects to consider the science supporting that dwell time, or the amount of time a piece of chicken stays a certain temperature, is also a factor in eliminating potential *Salmonella* from a piece of chicken. Specifically, FSIS recognizes in its own publication – Cooking Guideline for Meat and Poultry Products – that a 7-log reduction in *Salmonella* can be achieved at lower temperatures if it remains at that temperature for a longer period of time.[47] For example, according to Table 3 of the Guideline, many poultry products can achieve this lethality if held at temperatures as low as 154°F for under a minute. Although the Bruhn study suggests that 40% of consumers do not achieve lethality during normal cooking practices, this conclusion assumes the only way to achieve lethality is to have the product reach 165°F, which is factually incorrect. FSIS, however, recognizes that this is not the only way to achieve lethality in poultry products, which is spelled out in the Agency's own Cooking Guideline for Meat and Poultry Products.[48]

Consumers understand that poultry needs to be fully cooked. Unlike beef, restaurants do not ask how consumers prefer their chicken cooked. It is understood that poultry must be cooked through. Although the Proposed Framework looks to assert that many consumers do not properly cook poultry,

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[44] Maughan et al. at 973.
[45] 89 Fed. Reg. at 64700.
[46] C.M. Bruhm, *Chicken preparation in the home: An Observational Study*, 34(5) Food Protection Trends 318-330 (2014), available at https://www.proquest.com/trade-journals/chicken-preparation-home-observational-study/docview/1640787777/se-2.
[47] FSIS, *FSIS Cooking Guideline for Meat and Poultry products (Revised Appendix A),* Table 3, USDA (Dec. 2021), available at https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf.
[48] *Id*.

the sources referenced by FSIS are not robust and conclusions are frequently flawed. Further the Agency draws its own conclusions from the referenced studies, which is completely unscientific and completely ignores its own Guideline that does not support the Agency's rationale. For these reasons, FSIS does not have appropriate data or scientific support to contradict years of customary practice and the previous longstanding Agency position that *Salmonella* is not an adulterant in raw poultry products. In fact, FSIS has not presented any data supporting illnesses associated with undercooking.

D. FSIS's novel cross-contamination theory does not have sufficient support to be plausible.

As part of its justification for declaring *Salmonella* an adulterant in raw poultry, FSIS asserts that consumers do not ordinarily handle raw poultry in a manner that protects against cross-contamination with other foods during preparation. FSIS points to consumer handwashing studies and observations made in the above-described cooking studies to support this assertion, but these studies do not provide sufficient support for the Agency's novel position. The idea that a pathogen could be considered an adulterant in a food product because of its potential to cross-contaminate a different food product would set a precedent that will change the regulatory landscape for all foods going forward.

The Proposed Framework reviews several different handwashing and chicken handling studies concluding "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."[49] This conclusion overstates and misrepresents the findings of the cited studies.

- The Proposed Framework cites a 2015 observational study to assert only 12% of consumers washed their hands after handling raw poultry.[50] However, this mischaracterizes the study observation, which noted only 12% of participants *properly* washed their hands after handling poultry. The study defines proper handwashing as 20 seconds of washing with soap and hot water with 15 seconds of active rubbing. The study noted that the average handwashing activity took 13 seconds, which means most handwashing activities likely were not considered in determining the 12% statistic, even though these activities represent a reasonable and likely effective effort to control for cross-contamination.

- Another cited study completed in 2016 found that less than half of participants "properly" washed their hands after handling raw poultry products.[51] However, again this statistic only includes "proper hand washing" activities defined as washing hands with soap for a minimum of 20 seconds immediately after touching the raw poultry product without touching anything else. This strict definition of "properly" means these statistics will omit other handwashing activities (19 seconds, for example) that do not quite meet this high standard, and these do not reflect a meaningful evaluation of food safety practices.

- The Proposed Framework also highlights that consumers at times wash raw poultry products before cooking and that this process is a ready source of cross-contamination. However, the

[49] 89 Fed. Reg. at 64701.
[50] 89 Fed. Reg. at 64701; E. Mazengia et al., *Direct Observational Study of Cross-Contamination during Raw Poultry Handling: Practices in Private Homes*, 35(1) Food Protection Trends 8-23 (2015), available at https://www.foodprotection.org/files/food-protection-trends/JAN-FEB-15-mazengia.pdf.
[51] 89 Fed. Reg. at 64701; Maughan, et al.

referenced studies do not indicate whether, after the chicken is washed, actual cross-contamination occurred.[52]

Taking the position that the risk of cross-contamination during at home preparation plays a significant role in the determination of whether *Salmonella* is an adulterant in raw poultry and would have tremendous implications going forward. The arguments presented in the Proposed Framework could easily apply to any pathogen on any raw product which would fundamentally change the way food safety is regulated in the U.S. This dramatic shift in strategy is not supported by any indication that these cooking practices are leading causes of illnesses or outbreaks in the U.S., and it would be wildly inconsistent with how both FSIS and the Food and Drug Administration ("FDA") have long approached adulteration determinations. FSIS's cross-contamination theory is not well enough developed or scientifically supported to conclude that *Salmonella* is an adulterant in raw poultry.

III. COMPONENT THREE OF THE PROPOSED FRAMEWORK IS UNLAWFUL AND LEGALLY UNSOUND.

The Proposed Framework represents a dramatic shift in USDA policy that is not adequately supported by facts or legal precedent. For many years, FSIS has taken the position that *Salmonella* is not an adulterant in raw poultry because proper cooking practices will control the hazard. In this proposal, FSIS looks to completely discard this historical logic in favor of tenuous arguments that *Salmonella* is in fact an adulterant. The Poultry Products Inspection Act ("PPIA") does not support a finding that *Salmonella* is an adulterant in raw chicken as it is not an added substance, and it does not ordinarily render poultry products injurious to health. For these reasons and more, the Proposed Framework is legally unsound and should not be pursued further.

A. *Salmonella* is not an adulterant under 21 U.S.C. § 453(g)(1).

Fundamentally, the Proposed Framework is legally infirm because *Salmonella* is not an adulterant in raw chicken under the PPIA. Under the PPIA, a product is adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health."[53] Thus, whether a pathogen renders a product adulterated depends on whether the substance is added to the product or occurs naturally in the product. For inherent substances, the pathogen is an adulterant only if the substance is present in quantities that "ordinarily" render the product injurious to health. As FSIS has consistently recognized, *Salmonella* is not an adulterant in raw poultry because (i) *Salmonella* is not an added substance in raw poultry and (ii) *Salmonella* is not present in levels that render chicken injurious to health because customary cooking practices destroy any *Salmonella* that may be present. FSIS has offered no compelling rationale to change this interpretation.

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[52] *See* KM Kosa et al., *Older Adults and Parents of Young Children Have Different Handling Practices for Raw Poultry*, 82(2) J. of Food Protection 200–206 (2019), available at https://pubmed.ncbi.nlm.nih.gov/30673351/; and C.M. Bruhn, *Chicken Preparation in the Home: An Observational Study*, 34(5) *Food Protection Trends* 318–330 (2014), available at https://www.proquest.com/trade-journals/chicken-preparation-home-observational-study/docview/1640787777/se-2.

[53] 21 U.S.C. § 453(g)(1).

1. *Salmonella* is not an "added substance" under 21 U.S.C. § 453(g)(1), but instead is an inherent substance in poultry products.

Salmonella is not an added substance because it occurs naturally within the chicken biome. *Salmonella* is not an avian pathogen, and it exists naturally as part of the microflora in and on chicken. As explored in more detail in Section II.B above, *Salmonella* can exist in a chicken's skin, muscle tissue, and gut, and peer-reviewed literature establishes that healthy, asymptomatic birds are known to carry *Salmonella.*[54] USDA has traditionally viewed and treated *Salmonella* as an inherent substance and has rejected requests to consider *Salmonella* an added substance in all products.[55]

It is incorrect to say that *Salmonella* is not normally present in the muscle tissue of healthy birds. FSIS suggests that although *Salmonella* is present in the gastrointestinal tract of birds, the microorganism only makes it into the muscle tissue through cross-contamination during processing. As discussed, there is significant scientific evidence demonstrating that *Salmonella* can be found in edible parts of chickens before processing. In particular, *Salmonella* is known to naturally travel through the bird and can be found in the skin, connective tissue, and drumstick muscle, all of which are considered edible portions of the chicken.[56] Factually, it is incorrect to assert that the only way *Salmonella* reaches edible portions of a chicken is through cross-contamination in processing. Because of this, there is insufficient evidence for FSIS to conclude *Salmonella* is an added substance when found in chicken muscle.

The fact that *Salmonella* may be present in different concentrations in some parts of a chicken compared to others is also irrelevant to this analysis. The PPIA asks only whether the organism is an added substance when determining if it is an adulterant. To view all pathogens that can be somehow spread among or within products as "added substances" would read out of existence the second prong of § 453(g)(1) and is inconsistent with the normal meaning of the term. Well-established canons of statutory interpretation require that all words in a statute be given meaning, and that includes the "inherent substance" clause of Section 453(g)(1). Moreover, courts have been clear that an "added substance" refers to a substance not otherwise present in the food and added by man.[57]

Additionally, FSIS mischaracterizes the legal precedent relied on to assert *Salmonella* is an added substance in chicken. FSIS asserts *U.S. v. Anderson Seafoods, Inc.*[58] provides precedent and rational to support categorizing *Salmonella* as an adulterant in poultry. In *Anderson Seafoods*, the court was asked whether high levels of mercury found in swordfish could be considered an "added substance" on the rationale that at least some of the elevated mercury levels are attributable to human pollution

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[54] *See, e.g.*, C. P Rigney et al., *Salmonella serotypes in selected classes of food animal carcasses and raw ground products, January 1998 through December 2000*, 224(4) J. Am. Vet. Med. Assoc. 524–530 (Feb. 15, 2004), available at https://avmajournals.avma.org/view/journals/javma/224/4/javma.2004.224.524.xml.; C.W. Nde et al., *Cross contamination of turkey carcasses by Salmonella species during defeathering*, 86 Poultry Sci. 162–167 (2007), available at https://pubmed.ncbi.nlm.nih.gov/17179432/; I. Erol et al., *Serotype distribution of Salmonella isolates from turkey ground meat and meat parts*. Biomed Res. Int. (Jul. 10, 2013), available at https://pubmed.ncbi.nlm.nih.gov/23936785/.

[55] 89 Fed. Reg. at 64704.

[56] Claire-Sophie Rimet et al., *Salmonella Harborage Sites in Infected Poultry That May Contribute to Contamination of Ground Meat*, 3 Front. Sustain. Food Syst. (Feb. 2019) available at https://www.frontiersin.org/articles/10.3389/fsufs.2019.00002/full#:~:text=Chicken%20neck%20skin, days%20of%20age.

[57] *U.S. v. Forty Barrels and Twenty Kegs of Coca Cola*, 241 U.S. 265 (1915).

[58] *U.S. v. Anderson Seafood, Inc.*, 622 F.2d 157 (5th Cir. 1980).

in the water where the swordfish is harvested. The court supported this interpretation, holding that if a de minimis amount of mercury in swordfish is shown to result from industrial pollution, then all of the metal in the fish may be treated as an added substance. The facts of *Anderson Seafoods* cannot be readily analogized to *Salmonella* in poultry. The manner in which human intervention relates to the presence of mercury in seafood and *Salmonella* in raw chicken is entirely different. In *Anderson Seafoods*, industrial pollution caused the water where the swordfish are found to contain increased levels of mercury, which in turn results in greater concentrations of mercury found in the muscle tissue of the swordfish. In this way human intervention in the environment directly impacted the amount of heavy metal in the swordfish. In contrast, the level of *Salmonella* present in a chicken at slaughter is not directly related to a human intervention but rather is a natural function of the chicken's biome. Human intervention does not increase or decrease the amount of *Salmonella* in the chicken product. Even if some cross contamination during production results in an increase in the concentration of *Salmonella* in a particular part of the chicken, determining that this is sufficient to support an "added substance" determination is untenable given the traditional slaughter and handling practices in the poultry industry.

The *Anderson Seafood* holding does not provide a basis for FSIS to change its consistent position that *Salmonella* is not an added substance in poultry. Regardless of human intervention during processing, *Salmonella* naturally develops in the skin and muscle tissue of poultry and as such it is an inherent substance in raw poultry products. It is particularly telling that, in the 45 years since *Anderson Seafood* was decided, FDA, which was the Agency whose regulatory approach and governing statute were directly at issue in the case, has not interpreted the decision to provide the type of authority that FSIS now proposes to claim.

FSIS historically agreed that the facts of *Anderson Seafoods* are distinguishable from poultry and not a valid basis to consider *Salmonella* an adulterant in raw poultry. In response to the Center for Science in the Public Interest's (CSPI) 2011 Petition, for example, FSIS stated as follows regarding *Salmonella*'s status as an added substance in poultry:

> Furthermore, in *Anderson Seafoods*, the mercury in the fish was added to the environment by man, which contributed to its presence in the swordfish, whereas the presence of *Salmonella* in livestock and poultry is not directly added by man. Therefore, we disagree that the reasoning in *Anderson Seafoods* can be used to establish that ABR *Salmonella* is an added substance in raw meat and raw poultry.[59]

FSIS continued to distinguish the rationale of *Anderson Seafoods* from poultry products in response to a 2020 Petition:

> Moreover, FSIS is not persuaded by your argument that the court's interpretation of the Federal Food, Drug, and Cosmetic Act (FFDCA) in *Anderson Seafoods* applies to *Salmonella* in products regulated by FSIS. The *Anderson Seafoods* case differs in several material respects from the subject matter of the petition.[60]

[59] FSIS Final Response to CSPI Petition #14-06, pg. 5-6 (Feb. 7, 2018), available at https://www.fsis.usda.gov/sites/default/files/media_file/documents/11-06-FSIS-Final-Response-07312014.pdf.

[60] FSIS Final Response to Petition 20-01 Submitted by Marler Clark, pg. 2-3 (May 31, 2022), available at https://www.fsis.usda.gov/sites/default/files/media_file/2022-06/20-01-Final-Response-05312022.pdf.

Nothing has changed that would render the facts of *Anderson Seafoods* an appropriate legal basis to consider *Salmonella* an adulterant in raw poultry products.

In addition to *Anderson Seafood*, the Proposed Framework cites several additional cases in its discussion of whether *Salmonella* is an added substance in poultry. As illustrated below, the current case law supports concluding that *Salmonella* is not an added substance in raw poultry.

- *Continental Seafood, Inc. v. Schweiker*:[61] The court held *Salmonella* was an added substance in shrimp imported from India, relying in part on the conclusion that the presence of *Salmonella* was most likely result of insanitary conditions in the facility (e.g., unscreened, fly-infested processing areas, inadequate icing of shrimp, and the use of pitted and cracked work surface, among others). That fact pattern is distinct from *Salmonella* in poultry because shrimp is not known to have *Salmonella* naturally present in any part of the shrimp. In stark contrast, *Salmonella* is naturally present in parts of a chicken. It is telling that this case is over 40 years old, and FSIS has not previously relied on the case for the proposition that *Salmonella* is an added substance.

- *U.S. v. Forty Barrels and Twenty Kegs of Coca Cola*:[62] The court considered whether the caffeine present in Coca Cola would be considered an added substance in the beverage. The court held caffeine is an added substance and clarified that ingredients that are part of a product's formula can be considered an added substance despite being intentionally added. This case supports the contention that for an ingredient to be considered an "added substance" it must be artificially introduced by human intervention. Under this theory, *Salmonella* would not be considered an added substance in raw poultry because *Salmonella* is not introduced by human intervention, but rather it is naturally present in the chicken itself.

Finally, we question why FSIS is pursuing this rulemaking at this point, apparently without having determined whether and, if so, how, to reevaluate its position on whether *Salmonella* is an added substance in raw poultry. The Proposed Framework makes clear that FSIS has not determined the basis on which its proposed determination that *Salmonella* is an adulterant relies.[63] As this determination is critical to the justification and structure of the Proposed Framework, it is puzzling how the proposal could be issued without FSIS settling this matter and outlining the basis for its position. FSIS has not established that *Salmonella* present at or greater than 10 CFU/g "ordinarily" renders the chicken products injurious to health.

Because *Salmonella* is naturally present in chicken, for it to be considered an adulterant, the *Salmonella* must "ordinarily" render raw chicken injurious to health, which it does not. The PPIA establishes a very high standard to support a conclusion that a naturally occurring pathogen "ordinarily" renders a raw product adulterated. First, in the PPIA, Congress created a strong presumption against viewing a naturally occurring substance as an adulterant in raw products. Congress's choice of language is striking: under the PPIA, added substances adulterate food if they "may render it injurious to health," whereas a product with naturally present pathogens "shall *not* be

[61] 674 F.2d 38 (D.C. Cir., 1982).
[62] 241 U.S. 265 (1915).
[63] Specifically, FSIS has articulated three significant areas where it is seeking comments that directly impact the position regarding whether *Salmonella* is an added substance. *See* 89 Fed. Reg. at 64704-05. The addition of arguments regarding these topics in the Proposed Framework undermines the Agency's position by indicating the lack of evidence and data underlying the arguments.

considered adulterated" if the substance "does not ordinarily render it injurious."[64] The statute thus sets up two very different standards. "May" could imply FSIS has a measure of discretion in evaluating added substances, but the statute sets a significantly higher bar for naturally occurring substances. FSIS is prohibited from considering a naturally occurring substance a pathogen ("shall *not* be considered adulterated") unless it can meet the very high bar of proving that the substance would "ordinarily" render the product injurious to health. Reinforcing this high bar, in its statement of policy codified into the PPIA, Congress commanded that decisions such as product condemnation "shall be supported by scientific fact, information, or criteria."[65] By default, naturally occurring substances are not pathogens, and FSIS must go to great scientific lengths to establish otherwise.

Second, the plain meaning of "ordinarily" sets a very high bar. When a statute does not define a term – and the PPIA does not define "ordinarily injurious" – courts will consider its plain meaning with reference to its reasonable use, dictionary definitions, and its use in context.[66] Multiple dictionary definitions contemporaneous with the passage of the PPIA show us what Congress meant when it used "ordinarily." *Webster's* 1953 edition defines "ordinarily" as "according to established rules or settled method."[67] *Black's Law Dictionary,* 1951 edition, defines the adverb by reference to "ordinary," stating it means "regular" or "normal."[68] And *Oxford English Dictionary,* which examines the historical development of the term, defines it as "[b]elonging to the regular or usual order or course" or occurring in "regular custom or practice."[69] The term retains its meaning in modern parlance and as defined "usually; as a rule."[70] Thus, under the plain language of the PPIA, a naturally occurring substance can be considered an adulterant only if the substance "regularly" or "normally," or through "regular or usual . . . course" or "regular custom or practice," or "usually" or "as a rule" renders the product injurious to health.[71] This simply is not the case.

As is well established, thorough cooking destroys *Salmonella.* Specifically, cooking raw chicken to an internal temperature of 165°F achieves a 7-log reduction in *Salmonella.*[72] In fact, even a slightly lower temperature still achieves instant lethality (162°F or 163°F, depending on the fat content), as can reaching yet-lower-still temperatures with sufficient dwell time, often of just a few seconds.[73] Even in the event raw chicken were cooked at yet lower temperatures, there would be a substantial log-reduction in *Salmonella.* The increasing consumption of chicken on a per-capita basis and relatively stable incidence of *Salmonella* illnesses in the U.S., as described in Section I.C above, further demonstrates that *Salmonella* is not ordinarily injurious to health. If it were, a marked increase in

[64] 21 U.S.C. § 453(g)(1).
[65] 21 U.S.C. § 452.
[66] *Robinson v. Shell Oil Co.,* 519 U.S. 337, 341 (1997).
[67] Webster's New Twentieth Century Dictionary 1177 (1953).
[68] *Ordinary,* Black's Law Dictionary (4th ed. 1951).
[69] *Ordinary,* Oxford English Dictionary (2d ed., 1989).
[70] *Ordinarily,* Webster's New World College Dictionary (4th ed., 2010).
[71] The legislative history behind comparable language in the Federal Food, Drug, and Cosmetic Act reinforces this interpretation. In one debate, members stated "ordinarily injurious" meant "that people—substantial numbers of people—must actually be harmed by the product before it can be restricted in any way. This provision . . . puts the burden of proof on the FDA." 120 Cong. Rec. 36007 (1974) (Statement of Rep. Peter Kyros).
[72] FSIS, *FSIS Cooking Guidelines for Meat and Poultry Products (Revised Appendix A),* Table 3, USDA (Dec. 2021), https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf.
[73] *Id*.

chicken consumption would be correlated to a very obvious and marked increase in salmonellosis rates. But that is not what the data demonstrate.

As explained in Section II.C above, consumers customarily cook chicken in a manner that achieves thorough cooking and destroys *Salmonella*.[74] Consumers are regularly reminded to use a meat thermometer to cook chicken to an internal temperature of 165°F – including on the package itself – which achieves lethality. The Food Code specifies that chicken is to be served fully cooked whereas it indicates that whole-muscle, intact beef steak can be served or sold as ready-to-eat if it is seared and intact.[75] While NCC's strong recommendation is that consumers use a meat thermometer, other less analytical ways to gauge "doneness," such as cutting into the meat to see if it is visibly white and firm, are also highly likely to achieve lethality and certainly cannot be said to "usually" or "normally" result in the product being injurious to health. Chicken is not customarily cooked "rare" or "medium," and waitstaff at restaurants do not ask patrons how they would like their chicken cooked. Certainly, it is not the case that due to handling and cooking practices, chicken is ordinarily injurious to health.

Finally, FSIS's own data does not support the determination that *Salmonella* ordinarily renders raw poultry products injurious to health at or above a level of 10 CFU/g. In the Proposed Framework, FSIS estimates the rate at which raw chicken carcasses, chicken parts, and comminuted chicken test positive for *Salmonella* at a concentration at or above 10 CFU/g and identifies these rates as 1%, 0.07%, and 3%, respectively.[76] Based on these rates, FSIS estimates the probability of illness resulting from a serving of raw poultry products at the most aggressive virulence assumption as 0.612% for chicken carcasses, 0.34% for chicken parts, and 1.486% for comminuted chicken.[77] These rates cannot possibly support a conclusion that *Salmonella* in raw chicken is "ordinarily" injurious to health when the rate of illness is so low and clearly below the prevalence rates for *Salmonella* in these products. If *Salmonella* truly "ordinarily" rendered raw poultry products injurious to health, the Proposed Framework would have a significantly greater impact on public health, and the suggested contamination rates would result in millions of illnesses.

2. USDA's cross-contamination theory would create troubling precedent for all categories of food.

As discussed in Section II.D above, FSIS presents a novel concept by suggesting that the cross-contamination risk from consumers preparing chicken in their home is cause to determine *Salmonella* is an adulterant in raw poultry products. If FSIS asserts that *Salmonella* is an adulterant in raw poultry due to its alleged ability to contaminate ready to eat foods during at home preparation, almost all food-hazard combinations could be similarly characterized. No product could truly be sold as raw anymore.

[74] The D.C. Circuit Court made this point quite bluntly in *American Public Health Association v. Butz*, where the court noted the Department had previously taken the position that "the American consumer knows that raw meat and poultry are not sterile and, if handled improperly, perhaps could cause illness." The court summarized this position stating: "In other words, American Housewives and cooks normally are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis." *American Public Health Association v. Butz*, 511 F.2d 311, 334 (D.C. Cir., 1974).

[75] FDA Model Food Code, FDA, Ch. 3-18 to Ch. 3-22 (2022), available at https://www.fda.gov/media/164194/download?attachment.

[76] 89 Fed. Reg. at 64701.

[77] 89 Fed. Reg. at 64702.

We are aware of only one even remotely similar precedent for this treatment, and it is readily distinguished. Historically, when FDA learns of a potential *Salmonella* contamination in raw pet food, FDA expects the raw pet food to be recalled. The decision to recall is not based on risk to the consumer of the product (i.e., the pet), but rather because of the potential risk to humans who may handle the *Salmonella*-contaminated raw pet food and then themselves ingest the *Salmonella* (e.g., by failing to wash their hands before eating). This may be appropriate in the pet food space because consumers may not be generally aware that pet food can contain pathogens of concern for humans and because it may not be well known that pets may not be affected by some human pathogens. In contrast, consumers are well aware of the risk of *Salmonella* associated with raw poultry and know how to handle it appropriately.

Finally, the cross-contamination theory is supposedly supported by the consumer cooking studies discussed in Section II.C above, but these studies are flawed, misinterpreted, and hold consumers to an incredibly high standard for food safety and handwashing practices. We are not seeing *Salmonella* illnesses attributed to cross-contamination and relying on this argument to declare *Salmonella* an adulterant in raw poultry is a slippery slope that could have major consequences for all foods.

B. The presence of *Salmonella* in poultry products is fundamentally different than the presence of *E. coli* in beef and analogizing the two scenarios is misguided.

Throughout the Proposed Framework, FSIS analogizes this rulemaking to the determination that Shiga toxin producing *E. coli* is an adulterant in raw non-intact beef. *Salmonella* in raw chicken is fundamentally different than Shiga toxin producing *E. coli* (STECs) in raw non-intact beef, a fact acknowledged in the Proposed Framework.[78] Even so, FSIS still attempts to draw parallels between these product-pathogen pairs, but the analysis misses several key distinctions. Most notably, unlike *Salmonella* in raw poultry, *E. coli* is not naturally occurring in beef. In the Proposed Framework, FSIS attempts to reduce its 1994 decision declaring *E. coli* O157:H7 an adulterant in raw ground beef (and subsequent extension to STECs in raw non-intact beef) to a set of "criteria," all of which appear equally weighted: association with human illness or outbreaks, relatively low infectious dose, cause of serious of human illness, and survival under typical consumer cooking practices.[79] FSIS took this approach in determining *Salmonella* at a level of 1 CFU/g or higher is an adulterant in not-ready-to-eat breaded stuffed chicken products as well as in this Proposed Framework. However, that is not actually the approach FSIS took to support its 1994 and 2014 decisions, nor is it the analysis courts performed when evaluating FSIS's *E. coli* policy.

In fact, FSIS's analysis turned *primarily* on whether *E. coli* was likely to be destroyed under customary cooking practices for raw ground beef. In explaining its policy on *E. coli* O157:H7, FSIS provided background on the risks of *E. coli* O157:H7 but then expressly tied *E. coli* O157:H7's status as an adulterant to customary cooking practices: "Raw ground beef products present a significant public health risk *because* they are frequently consumed after preparation (*e.g.,* cooking hamburger to a rare or medium rate state) that does not destroy *E. coli* O157:H7 organisms that have been introduced

[78] *See* 89 Fed. Reg. at 65693 (quoting the Agency's response to a 2014 petition where it stated: "*Salmonella* does not appear to present the same issues as [*E. coli* O157:57], regardless of whether it is resistant or susceptible to antibiotics."); *see also* 89 Fed. Reg. at 65698 ("the symptoms of *Salmonella* infections are typically not reported to be as severe as some of those associated with STEC").
[79] 89 Fed. Reg. at 64694.

below the product's surface."[80] If that were not clear enough, FSIS continued, "the Agency believes that the status under the FMIA of beef products contaminated with *E. coli* O157:H7 *must depend* on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed."[81] Cooking practices were expressly the dispositive factor. This is reinforced by the fact that FSIS determined that intact cuts of beef, when contaminated with the exact same *E. coli* O157:H7, were not adulterated because "[i]ntact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner than ensures that these products are not contaminated with *E. coli* O157:H7."[82] FSIS again cited customary cooking practices as the dispositive point in its 2011 *Federal Register* notice declaring several other STECs to similarly be adulterants in raw non-intact beef.[83] Thus, rather than being a four-factor analysis as presented in the Proposed Framework, there is only question: whether the customary cooking practices would ordinarily render the product injurious to health. In fact, recent outbreak experience reinforces that consumers continue to not fully appreciate the importance of cooking raw beef through.[84] The same confusion does not exist for raw chicken.

Courts recognize this distinction as pivotal. In upholding FSIS's *E. coli* O157:H7 sampling program, and in a case that fundamentally turned on whether *E. coli* O157:H7 could properly be considered an adulterant in raw ground beef, the District Court for the Western District of Texas focused on whether the cooking practices that most Americans considered "proper" for ground beef were sufficiently "thorough" as to destroy *E. coli* O157:H7:

> However, unlike other pathogens, it is not "proper" cooking but "thorough" cooking that is necessary to protect consumers from *E. Coli.* The evidence submitted by Defendants indicates that many Americans consider ground beef to be properly cooked rare, medium rare, or medium. The evidence also indicated that *E. Coli* contaminated ground beef cooked in such a manner may cause serious physical problems, including death. Therefore, *E. Coli* is a substance that renders "injurious to health" what many Americans believe to be properly cooked ground beef.[85]

In *Texas Food Industry Association,* just as in FSIS's explanation, the entire analysis turned on whether customary consumer cooking practices were sufficient. Under the court's reasoning, had what consumers understood to be "proper" cooking been adequate to destroy *E. coli* O157:H7 in hamburgers, then the substance would not have been an adulterant (just as it is still not an adulterant on raw intact beef).

Raw chicken is handled very differently than ground beef. Consumers do not customarily consider it "proper" to cook a medium rare chicken breast. Ground chicken products such as chicken burgers or meatballs are customarily cooked thoroughly, not served rare, medium rare, or even medium. What consumers consider to be the "proper" or "customary" method is also a method that cooks chicken

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[80] FSIS, *Beef Products Contaminated with Escherichia coli O157:H7,* 64 Fed. Reg. 2803, 2803 (Jan. 19, 1999) (emphasis added).
[81] *Id*. (emphasis added).
[82] *Id*. at 2804 (emphasis added).
[83] FSIS, *Siga Toxin-Producing Escherichia coli in Certain Raw Beef Products,* 76 Fed. Reg. 58157, 58158 (Sept. 20, 2011).
[84] *See e.g.,* FSIS, *Wolverine Packing Co. Recalls Ground Beef Products Due to Possible E. Coli 0152:H7 Contamination*, USDA (Nov. 11, 2024), available at https://www.fsis.usda.gov/recalls-alerts/wolverine-packing-co--recalls-ground-beef-products-due-possible-e--coli-o157h7.
[85] *Texas Food Industry Ass'n v. Espy,* 870 F. Supp. 143, 149 (W.D. Tex., 1994).

"thoroughly."[86] FSIS makes the assertion in the proposed determination for not-ready-to-eat frozen stuffed chicken that consumers ordinarily cook raw chicken properly: "Under this proposal, such lots could be diverted for use in a fully cooked poultry product or for use in another raw poultry product, such as ground chicken, in which consumer preparation is more likely to mitigate the risk."[87]

Courts have recognized this distinction. The Fifth Circuit recognized that "*Salmonella* [is] present in a substantial proportion of meat and poultry products" and "is not an adulterant *per se"* because "normal cooking practices for meat and poultry destroy the *Salmonella* organism."[88] The D.C. Circuit reached a similar conclusion in *American Public Health Ass'n v. Butz,* holding "the presence of salmonellae on meat does not constitute adulteration" and that "American housewives and cooks are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis."[89] In other words, existing precedent indicates the mere "presence of *Salmonella* in meat products," without more, does not support USDA regulation under § 453(g)(1).[90]

FSIS, too, has long and consistently recognized that *Salmonella* is not an adulterant in raw poultry. For example, as recently as 2022, FSIS denied a petition requesting FSIS declare certain *Salmonella* strains to be adulterants in raw poultry.[91] In 2018, FSIS denied a different petition making a similar request to declare certain *Salmonella* strains as an adulterant in raw meat and poultry.[92] In its 2016 *Federal Register* notice announcing new *Salmonella* performance standards for poultry, FSIS clearly explained, "*Salmonella* is not an adulterant in [not-ready-to-eat] poultry products."[93] In 2014, FSIS rejected a petition to declare antibiotic resistant *Salmonella* an adulterant, stating "we are not aware of any data to suggest that consumers consider ground poultry . . . to be properly cooked when rare,

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[86] Other critical distinctions exist between STECs in raw non-intact beef and *Salmonella* in raw poultry. For example, *E. coli* typically enters the cattle slaughter process through cross contamination with fecal matter on the outside of the hide, which can get transferred to the meat if sanitary practices are not observed. By contract, *Salmonella* actually enters in the chicken naturally, including in edible parts of the chicken. No amount of process control or sanitary dressing can prevent its being in the product because it starts out in the product.

[87] 88 Fed. Reg. 26249, 26266.

[88] *Supreme Beef Processors, Inc. v. U.S. Dep't of Agric.,* 275 F.3d 432, 438–39 (5th Cir. 2001).

[89] *American Public Health Ass'n v. Butz,* 511 F.2d 331, 334 (D.C.Cir.1974).

[90] *See also, e.g., Starr Surplus Lines Ins. Co. v. Mountaire Farms Inc.,* 920 F.3d 111, 117 (1st Cir. 2019) ("[T]he mere fact of the FSIS-orchestrated recall does not give rise to the plausible inference that the type of *salmonella* found . . . could not be eliminated by proper cooking."); *Craten v. Foster Poultry Farms Inc.,* 305 F. Supp. 3d 1051, 1058 (D. Ariz. 2018) (observing that existing case law "suggests *Salmonella* is not an adulterant" and rejecting several state law tort claims because *Salmonella* "is killed through proper cooking, which is how raw chicken products are intended to be used").

[91] FSIS Final Response to Petition 20-01 Submitted by Marler Clark, pg. 2-3 (May 31, 2022), available at https://www.fsis.usda.gov/sites/default/files/media_file/2022-06/20-01-Final-Response-05312022.pdf.

[92] FSIS Final Response to CSPI Petition #11-06, pg. 5-6 (Feb. 7, 2018), available at https://www.fsis.usda.gov/sites/default/files/media_file/documents/11-06-FSIS-Final-Response-07312014.pdf.

[93] FSIS, *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 Fed. Reg. 7285, 7297 (Feb. 11, 2016).

medium rare, or medium."[94] Crucially, USDA has never argued that *Salmonella* is an adulterant under § 453(g)(1). Instead, it has argued the opposite in litigation and policy documents. For example, in the *Supreme Beef* case on the enforceability of *Salmonella* performance standards, the court noted, "The USDA agrees in this case that *Salmonella* is not a[n] . . . adulterant."[95]

In light of this long and consistent history, and even if the PPIA were to permit such an interpretation, FSIS would be hard-pressed to provide a rationale that its change in policy was not arbitrary and capricious or that an abrupt change in position was warranted by the record, especially given the fact that CDC has not demonstrated increases in illnesses despite increased consumption of chicken.[96] As it stands, FSIS has presented no data to support a conclusion that *Salmonella* in raw chicken "ordinarily" or "usually" renders chicken injurious to healthy under customary cooking practices. If FSIS continues to pursue this reasoning, it will set a challenging precedent going forward as all raw products carry a health risk if mishandled or undercooked. This precedent could lead to adulteration determination that would cripple industry and slash the food supply.

C. The presence of *Salmonella* in raw poultry does not render the product adulterated under 21 U.S.C. § 453(g)(3).

In addition to the determination that *Salmonella* is an adulterant under 21 U.S.C. § 453(g)(1), the Proposed Framework also "tentatively determined" that raw poultry products with one of the identified *Salmonella* serotypes present at a level at or above 10 CFU/g would be considered adulterated under 21 U.S.C. § 453(g)(3).[97] FSIS's rational for determining *Salmonella* in raw poultry products would render the products adulterated under Section 453(g)(3) is only briefly explained in a single footnote in the Proposed Framework:

> "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.'"[98]

Based on this limited explanation, FSIS appears to take one of two positions: either (1) situations that trigger Section 453(g)(1) also automatically trigger Section 453(g)(3), or (2) Section 453(g)(3) is a sort of catchall provision that encompasses any situation not specifically captured by the other adulteration provisions of Section 453(g). Neither is correct.

First, Section 453(g)(3) is not just duplicative of the other adulteration provisions. Congress organized Section 453(g) into clear categories encompassing different ways in which products are considered adulterated. Section 453(g)(1) encompasses the situations in which substances added to or inherent

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[94] Letter from Daniel Engeljohn, Assistant Adm'r, Off. of Pol'y & Program Dev., USDA, to Sarah Klein, Food Safety Program (July 31, 2014).
[95] *Supreme Beef,* 275 F.3d at 439 n. 21.
[96] *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 34 (1983).
[97] 89 Fed. Reg. at 64694-95.
[98] *Id*. at 64695.

in the products render the products adulterated, Section 453(g)(2) covers food additives, Section 453(g)(4) covers manufacturing conditions, and so on. A situation could trigger multiple adulteration provisions, but each violation would have to be established independently. FSIS provides no explanation as to why the presence of *Salmonella* in raw poultry products at or above 10 CFU/g causes those products to be unfit for food.

Second, and more importantly, Section 453(g)(3) is not a general catch-all provision giving FSIS authority to find a product to be adulterated whenever the Agency is unable to invoke one of the other adulteration provisions. Congress specifically addressed in Section 453(g)(1) the situations in which pathogens render a food adulterated. In doing so, Congress established a very specific framework with different standards applying to added and inherent substances. It would have made no sense for Congress to create such a precise set of standards for added and inherent substances in one subsection only to give in another subsection USDA carte-blanche authority to disregard those distinctions. Congress did not write the PPIA to allow USDA to use Section 453(g)(3) to make an organism an adulterant when USDA was not able to under Section 453(g)(1).

Case law interpreting 21 U.S.C. § 601(m)(3) further clarifies that Section 453(g)(3) is intended to cover specific scenarios. For example, in *United States v. Agnew*, the Tenth Circuit was asked to determine whether the Section 601(m)(3) of the FMIA, which mirrors Section 453(g)(3) of the PPIA, was unconstitutionally vague.[99] The court determined it was not and noted that although it is possible to read the provision broadly, the phrasing "any filthy, putrid, or decomposed substance" was clearly intended to address the scenario at issue in the case involving clearly rotting meat.[100] In another case, *United States v. 2,116 Boxes of Boned Beef Weighing Approximately 154,121 Pounds*, the Tenth Circuit held the implantation of the drug diethylstilbestrol (DES) into cattle did not violate § 601(m)(3) because it did not decompose the meat within the meaning of § 601(m)(3).[101] Because the implantation of the drug did not decompose the meat, the decision primarily turned on whether the drug was "otherwise unfit for food." The court relied on the interpretation of "otherwise unfit for food" in the context of the Federal Food, Drug, and Cosmetic Act as identical language exits in 21 U.S.C. § 342(a)(3). The court noted that the determination of whether something is "otherwise unfit for food" is based on what "an average person, under ordinary conditions, would use when finding food not suitable for chewing and swallowing."[102] Applying the test, the court found that the addition of DES did not make the meat "otherwise unfit for human food" because it did not result in "[u]reasonable toughness" or an "offensive texture, color, [or] consistency" nor did it "alter the normal ratio of edible nutritional meat to waste products."[103] Further, the court found that the addition of DES did not disintegrate, decompose, or change the meat within the meaning of the first clause of Section 601(m)(3).[104] The court commented that while the "otherwise unfit for food" standard does provide the Agency broad power, it does not allow the Agency to regulate added substances under of Section 601(m)(3).[105]

[99] 931 F.2d 1397 (10th Cir. 1991).
[100] *Id.* at 1401.
[101] 516 F. Supp. 321 (D. Kan. 1981), *aff'd*, 726 F.2d 1481 (10th Cir. 1984).
[102] *Id*. at 346.
[103] *Id*. at 347.
[104] *Id*. at 350.
[105] *Id.*

These cases illustrate that although Section 453(g)(3) provides the Agency some discretion to determine whether a food is adulterated, the provision is limited to certain scenarios of foods not otherwise covered by the PPIA.

D. The Major Question Doctrine dictates that this is a question better left for Congress.

The Proposed Framework amounts to a seismic and unprecedented shift in how FSIS regulates raw poultry. As recently explained by the Supreme Court in *West Virginia v. EPA*, in certain cases of "economic and political significance," an Agency must demonstrate "clear congressional authorization" to exercise its powers.[106] This proposal would see FSIS upend a more than fifty-year-old approach to how it regulates raw poultry and could have significant collateral consequences not only in law and policy but also the communities where these products are produced. Moreover, throughout the Proposed Framework, FSIS notes the uncertain or speculative nature of its decision and significant scientific gaps and poses 37 requests for more information, further demonstrating the Agency's uncertainty and the lack of a consensus in favor of such a drastic change in approach. This Proposed Framework presents the very definition of a major question requiring Congressional direction.

E. The record does not support concluding *Salmonella* is an adulterant in raw poultry products and as such the rule is arbitrary and capricious.

Under the Administrative Procedure Act, agency actions cannot be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." Courts have held that agency action is "arbitrary and capricious" when the agency has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise."[107] In determining whether an agency action is arbitrary and capricious, courts review the information available in the administrative record.

The Proposed Framework has failed to establish an adequate administrative record to support the rulemaking. In particular, the Proposed Framework represents a drastic change to longstanding Agency policy and this new position is based on speculative statements, inadequate and often contradictory scientific support, and outdated data. Many of these flaws are discussed elsewhere in these comments and are referenced here for ease, specifically:

- The Proposed Framework ignores the efforts made by industry to date to control the risk posed by *Salmonella* in raw poultry (*see* Section I). FSIS has not sufficiently established that the current efforts undertaken by industry are ineffective at controlling the risk posed by *Salmonella* in raw poultry. Further, FSIS even provides references indicating that current efforts *are* effective. FSIS must address this contrary information before any rulemaking on this topic can move forward.

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[106] *West Virginia v. EPA*, 142 S. Ct. 2587, 2613–14 (2022) (explaining that in certain cases of "economic and political significance," an agency must demonstrate "clear congressional authorization" to exercise its powers); *see also Nat'l Fed'n of Ind. Business v. OSHA,* 142 S. Ct. 661 (2022) (per curiam) (rejecting the Occupational Safety and Health Administration's claims of regulatory authority regarding emergency temporary standards imposing COVID-19 vaccination and testing requirements on a large portion of the national workforce); *Ala. Ass'n of Realtors v. HHS,* 141 S. Ct. 2485 (2021) (per curiam) (rejecting the CDC's claims of regulatory authority regarding a nationwide eviction moratorium).

[107] *Motor Vehicle Mfrs. Ass'n,* 463 U.S. at 43.

- The risk assessment upon which the rule is based is riddled with flaws and fails to support a position that the Proposed Framework will achieve the stated mission of meeting the Healthy People 2030 reduction goals (*see* Section II.A). Further, the risk assessment does not evaluate the proposed final product standard – at or above 10 CFU/g and one of three identified serotypes. The risk assessment only evaluates setting an adulterant standard at or above 10 CFU/g and completely ignores the identified serotypes.

- FSIS has not sufficiently established that it has the legal authority to promulgate the Proposed Framework because (1) it has not established that *Salmonella* is an added substance in raw poultry (*see* Sections II.B and III.A.1); (2) in the alternative, FSIS has not established that *Salmonella* is ordinarily harmful in raw poultry (*see* Section II.A.2); and (3) *Salmonella* is not an adulterant under 21 U.S.C. § 453(g)(3).

- The Proposed Framework has not provided sufficiently robust evidence to support FSIS's new position that consumers do not adequately control *Salmonella* risk through sufficient cooking practices (*see* Section II.C).

- Much of the research and data relied on by FSIS predates the implementation of performance standards that control for *Salmonella* risk, meaning it does not accurately reflect the current food safety landscape.

- Given the nominal public health impact the Proposed Framework is estimated to have, it does not address the purported issue the rule is aimed at resolving. (*see* Section VII).

In addition to these issues, the Proposed Framework itself also suggests that this rulemaking is premature and may not be effective. For example, throughout the Proposed Framework, FSIS requests comment and information on 37 issues or topics where it feels more information and input is needed.[108] Further, in discussing the testing plans needed to execute the Proposed Framework, FSIS notes that "data gathered from the sampling plan would enable the Agency to gauge more precisely the hazard posed by certain *Salmonella* levels and serotypes."[109] If FSIS feels it needs more data to precisely gauge the *Salmonella* hazard in raw poultry, it should pursue this data through an exploratory sampling project and not regulatory sampling against an adulterant standard. This need for additional information and data to support the rulemaking is underscored in the 2023 National Advisory Committee on Microbiological Criteria in Foods ("NACMCF") Report which lists nine recommendations of actions FSIS should take to better understand the nature of *Salmonella* in raw poultry products. Of the nine recommendations, three directly state FSIS should gather additional data and one recommendation even calls out the extensive data gaps identified by the committee and suggests this issue be reevaluated in three to five years when the data has been gathered and risk assessments have been completed.[110] These notable data gaps underscore that the administrative record is not sufficiently developed to support this rulemaking. It also calls into question the purpose of NACMCF if the Agency is simply going to ignore and disregard its own expert advisory body's recommendations, especially without clear explanation as to why.

[108] We were unable to comment specifically on each item due to lack of clarity around certain of the requests and availability of information to respond to others.
[109] 89 Fed. Reg. 64707.
[110] NACMCF, *Response to Questions Posed by the Food Safety and Inspection Service: Enhancing Salmonella control in Poultry Products*, 87 J. of Food Protection (Feb. 2024).

Additionally, FSIS has not provided sufficient data to justify the proposed threshold at or above 10 CFU/g coupled with the identified serotypes or demonstrated the availability of a test method to measure this standard. The Proposed Framework notes there is no meaningful difference in public health outcomes between a 1, 10, or 100 CFU/g threshold, stating "the resulting 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."[111] With little meaningful difference between considered thresholds, we are left to conclude that the decision to set the threshold level at 10 CFU/g was arbitrarily made. This statement also appears to contradict other conclusions made in the Proposed Framework, including the assertion that the probability of illness is greater when consuming a raw chicken product with 10 CFU/g of *Salmonella*[112] and the declaration "that raw chicken carcasses, parts, and comminuted chicken and turkey that contain *Salmonella* at or above 10 CFU/g and a serotype of public health significance are adulterated because the 2023 risk assessment found that servings contaminated with these *Salmonella* levels and serotypes are *much more likely* to cause illness."[113] For this statement to be true, we would expect the established at or above 10 CFU/g threshold to result in significantly fewer illnesses than the other proposed thresholds. Further, these contradictions and statements also suggest that the Proposed Framework is not targeting the true driver of *Salmonella* illnesses in the United States. The lack of predicted public health efficacy also demonstrates that the proposed solution is not appropriately responsive to the problem. This may be in part because FSIS seems to be proposing an approach premised on identifying a "needle in a haystack": using infrequent testing to identify exceedingly small and disparate pockets of elevated levels of *Salmonella* hidden in more than 46 billion pounds of product.

Beyond the flaws in the data used to support the Proposed Framework, the results of the risk assessment and FSIS's own projections show the Proposed Framework would fail to actually achieve the goals FSIS explicitly set out to meet through this rulemaking. As part of the Department of Public Health and Human Services' Healthy People Initiative, a target has been set to reduce poultry-based *Salmonella* illnesses in the U.S. by 25%.[114] FSIS is explicit that the proposal is intended to meet this goal: "Thus, to reach the 2030 target, illnesses must be reduced by 25 percent…To move closer to achieving this target, FSIS has determined 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."[115] The Proposed Framework estimates that *Salmonella* is responsible for 1.3 million illnesses a year with 125,115 and 42,669 *Salmonella* illnesses being attributed to chicken and turkey products respectively.[116] Based on FSIS's estimates, the proposal would at result in 1,000 fewer chicken related illnesses and 2,100 fewer turkey illnesses, which corresponds to a 0.7% reduction in chicken-related illnesses and a 4.9% reduction in turkey-related illnesses.[117] In fact, these

[111] 89 Fed. Reg. at 64703.
[112] 89 Fed. Reg. at 64702.
[113] 89 Fed. Reg. at 64723 (emphasis added).
[114] 89 Fed. Reg. at 64678.
[115] 89 Fed. Reg. at 64683.
[116] 89 Fed. Reg. at 64681.
[117] *See* 89 Fed. Reg. at 64703 tbl. 34 (the second table numbered "34"). This analysis uses what FSIS characterizes as the "medium" estimate, which actually significantly overstates the effects of the Proposed Framework by focusing only on the 10 CFU/g threshold and disregarding the serotype-specific component. What FSIS characterizes as its "low" estimate is actually FSIS's best estimate of the illnesses avoided using a combined threshold and serotype approach. The "high" estimate is unsupportable because it misconstrues the risk assessment and attempts to add product-class

figures over-estimate the benefits because they are based on the risk assessment's analysis of illness avoidance based on a standard applying to all *Salmonella* in an identified cluster, not the proposed serotype-specific approach. Moreover, they are premised on an interpretation that even FSIS admits is not appropriate: adding the illness categories together despite the risk assessment indicating they overlap and are not additive. Further, these estimates are based on a 10 CFU/g threshold with no regard to serotype. Thus, the Proposed Framework would be even less effective. Based on these estimates, the Proposed Framework will not come close to meeting the Healthy People 2030 target it was designed to achieve, and this does not even take into consideration the costs of implementing the Proposed Framework and the likely over-estimated public health benefits. As discussed further below, the costs of the Proposed Framework would be extreme.

In a similar vein, FSIS estimates that the net benefits from the Proposed Framework would range from $1.14 to $6.75 million. This is based primarily on FSIS's proposed implementation costs which grossly underestimates the costs to industry. Further, this estimate relies on the assumption that adequate rapid testing technology will be developed, but there is in fact no guarantee that this will be developed.

The alternative approach of an enumerated performance standard discussed further below would resolve all of these issues.

IV. ADDITIONAL FEEDBACK ON COMPONENT THREE.

As outlined in the above comments, NCC's position is that the Proposed Framework is unlawful and should not be implemented. In addition to the overarching – and fatal – concerns, NCC has specific comments on Component Three.

A. *Infantis* should not be included as a serotype of concern.

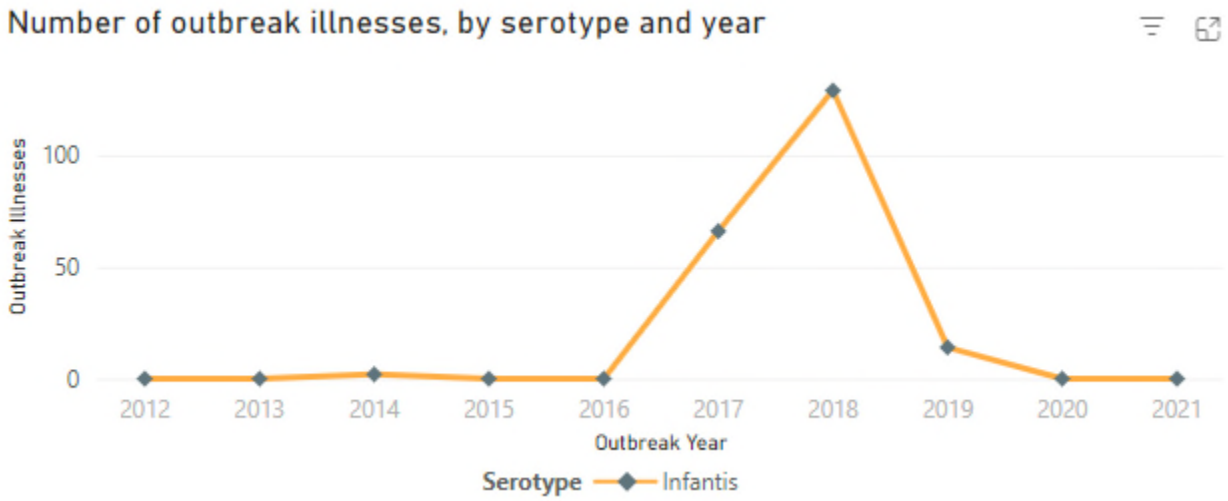
NCC supports FSIS's determination that *Infantis* does not meet the criteria of a serotype of public health concern as described in the Proposed Framework and therefore is not included in the Agency's proposed adulterant determination. Although *Infantis* is a serotype that in recent years has been associated with poultry, there is not sufficient evidence to support finding that chicken is driving U.S. *Infantis* illnesses. In particular, CDC outbreak data shows that *Infantis* illnesses from chicken products were a time-bound issue in and around 2018, but that since 2018, there has not been significant instance of chicken-related *Infantis* illness.[118] The chart below clearly depicts this trend.[119]

information even though FSIS acknowledges that the way the risk assessment was prepared precludes such an approach.

[118] CDC, *BEAM (Bacteria, Enterics, Ameba, and Mycotics) Dashboard*, Atlanta, Georgia: U.S. Department of Health and Human Services (accessed Dec. 11, 2024), available at . www.cdc.gov/ncezid/dfwed/BEAM-dashboard.html.

[119] *Id*.

Figure 3: *Salmonella* Infantis Outbreak Illnesses by Year



This data supports FSIS's assertion in the Proposed Framework that *Infantis* is not a serotype of public health concern as this appears to be a brief, transient instance of illness as opposed to a pervasive public health concern. The Proposed Framework and specifically the time frame proposed for reevaluating serotypes of public health concern should not be designed to respond to transient changes in the illness landscape. Finally, requiring companies to use limited resources to monitor and test for a serotype like *Infantis* that is not driving illnesses will detract attention from other serotypes with a greater public health impact where more progress could be made. As such, we support FSIS's conclusion that *Infantis* should not be included as a serotype of public health concern.

B. FSIS should not adopt a standard that treats *Salmonella* threshold and serotype presence independently.

The proposal asserts that any raw poultry product where *Salmonella* is present at a concentration of 10 CFU/g or greater AND is one of the three identified serotypes would be adulterated. It is important and correct that the determination is constructed as an "and" rather than "or" requirement, however, FSIS needs to provide more guidance on how this requirement would be implemented. Specifically, the Agency must provide guidance on how establishments would evaluate testing that indicates the presence of one of the three identified serotypes but under the 10 CFU/g threshold or testing that indicates a concentration of *Salmonella* is at or above 10 CFU/g and the serotype is determined not to be one of three identified serotypes. In either scenario, one aspect of the proposed adulteration standard, but not both would be tripped, but it is unclear what expectations FSIS may have. It would be critical for FSIS to establish very clear expectations for industry, inspectors, and consumers.

C. The implementation of the 10 CFU/g threshold in light of the inherent variability of testing technology at this level is unclear.

For the Proposed Framework to be effectively implemented, accurate and reliable quantification testing must be readily available. FSIS has identified the quantification testing method ("QUANT") as the most feasible testing available for high volume enumeration testing.[120] However, the QUANT

[120] *See* T. Boynton, et al., *FSIS Poultry Exploratory Sampling Program Report*, USDA FSIS, 8 (Jul. 29, 2024), available at

testing method involves inherent variability that will confound *Salmonella* enumeration testing results. FSIS assessed the reliability of the testing method when evaluating the Agency's Poultry Exploratory Sampling program and found the QUANT method only correctly identifies samples at the 10 CFU level 33% of the time.[121] Specifically, the researchers inoculated 60 samples of poultry with 5 CFU, 10 CFU, and 50 CFU concentrations of *Salmonella* and identified the rate at which the test method correctly identified the sample at either above or below 10 CFU. As illustrated in the table below, the QUANT method is subject to significant variability in its results at all levels.

QUANT Method

Actual Salmonella level (CFU/mL)	Counts Below 10 CFU/mL	Counts Above 10 CFU/mL	Method Accuracy
5	43/60	17/60	72%
10	40/60	20/60	33%
50	15/60	45/60	75%

Critically, this analysis demonstrates that a sample containing 5 CFU/g *Salmonella* (which would comply with the proposed Component Three standard) would be identified as exceeding the threshold more than a quarter of a time.

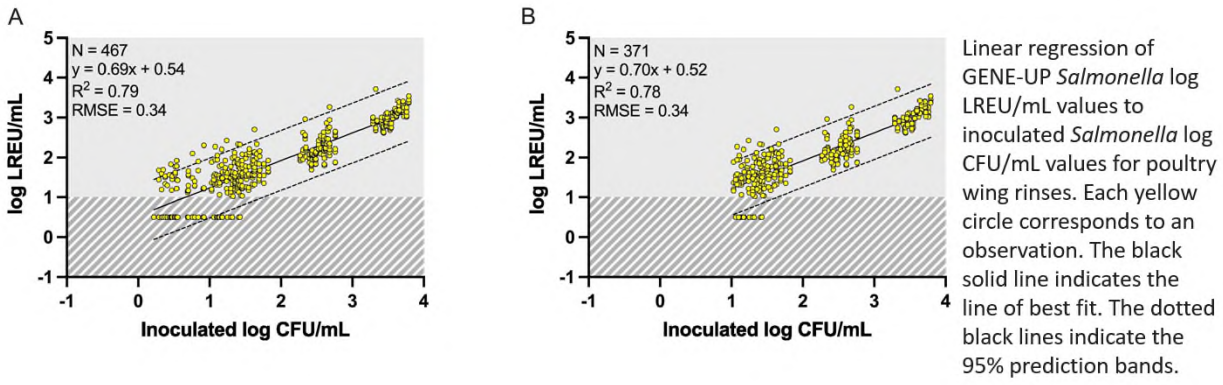
Similarly, a peer-reviewed article published in the *Journal of Food Protection* evaluated methods for identifying *Salmonella* in poultry rinses at the 10 CFU/g threshold. As part of that analysis, the authors showed that the 95% confidence interval for test results at the 10 CFU/g level encompassed a substantial number of values less than 10 CFU/g, as shown below in Figure 4.[122] This figure, extracted from the research paper, demonstrates that samples falling below the 10 CFU/g threshold could still be reported as being at or above the threshold.

https://www.fsis.usda.gov/sites/default/files/media_file/documents/Exploratory_Salmonella_Sampling_Report_July2024.pdf. ("While the MPN method outperformed the QUANT method, it is not a suitable means for running the high-throughput volume of poultry samples received each day at FSIS laboratories. The MPN method requires sixteen individual subsamples as opposed to the QUANT only requiring one.").

[121] *Id.* at 19.

[122] John W Schmidt, et al., *Evaluation of Methods for Identifying Poultry Wing Rinses With Salmonella Concentrations Greater Than or Equal to 10 CFU/mL*, 87(11) J. of Food Protection (Nov. 2024), available at https://www.sciencedirect.com/science/article/pii/S0362028X24001467?ref=pdf_download&fr=RR-2&rr=9028b1fcbe6cc973.

Figure 4: *Salmonella* Testing Confidence Intervals



Linear regression of GENE-UP *Salmonella* log LREU/mL values to inoculated *Salmonella* log CFU/mL values for poultry wing rinses. Each yellow circle corresponds to an observation. The black solid line indicates the line of best fit. The dotted black lines indicate the 95% prediction bands.

Determining that a product is adulterated is a legal conclusion with significant consequences, including loss of property (the product, attendant costs), civil liability, and even potentially criminal liability. It is wholly inappropriate to make such a determination based on a test that FSIS knows incorrectly characterizes compliant product as violative at such a high rate. And it would raise significant concerns under the Due Process Clause of the Constitution to deprive a company of its rights or to pursue criminal penalties based on such inaccurate information. It would be imperative to disclose the measurement uncertainty around the enumerated result.[123]

The inherent variability involved in food testing is a known and accepted issue, and because of this, reported limits must be considered within a range of variability.[124] It is unclear from the Proposed Framework whether FSIS intends to recognize the inherent variability in the testing available and make allowances for this variability. FSIS needs to address scenarios where a test result that appears at or above the 10 CFU/g threshold but is actually compliant with the threshold requirement.

D. The lotting practices currently used in poultry processing operations present a massive challenge under the Proposed Framework.

The Proposed Framework does not take into consideration customary industry lotting practices and how the implementation of the Proposed Framework would impact these practices. It is clear from the discussion of the sampling lot in the Proposed Framework that FSIS does not understand the burden that holding an entire lot to await test results would entail. Chicken production is extremely complex, with carcasses coming out of the chiller being used for a staggering variety of applications. Unlike beef production, which is primarily linear in nature, poultry processing is much more complicated. Once the carcass leaves the chiller, it can have many different destinations and each of its different parts can receive different processing. For example, the same bird can have meat that is used for tray packs, marinated products, and comminuted products. Each of these different products have different processing times and may even be sent to different establishments for processing. This creates further

[123] Further, FSIS needs to provide additional information regarding the controls in place to ensure accuracy of *Salmonella* enumeration results, the pass-fail criteria for these controls, the proficiency testing programs used to implement these controls, and how labs are maintaining GENE-Up QUANT in their scope of accreditation.

[124] Indeed, FDA employs this practice in its regulations regarding nutrition labeling and compliance stating "no regulatory action will be based on a determination of a nutrient value that falls above [or below] this level by a factor less than the variability generally recognized for the analytical method used in that food at the level involved." *See* 21 CFR 101.9(g)(5).

complication as slaughter establishments typically track lots by harvest date, while further processing establishments would track lots by pack date, making it difficult to track flocks through the supply chain. Under the Proposed Framework it is unclear how test results associated with one product will impact the status of other products derived from the same bird. Lotting practices do not necessarily track to the bird level, so identifying what lots of one product are impacted by the results of another would be near impossible.

Not only does the Proposed Framework ignore these well-known realities, but it also makes several assumptions that are not clearly supported by facts or data. For example, the Proposed Framework estimated that a single lot of chicken carcasses would include 46,000 carcasses for high and medium volume establishments, but it is unclear where this information came from and based on our member experience, this underestimates the true size of a lot if defined in the manner suggested in the Proposed Framework.

In the Proposed Framework, FSIS recommends establishments implement in-plant sampling plans to define lots but does not provide guidance on what type of sampling plan would be considered sufficient to establish lot independence given the complicated nature of chicken processing operations. This subjects chicken processing establishments to tremendous risks and uncertainty, as well as inflicts strain on the overall supply chain. Moreover, FSIS does not appear to consider the cost of installing and validating new interventions on each and every production line or the effects of increased testing (validation, verification, and process control monitoring) in the rule's cost-benefit analysis. If lot independence could be driven by testing, this would greatly increase the number of samples being taken in an establishment. This would impose direct costs for staffing, sampling, shipping, and analysis as well as constrain the availability of testing materials and laboratory availability. Further, under a finished product standard, if testing drives lot independence, then establishments could have to hold everything they test. As discussed below, raw poultry products do not have sufficient shelf life to be held for the period necessary under current testing technology.

Moreover, unclear lotting expectations risk substantial unintended consequences. First, many establishments have developed robust, validated less-than-daily sanitation practices that have been approved by FSIS. This is especially true for chiller tank systems, which require substantial amounts of water and which can be readily controlled and monitored. Second, establishments operating in areas with water restrictions may have limitations on water usage and therefore may not be permitted to perform daily sanitation given the amount of water necessary to complete a full sanitation shift, refill chill tanks, and other food safety intervention strategies. Because of this, these facilities may need to keep up to a week of product on hold while awaiting test results. These lotting challenges should be considered and incorporated into the cost-benefit analysis of this rulemaking to better reflect the true burden this would place on industry.

E. Testing will require extended hold times effectively destroying value of product.

The Proposed Framework also promises to subject raw chicken to extended and uncertain hold times. FSIS provides contradictory estimates for how long it will take to provide establishments final adulteration results after the sample is collected. In one section, FSIS acknowledges the following timeframe for final adulteration testing results:

- Based on current testing methodologies, FSIS estimates that *Salmonella* screening results and quantification results would routinely be available *2 days* after a arrives at a lab, which could be the day after the sample is collected.

- 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.[125]

In other words, FSIS acknowledges that under current testing practices and using available methodologies, final adulteration status will take at least 14 days. FSIS goes on to note that it could use "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."[126] However, this methodology is not currently available (at least not with any reliability) and FSIS notes that it is "actively working to explore technologies" with the necessary capabilities.[127] Without the necessary technology, it is unclear how FSIS will meet this 5 day time commitment. It is unclear what testing FSIS would be relying on, and it is unclear when these alternative technologies would be adopted.

But whether it is 5 days or 14 plus days, the testing timeline is too long in light of the shelf life of raw poultry products. The shelf life for some raw poultry products is as short as 5 days upon receipt at the grocery store. No raw product subject to testing would meet this timeline. Many other products have shelf-life requirements starting at 12 days, which means they would also be out of shelf life before FSIS has final adulteration status results under currently available testing technology. In addition to the shelf life concerns, this timing would lead to extended hold times, necessitate expanded cold storage, decrease the availability of chicken products, result in a strain on the supply chain, and impact the cost of chicken to consumers. Establishments would also be forced to add additional steps to the cold-chain system, which would increase the opportunity for inadvertent temperature abuse, cross contamination during storage, and other unintended consequences.

Given the uncertainty around how lots will be defined and the timeline for receiving test results, any FSIS or establishment testing would subject considerable amounts of product to sustained holds. This will create huge constraints on company storage as most companies have little to no storage capacity, and supply chain management issues as companies need space and time to hold each lot of product. Although the Proposed Framework seems to contemplate that companies will release product (or divert to fully cooked depending on the results) between receiving quantification results and receiving the serotype results, our conversations with members indicate this is far from certain, and an establishment may decide not to release product until both quantification and serotype results are known. This would require hold times of at least 5 days (but likely closer to 15) every single time a lot is tested for *Salmonella*. If FSIS is sampling once per week and each lot must be held, sampled lots from week to week may overlap, compounding the cold storage capacity and lot-tracing issues.

Whether it is practical or possible for an establishment to divert product subject to testing to a fully cooked formulation depends on multiple factors:

[125] 89 Fed. Reg. at 64707 (emphasis added).
[126] 89 Fed. Reg. at 64729.
[127] *Id*.

- Some raw product formulations cannot be used in a fully cooked product. For example, some raw products are made with marinades or spices that may not allow the product to be shifted to a fully cooked product.

- Some raw product packaging is incompatible with shifting to an alternate process due to labor and time constraints. For example, with retail chicken already in packaged trays, to shift to a fully cooked product, establishments would need manual labor resources to completely unwrap the product and repackage it for transportation to a fully cooked line or another establishment for cooking. This takes significant time and resources, results in wasted packaging material, and introduces the possibility of contamination from multiple points of handling and packaging as well as raising foreign material contamination risks.

- Some establishments do not have access to a fully cooked processing facility.

- Even establishments that have access to a fully cooked processing facility may not have the necessary space to shift all product on hold from both a storage and processing capacity standpoint.

- There is virtually no fully cooked demand for some raw products (e.g. bone-in chicken legs). Establishments would need to debone these parts, taking additional, time, labor, and cost as well as more strain on the shelf life of the product.

If product cannot be diverted to a fully cooked product, establishments may have to dispose of perfectly safe chicken to rendering or the landfill. Disposal costs are significant, and while the costs associated with food waste are difficult to ascertain, this is certainly a concern for industry, regulators, and consumers.

In addition to these practical, establishment-level concerns, the extended hold times will also pose a challenge to the broader supply chain. First, the extended hold times will impact the shelf life of these perishable products. With a shorter shelf life, retail stores will need to turn their inventory more frequently, which could result in less product available on store shelves and shorter shelf life in consumers' refrigerators. Second, the product on hold will need to be stored somewhere, likely (at least until new capacity is built) in refrigerated trucks on the processing establishment premises (if space is available), which is a lower quality solution to a refrigerated storage facility. The constraint on refrigerated storage facilities will be felt across the food supply chain in other refrigerated and frozen products as there is more demand for limited space. Increased storage costs will only result in increased overall food costs, which impacts all levels of the supply chain, including consumers. This costly and difficult change to the industry will impose huge burdens, and FSIS does not anticipate enough product being contaminated to justify this burden and loss to the food supply. These effects are discussed further below.

F. FSIS should clarify that testing only applies to truly finished product.

The Proposed Framework includes a finished product standard for raw poultry. FSIS must clarify which products the adulterant standard applies to and how the standard would be applied to products with additional ingredients. In many instances, raw poultry products are transferred from one establishment to another for further processing, and in some instances, this further processing includes the addition of non-poultry ingredients, such as spices and marinades. FSIS should clarify that the finished product standard only applies to truly finished product (i.e. product ready for shipment into commerce) because testing in process products is redundant, inconsistent, and unfair.

Testing and applying the finished product standard to in-process materials would penalize establishments that specialize in slaughter in comparison to establishments that perform both slaughter and further processing under one roof. In situations where the product will receive further processing at another establishment, the process will be subjected to duplicative testing, expanded uncertainty, and create unnecessary shelf-life concerns. If the product is tested in both processing establishments and the first processing establishment shows compliant test results, there is a risk that testing at the further processing establishment obtains different results, which in turn could affect product from the lot at the originating establishment. For example, trim from chicken parts that showed a conforming result at the originating establishment intended to be used in a comminuted product could be sent to a second establishment for grinding, and at that establishment the trim may be combined with trim from parts not yet tested against the standard. If the finished comminuted product is later found to be adulterated, it is likely not a result of contamination at the originating establishment, but it is not clear what product FSIS would consider implicated. Any standard would need to be focused only on the true, final finished product.

Additionally, it is unclear from the Proposed Framework how FSIS would handle finished products that violate the adulteration standard when the poultry product includes nonpoultry ingredients such as herbs or marinades. The addition of new ingredients has the potential to expose the poultry product to an adulterant and it is important that the adulteration is not incorrectly attributed to the poultry component when in fact the *Salmonella* was present due to an added ingredient. The testing required under the Proposed Framework does not provide the granularity needed to determine the root cause of the contamination and erroneously attributing the source of the contamination to the raw chicken product could implicate a large amount of raw product associated with the same production lot. Before moving forward with the rulemaking, FSIS must clarify these enforcement dynamics to ensure equity and fairness in the regulation's application.

G. The process of reevaluating serotypes of public health concerns must be structured and based on objective factors.

In the Proposed Framework, FSIS vaguely references that it will reassess the serotypes of public health concern on a 3 to 5 year basis. We ask FSIS to provide more concrete details as to how the serotype reassessment would occur and how this would fit into the lifecycle of a serotype. It is not appropriate for serotypes to constantly change in response to one-off outbreaks but should instead be focused on pervasive serotypes that are demonstrated to be driving substantial amounts of illness. Although they cannot eliminate a particular serotype, serotype-specific vaccines are a critical tool for managing preharvest levels and serotypes of *Salmonella*. Unfortunately, poultry vaccine development is an extremely slow process held back in many ways by cumbersome, outdated, and under-resourced government review processes. Because of this, the vaccine lifecycle should play a key role in the serotype reevaluation timeline. From isolation of the serotype until broilers with material antibodies are received at the processing plant can take 18 to 24 months. If serotypes are reassessed every 3 to 5 years, the industry will be forced to potentially change its vaccine strategy before the impact of the previous vaccine strategy is realized. Based on all of these factors, it is important that FSIS articulate the timeline, process, and requirements for determining which serotypes are classified as a public health concern in any additional iteration of this rulemaking. Further, FSIS should work with the Animal and Plant Health Inspection Service's ("APHIS's") Center for Veterinary Biologics to allow for the approval of additional serotype-specific commercial vaccines. Having access to these vaccines could further complement autogenous vaccines in a vaccination strategy.

H. The Proposed Framework presents numerous and significant enforcement and implementation challenges.

In addition to the enforcement and implementation challenges addressed throughout this section, including lotting complications, the threshold testing viability, the application of the Proposed Framework to tests where only one prong of the determination is satisfied, and the significant hold times, there are additional challenges that need to be addressed.

- The Proposed Framework does not provide guidance on how downstream or retail product testing that shows the product violates the adulteration standard would be considered. Once the product leaves an establishment, the processing plant loses all control over the product and potential contamination or environmental factors that may lead to increased *Salmonella* concentrations. FSIS needs to provide guidance on how these tests will factor into enforcement policies.

- In the Proposed Framework, the Agency requests comment on an alternative implementation approach to Component Three. This approach would focus final process verification sampling on establishments that have demonstrated a lack of process control.[128] Although NCC and its members view this as a more appropriate implementation approach, additional details around this alternative approach need to be provided. By focusing on establishments with a demonstrated sanitation issues, FSIS will be able to focus resources on the products of the highest risk and prevent unnecessary disruption to the supply chain from produced at low-risk establishments.

I. The Proposed Framework risks negatively influencing the incentives surrounding pathogen testing in establishments.

The nature of any adulterant standard is that it will substantially change the implications of test results, and thus the considerations around establishment testing. Currently, without an adulteration standard, establishments are free to evaluate the needs of their systems and design unique testing programs that meet the establishment's needs.[129] The Proposed Framework, however, risks severely compromising currently robust industry testing. The Proposed Framework's *Salmonella* testing would carry with it substantial costs, including extended product hold times and production disruption, as discussed elsewhere in these comments. Internal test results that exceed the Component Three standard would cause a product to be considered adulterated, significantly limiting the circumstances in which an establishment would likely be in a position to conduct such tests (e.g., only where there is a high level of confidence in the lot definition, there is complete control of the lot, and the establishment has prepared the infrastructure and logistics for an extended product hold). If the goal of the Proposed Framework is to encourage establishments to implement more or different testing and monitoring strategies to control for *Salmonella*, it is unclear whether the Proposed Framework will actually achieve this objective. For this reason, a performance standard would be a more efficient way of ensuring establishments are controlling *Salmonella* without changing the incentives for establishment monitoring.

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[128] 89 Fed. Reg. at 64709.

[129] Unfortunately, at this time, FSIS does not consider an establishment's data that uses threshold testing for *Salmonella*. FSIS will post an establishment as a Category 3 based on FSIS prevalence testing regardless of data the establishment may have to demonstrate any *Salmonella* positives are at a very low level.

J. It would make more sense to prioritize the highest risk products.

As is outlined throughout these comments, implementing the Proposed Framework would be incredibly disruptive to the poultry industry and the food supply and would entail significant implementation costs. If the Agency moves forward with this proposed approach, and once accurate and reliable testing methods are available, it would be more appropriate to focus a policy on comminuted chicken, which is the highest risk product category. Because of how it is produced, comminuted chicken is also the easiest product category to establish microbiologically independent lots for testing and holding.

FSIS's data demonstrates that comminuted products have the highest baseline risk per serving at a level 10-20 times higher than carcasses or parts.[130] The fantastically low probability of consumer exposure data presented in the Proposed Framework for parts and carcasses underscores that identifying products at or above the defined threshold is like trying to find a need in a haystack. The Proposed Framework indicates that if it were applied only to comminuted products, 71.4% of the predicted illness reduction would be achieved.[131] This data correlates with the historical recalls involving raw chicken products, in which all but one recall have been related to comminuted products. With many of the estimated benefits in the Proposed Framework being driven by comminuted products, should the Agency move forward with this proposed approach, it would be logical for FSIS to focus its attention here first before moving on to other products.

This approach would also have the benefit of allowing FSIS to evaluate the success of the Proposed Framework to determine whether it is actually effective without imposing substantial disruptions on the industry and food supply.

Moreover, products sold for further processing into cooked products and products sold into foodservice channels present an even lower risk than the already low risk presented by chicken generally. Foodservice professionals are trained in proper cooking and preparation techniques, and the cooking processes and techniques used in settings from quick-service to fine dining establishments all readily achieve lethality. There is also no material history of salmonellosis illness outbreaks associated with foodservice preparation of raw chicken. It makes little sense to apply the Component Three requirements to chicken intended for cooking at other plants or in foodservice settings.

K. A modified version of the alternative verification sampling approach would be effective.

Under the current design, performance standards would be effectively eliminated, which would remove a tool in FSIS's toolbelt. The proposed statistical process control program described under Component Two is not a sufficient alternative. We are recommending FSIS implement a quantifiable performance standard instead of the finished product standard. We believe this strategy will have more robust public health benefits without the level of disruption seen across the Proposed Framework. Process control through harvest, such as sanitary dressing and effectively implementing antimicrobial interventions is what will further reduce *Salmonella* in chicken. The purpose of plant testing is to verify the process. Testing is but one component of an overall food safety system. *Salmonella* results provide feedback to the establishment on whether the controls in place for microbial

[130] 89 Fed. Reg. at 64702. The risk, though, is low even for comminuted chicken.
[131] 89 Fed. Reg. at 64703.

contamination are effective, but testing is not itself a robust food safety control. It is the controls themselves that are effectively addressing *Salmonella*.

V. FEEDBACK ON COMPONENT TWO.

NCC members support the use of effective statistical process control programs. A robust statistical process control program uses real-time data that allows a plant to react rapidly to changes in control data. Microbiological data is an important tool for assessing a plant's process, but because microbiological data is not real time, and because Aerobic Plate Count ("APC") does not correlate strongly with *Salmonella* presence, it cannot provide the basis for a true statistical process control program. To this end, our members are supportive of the general principles underlying Component Two, but important changes would be required to make this an effective food safety approach.

Process controls are central to managing food safety in poultry slaughter and processing facilities and industry stakeholders support using these measures to control *Salmonella* risk. FSIS has long had the authority to enforce and manage process controls through the sanitary dressing regulations in 9 CFR Part 381. Our members' experience is that these regulations are inconsistently enforced and not prioritized in inspectional activities, but they provide FSIS an opportunity to set expectations and verify that establishments are operating effectively and under sanitary conditions. We would encourage FSIS to consider whether Component Two is necessary given FSIS's existing authority or whether modifications and additions to existing guidance would provide the best opportunity for meaningful public health impact.

A. Component Two generally provides a rational approach to the issues.

The Proposed Framework describes Component Two as requiring establishments to incorporate statistical process controls ("SPC") monitoring principles into the establishment's microbial monitoring program ("MMP").[132] This would include requiring implementing written corrective action and root cause analysis procedures that would be triggered when monitoring results deviate from the predefined criteria in the MPP. Additionally, FSIS is proposing a new guidance that includes a SPC sampling plan based on APC at rehang and post chill locations and specifies that establishments who implement this guidance would not need to provide additional validation to support their statistical methods. Finally, the proposed Component Two would also require records regarding an establishment's MPP be submitted to FSIS headquarters.

Broadly, our members agree that process control is a sound approach to monitoring the microbial status of a slaughter facility, however, aspects of the proposed program are problematic, such as pre-shipment review, electronic submission of records, specific sample locations, lack of the ability to have immediate feedback as to the process, and specific log-reduction requirements. Alternative approaches, however, may be more easily implementable for industry and FSIS and provide greater incentives for improvements that will help meet the Healthy People 2030 goals. We agree that successful pathogen reduction, including *Salmonella*, starts with strong process controls. It is critical that the updated regulations provide the best path for industry to control their process and have the right data to verify their efforts. We offer suggestions to that end below.

[132] 89 Fed. Reg. at 64680.

B. Incorporating SPC requirements into pre-shipment review would cripple industry without meaningfully impacting public health.

Component Two is currently positioned to impact pre-shipment review. The preamble to the Proposed Framework states that the MMP monitoring results and documented corrective actions be incorporated into the pre-shipment review process required under 9 CFR 417.5(c).[133] If pre-shipment review is required, this would effectively put the entire raw poultry industry on a full test and hold program. Further, it takes several days to receive APC testing results, which would dramatically compound the storage, capacity, and shelf-life concerns described in Section IV above.[134] In addition, this delay precludes the results from being the most effective indicator of process control. We request clarity from FSIS on this point of confusion and urge FSIS not to require that MMP results be incorporated into pre-shipment review.[135]

FSIS continues to point to the beef industry and success in driving down human illness associated with STEC. The beef industry did this by using testing data to evaluate their harvest process and refined process controls to ensure the safety of all products produced. Many falsely assume the testing done by the beef industry and the removal of individual lots testing positive is what led to public health improvements. The reality is that testing is not what improves public health – it is the changes to the process (used to produce all product) that improves public health. Sampling is simply a verification of the effectiveness of the process.

Further, irrespective of whether FSIS intends to establish a test and hold program, the proposed testing correlates poorly to *Salmonella* levels. Instead, the testing results generally indicate whether the establishment handled incoming birds to control all relevant sources of pathogens – e.g. fecal material, ingesta, and other bacteria – not just *Salmonella*. While microbial testing data is important to overarching food safety, establishments do not receive microbiological testing results in real time. By the time an establishment receives the data, it is already processing another farm or flock of birds and has made process changes in response to observed abnormalities. In other words, the test results do not lead to process changes – those are made in real time based on other, contemporaneous data and observations.

We recommend FSIS consider a version of Component Two that looks at these real time data points to assess *Salmonella* performance as part of monitoring and improving systems overall, rather than being tied into a lot-specific analysis. Real-time decisions provide the best opportunity to see positive changes in public health. Microbiological sampling can and should be used, but as a tool to verify effectiveness of such a program.

C. USDA should not require electronic submissions of statistical processing control records.

The proposed requirement that SPC records be submitted to USDA headquarters monthly is without precedent and should not be included in any further rulemaking on this topic. In particular, we are

[133] 89 Fed. Reg. at 64718.
[134] FSIS requires that 20% of results be quantifiable, so rapid testing would not be a viable option with current technology.
[135] Establishing a test and hold program based on SPC results is not appropriate. Poor SPC results do not mean the product lot of product is adulterated. Rather, SPC is a monitoring activity to ensure the system is operating within the expected parameters. Because of this, SPC results are a check on the system but not a direct indicator that product should be considered adulterated.

concerned that the requirement would be overly burdensome for both the Agency and establishments and that the information would not be easily interpreted by USDA headquarters because of the need for establishment-level context. Additionally, these records contain plant-identifying and commercially sensitive information, and it is unclear from the Proposed Framework how this information will be protected. Given the important role of process controls in poultry processing, we urge FSIS to reconsider this requirement, which makes it difficult for industry to support Component Two as proposed.

It is unclear whether providing the proposed records to USDA headquarters will have any impact on public health. Specifically, it is unclear whether this information would be useful without more context and information on the operations of the establishment and how those operations impact the information in the submitted records. Currently, onsite inspectors have access to this information and the ability to efficiently contact plant personnel to discuss questions or concerns identified in this data. By moving or creating an additional review at USDA headquarters, this context is lost and the resulting interpretations would not provide a holistic view of the establishment, its corrective actions, and the trends indicated. Not only would review by headquarters be less efficient, but it also requires new resources from both USDA and establishments to generate, format, check for accuracy, and interpret the reports. This information is already being taken into consideration and acted on at the establishment level, so very little benefit would be gained by the submission of these records, especially when balanced against the increased monetary and resource cost.

In addition to the lack of efficiency, there are also significant privacy considerations associated with this requirement. Specifically, the Freedom of Information Act ("FOIA") requires U.S. government bodies, including USDA, to disclose information at the request of citizens. USDA has not provided any assurances that the electronic SPC records would be protected from FOIA's requirements, and therefore there is significant risk that the confidential, proprietary, and competitively sensitive information contained in these records would be disclosed in response to FOIA requests.

Considering both the privacy concerns and lack of clear benefit related to the submission of these records, we urge FSIS to remove this requirement from any future rulemaking. Please note, NCC's members are interested in and supportive of Agency-industry data sharing initiatives, but would recommend these initiatives operate independently of the proposed *Salmonella* Framework.

D. It is unclear whether Component Two will act as an effective mechanism to reduce *Salmonella* illnesses.

The Proposed Framework casts doubt as to whether Component Two would have a measurable impact on public health due to the weak correlation between APC or *Enterobacteriaceae* (EB) levels and the presence of *Salmonella* organisms. Specifically, the Proposed Framework states ''studies show a weak correlation between indicators and either the presence or level of *Salmonella* post carcass wash" and "unpublished data provided by the poultry industry and university researchers suggest that indicator bacteria have very limited predictive value for the prevalence of *Salmonella*."[136] Based on this observation, it is unclear whether pursuing Component Two would make a measurable

[136] 89 Fed. Reg. at 64711 (FSIS quoting the 2023 NACMCF Report) and David A Vargas et al., *Data-Mining Poultry Processing Bio-Mapping Counts of Pathogens and Indicator Organisms for Food Safety Management Decision Making*, 12(4) Foods 898 (2023), available at https://www.mdpi.com/2304-8158/12/4/898.

difference to public health. As stated above, it is control of the process that will make a measurable difference in public health.

Additionally, the proposed enforcement strategy for Component Two does not appear to match with data regarding where microbial risk is highest. For example, FSIS supports a broad assertion that establishments are not following MMP requirements through noncompliance report data, however this is an incorrect use of the noncompliance report data.[137] The presence of a noncompliance report alone is not a clear measure of an establishment's overall compliance rate, especially because FSIS does not appear to be evaluating noncompliance reports issued relative to overall inspectional tasks. As another example, both the risk assessment and FSIS data demonstrate that smaller size or volume establishments are more likely to have higher levels of microorganisms. Logic would suggest that these establishments should be the focus of FSIS sampling and enforcement, but instead these establishments would be subject to almost no sampling or enforcement with only 13 samples being taken each year. Finally, in the Proposed Framework, FSIS assumes "most establishments would meet the proposed MMP requirements without having to make any changes that would result in costs."[138] This statement suggests that most establishments are in fact in control of their processes. If this is the case, this rulemaking in its entirety is unnecessary. NCC recommends that FSIS take more steps to understand the actual cost-benefit assessment of implementing Component Two before moving forward with this rulemaking.

E. The 1-Log reduction requirement would stifle innovation.

Component Two contemplates requiring MMPs to set an expected reduction target of at least 1-log in detected microbial levels between rehang and post chill.[139] This is not how SPC is typically used. SPC is designed to monitor whether the process is performing at the expected parameters, regardless of what those expected parameters are. It is independent of trying to reduce microbiological load through processing. NCC member companies reduce microbiological load by establishing robust multi-hurdle intervention systems. To provide meaningful outcomes, SPC should follow intervention design, not the other way around. Further, the proposal requires set sampling points and does not reflect any steps taken by an establishment after the second sampling point to address process control.

More fundamentally, we are concerned that this requirement would change incentives in a manner that would stifle innovation in preharvest controls and in plant controls before rehang. Specifically, our members report that it is not uncommon to find low microbial activity at their initial sampling points. Indeed, FSIS's exploratory sampling program found that only 18.4% of samples at rehang were above 10 CFU/g.[140] In many cases, even if the process controls in place work, at the next sampling point, a 1-log reduction would not be observed. The Proposed Framework does not provide an explanation as to how these scenarios would be addressed. Further, because a full 1-log reduction would be required, establishments that consistently see low microbial loads at their first sampling point may be disincentivized from pursuing preharvest interventions to further control microbial presence. As discussed throughout these comments, industry has been committed to implementing processes and interventions that minimize the microbial organisms entering the establishment and many of these

[137] 89 Fed. Reg. at 64712.
[138] 89 Fed. Reg. at 64727.
[139] 89 Fed. Reg. at 64714.
[140] Tye O. Boynton, et al., *FSIS Poultry Exploratory Sampling Report*, USDA FSIS, 7, available at https://www.fsis.usda.gov/sites/default/files/media_file/documents/Exploratory_Salmonella_Sampling_Report_July2024.pdf.

occur at preharvest. If establishments are penalized or disadvantaged for these practices, there will be less incentive to pursue new and innovative controls that occur before slaughter.

In addition to these concerning disincentives, aspects of the 1-log reduction requirement are unclear. First, what if a MMP has multiple sampling points, including outside of rehang and post-chill locations? Will a 1-log reduction be required between each sampling point or only between the first and last? Finally, how would this requirement be enforced? Would this immediately result in a noncompliance, or would additional steps be taken before a noncompliance report is issued? Overall, the 1-log reduction requirement would add significant confusion and potentially disincentivize robust preharvest practices. FSIS should incentivize (not penalize) establishments to use effective pathogen control interventions throughout the process. The Proposed Framework does just the opposite.

F. Additional Feedback.

In addition to the above-described feedback, below is additional feedback for consideration on the details underlying Component Two.

- FSIS should retract the proposed electronic submission requirements as it is overly burdensome to require industry to record data in a certain way and it is completely unnecessary to have to submit this information to headquarters when it is already available for in plant personnel to review.

- FSIS's requirement that SPC programs use a quantifiable test for at least 20% of results could stifle innovation in rapid testing which is an area of microorganism testing that needs to be improved for Component One to be feasible. There is nothing inherently wrong with using data distributions that have a non-normal distribution toward zero when zero values are a measure of success. Moreover, this approach risks penalizing establishments with strong microbiological results coming out of the chiller.

- FSIS should allow for flexibility in carcass rinse methods in instances where establishment validate the method effectiveness.

- Any further rulemaking should confirm that SPC results may be derived from in-house labs that have been accredited to perform the tests at issue.

- FSIS should provide more flexibility in sampling locations than only rehang and post-chill to allow SPC programs to more effectively address conditions specific to each establishment. Fixed sample location disincentives establishments from adding control measures before and after the selected sample locations.

- NCC is open to different sampling frequencies than those traditionally based on weekly slaughter volume when the frequencies would bring small establishments into the process faster and more effectively.

In summary, process control programs should help an establishment implement sanitary dressing procedures to prevent carcass contamination; implement effective decontamination and antimicrobial interventions; properly assess microbial testing results, including results for indicators of process control, at any point during slaughter; and use the results to drive continuous improvement in the process. They should not be part of lot-by-lot release determinations.

VI. FEEDBACK ON COMPONENT ONE.

As NCC articulated in comments on the Proposed Framework, the proposed requirement that processing facilities consider *Salmonella* on incoming flocks a hazard that is reasonably likely to occur and require testing on these incoming flocks should not be pursued. This requirement would not have been feasible to implement, was inconsistent with HACCP principles, and extended beyond FSIS's legal jurisdiction.

A. NCC supports a nonregulatory approach that moves Component One to guidance.

NCC appreciates FSIS's consideration of comments highlighting the burden of preharvest testing requirements, and our members are supportive of FSIS's decision to prioritize a non-regulatory approach to controlling *Salmonella* at preharvest and reducing the *Salmonella* load on birds at receiving. A nonregulatory approach is appropriate especially considering the numerous preharvest intervention strategies implemented by industry to reduce *Salmonella* loads coming into establishments without the need for a regulatory requirement. For example, robust preharvest *Salmonella* control strategies are widely implemented across the industry to include programs in hatcheries, feed mills, breeder houses, and broiler houses, including:

- Biosecurity programs;
- Equipment sanitation;
- Feed treatment;
- Litter treatment;
- Feeding of prebiotics and probiotics;
- Rodent/insect control;
- Cleanout programs; and
- Vaccinations.

Industry is taking significant steps to address *Salmonella* in preharvest, and FSIS's efforts in this area would be best focused on the development and use of vaccines. Industry is incredibly supportive of the use of vaccines to control for *Salmonella* and vaccines have proven to be effective at reducing, but not eliminating, the presence of certain serotypes. Current efforts to develop and implement new vaccines that would help limit the presence of *Salmonella* have been stymied by APHIS. Today, the European poultry industry has access to significantly more vaccines than we do here in the United States. These vaccines are safe and have proven effective, yet when the United States poultry industry has tried to bring this technology to the domestic market, it has been met with resistance – particularly modified live vaccines.

If FSIS wants to help facilitate industry efforts to control *Salmonella* in the preharvest environment, it should use its influence to collaborate with APHIS to improve the vaccine approval process for poultry vaccines. NCC and our members are willing and eager to partner with FSIS in this effort and work together on other initiatives or strategies impacting the preharvest space. In this way, a nonregulatory approach can be effective in controlling *Salmonella* preharvest as industry is supportive of these efforts and ready to collaborate.

B. Moving Component One to guidance is consistent with FSIS's legal authority.

Moving on-farm and incoming flock protections and measures to guidance is consistent with FSIS's statutorily defined scope of authority. The PPIA is clear that FSIS's authority begins at the official

establishment. FSIS's primary slaughter-related inspectional authorities are expressly limited to operations in official establishments:

- Ante mortem inspection: "[T]he Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante mortem inspection of poultry **in each official establishment** processing poultry or poultry products. . . ."[141]

- Post-mortem inspection: "The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors post mortem inspection of the carcass of each bird processed . . . in each **official establishment** processing such poultry or poultry products . . . ."[142]

- Sanitary practices: "Each **official establishment** slaughtering poultry or processing poultry products . . . or otherwise subject to inspection under this chapter shall have such premises, facilities, and equipment, and be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purposes of preventing the entry into . . . commerce, of poultry products which are adulterated."[143]

- General compliance: "No **establishment** processing poultry or poultry products for commerce otherwise subject to this chapter shall process any poultry or poultry product except in compliance with the requirements of this chapter."[144]

It is telling that even ante mortem inspection, which is inspection of live birds, must occur at the official establishment. Had Congress intended FSIS to oversee farms, Congress could have given that authority to FSIS. Instead, Congress specifically limited FSIS's inspectional and oversight activities to official establishments, even for the inspection of live birds. FSIS has long agreed with this limitation. For example, in the final rule implementing HACCP, FSIS expressly recognized that "FSIS does not intend nor is FSIS authorized, to mandate production practices on the farm."[145] Thus, not only does the statute specifically limit FSIS's authority to official establishments (and further distribution therefrom), but FSIS also expressly recognizes this limitation in its foundational rulemaking for the very HACCP framework that FSIS proposes using to regulate activity on farms.

C. It would be inappropriate to incorporate preharvest controls in the National Poultry Improvement Program.

The Proposed Framework indicates FSIS is considering incorporating certain preharvest controls into the current National Poultry Improvement Program (NPIP). The NPIP was established to provide a cooperative industry, state, and federal program to implement new diagnostic technology to improve poultry and poultry products. The central purpose of the NPIP is to enhance and protect animal health, and the related, internationally recognized certifications act as industry gold standard. Adding preharvest *Salmonella* controls to the NPIP will overextend the resources currently allocated to NPIP and move the program's focus away from its core animal health mission. This runs the risk of diluting the reputation and effectiveness of the program, which will have implications for exported products.

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[141] 21 U.S.C. § 455(a) (emphasis added).
[142] 21 U.S.C. § 455(b) (emphasis added).
[143] 21 U.S.C. § 455(a) (emphasis added).
[144] 21 U.S.C. § 459(a) (emphasis added).
[145] 61 Fed. Reg. 38806, 38810 (July 25, 1996).

Instead of establishing NPIP certifications or other mandatory programs, NCC supports the implementation of additional guidance or the development of voluntary programs. Over the years, industry has proven it is committed to implementing programs and strategies that are effective at controlling *Salmonella* preharvest when these programs are right-sized and actionable. A voluntary program would be effective in achieving the preharvest mission without diverting resources from areas where they would be more efficiently allocated.

D. Additional research is needed into preharvest controls.

NCC encourages FSIS and its regulatory partners to support additional research into preharvest controls. In particular, the Proposed Framework states that pilots are being conducted at two establishments to examine the merits of using preharvest results to optimize establishment intervention.[146] Based on the language in the Proposed Framework, the results from these pilots do not appear to have been collected or analyzed at this time. Before moving forward with any updated guidance, FSIS should finish this, and any other, data collection efforts.

VII. THE PROPOSED FRAMEWORK DOES NOT ADVANCE PUBLIC HEALTH GOALS.

Central to any agency rulemaking is that the rulemaking will have a measurable effect on the issue being addressed by the rule. Critically, the Proposed Framework notes that it is aimed at achieving the Healthy People 2030 targets, but the cost-benefit analysis shows that this goal would not be achieved. Industry is very supportive of controlling *Salmonella* in raw poultry and reducing the number of salmonellosis illnesses from poultry products, and we are confident that industry would adopt and support an implementable strategy that demonstrates a true measurable benefit on public health. Unfortunately, the Proposed Framework would not achieve its intended public health benefit, as FSIS even admits in the course of the proposal.

A. The cost-benefit analysis clearly shows that the Proposed Framework will not make a sufficient difference to public health to justify the rule.

The Proposed Framework would not come close to meeting the Healthy People 2030 target it was designed to achieve and would not result in a significant public health benefit in comparison to the cost of implementing the Proposed Framework. FSIS's cost-benefit analysis estimates that the net benefits from the Proposed Framework would range from $1.14 to $6.75 million.[147] This is based on FSIS's proposed implementation costs, which grossly underestimates the costs to industry, the overarching food supply chain, and consumers.

The incredibly small public health impact is driven primarily by how low the probability of exposure to an infectious dose of *Salmonella* is for each serving of poultry consumed. If we assume, as the Proposed Framework has, that the targeted infectious dose to avoid is 10 CFU/g, then the probability of exposure to this dose ranges from less than 0.01% for chicken parts to 0.79% for comminuted chicken, and this trend continues at lower proposed thresholds.[148] This low probability of exposure means that it would be incredibly difficult to identify any single product or lot contaminated at this level.

Even focusing on comminuted product, which data suggests is the product of highest concern, the data surrounding the actual number of illnesses avoided does not suggest that changing the threshold

[146] 89 Fed. Reg. at 64686.
[147] 89 Fed. Reg. at 64681.
[148] 89 Fed. Reg. at 64702.

level will dramatically change the number of illnesses. For comminuted products, illnesses avoided between a range of 0.03 CFU/g to 100 CFU/g were as follows: 600 for 100 CFU/g to 1,500 for 0.03 CFU/g. With only a change of 900 between these incredibly different thresholds, it is difficult to see how the Proposed Framework would make a meaningful difference. This suggests the Proposed Framework is not satisfactorily designed to achieve a measurable public health benefit. Further, it is important to note that the small public health impact would be even smaller if the Agency factored in the three serotypes targeted in the proposal. The risk assessment only evaluates the impact of *Salmonella* load and does not address the impact that singling out these specific serotypes would have on public health. Again, industry welcomes strategies and regulations that will protect consumers from *Salmonella* illnesses, but these strategies need to be effective to gain broad support. The Proposed Framework has not provided sufficient evidence of success to gain this broad support.

B. The Proposed Framework would only prevent a small number of illnesses.

The Proposed Framework estimates that *Salmonella* is responsible for 1.3 million illnesses a year with 125,115 and 42,669 *Salmonella* illnesses being attributed to chicken and turkey products respectively.[149] Based on the estimated illnesses avoided under the Proposed Framework, there would be 1,000 fewer chicken related illnesses and 2,100 fewer turkey illnesses which correspond to a 0.7% reduction in chicken-related illnesses and a 4.9% reduction in turkey-related illnesses.[150] This is not a significant reduction in illness and cannot support the promulgation of a rule that so dramatically changes the Agency's position of *Salmonella* in poultry and would cost industry and consumers hundreds of millions of dollars.

As previously mentioned, the 2023 risk assessment did not consider serotypes specifically (meaning it overstates the effects of the Proposed Framework) and still found an incredibly low number of illnesses avoided at 10 CFU/g: 1,000 illnesses avoided for carcasses, 200 for parts illnesses avoided, and 1,000 illnesses avoided for comminuted.[151] The construction of the risk assessment means that these numbers are not additive, though, and carcass-related illnesses appear to be inclusive of other illnesses, so the true number of illnesses avoided for all products would appear to be 1,000.[152] However, the Proposed Framework incorrectly treats these numbers as additive in estimating the number of illnesses avoided, which directly contradicts the Agency's explanation of its own risk assessment.[153] Regardless of whether these numbers are additive or not, the total number of estimated illnesses avoided is not significant to move the needle from a public health standpoint. Indeed, these benefits could readily be achieved (and likely exceeded) through the proposed alternative approach discussed later in these comments.

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[149] 89 Fed. Reg. at 64681.

[150] *See* 89 Fed. Reg. at 64703. *See also*, 89 Fed. Reg. at 64738 ("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."). Despite noting this, in the second Table 34 FSIS adds the illnesses avoided from each product categories, thereby overestimating the number of illnesses avoided in its benefit analysis. Consistent with the Singer Report provided as Attachment 2, we would expect the actual number of illnesses avoided under the Proposed Framework to be 1,000-1,500 as the 2,200 number double counts certain carcass-associated illness estimates.

[151] 89 Fed. Reg at 64738.

[152] 89 Fed. Reg at 64738.

[153] 89 Fed. Reg at 64738-39.

Finally, the biggest challenge facing industry under the Proposed Framework would be lotting products in an effective and productive manner. Across the board, comminuted products are continuously seen as the driver of *Salmonella* risk in raw poultry products with the highest probability of illness. Because comminuted products are the largest driver of illness and the lotting practices for these products are more easily implementable, should the Agency move forward with this proposal, it would make much more sense to first focus on these products before extending the requirements to additional products. Should the Agency move forward with this proposal, we urge FSIS to consider limiting the requirements in the Proposed Framework to just comminuted product based on the clear trends seen in both the risk assessment and Proposed Framework.

C. The Proposed Framework is unlikely to identify theoretically problematic lots.

As previously mentioned, the Proposed Framework is trying to find a needle in a haystack. As seen in Table 3, the 10 CFU/g threshold would impact only 3% of comminuted chicken, 1% of chicken carcasses, and 0.07% of chicken parts that are contaminated with *Salmonella*.[154] This is an incredibly low rate of contaminated products, and the products cannot effectively be identified through a testing program. Instead, the focus should be on process controls and performance standards which can provide more directional support for operational risk than the proposed finished product standard. Further the risk assessment suggests only 2.5 million pounds would be identified as testing positive for *Salmonella*, which represents only 0.0054% of total annual production (46.4 billion pounds of ready-to-eat chicken in 2023). These pounds will be incredibly difficult to identify given they will not be neatly compiled into a single tested lot.[155] The Agency's proposed testing-focused approach simply is not capable of identifying this minute amount of product.

D. The Proposed Framework will avoid very few recalls.

The Proposed Framework predicts that only one to three recalls will be avoided over the following ten years. It is unclear how FSIS came to this conclusion.[156] In the past ten years, FSIS indicates there were seven raw poultry recalls for *Salmonella*. If FSIS is correct and three recalls are avoided, this would result in a reduction of 43% of the recalls in the industry. As optimistic as this number is, it simply cannot be true when considering the data surrounding illnesses avoided. The average recall in the past ten years resulted in 171 illnesses and if FSIS's estimate is correct, avoided recalls alone would account for 16.5% of the predicted illnesses avoided.[157] Further, the benefits of avoided recalls are being realized through other initiatives. Establishments are investing significant resources in food safety and recall prevention, and the contention that individual establishments are underinvesting in food safety is simply untrue and unfounded.

E. The Proposed Framework's estimates of chicken illnesses is likely overstated.

Reading the Proposed Framework, one would think that nearly all cases of salmonellosis originate from raw poultry. This is not the case. Although recent CDC data suggests that chicken products are

[154] 89 Fed. Reg at 64701.
[155] 89 Fed. Reg at 64734.
[156] 89 Fed. Reg at 64740.
[157] *See Reports of Selected Salmonella Outbreak Investigations*, CDC (Sept. 6, 2024), available at https://www.cdc.gov/salmonella/outbreaks.html.

the greatest source of *Salmonella* illnesses, over 80% of illnesses are attributable to other sources.[158] FSIS relies heavily on this attribution data to make the case for the Proposed Framework, however the attribution data is flawed and does not tell the whole story. For example, the attribution data is collected at too broad a level so that it is impossible to understand the number of illnesses attributed to different types of poultry products that go through different types of processing, such as comminuted, parts, and whole carcasses. Even more concerning, this data includes both illnesses from consuming chicken products and handling backyard chickens. Failing to distinguish between these different types of products will prevent resources from being focused on the different products that will have the greatest actual impact on public health.

The data clearly shows that industry has been working effectively to reduce the presence of *Salmonella* in raw poultry products and the illness attribution data may be subject to a perception lag as consumers continue to report chicken as the cause of their illnesses.

F. The Proposed Framework is contrary to other administration policy initiatives.

At the beginning of his term, President Biden issued two executive orders that identified certain key priorities for the executive branch, including federal agencies. Relevant to the Proposed Framework are (1) Executive Order 14017: America's Supply Chain;[159] and (2) Executive Order 14036: Promoting Competition in the American Economy.[160] Both of these executive orders are focused on ensuring that the American supply chain works efficiently and that American consumers have access to critical goods and supplies. As mentioned previously, USDA estimates that the average American will consume over 100 pounds of chicken in 2024, and chicken has long been considered a staple of the American diet as a low-cost, nutritious protein source. In this way, raw chicken products are a key product in the American supply chain and these executive orders highlight the need to ensure access to raw poultry products is protected.

First, the Executive Order regarding America's Supply Chain highlights the need for a "resilient" supply chain. The Executive Order describes a resilient supply chain as "facilitating greater domestic production, a range of supply, built-in redundancies, [and] adequate stockpiles."[161] Based on these characteristics, implementing the Proposed Framework would result in a less resilient supply chain. First, the Proposed Framework will increase costs for producers, which will likely drive certain small producers out of the industry and therefore result in less redundancy and less domestic production. Second, the Proposed Framework anticipates an increase in the volume of product being used in fully cooked applications and this would naturally result in a decrease in the supply of raw chicken products. Finally, the shorter shelf lives of these products, due to increased facility hold times, will result in fewer strategic redundancies and inadequate stockpiles. In this way, the Proposed Framework directly contradicts the policy articulated in this Executive Order and does not work to achieve its objectives.

With respect to the Executive Order regarding Promoting Competition in the American Economy, the policy priorities articulated are focused on ensuring consumers have significant choice in products and goods moving through the supply chain. Underlying this Executive Order is the understanding that having more diverse producers in a market will result in more diverse products and market participants.

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[158] Interagency Food Safety Analytics Collaboration, *Foodborne illness source attribution estimates for Salmonella, Escherichia coli 0157, and Listeria monocytogenes – United States, 2022*, CDC (Dec. 13, 2024), available at https://www.cdc.gov/ifsac/php/data-research/annual-report-2022.html.
[159] Exec. Order 14,017, 86 Fed. Reg. 11849 (Feb. 24, 2021).
[160] Exec. Order 14,036, 86 Fed. Reg. 36987 (Jul. 9, 2021).
[161] Exec. Order 14,017, 86 Fed. Reg. 11849 (Feb. 24, 2021).

As discussed above, the Proposed Framework will undermine this policy because it will push some producers who cannot bear the costs of implementation out of the market and with more products being pushed to cooked applications, the variety of raw poultry products in the market will decrease. The Proposed Framework does not facilitate these principles and undermines the policies prioritized by the executive branch.

Not only does the Proposed Framework predict minimal public health benefits, it is also designed to undermine key supply chain policies articulated by President Biden to strengthen the U.S. supply chain and protect consumers. This is another reason why the Proposed Framework should not be implemented and should be rescinded by FSIS.

VIII. THE PROPOSED FRAMEWORK WILDLY UNDERESTIMATES COSTS.

Not only does the Proposed Framework fail to meaningfully advance public health, it does so at an enormous cost. FSIS's cost estimates for the Proposed Framework at $14.47 million.[162] This woefully underestimates the true costs of the proposal.

A group of stakeholders commissioned an independent economic analysis to better understand the true costs the Proposed Framework would impose.[163] That analysis concluded that "FSIS underestimates the costs of compliance," in part because the Agency "fails to account for supply chain disruptions" and other follow-on effects of the Proposed Framework, and that the proposal "poses risks to rural economies, employment, and industry competitiveness."[164] The analysis's key findings note:

1. Compliance costs will disproportionately burden smaller processors, risking further consolidation in the poultry sector and reducing competition.

2. Increased testing, product disposition protocols, and potential product rejection will lead to higher retail prices, shifting consumer behavior, and potentially decreasing poultry demand.

3. Divergent domestic standards may create barriers for U.S. poultry exporters, undermining their competitive standing in global markets.[165]

The report is enclosed as Attachment 3 and is incorporated in full into these comments. Among other issues, the report identifies the following deficiencies in FSIS's cost analysis, which cumulatively indicate FSIS has underestimated the costs of the Proposed Framework by hundreds of millions, potentially billions, of dollars:

- Storage of Tested Products.
    - Assumes establishments have existing access to cold storage capacity. Most lack sufficient capacity and would have to construct additional cold storage at a cost of $150-$170 per square foot or rent cold storage space at a rate of approximately $15-$20 per pallet.

[162] 89 Fed. Reg at 64734.
[163] *See* Attachment 3, Malone, Trey et al., *Economic Analysis of the FSIS Proposed Salmonella Control Measures*, (Jan. 8, 2025).
[164] *Id.* at 2.
[165] *Id.*

- Does not account for the fact that many establishments may need to use refrigerated trucks while developing new cold storage capacity. In addition to rental costs, idling a refrigerated truck consumes between $33.50 and $92.14 in diesel fuel per day.
- Overlooks additional labor, transportation, and logistical costs, as well as the consequential effects of disrupting a just-in-time inventory management system.
- Ignores effects of extended storage on product shelf life, quality, and spoilage risk.

- HACCP Plan Reassessments.
  - Overlooks potential modifications required of processes and equipment upgrades, which can cost $50,000-$200,000.
  - Overlooks that many establishments, especially smaller establishments, may rely more heavily on consultants to complex HACCP plan reassessments, which can cost $10,000-$20,000 in fees per establishment.
  - Ignores training costs, which can range from $5,000 to $10,000 per establishment.

- Sampling Costs.
  - Dramatically understates sampling costs. Sample materials costs can range from $2-$5 per test for in-house laboratories and $13-$20 for external testing. This can add up to monthly testing costs of $10,000-$40,000 per establishment for high-volume establishments.
  - Does not account for updating testing equipment or capabilities, which could cost $50,000-$100,000 per establishment, not including maintenance and other recurring costs.
  - Overlooks potential disparate impact on smaller establishments or companies, which may not have access to corporate laboratories or volumes of scale with external laboratories.
  - Erroneously assumes that testing requirements will be absorbed by existing labor. However, properly trained laboratory technicians are in high demand and typically fully utilized. Establishments would likely incur $5,000-$10,000 per month in additional labor-related costs.
  - Does not account for the extensive testing that would be required to validate new antimicrobial interventions or demonstrate lot independence across multiple lines and configurations.

- Electronic Data Submission.
  - Incorrectly assumes electronic data submissions will largely be handled with existing systems at negligible marginal cost. Smaller establishments in particular may be required to upgrade information technology systems, including hardware, software, and network infrastructure, costing an estimated $10,000-$50,000. Licensing fees and

cybersecurity measures may cost another $2,000-$5,000 per establishment, and additional labor would likely add another $1,000-$3,000 per month.

- Live Production Changes. Largely overlooks costs related to changes to live poultry production, which could alone exceed $1 billion:
    - New or changed vaccinations in broiler flocks would cost $26 million to $78 million per year per company for larger companies.
    - Changes to production practices such as feed additives, litter amendments, water treatments, and other changes would inject significant costs that would vary from farm to farm.
    - Changes to biosecurity protocols and infrastructure upgrades can cost $10,000-$30,000 per farm, and additional training and maintenance programs can add $5,000-$10,000 per farm. There are an estimated 25,000 broiler farms in the U.S.
- Disposing of Rejected Lots.
    - Overstates the ability to divert rejected product to other streams and overvalues the residual value of diverted products. FSIS incorrectly assumes there is significant excess demand, processing capacity, and geographical proximity in the cooked chicken market. Even if product can be redirected to cooking, there are significant labor costs and packaging waste, to cost of $0.10 to $0.20 per pound for labor associated with unpackaging rejected product for cooking or rendering. Cooked products would lose much more of their value than FSIS estimates.
    - Misconstrues disposal options and costs. In the likely even that cooking is not an option or not economically viable, product would have to be diverted to rendering or to landfill. Rendering presents all of the same logistical challenges as diversion for cooking, but with even less residual economic value to the processor. Rendering or landfilling typically incurs costs of about $50 to $100 per ton.
- Effect on Consumer Prices.
    - Disregards consumer price impacts. Projected cost increases are expected to increase consumer prices for raw poultry by 5-10%. This increase would disproportionately affect low-income consumers. The diversion of product would limit supply and result in less available low-cost protein.
- Longer-Term Effects.
    - Overlooks effects on small establishments. Smaller establishments or companies would be disproportionately affected, as they have more difficulty spreading fixed costs and likely have fewer technical resources. The Proposed Framework could create market conditions favoring consolidation.
    - Ignores effects on exports. By creating standards that differ from those of export markets, the Proposed Framework could jeopardize poultry exports and place U.S. poultry at a competitive disadvantage to other nations.

- Overlooks effects on rural communities. The broiler industry is the lifeblood of numerous rural communities, and NCC estimates that each processing job supports another 2.5 jobs in related sectors.[166] Imposing substantial costs on the broiler industry would disproportionately harm workers in rural communities.

In light of these and other costs, the study recommends that FSIS reevaluate the many costs imposed by the Proposed Framework and focus on developing a balanced approach to addressing *Salmonella* control.

Finally, FSIS failed to complete a sufficient regulatory alternative analysis, as it did not consider the public health benefits of setting a quantified performance standard, even though industry has presented this alternative to FSIS during public discussions on the Proposed Framework. Further FSIS concedes that performance standards have effectively changed behavior in the past and the desired results were only not achieved because prevalence alone was not the issue.[167] Under EO12866, the better alternative would have been to refine performance standards to meet the relevant objective as this would be a much lower cost and regulatory burden, especially since FSIS admits the Proposed Framework will not prevent a large number of illnesses. For all of these reasons, the cost estimate in the Proposed Framework is insufficient and does not accurately describe the true financial burden of the Proposed Framework.

IX. ADDITIONAL CONSIDERATIONS ARE NEEDED FOR THE PROPOSED FRAMEWORK TO BE EFFECTIVELY IMPLEMENTED.

A. Effective implementation would require more time than estimated in the Proposed Framework.

Industry would need more time to implement the Proposed Framework than is currently contemplated. Industry needs more than a year to work through compliance with the Proposed Framework, especially since this will need to include the development and implementation of vaccines, installation and validation of new equipment, expansion of cold storage, and ensuring adequate laboratory capacity and supplies. The entire poultry industry will be working on these initiatives at the same time, which will likely lead to supply chain and sourcing challenges. It is also unclear the timeline the Agency will need to obtain a timely and accurate test.

B. A phased-in risk-based approach would be more effective in implementing the Proposed Framework.

Should the Agency move forward with the Proposed Framework, NCC encourages FSIS to phase-in this rulemaking in a risk-based manner. Specifically, it is acknowledged in the Proposed Framework that the small establishments are driving illnesses from raw poultry. Despite this, under the Proposed Framework's implementation plan small establishments would not be required to comply for a number of years. One strategy to capture smaller establishments more quickly would be to base implementation on total annual production volume rather than establishment staffing. Another would be to abandon a phased approach and require all establishments to comply at once and provide a sufficient implementation period to allow small establishments to get on board. Importantly, if the

[166] *What is the Chicken Industry's Impact in Your Community?*, Chicken Feeds America (accessed Jan. 17, 2025), available at https://chickenfeedsamerica.org/.
[167] 89 Fed. Reg at 64722.

Agency were to consider *Salmonella* an adulterant under certain circumstances, it would be incumbent on FSIS as a public health Agency to address adulterated products across the board, not selectively.

X. NCC RECOMMENDS TAKING AN ALTERNATIVE APPROACH TO CONTROLLING THE RISK OF *SALMONELLA* ILLNESSES IN RAW POULTRY.

A. NCC recommends implementing enhanced process controls and quantitative performance standards.

Due to the number of flaws with the Proposed Framework articulated throughout these comments, NCC believes it would be best for FSIS to forgo establishing a finished product standard in favor of a **quantitative** voluntary performance standard supported by process controls. By removing the serotype requirement, but utilizing a voluntary enumerative performance standard, all *Salmonella* strains would be captured and industry would have time to implement additional preharvest measures including vaccines and ensure that their process control and intervention strategies are controlling *Salmonella* risk in their products. The Agency also would have time to find a reliable and accurate method. Because the Proposed Framework already contemplates severability, it would be simple for FSIS to continue to pursue Component Two with modifications as described in these comments while removing Component Three from the rulemaking. We believe that most of the deficiencies noted in these comments would be resolved by this approach, and FSIS specifically requested feedback on a similar alternative approach on Page 64709 of the Proposed Framework.

NCC stands ready to work with FSIS to develop and help implement a voluntary quantitative performance standard.

B. Updated performance standards would be more effective than the Proposed Framework.

As discussed in Section I.A, FSIS mischaracterizes the effect of performance standards on industry. The history of voluntary performance standards demonstrates they were extremely effective in directing industry performance. FSIS told establishments what targets to aim for, and establishments modified their operations and improved their processes and met those targets. Today, nearly all establishments meet the voluntary performance standards. And those that do not meet these standards are subject to heightened and more critical inspectional activities, such as public health risk evaluations and food safety assessments. The voluntary prevalence-based performance standards drove *Salmonella* prevalence from 25% to 9% for parts between 2016 and 2024.[168] In short, they were extremely effective in changing behavior and directing establishment efforts to meet a target, and they were an extremely efficient regulatory tool.

FSIS even acknowledges in the Proposed Framework that the performance standards worked to achieve the goal that was set, concluding that "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*."[169] Abandoning a

[168] USDA, *Quarterly Sampling Reports on Salmonella and Campylobacter*, FSIS (accessed on Jan. 16, 2025), available at https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/microbiological-testing-program-rte-meat-and-7.

[169] *See also,* e.g., 89 Fed. Reg. at 64683 ("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"), and 89 Fed. Reg. at 64722 ("the results of FSIS' *Salmonella*

regulatory approach that has been shown to be effective (and cost-efficient) makes no sense. If FSIS now believes it chose the wrong target, then the solution is to keep the tool that we know works and change the target.

Based on FSIS's desired policy goals, NCC recommends that FSIS avoid the extreme cost and disruption of the proposed Component Three and instead implement a new voluntary performance standard approach targeting a quantified *Salmonella* threshold for raw chicken products. The infrastructure for performance standards is already in place and would require a fraction of the cost to implement, yet it would have the greatest likelihood of impacting public health.

The testing methodology currently available does not have the sensitivity and specificity necessary for a plant to test and ensure a specific adulteration-based standard is met. Further, FSIS is not resourced to test at a high enough frequency to identify performance or product issues and drive actual public health improvements. Finally, *Salmonella* testing is not real-time and therefore under a product standard the sampled lot would have to be held pending results. Based on the time to results for these samples, there is not adequate cold storage to hold the sampled product which would lead to supply chain issues for the country. What the current methodology does have is utility in providing directional feedback to a plant to drive process improvements, especially if more frequent test results are collected and the data is considered for a more condensed period (e.g., the current 52-day window does not have utility for process control). Implementation of a quantified performance standard would incentivize industry to sample more frequently to ensure the process remains in control and the process control would be verified by the FSIS performance standards testing.

As was the case with driving down prevalence, updated performance standards would achieve the goal of driving down instances of products with greater than or equal to 10 CFU/g *Salmonella*, and they would do it much more efficiently and effectively than a final product standard.

C. Implementation considerations.

Because the infrastructure for performance standards is already in place, implementation would be significantly faster and cost effective. This would also allow small establishments to be brought under the regulation more quickly, which would address a large driver of the costs under the rule.

XI. CONCLUSION.

Industry shares FSIS's goal of reducing the number of *Salmonella* illnesses resulting from raw poultry products. Industry has been and will continue to work diligently to achieve this goal without prompting from USDA and has made significant progress to date. While the efforts and mission of the Proposed Framework are appreciated, it will not result in a significant public health benefit, it is not legally tenable, and should not be pursued further. The data and administrative record do not support the Proposed Framework and FSIS should instead consider pursuing a quantitative performance standard in conjunction with a modified version of the SPC program articulated in Component Two.

* * *

verification sampling show that the current prevalence-based performance standards approach has been effective in reducing the proportion of poultry products contaminated with *Salmonella*").

NCC appreciates the opportunity to comment on the Proposed Framework. Please feel free to contact us with any questions. Thank you for your consideration.

Respectfully Submitted,

Ashley B. Peterson, Ph.D.
Senior Vice President, Scientific and Regulatory Affairs
National Chicken Council

Enclosures

ATTACHMENT 1

NCC Comments to Docket No. FSIS-2022-0029: Proposed Framework for Controlling *Salmonella* in Poultry (December 16, 2022)

NATIONAL CHICKEN COUNCIL

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December 16, 2022

Submitted electronically via regulations.gov

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Re: Docket No. FSIS-2022-0029: Proposed Framework for Controlling *Salmonella* in Poultry

Dear Ms. Eskin:

The National Chicken Council (NCC) appreciates the opportunity to provide comments regarding the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS or the Agency) Proposed Framework for controlling *Salmonella* in poultry. NCC is the national, non-profit trade association that represents vertically integrated companies that produce and process more than 95 percent of the chicken marketed in the United States.

The Agency's Proposed *Salmonella* Framework raises several questions about numerous complex topics, including risk assessment and public health modeling, pathogenicity data, current and future laboratory testing technologies, detailed applications of highly technical Hazard Analysis and Critical Control Point (HACCP) systems, and legal and technical considerations, to name but a few. NCC member companies would be significantly impacted by the Agency's Proposed Framework, and NCC encourages the Agency to take a science-based, data-driven approach to impacting public health. However, as the Proposed Framework is not based on science, data, or the results of a risk assessment(s), it is challenging for the regulated industry to provide meaningful comments. Instead, we encourage the Agency to take a more measured approach and use robust data demonstrating true impact on public health when proposing sweeping regulatory changes.

The concerted efforts by both the broiler chicken industry and FSIS to drive down *Salmonella* rates have been enormously successful. Based off the most recent FSIS testing results[1], *Salmonella* prevalence on young chicken carcasses is 3.1% and *Salmonella* prevalence on chicken parts is 7.1% across all broiler processing establishments. These testing results are well below the *Salmonella*

[1]FSIS, Sampling *Results for FSIS Regulated Products*, USDA.gov (2022), https://www.fsis.usda.gov/science-data/sampling-program/sampling-results-fsis-regulated-products.

performance standard for both young chicken carcasses and chicken parts. Coupled with performance standards, currently over 90% of the industry is meeting or exceeding the performance standard for both young chicken carcasses and chicken parts.[2] In just the past few years, FSIS has significantly tightened existing *Salmonella* standards; introduced new performance standards for chicken parts; rolled out a new, scientifically driven, modernized poultry inspection system that allows for greater testing and analysis; released detailed guidance on controlling *Salmonella* through processing controls; and approved numerous new interventions; among many other endeavors. FSIS has taken or is in the process of rolling out similar programs for other species. These actions are consistent with the science-based, data-driven actions NCC believes are beneficial to public health.

As with FSIS, food safety is a top priority for the broiler chicken industry, and we support changes in food safety regulations that are based on sound science, robust data, and are demonstrated to positively impact public health. For years the industry has implemented a multi-hurdle approach focused on the continual reduction of *Salmonella* from farm to fork – implementing robust vaccination, biosecurity, sanitation, and other effective measures.

In 1996, the CDC created FoodNet Fast to display data for select pathogens transmitted through food, including *Salmonella*.[3] While the incidence of salmonellosis in humans has remained relatively unchanged since 1996, Americans eat significantly more chicken and chicken products today than in 1996. In 1996, chicken consumption in the U.S. was 69.7 pounds per person. In 2022, USDA estimates that Americans will consume 99.0 pounds of chicken per person.[4] This reflects a 42% increase in chicken consumption over the past 26 years. Neither FoodNet Fast nor Interagency Food Safety Analytics Collaboration (IFSAC)[5] takes into account consumption patterns of various food sources, including chicken. When the data from both FoodNet Fast and IFSAC are analyzed based on per-pound consumption of chicken, the rate of salmonellosis associated with chicken is shown to have decreased over the past ten-plus years. This data demonstrates that the robust public-health measures implemented by FSIS and the chicken industry over the past decade have been working.

In short, FSIS's existing framework for approaching *Salmonella* control has been working, and NCC encourages FSIS to continue using the latest science and industry-Agency collaborations to drive improvements in this framework. For example, as discussed in these comments, science-based changes such as transitioning to an enumeration-based performance standard would apply new technological and scientific developments to FSIS's proven approach and would drive continued food safety improvements.

The Proposed Framework would abandon these approaches for legally infirm and technologically infeasible strategies with no clear supporting data. While NCC appreciates FSIS's interest in thinking creatively about food safety, the Proposed Framework is not the right approach. First, the Proposed Framework appears premised on legally infirm conclusions that *Salmonella* may be considered an adulterant in raw poultry and that FSIS can mandate on-farm activities. Second, the Proposed Framework is presented nearly devoid of data, and it lacks specificity as to how the Agency plans to implement and enforce the proposed changes. Additionally, there appears to be a significant misunderstanding about how the broiler industry operates, the industry's supply chain structure, and current industry practices regarding the control of *Salmonella*. As written, the Proposed Framework threatens the economic viability of the entire poultry sector and threatens negative impacts on family

[2]Salmonella Verification Testing: October 31, 2021 through October 29, 2022, FSIS (2022), https://www.fsis.usda.gov/news-events/publications/salmonella-verification-testing-october-31-2021-through-october-29-2022.
[3]FoodNet Fast, Center for Disease Control (2022), https://wwwn.cdc.gov/foodnetfast/
[4]USDA, World Agricultural Supply and Demand Estimates (Dec. 9, 2022), https://www.usda.gov/oce/commodity/wasde/wasde1222.pdf.
[5]Center for Disease Control, *Interagency Food Safety Analytics Collaboration (IFSAC)*, CDC.gov (2022), https://www.cdc.gov/foodsafety/ifsac/publications.html

farmers, company employees, and consumers. The Proposed Framework would have negative impacts on both the availability of chicken and the cost of chicken to consumers of U.S. chicken around the world. Overall, the Proposed Framework appears to be moving away from long-standing HACCP-based principals that focus on identifying and controlling risk to a command and control, once-size-fits-all approach that could have significant negative public health outcomes.

These comments address overarching concerns regarding FSIS's statutory authority under the Poultry Products Inspection Act (PPIA) and the lack of supporting data presented with the Proposed Framework, provide feedback on each of the three Components, and finally address several cross-cutting issues raised in the Proposed Framework.

***Salmonella* Is Not an Adulterant Under the Poultry Products Inspection Act**

Fundamentally, the Proposed Framework is legally infirm because *Salmonella* is not an adulterant in raw chicken under the PPIA.

Under the PPIA, a product is adulterated if it "bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated under this clause if the quantity of such substance in or on such article does not ordinarily render it injurious to health."[6] Thus, whether a pathogen renders a product adulterated depends on whether the substance is added to the product or occurs naturally in the product. For added substances, the pathogen is an adulterant only if the substance is present in quantities that "ordinarily" render the product injurious to health. As FSIS has consistently recognized, *Salmonella* is not an adulterant in raw poultry because (i) *Salmonella is* not an added substance in raw poultry and (ii) *Salmonella* is not present in levels that render chicken injurious to health because customary cooking practices destroy any *Salmonella* that may be present. FSIS has offered nothing to change this interpretation.

First, *Salmonella* is not an added substance because it occurs naturally within the chicken biome. *Salmonella* is not an avian pathogen, and it exists naturally as part of the microflora in and on chicken. *Salmonella* can exist in a chicken's skin, muscle tissue, and gut. Peer-reviewed literature establishes that healthy, asymptomatic birds are known to carry *Salmonella*.[7] Researchers have also identified *Salmonella* in chicken neck skin, on the outer layer of skin, on feather follicles, connective tissue, and in drumstick muscle.[8] Moreover, literature shows correlations between *Salmonella* loads on the farm or in birds and at various processing steps, reinforcing that *Salmonella* enters the process via the chickens themselves.[9]

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[6] 21 U.S.C. § 453(g)(1).

[7] *See, e.g.*, Rigney, C. P., Salamone, B. P., Anandaraman, N., Rose, B. E., Umholtz, R. L., Ferris, K. E., et al. (2004). Salmonella serotypes in selected classes of food animal carcasses and raw ground products, January 1998 through December 2000. J. Am. Vet. Med. Assoc. 224, 524–530. doi: 10.2460/javma.2004.224.524; Nde, C. W., Mcevoy, J. M., Sherwood, J. S., and Logue, C. M. (2007). Cross contamination of turkey carcasses by Salmonella species during defeathering. Poult. Sci. 86, 162–167. doi: 10.1093/ps/86.1.162; Erol, I., Goncuoglu, M., Ayaz, N. D., Ellerbroek, L., Ormanci, F. S., and Kangal, O. I. (2013). Serotype distribution of Salmonella isolates from turkey ground meat and meat parts. Biomed Res. Int. 2013, 281591. doi: 10.1155/2013/2 81591.

[8] *See* Rimet C-S, Maurer JJ, Pickler L, Stabler L, Johnson KK, Berghaus RD, Villegas AM, Lee M and França M (2019) Salmonella Harborage Sites in Infected Poultry That May Contribute to Contamination of Ground Meat. Front. Sustain. Food Syst. 3:2. doi: 10.3389/fsufs.2019.00002.

[9] *See, e.g.*, Berghaus, R.D., Thayer, S.G., Law, B. F., Mild, R.M., Hofacre, C.L., and Singer, R.S. 2013. Enumeration of Salmonella and Campylobacter spp. in Environmental Farm Samples and Processing Plant Carcass Rinses from Commercial Broiler Chicken Flocks. Applied and Environmental Microbiology. 79:4106-4114; Volkova VV, Bailey RH, Rybolt ML, Dazo-Galarneau K, Hubbard SA, Magee D, Byrd JA, Wills RW. 2010. Inter-relationships of Salmonella status of flock and grow-out

The fact that *Salmonella* may be present in greater expected concentrations in some parts of a chicken than others is irrelevant to this analysis, as is the fact that *Salmonella*, as with any microbe, can be spread through cross-contact during processing. The PPIA asks only whether the organism is an added substance when determining if it is an adulterant. To view all pathogens that can be somehow spread among or within products as "added substances" would read out of existence the second prong of § 453(g)(1) and is simply inconsistent with the normal meaning of the term. Moreover, courts have been clear that an "added substance" refers to a substance not otherwise present in the food and added by man.[10] As established, *Salmonella* occurs naturally within chickens. *Salmonella* is not an added substance in raw poultry, and thus it is an adulterant only if it "ordinarily" renders the product injurious to health.[11] It does not.

Salmonella does not "ordinarily" render raw chicken injurious to health. The PPIA establishes a very high standard to support a conclusion that a naturally occurring pathogen "ordinarily" renders a raw product adulterated. First, in the PPIA, Congress created a strong presumption against viewing a naturally occurring substance as an adulterant in raw products. Congress's choice of language is striking: under the PPIA, added substances adulterate food if they "*may* render it injurious to health," whereas a product with naturally present pathogens "*shall not* be considered adulterated" if the substance "does not ordinarily render it injurious."[12] The statute thus sets up two very different standards. "May" could imply FSIS has a measure of discretion in evaluating added substances, but the statute sets a significantly higher bar for naturally occurring substances. FSIS is prohibited from considering a naturally occurring substance a pathogen ("*shall not* be considered adulterated") unless it can meet the very high bar of proving that the substance would "ordinarily" render the product injurious to health. Reinforcing this high bar, in its statement of policy codified into the PPIA, Congress commanded that decisions such as product condemnation "shall be supported by scientific fact, information, or criteria."[13] By default, naturally occurring substances are not pathogens, and FSIS must go to great scientific lengths to establish otherwise.

Second, the plain meaning of "ordinarily" sets a very high bar. When a statute does not define a term – and the PPIA does not define "ordinarily injurious" – courts will consider its plain meaning with reference to its reasonable use, dictionary definitions, and its use in context.[14] Multiple dictionary definitions contemporaneous with the passage of the PPIA show us what Congress meant when it used "ordinarily." *Webster's* 1953 edition defines "ordinarily" as "according to established rules or settled

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environment at sequential segments in broiler production and processing. Zoonoses Public Health 57:463–475; Fluckey, WM, Sanchez MX, McKee SR, Smith D, Pendleton E, Brashears MM. 2003. Establishment of a microbiological profile for an air-chilling poultry operation in the United States. J. Food Prot. 66:272–279.

[10]*See United States v. Coca Cola*, 241 U.S. 265 (1915); *United States v. Anderson Seafoods, Inc.* 622 F.2d 157, 160 (5th Cir. 1980).

[11]FSIS recognized that *Salmonella* is not an added substance in its recent 2022 denial of a petition requesting *Salmonella* be declared as an adulterant, noting that "FSIS has traditionally viewed *Salmonella* as 'naturally occurring' in food animals." Letter from Rachel Edelstein to William D. Marler, Esq, at 3 (May 31, 2022). Although FSIS in that petition response noted it was considering reassessing its long-held view, the Agency still has provided no information to explain why *Salmonella*—which comes into plants on chicken skin and inside chickens, including in the muscle tissue—is not a substance naturally occurring in chickens. More established agency precedent reinforces that *Salmonella* is naturally occurring in raw chicken. *See, e.g.*, Letter from Carmen Rottenberg, Acting Deputy Undersecretary, Office of Food Safety, to Laura MacCleery, Director, Center for Science in the Public Interest, at 1-2 (Feb. 07, 2018) ("We also disagree with your assertion that ABR *Salmonella* is an 'added substance' within the meaning of the adulteration provisions of the FMIA and PPIA.").

[12]21 U.S.C. § 453(g)(1).

[13]21 U.S.C. § 452.

[14]*Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997).

method."[15] *Black's Law Dictionary*, 1951 edition, defines the adverb by reference to "ordinary," stating it means "regular" or "normal."[16] And *Oxford English Dictionary*, which examines the historical development of the term, defines it as "[b]elonging to the regular or usual order or course" or occurring in "regular custom or practice."[17] The term retains its meaning in modern parlance and as defined "usually; as a rule."[18] Thus, under the plain language of the PPIA, a naturally occurring substance can be considered an adulterant only if the substance "regularly" or "normally," or through "regular or usual . . . course" or "regular custom or practice," or "usually" or "as a rule" renders the product injurious to health.[19] This simply is not the case.

As is well established, thorough cooking destroys *Salmonella*. Specifically, cooking raw chicken to an internal temperature of 165°F achieves a 7-log reduction in *Salmonella*.[20] In fact, even a slightly lower temperature still achieves instant lethality (162°F or 163°F, depending on the fat content), as can reaching yet-lower-still temperatures with sufficient dwell time, often of just a few seconds.[21] Even in the event raw chicken were cooked at yet lower temperatures, there would be a substantial log-reduction in *Salmonella*.

Consumers customarily cook chicken in a manner that achieves thorough cooking and destroys *Salmonella*. Chicken is customarily cooked through. Consumers are regularly reminded to use a meat thermometer to cook chicken to an internal temperature of 165°F – including on the package itself – which achieves lethality. While NCC's strong recommendation is that consumers use a meat thermometer, other less analytical ways to gauge "doneness", such as cutting into the meat to see if it is visibly white and firm, are also highly likely to achieve lethality and certainly cannot be said to "usually" or "normally" result in the product being injurious to health. Chicken is not customarily cooked "rare" or "medium," and waitstaff at restaurants do not ask patrons how they would like their chicken cooked because the default approach is to cook chicken all the way through. Certainly, it is not the case that due to handling and cooking practices, *Salmonella* in "regular custom or practices" causes the chicken to be injurious to health.

In this manner, *Salmonella* in raw chicken is fundamentally different than Shiga toxin producing *E. coli* (STECs) in raw non-intact beef. FSIS attempts to draw parallels between these product-pathogen pairs, but the analysis misses the key distinctions. In the Proposed Framework, FSIS attempts to reduce its 1994 decision declaring *E. coli* O157:H7 an adulterant in raw ground beef (and subsequent extension to STECs in raw non-intact beef) to a set of "criteria," all of which appear equally weighted: association with human illness, low infectious dose, severity of human illness, and typical consumer cooking practices.[22] However, that is not actually the approach FSIS took, nor is it the analysis courts performed when evaluating FSIS's *E. coli* policy.

In fact, FSIS's analysis turned *primarily* on whether *E. coli* was likely to be destroyed under customary cooking practices for raw ground beef. In explaining its policy on *E. coli* O157:H7, FSIS provided

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[15]Webster's New Twentieth Century Dictionary 1177 (1953).
[16]*Ordinary*, Black's Law Dictionary (4th ed. 1951).
[17]*Ordinary*, Oxford English Dictionary (2d ed., 1989).
[18]*Ordinarily*, Webster's New World College Dictionary (4th ed., 2010).
[19]The legislative history behind comparable language in the Federal Food, Drug, and Cosmetic Act reinforces this interpretation. In one debate, members stated "ordinarily injurious" meant "that people—substantial numbers of people—must actually be harmed by the product before it can be restricted in any way. This provision . . . puts the burden of proof on the FDA." 120 Cong. Rec. 36007 (1974) (Statement of Rep. Peter Kyros).
[20]FSIS, *FSIS Cooking Guidelines for Meat and Poultry Products (Revised Appendix A)*, Table 3, USDA.gov (2021), https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf.
[21]FSIS, *FSIS Cooking Guidelines for Meat and Poultry Products (Revised Appendix A)*, Table 3, USDA.gov (2021), https://www.fsis.usda.gov/sites/default/files/media_file/2021-12/Appendix-A.pdf.
[22]Proposed *Salmonella* Framework at 10.

background on the risks of *E. coli* O157:H7 but then expressly tied *E. coli* O157:H7's status as an adulterant to cooking practices: "Raw ground beef products present a significant public health risk *because* they are frequently consumed after preparation (*e.g.*, cooking hamburger to a rare or medium rate state) that does not destroy *E. coli* O157:H7 organisms that have been introduced below the product's surface."[23] If that were not clear enough, FSIS continued, "the Agency believes that the status under the FMIA of beef products contaminated with *E. coli* O157:H7 *must depend* on whether there is adequate assurance that subsequent handling of the product will result in food that is not contaminated when consumed."[24] Cooking practices were expressly the dispositive factor. This is reinforced by the fact that FSIS determined that intact cuts of beef, when contaminated with the exact same *E. coli* O157:H7, were not adulterated because "[i]ntact steaks and roasts and other intact cuts of muscle with surface contamination are customarily cooked in a manner than ensures that these products are not contaminated with *E. coli* O157:H7."[25] FSIS again cited to customary cooking practices as the dispositive point in its 2011 *Federal Register* notice declaring several other STECs to similarly be adulterants in raw non-intact beef.[26] Thus, rather than being a four-factor analysis as presented in the Proposed Framework, there is only question: whether the customary cooking practices would ordinarily render the product injurious to health.

Courts recognize this distinction as pivotal. In upholding FSIS's *E. coli* O157:H7 sampling program, and in a case that fundamentally turned on whether *E. coli* O157:H7 could properly be considered an adulterant in raw ground beef, the District Court for the Western District of Texas focused on whether the cooking practices that most Americans considered "proper" for ground beef were sufficiently "thorough" as to destroy *E. coli* O157:H7:

> However, unlike other pathogens, it is not "proper" cooking but "thorough" cooking that is necessary to protect consumers from *E. Coli.* The evidence submitted by Defendants indicates that many Americans consider ground beef to be properly cooked rare, medium rare, or medium. The evidence also indicated that *E. Coli* contaminated ground beef cooked in such a manner may cause serious physical problems, including death. Therefore, *E. Coli* is a substance that renders "injurious to health" what many Americans believe to be properly cooked ground beef.[27]

In *Texas Food Industry Association*, just as in FSIS's explanation, the entire analysis turned on whether customary consumer cooking practices were sufficient. Under the court's reasoning, had what consumers understood to be "proper" cooking been adequate to destroy *E. coli* O157:H7 in hamburgers, then the substance would not have been an adulterant (just as it is still not an adulterant on raw intact beef).

But raw chicken is handled very differently than ground beef. Consumers do not customarily consider it "proper" to cook a medium rare chicken breast. Even ground chicken products such as chicken burgers or meatballs are customarily cooked through, not served rare. What consumers consider to be the "proper" or "customary" method is also a method that cooks chicken "thoroughly."[28]

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[23]FSIS*, Beef Products Contaminated with* Escherichia Coli *O157:H7*, 64 Fed. Reg. 2803, 2803 (Jan. 19, 1999) (emphasis added).
[24]Id (emphasis added).
[25]Id at 2804 (emphasis added).
[26]FSIS, *Siga Toxin-Producing* Escherichia coli *in Certain Raw Beef Products*, 76 Fed. Reg. 58157, 58158 (Sept. 20, 2011).
[27]*Texas Food Industry Ass'n v. Espy*, 870 F. Supp. 143, 149 (W.D. Tex., 1994).
[28]Other critical distinctions exist between STECs in raw non-intact beef and *Salmonella* in raw poultry. For example, *E. coli* typically enters the cattle slaughter process through cross contamination with fecal matter on the outside of the hide, which can get transferred to the meat if sanitary practices are not observed. By contract, *Salmonella* actually enters in the chicken, including in edible parts of the chicken.

Courts have likewise recognized this distinction. The Fifth Circuit recognized that "*Salmonella* [is] present in a substantial proportion of meat and poultry products" and "is not an adulterant *per se*" because "normal cooking practices for meat and poultry destroy the *Salmonella* organism."[29] The D.C. Circuit reached a similar conclusion in *American Public Health Ass'n v. Butz*, holding "the presence of salmonellae on meat does not constitute adulteration" and that "American housewives and cooks are not ignorant or stupid and their methods of preparing and cooking of food do not ordinarily result in salmonellosis."[30] In other words, existing circuit precedent indicates the mere "presence of *Salmonella* in meat products," without more, does not support USDA regulation under § 453(g)(1).[31]

FSIS, too, has long and consistently recognized that *Salmonella* is not an adulterant in raw poultry. For example, as recently as this year, FSIS denied a petition requesting FSIS declare certain *Salmonella* strains to be adulterants in raw poultry. In 2018, FSIS denied a different petition making a similar request to declare certain *Salmonella* strains as an adulterant in raw meat and poultry. In its 2016 *Federal Register* notice announcing new *Salmonella* performance standards for poultry, FSIS clearly explained, "*Salmonella* is not an adulterant in NRTE poultry products."[32] In 2014, FSIS rejected a petition to declare antibiotic resistant *Salmonella* an adulterant, stating "we are not aware of any data to suggest that consumers consider ground poultry . . . to be properly cooked when rare, medium rare, or medium."[33] Crucially, USDA has never argued that *Salmonella* is an adulterant under § 453(g)(1). Instead, it has argued the opposite in litigation and policy documents. For example, in the *Supreme Beef* case on the enforceability of *Salmonella* performance standards, the court noted, "The USDA agrees in this case that *Salmonella* is not a[n] . . . adulterant."[34]

In light of this long and consistent history, and even if the PPIA were to permit such an interpretation, FSIS would be hard-pressed to provide a rationale that its change in policy was not arbitrary and capricious or that an abrupt change in position was warranted by the record.[35] As it stands, FSIS has presented no data to support a conclusion that *Salmonella* in raw chicken "ordinarily" or "usually" renders chicken injurious to healthy under customary cooking practices.

Finally, the Proposed Framework would entail creating new substantive requirements affecting the rights of NCC member companies, which would make it a legislative rule, and would require amending or creating multiple regulations. If FSIS were to pursue the Proposed Framework, the Administrative Procedure Act would require FSIS to engage in a substantial amount of notice-and-comment rulemaking, which would require FSIS to develop and make available for public comment a record

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No amount of process control or sanitary dressing can prevent its being in the product because it starts out in the product.

[29]*Supreme Beef Processors, Inc. v. U.S. Dep't of Agric.*, 275 F.3d 432, 438–39 (5th Cir. 2001).

[30]*American Public Health Ass'n v. Butz*, 511 F.2d 331, 334 (D.C.Cir.1974).

[31]*See also, e.g.*, *Starr Surplus Lines Ins. Co. v. Mountaire Farms Inc*., 920 F.3d 111, 117 (1st Cir. 2019) ("[T]he mere fact of the FSIS-orchestrated recall does not give rise to the plausible inference that the type of salmonella found . . . could not be eliminated by proper cooking."); *Craten v. Foster Poultry Farms Inc*., 305 F. Supp. 3d 1051, 1058 (D. Ariz. 2018) (observing that existing case law "suggests Salmonella is not an adulterant" and rejecting several state law tort claims because Salmonella "is killed through proper cooking, which is how raw chicken products are intended to be used").

[32]FSIS, *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 Fed. Reg. 7285, 7297 (Feb. 11, 2016).

[33]Letter from Daniel Engeljohn, Assistant Adm'r, Off. of Pol'y & Program Dev., USDA, to Sarah Klein, Food Safety Program (July 31, 2014).

[34]*Supreme Beef*, 275 F.3d at 439 n.21.

[35]*See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 34 (1983).

comprehensively addressing the numerous factual and scientific issues raised by the Proposed Framework.

Fundamentally, FSIS has provided no explanation for making an abrupt change in its approach to *Salmonella* in raw poultry, as it would be required to do. Under the plain language of the PPIA and long-standing caselaw, FSIS cannot compile a scientific basis for declaring *Salmonella* an adulterant in raw poultry. Accordingly, the Proposed Framework stands on infirm legal footing. We urge FSIS to instead pursue alternative approaches for which it has authority, such as revamped *Salmonella* performance standards, as explained elsewhere in these comments.

The Proposed Framework Lacks Adequate Supporting Data

As a public health agency, FSIS has long promoted the use of sound science-based decision-making, which by definition must be based on, and driven by, scientific data. FSIS has presented no data to suggest a change in policy is needed or to the support the proposals or assumptions in the Proposed Framework. This is regrettable, as without supporting data, the Proposed Framework appears almost entirely speculative. The complete lack of data makes it impossible to provide meaningful feedback on key areas, such as whether the data calls for a change in policy, whether the Proposed Framework is supported by the data, and whether the specific elements of the Proposed Framework were developed appropriately in light of that data. NCC firmly believes that it is imperative that public health decisions and policy follow the data, not the other way around.

Data Issues Related to the Proposed Framework

FSIS must first develop data and conduct risk assessments and use that data to determine what, if any, policy changes are called for. There are a number of key missing data elements. For example:

- There is no data to support the idea that *Salmonella* levels on incoming flocks overwhelm food safety systems or would need to be monitored.
- There is not data to demonstrate that setting a finished product standard would have public health impacts, or what standard to even set.
- There is no data to suggest that additional testing during the process beyond what is already done would be impactful.
- We understand that FSIS has not even begun the two risk assessments, which would presumably provide useful insight to use in developing policy proposals.

In effect, the Proposed Framework seems to reflect a presumption that the proposed changes would be effective and has asked stakeholders to rebut that presumption. This applies the policy development process backwards.

Moreover, without data or details, it is impossible to provide meaningful feedback on the proposal. For example, stakeholders have no ability to assess whether the data supports the proposed actions or whether the actions are appropriate in light of the data. The Proposed Framework is devoid of virtually all key details, raising many questions and leaving just as many unanswered. To take but one example, FSIS has not explained why it has contemplated proposing a 1 CFU/g finished product standard, especially given that FSIS testing has a limit of detection (LOD) at 10 CFU/g and cannot accurately enumerate at the 1 CFU/g level and that FSIS has not begun two risk assessments seemingly designed to address this exact question.

What little data FSIS has referenced contains significant flaws:

- CDC's National Outbreak Reporting System, or NORs, is a web-based platform that launched in 2009.[36] It is used by local, state, and territorial health departments in the United States to report all waterborne and foodborne disease outbreaks and enteric disease outbreaks transmitted by contact with environmental sources, infected persons or animals, or unknown modes of transmission to CDC. From 2009 to 2020, NORs reported 15,344 poultry-related *Salmonella* illnesses, which represents 29.3% of all *Salmonella* illnesses (there were 52,374 total *Salmonella* illnesses reported from 2009 to 2020). Critically, however, that figure lumps together illness from both live poultry (e.g., handling a backyard flock) and consumption of poultry. Separating out the live-poultry exposures yields a very different result. 8,475 of the 15,344 poultry-related illnesses were attributed to live poultry – for example, handling chicks or interacting with backyard flocks – and not related to chicken consumption at all. Chicken consumption accounts for 5,076 cases in the NORS data, which represent 9.7% of all salmonellosis cases in the U.S. from 2009 to 2020. While the industry is committed to driving this number down further, failing to properly distinguish foodborne illness and the more-prevalent live-bird exposures significantly overstates the effect of chicken consumption on illness burden in the NORs data.

- The IFSAC report makes clear several important limitations: The illness estimates "should not be interpreted as suggesting that all foods in a category are equally likely to transmit pathogens." The authors also urge "caution" in "comparing estimates across years" as the percentages reflect a relative contribution to illness burden, which means a category could see its actual illness contribution decrease yet its relative percentage increase if other categories dropped even further. The authors expressly "advise using these results with other scientific data for decision-making."[37] The IFSAC report alone cannot drive scientifically based policy. Further, the illness contribution attributed to chicken is statistically indistinguishable from that of fruits, seeded vegetables, and pork and is followed very closely by "other produce."[38] This statistical parity between product categories suggests that a coordinated approach applying measured strategies against all of these categories would have a much greater public health impact than merely singling out one category without addressing the other.

- As previously mentioned, salmonellosis incident rates attributed to chicken have decreased over the last decade when per-capita chicken consumption patterns are considered. Changes in consumption patterns are critical for assessing foodborne illness and must be considered to properly evaluate changes in illness rates or the significance of source attribution.

- If FoodNet Fast, NORS, and IFSAC data were reflective of consumption patterns of chicken over time, the overall burden of illness attributed to chicken would actually have decreased.

- FSIS has also left unaddressed whether the Proposed Framework would make an impact on the Healthy People 2030 goals, and if so, what impact would be anticipated and how it would be determined.

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[36]Center for Disease Control, *National Outbreak Reporting System, Center for Disease Control, CDC.gov* (2019), https://www.cdc.gov/nors/index.html.

[37]The Interagency Food Safety Analytics Collaboration, *Foodborne illness source attribution estimates from 2020 for Salmonella, Escherichia coli O157, and Listeria monocytogenes using multi-year outbreak surveillance data, United States*, at 12 (Nov. 2022), https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2020-report-TriAgency-508.pdf.

[38]The Interagency Food Safety Analytics Collaboration, *Foodborne illness source attribution estimates from 2020 for Salmonella, Escherichia coli O157, and Listeria monocytogenes using multi-year outbreak surveillance data, United States*, at 8 (Nov. 2022), https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2020-report-TriAgency-508.pdf.

In light of these substantial data gaps, it is essential that FSIS prioritize generating and making publicly-available key data before continuing further in this process. The Agency is currently working towards the development of two quantitative risk assessments – one focused on *Salmonella* in chicken and the other focused on *Salmonella* in turkey. In the July 1, 2022, *Constituent Update*, FSIS announced that it has signed a cooperative agreement with the University of Maryland's Joint Institute for Food Safety and Applied Nutrition (JIFSAN) in partnership with EpiX Analytics to help in the Agency's data collection effort for these risk assessments. NCC has engaged with JIFSAN routinely since July 2022 to understand this group's approach to data collection, the specific data needs, and how NCC and our member companies can aid in this process. Unfortunately, FSIS only provided the JIFSAN team three months to work with trade associations like NCC to understand data needs, develop a platform by which data could be shared, and fully understand the goals of the Agency. This timeline has proven to be insufficient as we are approaching the end of 2022 and this group, in conjunction with several trade associations, industry representatives, and FSIS, has still not been able to execute the intended data collection effort.

Although the process has not progressed as quickly as FSIS seemed to expect, NCC believes that the approach to formalize two risk assessments is appropriate. Moreover, we support the risk management questions that the risk assessments intend to address including:

1. What public health impact (change in illnesses, hospitalizations, and deaths) is achieved by eliminating a proportion of chicken (or turkey) at receiving 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 re-hang to post-chill? Monitoring could include analytes such as Enterobacteriaceae, Aerobic Plate Count, 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?

As stated in the July 1, 2022, Constituent Update, "These risk management questions reflect the information needed to evaluate and compare the public health benefits of policy options for controlling Salmonella in poultry." The Agency went on to state that the risk assessments would undergo an independent peer review and be released publicly once completed. To reiterate, NCC fully supports the completion of and the independent peer review of both risk assessments. NCC believes that it is imperative that any policy changes rely on the results of the risk assessments and without that information, it is impossible to understand what regulatory changes, if any, would impact public health. It also makes it very challenging for the regulated industry to provide meaningful comments with this information lacking, and the Agency has not disclosed their sources of data used to develop the Proposed Framework. Without the completion, peer review, and publication of the two risk assessments, the Agency risks operating without the benefit of a robust record, undermining informed decision making.

Finally, there are two national advisory committees whose recommendations may influence the content of the Proposed Framework: the National Advisory Committee on the Microbiological Criteria for Foods (NACMCF) and the National Advisory Committee on Meat and Poultry Inspection (NACMPI). Charges of both advisory committees include a focus on *Salmonella* in poultry among other topics. We encourage FSIS to update its thinking on the Proposed Framework in light of many of the recommendations by these advisory committees.

Data Recommendations

Given the critical role data plays in public health decisions, NCC provides the following data recommendations:

1. Complete the two risk assessment studies, submit them for peer review, and release them for public review once complete.
2. Use the risk assessment results to inform further development of the Proposed Framework.
3. Provide the public a detailed report with the data, information, and scientific analysis supporting the key elements of the Proposed Framework and provide an opportunity for public comment on the Proposed Framework based on the report.
4. Consider key NACMCF and NACMPI recommendations as they may apply to the Proposed Framework.
5. Hold technical meetings with stakeholders to discuss in detail the changes and complications that would be raised by any aspect of the Proposed Framework being contemplated. These should be made part of the administrative record in any subsequent rulemaking, and they should be held before any rulemaking is initiated to facilitate open dialogue.

Feedback on Component 1 – Incoming Flock Testing

NCC has significant concerns that Component 1 of the Proposed Framework exceeds FSIS's authorities, is not supported by data, would be impractical, and is unnecessary. We suggest alternative approaches that will better achieve FSIS's objectives within the confines of law and reality.

Component 1 would have FSIS mandate on-farm testing, impose an incoming flock *Salmonella* standard, seemingly provide FSIS inspectors with the ability to dictate which flocks may or may not enter an establishment, and force establishments to view *Salmonella* as a hazard reasonably likely to occur (RLTO) at receiving. None of these actions are appropriate, and they risk significantly undermining existing policy and systems.

FSIS Lacks Authority to Regulate Farms

First, FSIS lacks jurisdiction to mandate on-farm testing, although Component 1 would do just that. The PPIA is clear that FSIS's authority begins at the official establishment. FSIS's primary slaughter-related inspectional authorities are expressly limited to operations in official establishments:

- Ante mortem inspection: "[T]he Secretary shall, where and to the extent considered by him necessary, cause to be made by inspectors ante mortem inspection of poultry **in each official establishment** processing poultry or poultry products. . . ."[39]
- Post-mortem inspection: "The Secretary, whenever processing operations are being conducted, shall cause to be made by inspectors post mortem inspection of the carcass of each bird processed . . . in each **official establishment** processing such poultry or poultry products . . . ."[40]
- Sanitary practices: "Each **official establishment** slaughtering poultry or processing poultry products . . . or otherwise subject to inspection under this chapter shall have such premises, facilities, and equipment, and be operated in accordance with such sanitary practices, as are required by regulations promulgated by the Secretary for the purposes of preventing the entry into . . . commerce, of poultry products which are adulterated."[41]

[39] 21 U.S.C. § 455(a).
[40] 21 U.S.C. § 455(b).
[41] 21 U.S.C. § 456(a).

- General compliance: "No **establishment** processing poultry or poultry products for commerce otherwise subject to this chapter shall process any poultry or poultry product except in compliance with the requirements of this chapter."[42]

It is telling that even ante mortem inspection, which is inspection of live birds, must occur at the official establishment. Had Congress wished for FSIS to be able to oversee farms, Congress could have given that authority to FSIS. Instead, Congress specifically limited FSIS's inspectional and oversight activities to official establishments, even for the inspection of live birds. FSIS has long agreed with this limitation. For example, in the final rule implementing HACCP, FSIS expressly recognized that "FSIS does not intend nor is FSIS authorized, to mandate production practices on the farm."[43] Thus, not only does the statute specifically limit FSIS's authority to official establishments (and further distribution therefrom), but FSIS also expressly recognizes this limitation in its foundational rulemaking for the very HACCP framework that FSIS proposes using to regulate activity on farms.

By establishing *Salmonella* thresholds for incoming flocks, FSIS would require that farms take actions to prevent *Salmonella* levels on flocks from exceeding the incoming threshold level. Farms would have to figure out how to monitor *Salmonella* levels and would be required to take actions to bring levels to within FSIS's target, otherwise the flocks are of essentially no economic value. FSIS is very clear about its intent. Component 1 is entitled, "Requiring incoming flocks be tested for *Salmonella* before entering an establishment."[44] This testing would have to occur on farms, and by the plain language of the Proposed Framework would happen before reaching the establishment. In other words, FSIS would be "mandating production practices on the farms," which FSIS has long recognized it may not do. Positioning the threshold merely as a receiving criteria that applies to the official establishment does not help because the only way to ensure a flock meets the incoming criteria is to require a farm to take various actions to ensure the threshold is met. No matter how FSIS phrases the threshold, the application of a threshold would require farms take actions, which FSIS may not do. FSIS cannot achieve through an indirect regulation what it lacks authority to do directly.

Further, setting a *Salmonella* threshold for incoming flocks necessarily implies that *Salmonella* above the threshold (1) renders the incoming birds adulterated and (2) that the purported adulteration cannot be corrected through processing. The only explanation for prohibiting entry of flocks that test above a certain *Salmonella* threshold is that the flocks would somehow irreparably adulterate any finished product that would be produced from them. FSIS would have no basis to arbitrarily restrict the use of flocks otherwise. But as explained above, *Salmonella* does not render raw poultry adulterated, and FSIS has presented no evidence to change this longstanding conclusion. Moreover, by categorically prohibiting entry, FSIS is indicating there is no means for an establishment to correct the purported adulteration, otherwise under HACCP principles the establishment could accept and process the product to correct the issue. FSIS has presented no evidence to indicate that flocks with *Salmonella* above a certain threshold are *per se* adulterated, much less somehow irreparably so.

Additional Issues Pertaining to Component 1

Even setting aside FSIS's lack of authority to regulate on-farm activities, Component 1 suffers from numerous other issues. First, FSIS has presented no data to demonstrate that an incoming threshold is necessary for an establishment to maintain process control and sufficiently reduce *Salmonella* during processing; no information to explain how a threshold would be determined or what data FSIS or an establishment would use to do so; no data to establish that on-farm *Salmonella* sampling several weeks before a flock is processed correlates in a reliable way to actual incoming *Salmonella* loads at the beginning of processing; no data to demonstrate that reducing incoming loads would achieve any particular public health impact; and no data to demonstrate that incoming loads require measuring for

[42] 21 U.S.C. § 459(a).
[43] 61 Fed. Reg. 38806, 38810 (July 25, 1996).
[44] *Salmonella* Framework at 5 (emphasis added).

HACCP systems to operate as designed. Without data to support such a substantial policy shift, the Agency cannot justify its approach, nor can stakeholders meaningfully provide informed feedback on whether the approach is justified by or consistent with the data. Science-based policymaking must start with data.

Second, a mandatory receiving threshold would be fundamentally inconsistent with HACCP principles. Under HACCP, establishments, not inspectors, make decisions about how to execute their food safety systems. FSIS's role is to verify that the HACCP system is designed and scientifically supported in accordance with FSIS regulations and that the establishment is implementing the HACCP plan as intended. FSIS's role decidedly is not to tell an establishment which flocks may be processed, and which may not. Component 1 would wind back the food safety clock a quarter century and reimpose a long-abandoned command and control approach to poultry processing.

Third, Component 1's proposed requirement that establishments declare *Salmonella* as a hazard RLTO at receiving is inconsistent with HACCP principles. Under HACCP, the establishment – not FSIS – is required to conduct its own hazard analysis, identify those hazards that are RLTO in the process, and implement Critical Control Points (CCPs) accordingly. If *Salmonella* were a hazard RLTO at receiving, it is unclear what step would be the CCP and how an establishment would be expected to validate that CCP.

Fourth, Component 1 is likewise inconsistent with established FSIS inspectional approaches because FSIS cannot verify the testing. FSIS typically must be able to verify the data used by an establishment to support its food safety system, but it is unclear how FSIS would verify incoming flock testing that occurred on a farm several weeks before a flock arrived at the establishment. FSIS's proposal to conduct verification testing at rehang is not appropriate for verifying on-farm testing. Several weeks would have passed from the time an on-farm sample was collected and FSIS's rehang sampling, and the microflora would be expected to change during this time. On-farm data would likely be collected by drag or boot swabs, which is a very different sampling process than taking a rehang sample. More importantly, however, is that fact that there is inconclusive evidence as to what method of on-farm testing actually yields repeatable and defensible results. Additionally, different enumeration technologies could yield different results and different confidence intervals. Moreover, between the time of on-farm testing and rehang sampling, the birds or carcasses will have undergone multiple interventions and processing interventions that affect *Salmonella* load. Even the Agency's own instructions in the Raw Chicken Parts Sampling Program require IPP to sample eligible chicken parts after the last intervention is applied.[45] Simply put, rehang samples would not correlate with on-farm samples, nor has FSIS provided any data to demonstrate otherwise.

Fifth, pre-harvest sampling would impose significant burden across the entire industry. NCC estimates that between 260,000 and 300,000 flocks were required to reach USDA's estimate for chickens processed in 2021. That would require collecting and testing between 260,000 and 300,000 samples annually, in rural locations, to comply with the proposal, and that is assuming each flock requires only one test. This would impose a substantial cost, pose unnecessary biosecurity risks, and overwhelm existing laboratory capacity and supply availability.

Sixth, challenges would also complicate FSIS verification sampling. For example, FSIS would have to collect a large number of samples to obtain a statistically reliable measure of the *Salmonella* level of a flock – one hot rehang sample would not suffice. It is doubtful FSIS has the sampling or laboratory capacity for this. It is also not clear how FSIS would handle outliers. For example, would the flock be evaluated by the average load or by the highest result, and how would FSIS obtain enough samples to have a sufficiently narrow confidence interval around the result? And even if FSIS could obtain this

[45]FSIS, *Raw Chicken Parts Sampling Program*, USDA.gov (2021), https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/10250.1-Raw-Chicken-Parts-Sampling-Program.pdf.

information, how would FSIS be able to meaningfully compare it to on-farm sampling conducted weeks earlier, using different sampling and possibly test methods, and reflecting birds before they had undergone various processing steps?

Seventh, it is unclear how FSIS would handle the inherent delay in receiving results for its verification testing, which, especially for enumeration, could take a significant amount of time until results are obtained. The flock would likely have been processed, the resulting products shipped, and perhaps even consumed well before FSIS received its verification results. But if the purpose of rehang sampling is to verify the establishment is properly conducing on-farm sampling and meeting the Agency's pre-determined threshold at live receiving, several serious logistical and practical problems arise. If FSIS is framing the proposed live receiving threshold as an acceptance criterion, with the implication being that a flock whose verification sampling exceeds the threshold should be rejected, then typically the establishment would be expected to hold the flock pending the results of FSIS's verification sampling. But holding an entire flock's worth of production every time FSIS conducted verification sampling would be extraordinarily burdensome and in effect impossible for most establishments. But if the establishment were allowed to ship the product before FSIS received the rehang verification results, it is unclear how the establishment would be able to implement corrective action. And it is entirely unclear how FSIS would view a situation in which the FSIS rehang verification sample was above the live receiving "threshold" yet the product from that flock met an enforceable finished product standard.

Additional logistical and practical problems abound. For example:

- It is unclear at what time period a flock would be required to be tested, how that would be determined, whether it would vary for different bird types, housing conditions, farm location, and market weight of the flock, among many other compounding factors.
- It is unclear what test method should be used for on-farm testing, as different methods might yield different types of results.
- Mandating such a high volume of on-farm testing could pose significant logistical difficulties in getting supplies and samples, especially to and from remote rural areas.
- It is entirely unclear what on-farm testing strategies would best reflect the load (or, if used, serotypes) actually entering the plant. Substantial industry testing has shown this is very difficult to do, and FSIS has provided no data on this point.
- How would issues such as testing delays, lost samples, equivocal results, or lab error resulting in a flock not having an on-farm test result be handled? A flock cannot be held past its target catch date without risking serious bird welfare issues.

FSIS has not addressed what would happen to a flock that tested above threshold. FSIS's contemplated policy could have catastrophic bird welfare outcomes and could result in flocks being needlessly held, delayed, diverted, or euthanized. Likewise, the proposal risks imposing substantial financial losses on the family farmers who raise the majority of broiler chickens and now might be left with flocks that cannot be brought to market and processed.

At bottom, FSIS's contemplated proposal would introduce a tremendous number of challenges and would be inconsistent with established HACCP principles. The reality is that the industry already implements numerous preharvest intervention strategies to reduce *Salmonella* loads coming into establishments, and they have done so even though they are not required to. For example, robust preharvest *Salmonella* control strategies are widely implemented across the industry to include programs in the hatchery, feed mill, breeder house, and broiler house. These programs include, but are not limited to:

- Biosecurity programs
- Equipment sanitation
- Feed treatment

- Litter treatment
- Water sanitation programs
- Feeding of prebiotics and probiotics
- Rodent/insect control
- Cleanout programs
- Vaccinations

The industry is already taking significant steps to address *Salmonella* in preharvest. Component 1 would contribute nothing but would impose considerable cost and complication. If FSIS's objective is to enhance process control and drive down finished product *Salmonella* levels, a much more direct and efficient approach would be to consider an enumerated performance standard for finished products and allow establishments to innovate and design their systems as appropriate to meet that target.

Component 1 Recommendations

In light of the substantial legal, scientific, and practical considerations associated with Component 1, NCC recommends the following:

1. FSIS should not establish incoming flock thresholds.
2. If FSIS wants to better understand process control throughout the process, from live receiving to pack-out, FSIS should engage in more extensive exploratory rehang sampling programs and use that data, along with FSIS data from other sampling points, to analyze process control throughout processing and to inform risk assessment modeling.
3. As discussed further below, FSIS should instead consider an enumerative performance standard after a baseline and qualitative risk assessment is performed. Establishments should be provided the flexibility to design science-based systems specific to their operations to meet that standard.

Feedback on Component 2 – In-Process Testing

NCC is concerned that Component 2 would be too prescriptive and could stifle food safety innovation. Component 2 would require establishments to conduct in-process testing at specified points using certain indicator organisms. Establishments already conduct extensive in-process testing, and a command-and-control-style approach dictating testing at certain points would be counterproductive.

As with other elements of the Proposed Framework, FSIS has provided no data to explain why Component 2 is needed, what benefits Component 2 would have on food safety outcomes, or how the testing locations, frequencies, or target organisms would be selected, among others. Without this information, it is impossible to thoroughly evaluate options, offer meaningful feedback, or understand whether the Agency's proposal is a reasonable response to the data. As with the other Components, it is critical that FSIS first develop and make available its data and then make decisions based on that data in a transparent manner.

As discussed above, HACCP principles dictate that establishments, not FSIS, are to develop and implement their food safety plans, including any process control monitoring strategies. Chicken processors do this, and processors collect substantial volumes of data throughout their processes. It is inappropriate to dictate specifically where an establishment must sample, how frequently it must sample, and what it must sample for. Doing so risks stifling innovation. An overly rigid sampling framework will hinder innovation and technology development by creating outsized focus on specific points and specific target organisms. Instead, plants should be encouraged to innovate by testing at the appropriate point for their systems, which in turn will provide more data and more impetus to drive technological improvements. A rigid framework also risks punishing companies whose food safety systems are better monitored using different testing protocols than called for under FSIS's one-size-fits-

all approach. Such a company would be forced to choose between incurring the cost of additional sampling or implementing FSIS's less-effective approach. Similarly, a rigid framework risks diverting limited company resources away from the most effective sampling points to meet the regulatory sampling requirements. None of these outcomes promote food safety.

Moreover, FSIS seems to contemplate requiring all establishments to follow the same process control methodologies, or perhaps requiring all establishments to meet the same process control standard. This would be inappropriate. Each establishment must be free to monitor process control as appropriate for their systems. FSIS has provided no data to show that it is appropriate or even feasible to evaluate all establishments using the same standard, especially if establishments have different line configurations or intervention strategies relative to FSIS-mandated sampling points. Without more information about what FSIS means by "requiring establishments to use the same statistical process-control method," it is difficult to provide specific feedback, but establishments need the ability to design their testing programs to reflect their processes, and they should be evaluated on their ability to implement their plans successfully, not against a rigid benchmark that might not reflect their operations. FSIS's science-based changes implemented through the New Poultry Inspection System created the opportunity for greater science-based decision-making by enhancing establishments' flexibility and promoting more science-based verification activities by FSIS. Mandating that establishments follow fixed sampling plans would be a step backward from this more modernized approach. Instead, FSIS should be encouraging establishments to innovate and implement tailored food safety systems.

Component 2 Recommendations

In light of these concerns, NCC makes the following recommendations:

1. Consider specifying where, when, and how FSIS will collect process control verification samples, and let establishments develop their own individual sampling plans as appropriate for their operations. This approach would provide FSIS a consistent frame of reference but leave establishments free to design their processes as they determine will best promote food safety.
2. Use FSIS verification sampling results to feed into risk assessment modeling to better understand process control considerations.
3. Encourage individualized sampling plans and strategies for establishments.
4. Encourage plants to utilize Statistical Process Control (SPC) by providing detailed guidance on options for application and key locations. This could be particularly helpful for small and very small establishments and could be developed in conjunction with the appropriate academic institution.

Feedback on Component 3 – Enforceable Final Product Standard

NCC strongly opposes setting an enforceable finished product standard for raw chicken. Such a standard would be legally infirm since FSIS has provided no data to demonstrate why any standard, much less the contemplated 1 CFU/g threshold, is scientifically appropriate. Regardless of how implemented, an enforceable finished product standard would impose substantial logistical and technical challenges on the industry.

FSIS Lacks Legal Authority to Implement a Finished Product Standard for Raw Chicken

FSIS lacks statutory authority to establish an enforceable finished product standard for *Salmonella.* For a threshold-based finished product standard to be legally enforceable, FSIS would have to determine, through scientific data, that the substance is not an added substance, and that the substance would "ordinarily render [the product] injurious to health" at levels above the threshold. Otherwise, the product would not be adulterated and there would be no legal mechanism FSIS could use to enforce the standard. As explained above, *Salmonella* is not an adulterant in raw chicken, a position consistently reflected in decades of Agency policy and court decisions.

Such a cavalier proposed change to Agency policy is especially alarming because FSIS has provided absolutely no data to support its proposal. FSIS has provided no data, in the context of the Proposed Framework or otherwise, to support a conclusion that *Salmonella* above any threshold level would "ordinarily render" raw chicken injurious to health, much less the 1 CFU/g threshold contemplated in the Proposed Framework. Nor is NCC aware of any.

NCC is gravely concerned that FSIS has abandoned science-based decision-making in Component 3. Sound science-based policymaking requires first developing data and then developing policies in light of that data. In the Proposed Framework, FSIS has gone about its decision-making backwards. FSIS appears to have a desired outcome in mind and has asked for data to support it. The 1 CFU/g threshold previewed in the Proposed Framework appears entirely arbitrary. If anything, it appears simply to be set as close to zero as possible without actually creating a zero-tolerance standard.

FSIS has not explained why an enforceable product standard is appropriate, why it should be set at 1 CFU/g, or why it should apply uniformly to all raw poultry regardless of differing commercial and consumer applications and known differences in *Salmonella* levels in different types of poultry.

Just as troubling, the Proposed Framework suggests FSIS is not interested in developing data to test its proposed threshold. For example, FSIS has indicated it does not intend to conduct a baseline enumeration survey, which would make it impossible to assess the current level of Salmonella present on raw poultry and to determine the public impacts of this or any other change. We question how FSIS can be confident that 1 CFU/g is an appropriate threshold for a finished product standard when FSIS does not even know what levels are actually present on finished products today. Moreover, FSIS has indicated it is conducting two risk assessments, but we understand the data collection analysis to begin those risk assessments has not even begun. We fail to understand why FSIS would, knowing that it is conducting risk assessments to provide information addressing this very point, nonetheless move forward and propose a specific finished product threshold at this point. The appropriate approach would be to conduct the risk assessments, conduct a baseline, gather and analyze any additional data needed, and only then determine whether a finished product standard might be appropriate and, if so, how to develop such a standard.

Moreover, while a risk assessment is essential for projecting the likely effect of different proposed standards on public health and product risks, for a risk assessment to provide value, the risk must be accurately identified, analyzed, and evaluated. A risk assessment is but one component of the broader science-based decision-making process. To determine the level of risk mitigation that would have a meaningful impact on public health, the Agency must implement a comprehensive risk analysis strategy, which must include three components: the risk assessment itself, risk communication, and risk management. Moreover, a risk assessment cannot itself determine whether a product is adulterated. That standard is established in the PPIA, which as discussed above requires demonstrating that a naturally occurring substance renders the product "ordinarily" injurious to health.

Finally, we understand that FSIS may be considering applying a potential finished product standard differently depending on the size of the establishment. If the finished product standard is an adulteration standard – which is the only way it could be enforceable – the PPIA provides no such flexibility. Under the PPIA, if a product is adulterated, the product is adulterated regardless of the size of the establishment involved.

At bottom, the PPIA's adulteration standard for naturally occurring substances requires a very clear scientific analysis: the substance has to "ordinarily" render the product injurious to health at the threshold level. Otherwise, by law, the product is not adulterated. FSIS has not provided any information to support such a determination. And without such information, it is impossible to meaningfully critique the contemplated approach.

Component 3 Raises Myriad Unresolved Issues

Beyond the grave legal concerns, Component 3 raises numerous other complex issues that remain unaddressed. For example, the necessary testing technology simply does not exist. FSIS's assumption that testing technology with sufficient throughput, sensitivity, and speed will materialize simply because FSIS wills it is arbitrary. In fact, FSIS's own newly approved testing technology has a LOD of *Salmonella* at 10 CFU/g, so it is unclear how FSIS would even evaluate compliance with the contemplated 1 CFU/g standard. Moreover, the fact that FSIS is unable to accurately quantify *Salmonella* at 1 CFU/g with its method casts considerable doubt on how FSIS developed this proposed standard.

Moreover, raw chicken is a highly perishable product with a short shelf life, and supply chains are not set up to hold substantial quantities of raw chicken. But an enforceable finished product standard would require testing and holding of enormous quantities of raw chicken until results are received. There simply is not enough cold storage in the country to accomplish this, and a widescale test and hold program would significantly degrade product shelf life and quality. Companies may be forced to destroy product or divert it to the cooking market, which accounts for only a modest amount of chicken production and would quickly find both demand and processing capacity outstripped. FSIS's policy threatens to constrict the supply of raw chicken, which in turn risks driving up food inflation and heightening food insecurity for America's most vulnerable families.

Likewise, an "enforceable" final product standard implies that FSIS would request a recall if a product were found to exceed the standard, and it is entirely unclear how lotting would be determined when establishing the scope of a recall. For example: Would lots be defined on a flock-by-flock basis? What about other flocks processed earlier or later that day? Would all chicken that contacted the same chiller water be included in recall? How would rework and hang-backs be handled? If parts of a day's production were sent to a different use, would all products from that day or flock be implicated? If a specific part, such as thighs, exceeded the standard, would that also affect other parts made from that flock, such as breasts? What if some types of parts exceed the standard but others do not? All of these questions, and many more, would require careful, considered analysis. NCC is extremely concerned that under the Proposed Framework, a single test result could cause the recall of an extremely large amount of product. There are much better ways to focus efforts on driving down levels of *Salmonella* without raising these extremely complicated issues.

FSIS has also provided no information on how it would expect establishments to test entire production lots of raw chicken in a statistically meaningful way. Raw chicken is not like raw non-intact beef, where lots can be limited to specific source materials and tested individually. Raw chicken production lots are very large, and *Salmonella* is unlikely to be uniformly distributed in a lot. As a result, it would be necessary to collect a tremendous number of samples to have confidence that the result is representative of the entire production lot. A single sample would be wholly inadequate. It is unclear if FSIS has the laboratory resources to adequately sample and analyze finished products lots, and it would impose considerable costs on establishments to do so. Moreover, raw poultry cannot be lotted in a way to limit lot size for finished product testing, and there would be no way to form lots conducive to a finished product test and hold program. We are also concerned about establishments that implement a less than daily (LTD) sanitation program and how those establishments would be expected to lot product. For example, due to time and difficulty involved, some establishments do not completely empty their chiller systems daily and instead have validated LTD sanitation programs in conjunction with FSIS. This facilitates efficient operations and protects the environment by reducing water and chemical use. The environmental impact and resources associated with losing a LTD sanitation program would be significant and must be considered.

Further, to the extent the Agency were considering applying a finished product standard differently based on establishment size or conducting sampling for small or very small establishments, it is unclear

how the Agency would take the necessary number of samples and still have remaining lab capacity to complete any verification sampling.

In practice, a standard like that contemplated in Component 3 would impose substantial cost on the industry, would divert tremendous amounts of raw chicken to less-demanded cooking applications (and would overwhelm the already saturated market for cooked chicken as well as capacity to cook it), and ultimately would mean less chicken at higher costs for consumers.

Component 3 Recommendations

NCC strongly opposed Component 3. FSIS lacks statutory authority to implement it, and the proposal raises numerous insurmountable technical issues. Instead, NCC recommends the following for enhancing *Salmonella* control in raw poultry finished products:

1. Conduct an enumerative baseline for *Salmonella* in raw poultry, focusing on different parts and perhaps different end-use applications or differences between slaughter and further processing facilities. Develop robust enumeration data for different parts.
2. Use enumerative baseline data to inform a risk assessment model.
3. Develop an enumerative performance standard to replace the current presence-based performance standard that is focused on specific parts.
4. Enhance labeling and consumer education. NCC has petitioned FSIS multiple times for more robust and modern labeling for certain types of raw poultry, which FSIS has yet to act on.

In particular, NCC believes that an enumerative performance standard would advance FSIS's public health goals in a much simpler and easier-to-implement manner. History has shown that chicken processors will make changes to meet voluntary performance standards. A properly constructed enumerative performance standard would achieve the same objective of driving down levels of *Salmonella* on finished product raw poultry, but with a number of benefits over the proposed Component 3. An enumerative performance standard provides the Agency and establishments with greater flexibility; can be implemented quickly without the need to rely on a novel application of the adulteration standard; is more responsive to existing supply chains and distribution practices; would not require new rapid testing technologies or complex test and hold programs (but the existence of the program would provide demand to spur testing innovation anyway); and would generate valuable long-term data about *Salmonella* levels on finished product. We strongly encourage FSIS to explore this pathway instead of the proposed Component 3, and NCC stands ready to collaborate with FSIS on this approach.

Cross-Cutting Considerations

NCC has feedback on several cross-cutting considerations related to the Proposed Framework.

Developing a Robust Data-Sharing Mechanism is a Critical Prerequisite Step

Throughout our comments, we have expressed concern about the lack of data and scientific analysis supporting the Proposed Framework. Chicken processors collected substantial quantities of data, dwarfing that collected by FSIS through verification and exploratory sampling. For more than a decade, NCC has sought a mechanism to facilitate aggregate data sharing with FSIS. NCC members are interested in developing an appropriate data-sharing process. In particular, NCC urges FSIS to develop a data-sharing framework that is consistent with the Freedom of Information Act exemption (b)(3), either with FSIS or a sister agency within USDA.[46] This data would provide FSIS with substantially more insight into food safety systems throughout the industry and would facilitate policy development and risk assessment modeling.

[46] 5 U.S.C. § 552(b)(3).

Serotype and Virulence-Based Testing is Not Practical with Current Technology

NCC supports efforts to enhance cutting-edge technologies to better understand *Salmonella* risks. Advanced testing technologies such as serotype-specific testing and virulence-based testing show great promise but, as FSIS recognized in the Proposed Framework, will require additional development before they can be used widely and effectively in everyday food processing operations. We encourage FSIS to support the continued development of and innovation with these technologies, but they are not quick, affordable, or available enough to be used widely in food processing operations. Moreover, we encourage FSIS to support further research on virulence factors and how they may impact public health.

The Proposal Risks Significant Disruption to the Industry and Threatens Food Prices for Consumers

Many aspects of the Proposed Framework threaten to drive up costs and cut availability of chicken. This would be an extremely unfortunate outcome, especially in light of recent record across-the-board inflation and the continuing food insecurity afflicting millions of American families. Chicken is American's most affordable and most consumed protein. It is nutritious and versatile, and it is a staple protein for many, and critically for those families trying to make the most out of every food dollar. Moreover, chicken makes up a significant portion of food bank donations and purchases for federal and state nutrition assistance programs. Aspects of the Proposed Framework threaten to undermine chicken availability.

For example, Component 1 would seem to contemplate entire flocks being turned away from plants before they are even processed. This would have devastating animal welfare implications, and it would reduce the supply of chicken in the market, in turn driving up costs. Likewise, a finished product standard would likely cause substantial amounts of product to be diverted to cooking operations. However, there is limited use and demand for precooked chicken, and that demand is largely saturated. Moreover, there is limited capacity to actually produce cooked chicken. Combined, these factors mean that much of the chicken that FSIS likely anticipates would be diverted to cooking operations would simply be destroyed, again reducing the supply of chicken and driving up costs. It would be most unfortunate for FSIS to choose this moment to worsen food insecurity and to drive up consumer food prices.

Further, the family farmers who raise most of the broiler chickens processed in the United States would be put at great financial risk if FSIS were to subject the marketability of the flocks they raise to a live receiving threshold. It is entirely unclear how FSIS anticipates the threshold affecting farmers, and this change could inject tremendous uncertainty into what has long been a prosperous way to deploy farming capital.

Conclusion

NCC appreciates the opportunity to provide comment on FSIS's Proposed *Salmonella* Framework. NCC member companies share FSIS's goal of reducing *Salmonella* levels on raw chicken and, ultimately, driving down salmonellosis cases. The chicken industry has made tremendous advances in reducing *Salmonella* presence, and the industry continues to drive down *Salmonella*. However, NCC has serious concerns about many aspects of the Proposed Framework. The Proposed Framework contemplates actions that exceed FSIS's statutory authority, that would be extremely difficult and perhaps impossible to implement, and that are not consistent with modern food safety approaches. Moreover, the lack of supporting information and data makes it extremely difficult to meaningfully evaluate and provide feedback on the Proposed Framework. NCC is concerned that policy appears to be getting ahead of the science.

NCC urges FSIS to instead pursue the recommendations made in these comments. The Agency should continue to work closely with all stakeholders through hosting technical meetings prior to the issuance of a proposed rule to ensure the ability for two-way dialogue and the development of the best approach forward based. These recommendations – in particular, conducting additional data gathering and analysis, developing an appropriate industry-agency data sharing protocol, and developing an enumerated performance standard – would significantly advance public health objectives while avoiding many of the complications, uncertainties, and costs raised by the Proposed Framework.

Please feel free to contact us with any questions regarding the above request. Thank you for your consideration.

Respectfully submitted,

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National Chicken Council

ATTACHMENT 2

Randall S. Singer, *Salmonella* Framework for Raw Poultry Products Critical Review (January 17, 2025)

Salmonella Framework for Raw Poultry Products Critical Review

January 17, 2025

Randall S. Singer, DVM, MPVM, PhD
Professor of Epidemiology
University of Minnesota

Executive Summary

The Healthy People 2030 target is to reduce the *Salmonella* illness national case rate by 25 percent. Because poultry, specifically chicken and turkey, are potentially important sources of human salmonellosis illnesses, USDA FSIS has introduced a new proposed *Salmonella* Framework with the goal of reducing salmonellosis illnesses attributable to chicken and turkey by 25%. The proposed changes include a Final Product Standard that states "Raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey are adulterated if: 1) They contain any type of *Salmonella* ≥ 10 cfu/mL or 10 cfu/g **AND** 2) Contain any detectable level of at least one of the *Salmonella* serotypes of public health significance identified for that commodity." The proposed *Salmonella* framework also includes a Statistical Process Control (SPC) program with the goal of reducing Aerobic Counts (AC) by at least one log between two sampling points in the processing plant.

The risk assessments that were conducted for this Framework demonstrate that the maximum predicted reduction in human salmonellosis illnesses following implementation of the proposed Final Product Standard is far below the HP2030 target of 25%. Even with assumptions that tend to maximize the potential decrease in human illness, this burdensome and precedent-setting program would have little noticeable impact on human salmonellosis. Some of the key deficiencies of this proposal are summarized below and are described in more detail later in this document.

In the Federal Register Notice (FRN) published August 7, 2024, four risk management questions are posed. The second risk management question asks: 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? Even though the proposed Final Product Standard includes both of these criteria (enumeration threshold and serotypes of public health significance criteria), surprisingly the risk assessments never address both of these criteria together, and therefore, all of the estimated illnesses prevented are based on an incomplete application of the proposed Final Product Standard. **It is unfathomable that USDA FSIS would propose a precedent-setting Final Product Standard on raw, not ready-to-eat (NRTE) poultry without actually evaluating the criteria of this standard.**

Another surprising deficiency in this proposed Framework is the lack of serotype-specific data for the products being considered. Specifically, serotype data were only available from the FSIS two-point chicken carcass data (rehang and post-chill); no data were collected for chicken parts, comminuted chicken or comminuted turkey, and therefore, no serotype analyses could be conducted for these products even though they are components of the proposed Final Product Standard.

I commend FSIS for undertaking this task, as there is a need to update the Performance Standards for chicken and turkey. The various models that were built have helped identify key data gaps that should be filled to more accurately estimate the efficacy of policy changes. Unfortunately, there are a significant number of data gaps in these models that limit the utility and predictive capability of the models.

Summary Points

- The proposed Final Product Standard represents perhaps the most significant change to meat inspection since HACCP. It is not analogous to STEC in ground beef or *Salmonella* in raw, not ready-to-eat not ready-to-eat (NRTE) breaded stuffed chicken. One would hope and expect that prior to implementing a regulatory change as significant as this, models would be developed to predict the potential benefit to human health and the impacts on the poultry industry. Risk assessments were developed for chicken and turkey, and the number of illnesses prevented was estimated. However, the risk assessments did not address both the enumeration-based criterion and the serotypes of public health significance criterion of the proposed Final Product Standard in the same model. It is entirely inappropriate to implement a Final Product Standard without evaluating the impact that the criteria for the standard will have on the industry and public health.
- The estimated number of illnesses prevented is inflated for chicken. The model multiplies the proportion of illnesses prevented for carcasses by all illnesses attributed to chicken and not just the number attributed to chicken carcasses. FSIS states in the chicken risk assessment that the estimated number of illnesses prevented attributed to chicken carcasses, chicken parts, and comminuted chicken are not additive, and yet the second Table 34 in the FRN sums the three products to arrive at an estimated 2,200 illnesses prevented following implementation of the enumeration-based Final Product Standard in chicken. However, if FSIS had done this calculation correctly, the numbers would be approximately 138 for carcass, 200 for parts and 1,000 for comminuted chicken, for a total of 1,338 estimated illnesses prevented. This number is much lower than the stated 2,200 as reported in Table 34.
- The risk assessments assume perfect accuracy in the diagnostic assay used to enumerate *Salmonella*. As shown in the FSIS analysis, the enumeration assay evaluated by FSIS has many false positives and false negatives, especially when the true *Salmonella* concentration is near the threshold of 10 cfu/mL(g). The impact of an imperfect diagnostic assay is an increased cost to industry (due to false positives) and a reduced benefit to public health outcomes (due to false negatives). Failing to incorporate the assay performance into the model results in fewer illnesses prevented than was predicted, perhaps by 25% or more.
- The estimated number of annual illnesses attributed to chicken and turkey in the U.S. uses an outdated under-diagnosis factor that does not account for inter-serotype (or inter-strain) differences in virulence. The *Salmonella* Framework is based heavily on the notion that there is heterogeneity in virulence among serotypes (and strains). One would expect virulent strains to cause a more severe disease, thus reducing the under-diagnosis multiplier for these virulent infections.
- The models assume that the number of illnesses attributable to specific chicken and turkey products is proportional to the number of servings of each product consumed during the year. This assumption of equal risk among different products is overly simplistic and highlights the lack of product-specific data that should have been collected (or estimated) prior to proposing a Final Product Standard.
- The virulence model for categorizing *Salmonella* serotypes, which represents a major advance in *Salmonella* bioinformatic analyses, is overly simplistic and does nothing to help reduce the impact of specific *Salmonella* serotypes derived from poultry on human health outcomes. The model treats all known and hypothetical virulence genes (factors)

equally and uses a simple cluster algorithm that labels some highly virulent serotypes as "low virulence." The model assumes that all serotypes within a cluster have equal virulence. The model assumes that a serotype found in multiple host species has equal virulence across species, implying no strain variation across species. The model actually includes more than 10,000 beef-sourced isolates in the cluster algorithm. For reasons that will be discussed below, including serocluster (and serotypes of public health significance) in the Final Product Standard criteria **reduces** the public health impact of the proposed Framework. Consequently, a better program would eliminate the serotype component of the criteria and instead focus on the enumeration-based criterion.

- The contamination distribution is used to model the initial contamination of products being regulated in this Framework. Strangely, all three chicken products (carcasses, parts and comminuted chicken) are modeled with the same distribution, even though FSIS data show that these product types have very different levels of contamination. Further, the single contamination distribution for chicken is based on a weighting of the product-specific contamination distributions, with the weighting based on the proportion of servings of each product consumed during the year (similar to the product-specific illness attribution).
- The attenuation distribution used by FSIS, which explains the growth or die-off of *Salmonella* on the product as it moves from the processing plant to the point of consumption, is the same for all chicken and turkey products. This inherently assumes that all of these products behave identically, including the likelihood that they will be mishandled and/or undercooked by the consumer.
- The dose-response function for the high virulence serotypes is based on non-poultry data for two serotypes. The final function is applied to all serotypes in the high virulence cluster, regardless of strain (and actual virulence potential) within the serotype.
- The Risk Multiplier is a biased parameter of the model, as the numerator is a surrogate for virulence of serotypes in the cluster while the denominator is a surrogate for the frequency that the serotypes are found in poultry samples in the processing plant. This confounded measure is used estimate the dose-response function of the "low virulence cluster" by reducing the dose-response function of the "high virulence cluster." This parameter, which does not actually relate to virulence at all, has no place being used to adjust a dose-response function, especially when the dose-response function for both the high and low virulence clusters could have been derived in the same way.
- The Risk Multiplier assumes that all serotypes in the cluster have an identical virulence, and further, that all strains within a serotype also have an identical virulence. The result of using the Risk Multiplier to adjust the dose-response function for the low virulence serotypes results in an inflated number of estimated illnesses that can be prevented following the implementation of the enumeration-based Final Product Standard.
- In the turkey risk assessment presented by FSIS in this Framework, data to inform multiple parameters were lacking, and consequently, chicken data were used to estimate these parameters in the turkey model. No uncertainty adjustment seems to have been included in the turkey model to account for the use of chicken data. It is inappropriate to use chicken data to estimate parameters in the turkey risk assessment, especially for a proposed regulatory change as significant as this. The agency or others should have collected the necessary data for the models prior to publishing the final *Salmonella* Framework.

Alternative Program

For reasons discussed below, a Final Product Standard is not the best way forward, at least at this time. For more than two decades, USDA-FSIS has been fixated on prevalence (presence-absence) as an indicator of risk. As I described in my comment posted to FSIS Docket No. FSIS-2022-0029 in December 2022, prevalence is not an indicator of risk, and therefore, the lack of correlation between the reduction in *Salmonella* prevalence across all poultry products and the stable incidence of human salmonellosis can be attributed to the agency targeting an inaccurate metric of risk. Rather than implementing a Final Product Standard that was never fully evaluated and, even under risk-maximizing assumptions, will fail to achieve the desired 25% reduction in human salmonellosis illnesses attributed to raw, NRTE poultry, I propose an alternative program. Specifically, FSIS should set an enumeration-based Performance Standard (such as the 10 cfu/mL or cfu/g on the products described in the Framework) of **any** *Salmonella*, not just the serotypes of public health significance identified by the models. Second, to ensure that microbiological controls in the processing plant are functioning, a proper SPC could be implemented upstream of the final product (for example, at rehang and post-chill). The combination of these two interventions will likely have a much greater impact on human salmonellosis than the program described in the Framework.

In Table 37 below, which was taken from the FRN (p. 64743), five regulatory alternatives are presented. These alternatives either maintain the status quo or make changes to the enumeration threshold for the Final Product Standard. FSIS should consider my alternative that uses SPC and an enumeration-based Performance Standard to reduce human salmonellosis attributable to poultry.

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.

Justification for this Performance Standard approach is clearly stated in the documents released by FSIS as part of this *Salmonella* Framework proposal. For example, in the Chicken *Salmonella* Risk Assessment (SRA), FSIS states that "Public dissemination of establishment categorization has been shown to serve as a market-based incentive to encourage establishments to reduce

Salmonella contamination in failing establishments" (Chicken SRA, p. 39 and Ollinger, 2020). FSIS later states that:

> there is no mandatory enforcement action once an establishment fails a performance standard. Risk assessments of performance standards attribute improvements in public health to the actions taken by failing establishments to become passing establishments (FSIS, 2015). Those assessments assume that the motivation for improvement is via market forces that penalize failing establishments and/or reward passing establishments. Therefore, failing establishments and public health improve as an indirect effect of the performance standards (Chicken SRA, p. 126).

As seen from every prior change to the poultry Performance Standards, the industry adapts to these changes. Implementing an enumeration-based Performance Standard will push the companies to meet/exceed that Performance Standard during all production shifts and not just those on FSIS sampling days. A change in the poultry Performance Standards is the logical next step and is supported by past evidence of efficacy.

Introduction

As stated in the *Salmonella* Framework FRN, "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. However, these measures have yet to have an observable impact on *Salmonella* illnesses." (p. 64683). This is an important admission by FSIS for several reasons. First, it implies that the poultry industry has adjusted and adapted to every change that FSIS has made to the Performance Standards over the past two decades. In other words, the voluntary Performance Standards enacted by FSIS have resulted in substantive change by the poultry industry. The observation that human illness rates have not changed is not a statement against the poultry industry but rather that FSIS was not focused on predictors of actual risk to human health. Second, the statement implies that all human salmonellosis illnesses should have declined because of the actions of the poultry industry. In reality, only those illnesses that are attributed to poultry products would have been prevented, and these estimates are based on uncertain calculations of attribution. A recent paper published in the journal Risk Analysis in 2024 found "declining trends in illness due to the poultry-associated serotypes and increasing trends in illness due to *Salmonella* serotypes not associated with poultry." (Powell, 2024). Finally, this statement by FSIS implies that the current proposed *Salmonella* Framework would have an observable impact on human salmonellosis rates. "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. Thus, to reach the 2030 target, illnesses must be reduced by 25 percent" (p. 64683). As clearly reported in the chicken and turkey SRAs and in the FRN, the best guess of the direct impact of this proposed *Salmonella* Framework would reduce human illnesses very little; the estimated percentage reduction in poultry-attributed illnesses is actually 1.99% (3,338 poultry illnesses prevented / 167,784 poultry-attributed illnesses; this number of illnesses prevented is different from Table 5 of the FRN due to an error by FSIS, as described below). This translates into a reduction in the overall *Salmonella* illness rate of 0.46% (3,338 / 723,207 total salmonellosis illnesses). Both of these decreases are far below the targeted 25% reduction.

Table 5 of the FRN shows the estimated number of illnesses prevented following implementation of an enumeration-based Final Product Standard; the estimates do not include the serotype of public health significance criterion of the Final Product Standard, as the risk assessments do not model both criteria of the proposed Final Product Standard in the same model. According to the chicken SRA, "At a level threshold of 10 cfu/mL, the number of illnesses prevented is essentially zero" (Chicken SRA, p. 104). This level (10 cfu/mL(g)) was chosen for multiple reasons, but as stated in the FRN:

> 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

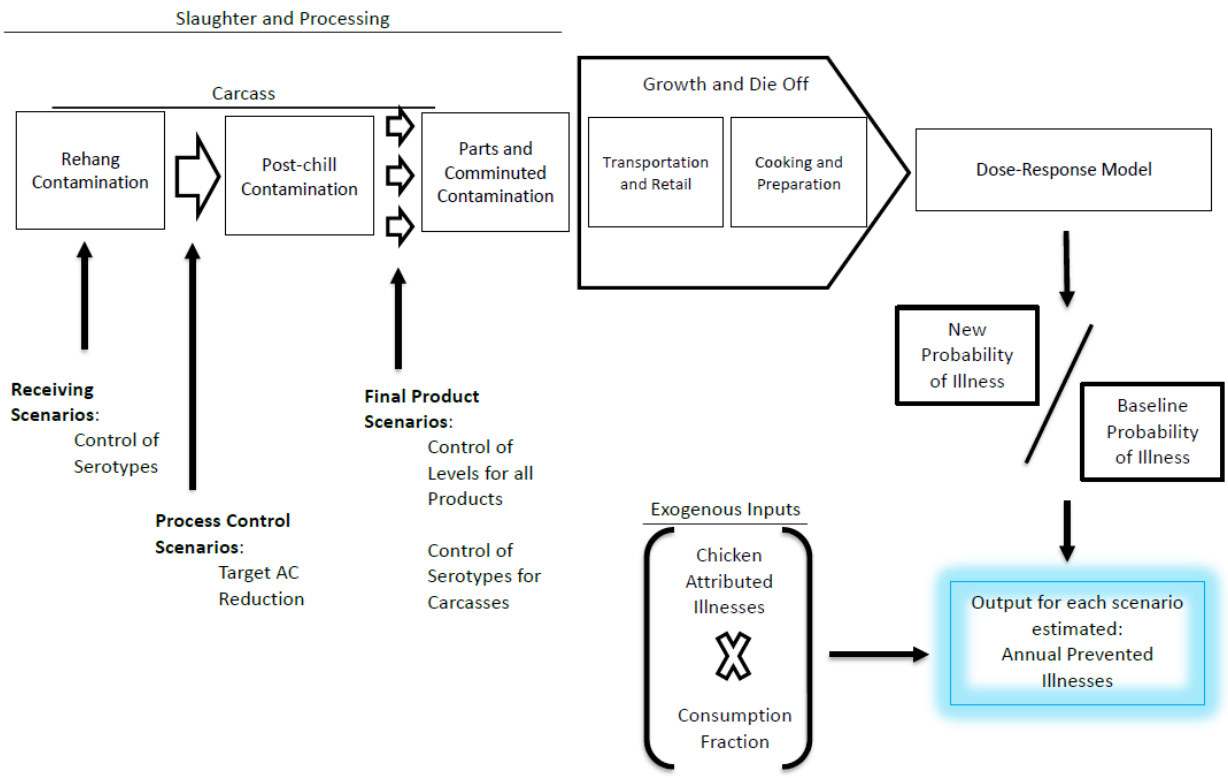
proposing 10 cfu/mL(g) as the *Salmonella* level for the proposed final product standards. (FRN, p. 64703).

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)

According to the FRN, "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" (FRN, p. 64692). Consequently, FSIS states that "the Agency has tentatively decided to phase out all current *Salmonella* performance standards for poultry" (FRN, p. 64680). While FSIS is correct that the current Performance Standards are based on prevalence and therefore do not distinguish high-load final products that might present an elevated risk to the consumer, that is not justification for saying that Performance Standards should be phased out. Instead, a new, enumeration-based Performance Standard should be created. The impact of such a program would be much greater than a Final Product Standard that is based on testing of, at most, a single lot per week. Furthermore, although the serotype and virulence profile of the *Salmonella* on a product affect the likelihood of illness to the consumer, an enumeration-based standard without the serotype criterion will have a greater impact on public health because it will target all serotypes. In other words, using an enumeration-based standard, regardless of type of *Salmonella* present, will keep all *Salmonella* at these "trace amounts" thereby imparting maximum risk reduction.

As stated in the Chicken SRA, "The amount of *Salmonella* on chicken carcasses regulated by FSIS has decreased over time. Comparison of the FSIS 2022 Exploratory Sampling post-chill data to the previous FSIS chicken carcass microbiological baseline (FSIS, 2009a) shows a 59% reduction in volume-weighted *Salmonella* prevalence (from 0.075 in 2009 down to 0.031 in 2022)." (Chicken SRA, p. 23). This lack of efficacy in reducing human illnesses should raise the key question: Is there an alternative program that would have a greater impact at reducing the human salmonellosis illness rate attributed to poultry products? The answer is "Yes." In this report, I will try to highlight some of the problems with the current proposed Framework that also support the program that I proposed above that would ultimately provide a much greater impact than this *Salmonella* Framework. I will comment on various parameters used in the SRAs. I order my comments using the schematic of the overall Framework structure (below) as a guide. I first comment attribution and estimated number of illnesses attributed to chicken and turkey. I then discuss Component 3 issues, which include the enumeration-based criterion, the serotype of public health significance criterion, the contamination distribution, the attenuation distribution, the dose-response model, and the risk multiplier. I then comment on Component 2, and specifically, the use of SPC. Finally, I comment briefly on Component 1, even though it is not currently being proposed for implementation by FSIS.



Attribution

The first step of the risk assessment approach is to estimate the number of human salmonellosis illnesses that are attributable to chicken and turkey produced and consumed in the U.S. The SRAs describe how the number of annual illnesses attributable to chicken and turkey was estimated. There were an estimated 125,115 chicken-associated and 42,669 turkey-associated *Salmonella* illnesses per year. As stated in the SRAs, this value is calculated as the product of the total number of CDC FoodNet cases per year (7,600), the share of these cases that are foodborne (66%) and of domestic origin (89%), the under-diagnosis multiplier for *Salmonella* (24.3) (Ebel, 2012c), dividing by the FoodNet catchment area (15%), and multiplying by the IFSAC attribution estimates to chicken (17.3%) or turkey (5.9%).

Given that the focus of the SRA outputs is to estimate the number of annual illnesses that can be prevented through the proposed regulatory changes, the percentage reduction in illness incidence is likely more important than the absolute number. Regardless, if the percentage of human salmonellosis cases attributable to chicken and turkey is less than the estimate used in the calculation, the actual impact on human health as a result of this proposed *Salmonella* Framework will be less than reported. These IFSAC attribution estimates are based on outbreak data and are therefore influenced by the decision by public health agencies such as the CDC to declare an outbreak or to consider an outbreak over. This will be discussed later in the report but becomes important, as many salmonellosis illnesses are considered sporadic (not linked to an outbreak) and thus do not help inform attribution estimates.

Aside from the IFSAC attribution estimates, another important parameter used in the illness estimate calculation is the under-diagnosis multiplier. This is an outdated estimate (revised by Scallan et al. 2011 and Ebel et al., 2012) and does not differentiate among serotypes or strains within serotypes; a single under-diagnosis value is used for all serotypes and strains, regardless of virulence. Given that so much of this *Salmonella* Framework is devoted to differentiating high virulence from lower virulence serotypes, it is unfortunate that more attention was not given to this parameter. One would expect virulent strains to cause a more severe disease, thus reducing the under-diagnosis multiplier for these virulent infections.

Another component to attribution estimates that is important in the *Salmonella* Framework is to attribute the illnesses to the specific chicken and turkey products being regulated in the Framework. In the chicken SRA, the estimated human salmonellosis illnesses attributed to chicken "are distributed across products by assuming the proportion of servings consumed (0.11, 0.83 and 0.06) is proportional to illnesses resulting from exposure to carcasses (whole chickens), parts and comminuted (ground) forms of chicken, respectively" (Chicken SRA p. 86). For turkey, the SRA assumed that "0.42 of all turkey-associated *Salmonella* illnesses result from exposure to comminuted (ground) turkey products, which is approximately 17,921 (Lambertini, 2021)." (Turkey SRA, p. 86). This 42% estimate by Lambertini comes from the CDC National Health and Nutrition Examination Surveys (NHANES) conducted 2013 – 2014, more than a decade ago. Regardless, attributing product-specific illnesses proportional to servings consumed assumes that all products are equally likely to cause disease, an assumption that is unlikely to be accurate. As will be seen with other parameters of the SRA models, there is considerable missing data relative to product-specific characteristics. Before proposing a Final Product Standard on these products, one would hope that these product-specific data gaps would have been filled.

Serocluster Assignment

In this *Salmonella* Framework, FSIS sought to categorize *Salmonella* serotypes by their virulence, meaning their ability to cause severe disease in people. Part of the reason for doing this was to identify serotypes of public health significance that would then become part of the Final Product Standard criteria. These virulence cluster assignments would also be used in the risk assessments to predict the number of illnesses that could be prevented through a reduction of high virulence *Salmonella* serotypes on chicken and turkey products. I commend FSIS and EpiX Analytics for using a scientific approach to categorize serotypes based on their potential virulence. However, the model that was built for this cluster assignment is flawed for various reasons, at least with respect to its application in the *Salmonella* Framework. However, as I discuss throughout this report, I do not believe that categorizing serotypes into virulence clusters is necessary, as a regulatory change that would have the biggest impact on public health would ignore serotypes and instead focus only on the enumeration-based threshold. In other words, all *Salmonella* serotypes would be targeted and not just the three identified as significant to public health for each commodity.

To separate serotypes into seroclusters, EpiX Analytics downloaded *Salmonella* genomes from sources including chicken, turkey, human and beef. The serocluster model was first published in PLoS ONE as a beef model (Fenske et al., 2023). In total, 40,038 *S. enterica* isolates of different

serotypes from these four sources were used in the model. Each genome was evaluated for the presence of known or hypothetical virulence genes, many of which have only been described in *Enterobacteriaceae* other than *Salmonella*. In total, approximately 5,000 genes were evaluated. Random forest models were created based on the presence/absence of these genes. No information was provided to the model regarding the importance of specific virulence genes in causing severe human illness. Many of the genes used in the models have not been proven to actually be *Salmonella* virulence factors (only about 150 virulence genes have evidence as being virulence factors in *Salmonella*). Therefore, the presence/absence of the virulence genes evaluated in these models may not be reflective of a strain's virulence potential. The chicken SRA specifically states "Moreover, clustering was agnostic to the biological function or role of individual virulence factors as well as point mutations or insertions/deletions of genes that can modify gene function resulting in public health risk as illustrated by the emergence of *Salmonella* Reading (Miller, 2020)" (Chicken SRA 53). I am a co-author on the Miller et al. paper and can attest to the fact that not all strains within a serotype have equal virulence, and the array of specific virulence factors (not just the total number) influences a strain's virulence.

The documents then state that "Virulence genes that were present in the majority of isolates (>95%) as well as limited gene presentation (i.e., <10 total isolates) were removed from further analysis. Hence, 193 genes available for the clustering analysis included 57 *Salmonella* VFs, 94 *E. coli* VFs, 10 *Shigella* VFs, and 32 *Yersinia* VFs. 53" (Chicken SRA, p. 53). When the clusters that were generated based on this simplistic approach are compared to an actual phylogenetic tree of *Salmonella enterica* (based on SNPs), the trees are nearly identical, showing that the cluster assignments did not accurately characterize individual serotype or individual strain virulence differences. Experimental evidence for actual invasive potential does not agree with the serocluster tree. For example, there are highly invasive serotypes falling into the "low virulence" cluster, and vice versa. As we published in the Miller et al. paper (2020), there are also major virulence differences among strains within a serotype.

Ultimately, FSIS decided to use the two-cluster model, one being labeled as "high virulence" and the other as "low virulence." Strangely, the FRN says that "The committee [NACMCF] 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" (FRN, p. 64695). If these serotypes are poultry-associated and are associated with the highest number of illnesses, it should be an indicator that the serocluster assignment, which put Infantis and Heidelberg into the low virulence cluster, is not performing properly. FSIS states that the "clusters were validated by linking them to epidemiological data (i.e., documented outbreaks attributed to poultry sources with consideration of prevalence in animal sources from FSIS poultry sampling programs)" (Chicken SRA, p. 55). This is not validation of the model, as shown above where Infantis and Heidelberg were identified by NACMCF as being important poultry serotypes that cause human illness but that were included in the low virulence cluster. These cluster assignments were later used in the SRAs to estimate the Risk Multiplier parameter of the models, which is basically the step that FSIS says is the validation.

Furthermore, different host species can harbor different strains of the same *Salmonella* serotypes. This is important because the models developed by EpiX Analytics incorporated over 10,000 beef *Salmonella* isolates into the models. It is unknown how strongly these beef isolates altered

the cluster assignments for different *Salmonella* serotypes, as it does not appear an analysis was conducted without these isolates. According to the downloadable FSIS Bioinformatic spreadsheet, "*Salmonella* virulence does not depend on host or origin (i.e., isolation source such as chicken, turkey, beef, etc.)." This assumption is untrue, as there are considerable intra-serotype inter-strain differences in virulence, and some of this heterogeneity can be clustered by source.

Because I argue in this report that the use of *Salmonella* serotypes in the proposed regulatory changes actually reduces the public health impact of the program, it might appear that there is no need to belabor the serocluster assignment discussion. Also, as I have stated previously, the criterion of the proposed Final Product Standard involving serotypes of public health significance was not evaluated in concert with the enumeration threshold in the SRAs. However, the serocluster assignment does get used in the models in important ways, and thus it is critical to highlight the assumptions and weaknesses of the serocluster models.

For example, the arbitrary decision to divide the isolates into two clusters defined as high and low virulence then gets used to generate the Risk Multipliers that will be discussed later in this report. These Risk Multipliers are used to modify the dose-response models and to estimate the potential number of illnesses that could be prevented. Determining which serotypes belong in which cluster thus has importance to the outcomes of the SRAs, and these estimates of virulence differences among the clusters could be highly driven by a small subset of serotypes within the cluster, by a strain variant within a serotype, or by host species differences in virulence traits of isolates within a serotype (i.e., beef versus poultry isolates of the same serotype). For example, if Typhimurium is by far the dominant serotype of cluster 1 isolates, the case rate and hospitalization rate will be driven by Typhimurium and not necessarily by other serotypes within the cluster.

FSIS repeatedly states that the dose-response model developed by EpiX Analytics was "genomically validated." This is a strange (and somewhat meaningless) statement, as the dose-response model uses serotype-specific estimates from published studies. The simplistic approach to clustering isolates based on an agnostic model of virulence factor presence/absence is not a validation of a dose-response model, as described below in the dose-response section. In fact, as described above, the serocluster model is extremely crude, using only two clusters that are unable to differentiate serotypes or strains within serotypes.

The serocluster modeling approach and subsequent use of the two cluster assignments in the SRAs includes many implicit and explicit assumptions. For example, as noted by FSIS, "all serotypes in each cluster are considered to be equally virulent for the purpose of this analysis" (Taken from Table 3 of the Chicken SRA). This is a clearly flawed assumption, as FSIS has identified serotypes Infantis, Enteritidis, and Typhimurium as Key Performance Indicators (KPIs), and yet Infantis is clustered with the low virulence serotypes by the model.

In the FRN, FSIS states that:

> 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. 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, also determined that Infantis is less virulent than many other serotypes with the exception of Kentucky. (FRN, p. 64697).

This is a highly flawed assessment and is a clear indication that the serocluster model failed. As will be discussed later in the dose-response section, *S.* Infantis was modeled as having one of the lowest infectious doses. On the next page of the FRN, FSIS states "The median *Salmonella* dose predicted to result in 50 percent of exposed individuals becoming ill (IllD50) 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" (FRN, p. 64698). From this statement, it should be apparent that there are strains of *S.* Infantis that have a very low infectious dose, demonstrating the high virulence of some of the *S.* Infantis strains. FSIS states "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" (FRN, p. 64697). Given that the REPJFX01 strain is just one of many within the Infantis serotype, it would seem inappropriate to label an entire serotype as significant to public health. The serocluster model fails to incorporate intra-serotype strain differences, which are key to understanding virulence differences among isolates.

Enumeration-Based Standard

The schematic depiction of an enumeration-based standard is shown in the figure below, which is taken from Figure 22 of the Turkey SRA. Before the enumeration standard is applied, lots of product are either above or below this threshold. However, the true status of each lot is unknown. The fraction of lots that pass (ω) the standard can still get people sick, but the load of *Salmonella* in these lots will generally be lower than the lots that fail (1-ω). After the standard is applied, there will still be lots that are truly above or below the enumeration threshold (ω), but only those lots sampled and tested by FSIS and that exceed the threshold would be diverted (α). As can be seen in the formulas below, the serocluster assignment is used in the estimation of the number of illnesses; the dose-response section below shows how illness associated with the high virulence cluster (C1) is more likely at the same dose than the lower virulence cluster (C2).

As can be seen in this schematic, there is no parameter for diagnostic test accuracy. In other words, the model does not seem to account for mistakes in determining whether a sample is above or below the 10 cfu/mL(g) threshold. As stated in both SRAs:

> All public health outcome predictions presented in this chapter are based on a determination of pass/fail status of each lot using a test with high accuracy, and the testing method used for risk management option implementation should be considered when evaluating the results below, as discussed in the NACMCF 2023 response (NACMCF, 2023)." (Chicken SRA, p. 89 and Turkey SRA, p. 77).

In other words, the model assumes a test of perfect accuracy.

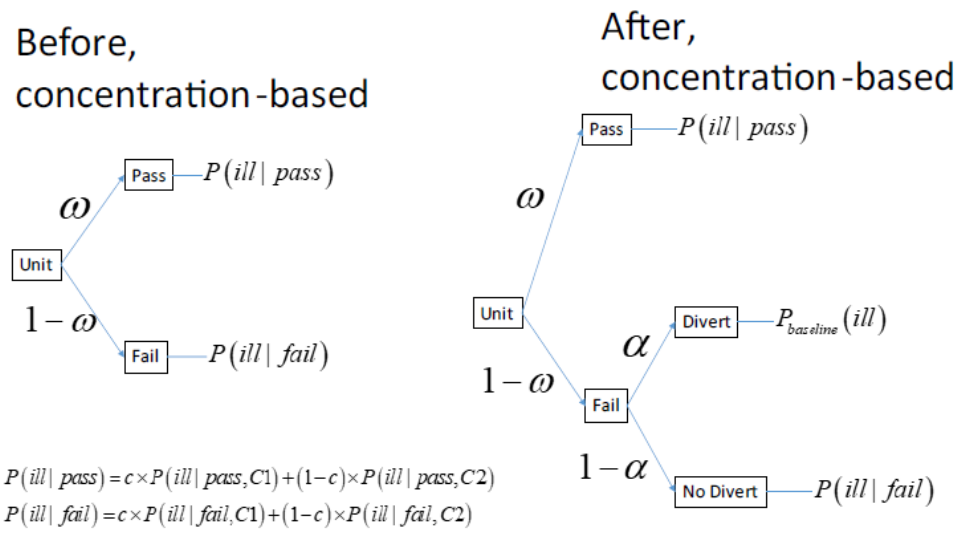


Figure 22: Schematic depiction of the possible pathways which product moves before and after implementation of a concentration-based diversion strategy.

The 2x2 table below shows how we can look at the true status of a sample (above or below the 10 cfu threshold) and whether the laboratory test gives a result above or below the threshold. The squares in the 2x2 table show whether the result would be considered True Negative, False Positive, True Positive or False Negative. The sensitivity of the assay can be thought of as the True Positive rate, calculated as TP/(TP+FN). The specificity can be thought of as the True Negative rate, calculated as TN/(TN+FP). Using this information, we can assess whether the assumption of a test with high accuracy is upheld.

		True Status	
		< 10 cfu / g	**≥ 10 cfu / g**
Test Status	**< 10 cfu / g**	True Negative	False Negative
	≥ 10 cfu / g	False Positive	True Positive
		Specificity	**Sensitivity**

FSIS reports using the bioMérieux's GENE-UP® QUANT *Salmonella* test (Quant) to test samples for *Salmonella* load and comparing these results to the MPN method. When assessing the performance of a quantitative assay, it is important to know the Limit of Quantification (LOQ), which can be defined as the lowest amount of analyte in a sample which can be quantitatively determined with suitable precision and accuracy. According to the FRN, "the lower LOQ for the *Salmonella* tests utilized by FSIS was 10 cfu/mL" (FRN, p. 64712). According to FSIS, "The limit of detection (LOD) of the quantitative polymerase chain reaction (qPCR) enumeration technology used by FSIS at present is 10 cfu/g or /mL (FSIS, 2022b)" (Chicken SRA, p. 25). If the LOD is 10 cfu/mL, then the LOQ should be higher, as it is typically impossible to have quantitative accuracy at the same level as the LOD.

The table below is taken from Table 2 of the Exploratory *Salmonella* Sampling Report document. It shows the results of the testing conducted by FSIS with samples that were spiked to known concentrations of a *Salmonella* Typhimurium isolate. The row showing results for Actual *Salmonella* level of 5 cfu/mL represents samples that are truly below the 10 cfu threshold. As can be seen, the Quant assay determined that 17 of 60 samples had *Salmonella* levels above 10 cfu/mL. This gives a Specificity of 72%. Stated another way, 28% of the time, product would be falsely identified as failing the Final Product Standard. This result represents a cost for the poultry company because of diversion of product falsely identified as failing the standard. The row showing results for Actual *Salmonella* level of 50 cfu/mL represents samples that are truly above the 10 cfu threshold. As can be seen, the Quant assay determined that 15 of 60 samples had *Salmonella* levels below 10 cfu/mL. This gives a Sensitivity of 75%. Stated another way, 25% of the time, product would be falsely identified as meeting the standard and consequently the product would be shipped into commerce. This represents a failure of the proposed system and reduces the predicted impact that the proposed Final Product Standard will have on reducing human salmonellosis illnesses.

QUANT Method				MPN Method			
Actual Salmonella level (CFU/mL)	Counts Below 10 CFU/mL	Counts Above 10 CFU/mL	Method Accuracy	Actual Salmonella level (CFU/mL)	Counts Below 10 CFU/mL	Counts Above 10 CFU/mL	Method Accuracy
5	43/60	17/60	72%	5	60/60	0/60	100%
10	40/60	20/60	33%	10	35/60	25/60	42%
50	15/60	45/60	75%	50	15/60	45/60	75%

It should be clear from this analysis that the assay being used currently by FSIS is not highly accurate at the concentration being proposed for the enumeration-based Final Product Standard. This is highly problematic for a program designed around an adulterant standard. However, if the discussion were to shift to an enumeration-based Performance Standard, as I outlined at the start of this report, there would be much less concern whether an individual lot falsely tests positive or negative, as the company would be using the assay on all production lots and would better understand the importance of a single result in the context of the overall trends in the processing plant.

Furthermore, the FRN states 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." (FRN, p. 64707). This is likely a best-case scenario and would be a major challenge for the production of some of the products included in this regulatory change. However, we should not be hindered by current technology as we develop a plan. If 10 cfu/mL(g) is determined to be a relevant public health threshold, then a program can still be designed around this level. Using an imperfect test with a delayed turnaround would be problematic in an enumeration-based Final Product Standard system but might work suitably in an enumeration-based Performance Standard system. The Final Product Standard requires test-and-hold with severe consequences for samples exceeding the threshold. I can envision a situation in which companies choose to destroy all product tested in the FSIS lot rather than wait for the test results. This does not help public health because in this situation, no other production lots might get tested for *Salmonella* concentration. An enumeration-based Performance Standard does not suffer from the possible disincentive to companies of testing product not included in the FSIS sampled lot.

Contamination Distribution

The SRAs use a lognormal distribution to model the initial contamination of the products being regulated in the proposed Final Product Standard. The Chicken SRA describes different contamination distributions for carcasses, parts and comminuted product (see Chicken SRA, pp. 73-75). The figure below, which is taken from Figure 21 of the Turkey SRA, shows the differences in contamination across the three chicken products as well as comminuted turkey. Regardless of the fact that the three chicken products have different contamination distributions, the Chicken SRA uses a single contamination distribution for all three products. As stated in the SRA, "a lognormal distribution (Log10Normal(-3.037117, 1.279985)) was used that reflected the initial contamination of a mixture of the three raw chicken products – carcasses, parts and comminuted – according to their relative frequencies of consumption (see subsection Chicken Consumption)." (Chicken SRA, p. 90). In other words, the three different contamination distributions for the three different chicken products were combined into a single distribution, with the weighting of each individual distribution based on the frequency of consumption of that product (11%, 83% and 6% for whole carcass, parts and comminuted, respectively). The estimated number of illnesses attributed to chicken was partitioned using the same breakdown. Overall, the chicken model has failed to assess risk associated with each individual product, and the use of a single contamination distribution for all three chicken product types is another example.

The contamination distribution for the turkey SRA is also confusing. In the turkey SRA, FSIS states that "A simplifying assumption was adopted due to the lack of complete data in terms of *Salmonella* contamination across all raw turkey products. The role and contribution from turkey carcasses and turkey parts is highly uncertain. On the other hand, robust data on the *Salmonella* contamination of raw chicken products provides a reliable starting point." (Turkey SRA, p. 80). The document continues by saying "Therefore, a lognormal distribution (Log10Normal(-3.037117, 1.279985)) was used to reflect the initial contamination of *Salmonella* in a mixture of raw poultry products… Hence, under the current approach, the method will likely overestimate

the risk associated to comminuted turkey final products" (Turkey SRA, p. 81). However, in the remainder of the document, it appears that a different lognormal distribution (Log10Normal(-4.857, 2.333) was used in the risk calculations. This other contamination distribution better reflects the comminuted turkey data shown in the figure below.

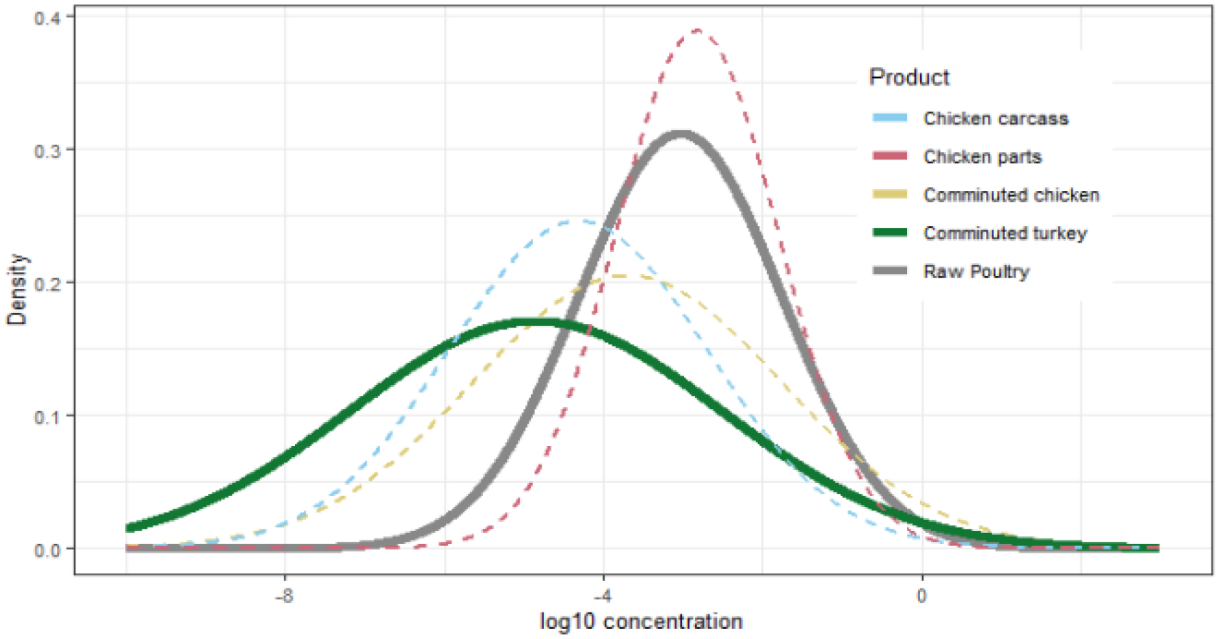


Figure 21: Concentration distribution comparison between comminuted turkey and comminuted chicken and the overarching *Salmonella* contamination distribution in raw poultry products.

Attenuation Distribution

The SRAs include a parameter that adjusts the dose of *Salmonella* on the final product during its transit from the processing plant to the point of consumption. As stated in the SRAs:

> We summarize the effects of the myriad of pathways contaminated product may follow from the end of processing through commerce and preparation using an attenuation distribution. This attenuation distribution captures the variability associated with mixing, partitioning, growth, cooking and serving size processes between production and consumption. A lognormal attenuation distribution (μ = −5.00 log10, σ = 1.91 log10) was calibrated previously for chicken. (Turkey SRA, p. 36).

The SRA then states "Lacking alternative estimates, this default attenuation distribution is used across analyses of chicken products (carcasses, parts, comminuted chicken) as well as comminuted turkey (which is generally handled/consumed in a similar manner as comminuted chicken products)" (Turkey SRA, p. 36).

While the intent of the attenuation distribution is to allow the contamination level to be amended given the potential growth or death of *Salmonella* on the poultry product from the processing plant to point of consumption, the fact that a single distribution was used for all products in both

chicken and turkey seems pointless. Perhaps this is why the SRAs state "both the attenuation and dose-response functions have limited influence on the full model's estimates; i.e., the full model's results are not highly influenced by either attenuation or dose-response. Nevertheless, application of attenuation and dose-response are necessary for improved accuracy in estimates as the threshold increases." (Chicken SRA, p. 113). It is concerning that the SRA models were intended to model illnesses prevented after the regulatory changes, but this important attenuation parameter was not adjusted by product type. It is hard to imagine that *Salmonella* attenuation is identical among chicken carcasses, chicken parts and comminuted chicken, given that this attenuation is meant to include all variability associated with "mixing, partitioning, growth, cooking and serving size processes between production and consumption." Even more concerning is the complete lack of data for comminuted turkey, thus requiring the use of a chicken parameter derived in a 2015 publication by Ebel and Williams. Given the importance of the proposal to establish a Final Product Standard whose efficacy is based on the ability to reduce human illnesses, this important parameter should have been based on better data that are species and product specific.

Risk Multiplier

The Risk Multiplier (RM) is a very important parameter of the SRAs but makes assumptions that are problematic. It is meant to show the increased risk associated with the high virulence serocluster when compared to the low virulence seroculster, but in reality it is a confounded parameter that combines the importance of the serocluster to human illnesses weighted by the frequency that serotypes within the cluster are found in poultry samples. According to FSIS, "the clusters were validated by linking them to epidemiological data (i.e., documented outbreaks attributed to poultry sources with consideration of prevalence in animal sources from FSIS poultry sampling programs). In this sense, the relative risk estimate is skewed towards strains to which a poultry consumer is likely to be exposed." (Chicken SRA, p. 55). The RM is used to modify the dose-response curve of the high virulence cluster to create a curve for the low virulence cluster, which subsequently affects the predicted number of illnesses prevented through the implementation of the proposed regulatory changes.

To understand the problems with this parameter, it is necessary to explore its derivation. As shown in the figure below (Figure 3 from the Turkey SRA), the RM derivation relies on the serocluster model previously discussed. The numerator of the RM for a given serocluster is the weighted proportion of the time that serotypes within each cluster are associated with salmonellosis outbreaks attributed to chicken or turkey. In other words, the numerator is meant to reflect a measure of serocluster severity. However, only illnesses that have been declared by a public health agency such as the CDC as being part of an outbreak are included in the numerator. Serotypes that cause disease sporadically would not be accounted for in this calculation. Also, the size and duration of outbreaks can be subjectively affected by the public health agencies, which would affect the RM estimation. As an example of this, I will briefly explore the yearlong *Salmonella* Infantis outbreak from 2018-2019 (https://archive.cdc.gov/#/details?url=https://www.cdc.gov/salmonella/infantis-10-18/index.html). In February 2019, the outbreak was declared over by the CDC. This was not because *Salmonella* Infantis had been eliminated from chicken or because there were no new

illnesses caused by this serotype. On the contrary, the outbreak was declared over because the incidence rate had reached a stable level. All of the cases of *S.* Infantis attributed to chicken that occurred after the outbreak was declared over would not be included in the RM estimation.

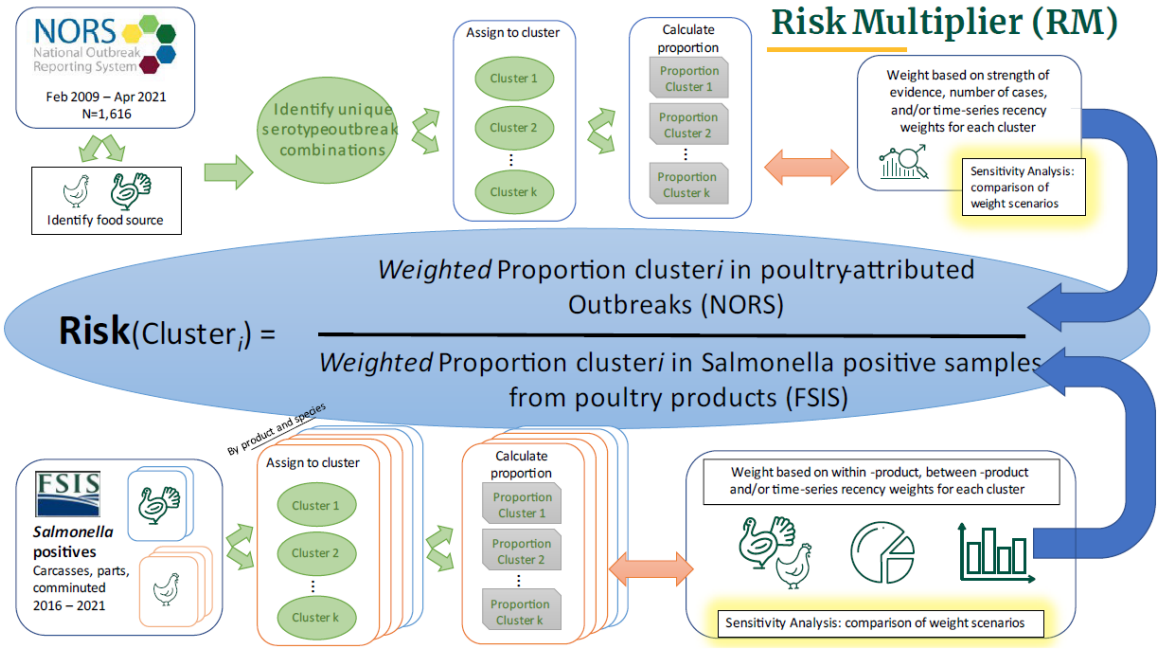


Figure 3: FSIS diagram of risk multiplier estimation for each serocluster.

The denominator of the RM is frequency-weighted, representing the proportion of poultry samples that have one of the serotypes in the respective cluster. These are samples collected by FSIS and are therefore isolates collected from within the processing plant. It is unknown how many of these isolates ended up in commerce and subsequently have the ability to expose the consumer. It is also impossible to know how the culture media used by FSIS affects the serotype detected in the sample (Singer et al., 2009). Regardless, it is unclear why a measure of a serotype's frequency in poultry samples would be used to adjust a dose-response relationship. This is why I consider the RM parameter to be a confounded metric, combining both outbreak potential (a surrogate of virulence) and FSIS-sample prevalence (a surrogate of frequency that has nothing to do with virulence). This type of confounded metric should not be used to adjust a dose-response function.

The end result is a ratio that does not reflect what the modelers seem to think it does. The RM ratio is calculated as 5.66 (2.15/0.38), representing the high virulence (C1) cluster risk over the low virulence (C2) cluster risk. This is shown in the table below, which is taken from Table 13 in the Chicken SRA. FSIS states "the probability of illness per serving from C1 exposures is 5.66 times larger than the probability of illness per serving from C2 exposures. Therefore, the parameters for the two dose-response function must be selected to maintain this relative probability of illness" (Chicken SRA, p. 91). This constraint on the dose-response functions will be discussed more below, but in essence this assumes that the outcome of the dose-response of C2 (probability of illness given a certain dose) is homogenously 5.66 times lower than C1.

Table 13: Risk multiplier estimation including the 95% confidence interval for k=2 seroclusters derived by EpiX Analytics.

	Cluster 1	Cluster 2	Not Assigned
Proportion in outbreaks (numerator)	0.71 [0.58; 0.83]	0.25 [0.14; 0.38]	0.039 [0.012; 0.081]
Proportion in poultry (denominator)	0.33 [0.31, 0.35]	0.66 [0.64; 0.68]	0.010 [0.006; 0.017]
Risk multiplier	**2.1 [1.7; 2.5]**	**0.38 [0.21; 0.58]**	**3.9 [1.1; 9.1]**

There was supposedly a sensitivity analysis conducted on the RM parameter, but this sensitivity analysis only focused on the weighting scheme used for the numerator and denominator. The sensitivity analysis did not address the importance of having all strains of a serotype in the same cluster nor the assumption that all serotypes in the cluster represent an equal risk.

Finally, data were clearly lacking from turkey. FSIS states in the chicken SRA that "including turkey data does not change the results of this chicken *Salmonella* serocluster risk analysis. On the other hand, turkey data is not sufficient to determine risk, and chicken data is necessary for a turkey analysis" (Chicken SRA, p. 61). This is due to limited serotype information from turkey samples. To complete the turkey SRA, chicken data were often used in parameter estimation. This is a clear indication that data gaps exist and that additional data need to be collected, especially prior to implementing a regulatory change as significant as a Final Product standard in raw, NRTE poultry products.

Dose-Response

Dose-response models are needed in these quantitative SRAs because the likelihood of becoming ill following exposure to *Salmonella* depends on the dose as well as the virulence of the *Salmonella* strain. Many dose-response functions have been derived for different *Salmonella* serotypes based on data collected during outbreaks. The functions that are derived around the collected data do not necessarily predict the likelihood of infection (and illness) at the lower ends of these dose-response curves. According to FSIS, "The median *Salmonella* dose predicted to result in 50 percent of exposed individuals becoming ill (IllD50) was 3,360 cfu (95 percent range: 18–3.2×109), 1,500 cfu (38–8.8×107), and 1 cfu (0.69–1.0×106) for Enteritidis, Typhimurium and Infantis, respectively" (FRN, p. 64697-8). As stated previously, even though Infantis is predicted to have a very low infectious dose (implying high virulence), the flawed application of the serocluster model includes Infantis with the low virulence cluster.

There is a strange commentary on virulence and dose in the FRN. FSIS states:

> 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." (FRN, p. 64698).

This is a strange justification for dose-response conclusions, Also, key "low virulence" serotypes that have strains with higher virulence were included in cluster 2.

To generate the dose-response function for cluster 1 (the high virulence cluster), EpiX Analytics used "data from the literature on Enteritidis and Typhimurium (two primary serotypes in cluster 1) and scaled a second dose-response model for the lower virulence cluster 2 based on the risk multiplier ratios" (Chicken SRA, p. 64). In other words, dose-response data were used for two of the serotypes in the high virulence cluster. The outbreaks from which the dose-response data were derived were rarely associated with poultry products. Once the dose-response function was derived, this function was used for all serotypes and strains within the cluster, thereby making the implicit assumption that every strain of every serotype in the cluster would behave about the same (an assumption that is not supported by the data).

To generate the dose-response function for cluster 2 (the low virulence cluster), one might expect EpiX Analytics to use data from outbreaks caused by serotypes in cluster 2 in a manner similar to cluster 1. This is not what was done, however. For cluster 2, the dose-response function was derived by assuming that the Risk Multiplier expresses the difference in virulence between clusters 1 and 2 and therefore can also be used to modify the dose-response function. In other words, because the Risk Multiplier was estimated to be 5.66, the high virulence cluster dose-response was reduced 5.66-fold. FSIS states that an RM value of 5.66 indicates that "the probability of illness per serving from C1 exposures is 5.66 times larger than the probability of illness per serving from C2 exposures. Therefore, the parameters for the two dose-response function must be selected to maintain this relative probability of illness." (Chicken SRA, p. 91).

As can be seen in the equation below, EpiX Analytics assumed that the ratio of the two dose-response functions (left side of equation) should be equal to the Risk Multiplier (right side of equation). Consequently, the low virulence cluster dose-response function has no basis in data collected from the dose-response functions of serotypes contained within the cluster but instead on the flawed Risk Multiplier parameter. The RM parameter uses a frequency-based denominator (frequency of *Salmonella* in FSIS-sampled product) which should not be used to modify a dose-response function.

$$\frac{\int R_1(d)h(d)\partial d}{\int R_2(d)h(d)\partial d} = \frac{RR_1}{RR_2}$$

After performing sensitivity and uncertainty analyses on parameters such as the dose-response functions, FSIS states that:

> Such findings support the general idea that both the attenuation and dose-response functions have limited influence on the full model's estimates; i.e., the full model's results are not highly influenced by either attenuation or dose-response. Nevertheless, application of attenuation and dose-response are necessary for improved accuracy in estimates as the threshold increases. (Chicken SRA, p. 113).

Perhaps the reason for the limited influence of the dose-response functions on the model outputs is that a single function was derived for every strain of every serotype in the high virulence cluster, and then this same function was reduced 5.66-fold to account for all strains of all serotypes in the low virulence cluster. This lack of precision and heterogeneity around the dose-response function would clearly lead to the parameter being considered unimportant in the model.

FSIS justifies making *Salmonella* an adulterant by comparing this current approach to that taken with Shiga toxin-producing *E. coli* (STEC). This is an entirely fallacious comparison for multiple reasons. First, the infectious dose of the two organisms is very different. STEC have a much lower estimated infectious dose than *Salmonella*. Second, the severity of the illness caused by the two is drastically different. STEC infections result in hospitalization and often death, with many patients developing hemolytic uremic syndrome (HUS). Most salmonellosis cases are self-limiting, and very few need additional therapy beyond supportive care. Third, *Salmonella* is ubiquitous in the poultry industry, which means that most flocks will be positive for *Salmonella*. *Salmonella* might not be present in every bird within the flock, but in poultry production, the flock is the unit. STEC infect the individual animal (cow), and carriers can be identified and culled without sacrificing the entire herd. For *Salmonella*-positive flocks, the entire flock would have to be eliminated or diverted, as it is not feasible to test each individual animal. On the farm, STEC was always a much rarer bacterium than *Salmonella*, and *Salmonella* is very well-adapted to the bird. Fourth, STEC do not cause disease in cattle, whereas *Salmonella* can sometimes be an avian pathogen. Finally, cattle and poultry slaughtering processes are very different. These are just some of the differences between *Salmonella* and STEC; STEC should not be used as an analogous organism to justify this proposed Framework.

Overestimation of Chicken-Attributed Illnesses Prevented

The expected number of illnesses prevented is shown in various tables in the documents, including in the FRN. For example, Table 5 in the FRN says that 1,000, 200 and 1,000 illnesses would be prevented due to consumption of chicken carcasses, chicken parts, and comminuted chicken, respectively. The second Table 34 in the FRN gives the same numbers (shown below), but also adds a total for all chicken products: 2,200. I am focusing on the High column, as these results reflect the baseline enumeration-based Final Product Standard model. It is strange that this table sums all chicken-attributed illnesses prevented into one number. Specifically, FSIS states that "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." (FRN, p. 64738). In other words, we cannot sum the chicken product numbers in Table 5 (or Table 34) to estimate the total number of illnesses that might be prevented. To show how the number of prevented illnesses attributed to chicken is inflated, I will work through the derivation of the numbers in Tables 5 and 34 of the FRN.

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

Within the Chicken SRA, FSIS states that "A chicken carcass performance standard that diverts test-positive lots based on a threshold level of 0.033 cfu/mL (i.e., 1 cfu of *Salmonella* per 300 mL poultry rinsate) is the most effective risk management option to reduce foodborne *Salmonella* from chicken carcasses, with 4,700 illnesses prevented annually, which equates to 3.8 percent of the approximately 125,000 overall chicken illnesses that occur each year. The public health impact (in terms of illnesses prevented) of the chicken carcass final product standards encompasses the illnesses estimates for all secondary chicken products, as the majority of those secondary products are fabricated from carcasses." (Chicken SRA, p. 30). As can be seen in this calculation, the estimated number of illnesses prevented for chicken carcasses includes all illnesses prevented for parts and comminuted chicken as well. This can be seen using some of the tables included in the Chicken SRA document.

First, Table 11 of the Chicken SRA shows parameter estimates for the model. Below, I have extracted the row from Table 11 that shows the number of illnesses attributed to each of the chicken products (p. 51). The number of illnesses listed for carcasses is actually the total number of illnesses attributed to chicken consumption. Again, it appears that the reason for including all illnesses under "carcasses" is because of the statement that "the chicken carcass final product standards encompasses the illnesses estimates for all secondary chicken products, as the majority of those secondary products are fabricated from carcasses." (Chicken SRA, p. 30 and p. 156).

number of illnesses before policy	λ_{ill}	carcasses=125,115 parts=103,845 comminuted=7507	illnesses/year

Table 38 of the Chicken SRA (shown below) reports the parameter distributions for the percent reduction in illnesses for the various chicken products. If we look at the Pert distribution for the 0.03 cfu/mL and for chicken carcasses, the distribution is a Pert(0.0095, 0.0369, 0.0444). The three parameters of the Pert distribution are the Minimum, Mode and Maximum values. The median of the Pert can be derived with the formula (Min + (6*Mode) + Maximum) / 8, which gives a median percent reduction of 0.0344. To arrive at the number of illnesses prevented, FSIS multiplied 3.8% (rather than the mode, 3.69% or median, 3.44% from the Pert distribution) by the total number of chicken-attributed illnesses (125,115) rather than the total number of chicken carcasses-attributed illnesses (13,763, see Table 28 of Chicken SRA). Multiplying 125,000 * 0.038 = 4,750, which is basically the number that FSIS cites in the paragraph included above.

Table 38: Descriptions of the uncertainty distributions for the parameters used to estimate annual illnesses prevented are shown.

Concentration threshold*	Variable	Chicken carcasses	Chicken parts	Comminuted chicken
	λ_{ill}, mean (95% CI)	125,000 (73,000 – 193,000)	104,000 (60,000 – 160,000)	8,000 (4,000 – 12,000)
0.03 cfu/mL	percent reduction	Pert(min=0.0095, mode=0.0369, max=0.0444)	Pert(min=0.0192, mode=0.0757, max=0.1005)	Pert(min=0.096, mode=0.1964, max=0.2033)
1 cfu/mL	percent reduction	Pert(0.0016, 0.0194, 0.0392)	Pert(0.0011, 0.0138, 0.0383)	Pert(0.04, 0.1852, 0.2252)
10 cfu/mL	percent reduction	Pert(0.0003, 0.0083, 0.03)	Pert(0, 0.0021, 0.0083)	Pert(0.0148, 0.1389, 0.2267)
100 cfu/mL	percent reduction	Pert(0.0001, 0.0017, 0.0186)	Pert(0, 0.0002, 0.0008)	Pert(0.0042, 0.0817, 0.2189)

To see how the number of illnesses prevented might be more accurately estimated, we can again use Table 38 (shown above) from the Chicken SRA. At the 10cfu/mL(g) concentration threshold, the chicken carcass distribution is modeled as a Pert(0.0003, 0.0083, 0.03). The median of this Pert distribution equals approximately 1.0% percent reduction in illness. Using this median estimate and the total number of chicken carcass-attributed illnesses (13,763) instead of the total number of all chicken-attributed illnesses gives an estimated 138 illnesses prevented from carcass-attributed illnesses, thus giving a total of 138+200+1,000=1,338 illnesses prevented, not 2,200. A total of 1,338 illnesses prevented represents approximately 1.07% of estimated chicken-attributed illnesses prevented with this Final Product Standard policy (1,338/125,115). This number of illnesses prevented does not include the serocluster criterion of the proposed Final Product Standard, which would further reduce the number of illnesses prevented.

In summary, the total estimated number of illnesses prevented from chicken consumption is likely between 1,000 and 1,500 under this proposed enumeration-based Final Product Standard. The number 2,200 shown in Table 34 of the FRN is double counting the carcass-associated illness estimates.

Component 2: Enhanced process control

I fully support the addition of a proper statistical process control (SPC) program, as I've discussed earlier under my Alternative Program proposal. The purpose of this upstream SPC is to ensure that the microbial interventions of the processing plant are functioning properly. As stated throughout the documents included with the *Salmonella* Framework proposal, published studies and "unpublished data provided by the poultry industry and university researchers suggests that indicator bacteria have very limited predictive value for the prevalence of *Salmonella.*" (FRN, p. 64711). Because these results are not predictive of *Salmonella* outcomes, companies should have flexibility in the design of the SPC program, as long as biologically relevant reductions in indicator bacteria (and therefore efficacious microbial interventions) can be documented.

Collecting samples at rehang and post-chill, as proposed by FSIS, seems like logical locations in the plant to conduct the SPC program. In a previous paper on which I am co-author (Berghaus et al., 2013), rehang was predictive of post-chill and would be a good in-plant location for sampling to document reductions in indicators such as Aerobic Count (AC). Again, there should be flexibility here regarding which bacterial indicators to monitor and what reduction in bacterial load between sampling sites represents a successful program.

The FSIS documents are confusing because, at times, the proposed SPC program is described as two-sided. For example, the FRN states that "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" (FRN, p. 64710). Why would a reduction below the minimum be considered out of control? One would think that reductions that exceed lower specification limits would be a good thing. The SPC program should be one-sided, in which results that exceed the upper specification limit are considered out of compliance.

I am concerned about FSIS' opinion regarding the use of EB or *Salmonella* in the SPC. Specifically, FSIS sates that "microbial monitoring of EB or *Salmonella* is unlikely to yield the reliable quantified results necessary for an individual establishment to support SPC monitoring" (FRN, p. 64712). This conclusion is based on some samples having EB or *Salmonella* loads below the LOQ. However, why is left-censored data a bad thing? Microbial levels below the LOQ should represent a desirable outcome, and if the post-chill samples have results below the LOQ, this should indicate a successful intervention. Regardless, FSIS states that "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" (FRN, p. 713), and while this is not a good reason to use AC as the indicator organism for an SPC program, AC might be an easier microbial target to monitor for many of the poultry processing plants. The combination of an actual SPC for AC upstream with an enumeration-based Performance Standard should provide a large impact on salmonellosis illnesses, but as I have stated previously, this was not modeled in the current *Salmonella* framework.

The proposed level of reduction in AC, as described in the *Salmonella* Framework, is also confusing. According to FSIS, the:

> 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. (FRN, p. 64713).

The FRN goes on to state that 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" (FRN, p. 64713). FSIS then states that "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" (FRN, p.64714).

It is extremely confusing to read through the SRAs and the FRN in which data are presented that show that the industry already reduces AC by 2-3 logs, and that this reduction might be correlated with reduced *Salmonella* prevalence post-chill, at least in chicken. However, these same documents then propose a threshold for AC reduction equal to 1 log. How does a 1 log reduction help? Is this small reduction correlated with reductions in *Salmonella*? Is a 1 log

reduction indicative of a process that is in control? Was any modeling conducted to evaluate a 1 log reduction?

Another confusing aspect of the SPC proposal by FSIS is the lack of consideration of incoming load in the SPC thresholds. If the goal is to reduce by 1 log (or better yet, 2 to 3 logs, as I have mentioned above in my Alternative Program section), companies would be rewarded for having high *Salmonella* loads at rehang because it would be easier to reduce this high level of contamination. For a company whose *Salmonella* loads are already low at rehang, it would be harder to reduce those low loads further. The SPC program needs to include a biologically relevant reduction target between sampling points as well as consideration for the incoming load of the indicator organism at rehang.

The Chicken SRA states that:

> As a result of these weak relationships between AC and *Salmonella* prevalence, it follows that the correlation between AC and *Salmonella* serotypes or levels is also weak. Therefore, it was not possible to assess the risk management question regarding the public health impact (illnesses, hospitalizations, and deaths) of monitoring/enforcing process control from rehang to post-chill in the same manner as it was estimated for final product standards. (Chicken SRA, p. 34).

Thus, it appears that we have no idea how useful an SPC program will be in reducing *Salmonella* illnesses. Regardless, I still believe that a proper SPC program linked to an enumeration-based Performance Standard will have a considerable impact on poultry-attributed *Salmonella* illnesses.

Component 1: Incoming flock testing

Although FSIS states that it "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" (FRN, p. 64680), I will briefly address Component 1 of the Framework because it relates to a specific question that FSIS has posed. Namely, the FRN states that "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" (FRN, p. 64679). This has relevance in the context of Component 1 and live production *Salmonella* interventions.

Chicken and turkey companies spend a considerable amount of time and money controlling *Salmonella* in live production. Their obvious goal is to reduce *Salmonella* loads as much as possible before the birds go to the processing plant so that the in-plant interventions can be as efficacious as possible. The lower the incoming load, the more effective these interventions are likely to be. Regulating companies on incoming load or serotypes is misguided, as different companies will pursue different approaches to ensure that their final product is as low risk as possible. Consequently, FSIS should stay focused on ensuring that plants have adequate process control (through the SPC Component 2) and are keeping *Salmonella* loads below an enumeration-based threshold (variation of Component 3).

Poultry companies already focus on *Salmonella* preharvest control in various phases of production, including the commercial birds, the hatchery, and the breeders. It is very difficult to control *Salmonella* completely, as *Salmonella* is a commensal organism in chickens and turkeys and is well-adapted to the avian host. Controlling *Salmonella* has always been a challenge, and preharvest interventions are expensive and imperfect. I previously published a paper showing that companies were practicing preharvest intervention but with limited success due to imperfect solutions (Hwang & Singer, 2020). No preharvest interventions have proven to prevent *Salmonella* presence on incoming chicken flocks. If there were such interventions, then the entire poultry industry would have incorporated them rather than spend an inordinate amount of time and money with postharvest measures.

Controlling specific serotypes of *Salmonella* is extremely problematic, as there are very few serotype-specific mitigation strategies. FSIS states that "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.*" (FRN, p. 64719). Vaccination is a key intervention approach, and companies actively use *Salmonella* vaccines, including autogenous vaccines targeting key serovars. Vaccination is already being used in the breeder flocks, as many of the serotypes of public health significance can be transmitted vertically, from the breeder hens to their progeny. As stated in the FRN, "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." (FRN, p. 64720). What is being proposed is not novel and has been a strategy for the poultry industry for many years.

As shown in a previous paper, it can take a considerable amount of time (at least 18 months) for the effects of vaccination of breeders to be seen in commercial birds, and this is assuming high efficacy of vaccine (Liljebjelke et al., 2005). This fact has been known for many years. The FSIS documents seem to assume that vaccination is a key method for eliminating a serotype of concern. *Salmonella* Heidelberg is given as an example. However, this is a simplistic view of the reasons for the decline of *S.* Heidelberg. *S.* Infantis appeared in U.S. poultry, as well as poultry around the world, without warning. Broiler companies have focused on this serotype for years. There seems to be an expectation by the public health agencies that this serotype should have been eliminated already and yet it remains a main serotype seen in broiler production and on final product. There is no perfect approach to *Salmonella* elimination from poultry, and to assume that the presence of *Salmonella* in incoming birds demonstrates a lack of focus on preharvest measures is inaccurate.

Given that it can take 18 months or more to see an effect of the vaccine in breeders on *Salmonella* in commercial birds, changing the serotypes of public health significance on a timeframe of less than 3 years would be problematic for vaccine design and administration within the entire production system. A timeframe of 5 years or more for changing the serotypes of public health significance ensures that the production companies are not constantly changing their focus without sufficient time to see the effects of the vaccination program. In other words,

if a public health agency notices a new serotype causing human illnesses, and if this serotype is associated with poultry, it will take two years or more to implement a vaccine intervention and see the downstream effect. Companies need to be notified as early as possible about a possible new serotype of concern so that they can begin targeting that emerging serotype in live production. Changing the serotypes on which the companies are being regulated (which is different than notifying the companies of a new signal of concern) assumes that the intervention can quickly reduce the incidence of this serotype. Just because "new information on *Salmonella* serotypes associated with human illness" might become available, it still takes time (years) to change the intervention program (vaccine) and see the downstream effect.

Other Comments

- Throughout the proposed *Salmonella* Framework, there are many examples of data gaps that should have been filled prior to issuing this proposed drastic change to poultry inspection. For example, many of the parameters used in the turkey SRA are missing turkey-specific data; chicken data are used as a surrogate for the turkey data. Data are often lacking regarding the chicken products being regulated under this proposed Framework. It seems entirely inappropriate to propose a regulatory change of this magnitude without data specific to the products being regulated.
- The product "chicken parts" is included in this proposed Framework, but no real definition is given to this product. It does not seem reasonable to assume that chicken wings, chicken thighs, chicken breasts, and other chicken parts behave the same with respect to the model parameters. This is not a homogenous category.
- FSIS states that "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." (FRN, p. 64741). This is an incredibly inflammatory opinion. Does FSIS have data to back up this statement?
- Throughout the *Salmonella* Framework documents, FSIS clearly shows a major disparity between large and small volume establishments. For example, FSIS states in the Chicken SRA "For the poultry industry, *Salmonella* and *Campylobacter* occurrence is more frequent on products produced by lower-volume establishments. The opposite phenomenon is observed in the pork and beef industries, where a small number of large establishments account for the majority of the contaminated product reaching consumers (Williams, 2022)." (Chicken SRA 68). There is the additional statement that "*Salmonella* carcass post-chill contamination is now predominantly in low-volume production establishments (those establishments slaughtering less than 10 million carcasses per year)." (Chicken SRA, p. 24). Figure 2 from the Chicken SRA (p. 24), shown below, demonstrates that the small volume establishments have a larger problem with *Salmonella*. Why is implementation of the proposed Framework delayed for these establishments? The estimated number of illnesses prevented does not account for this delayed implementation, and thus the impact of the proposed program may not be realized for years.

- The *Salmonella* Framework documents repeatedly state that the risk assessments and other models were peer-reviewed. However, the actual peer-review process used does not appear to be the same as that used by peer-reviewed journals. For example, how were the reviewers selected? Reviewers were given a very short window of time to review these massive documents/models. How did the agency respond to the reviewers' concerns? Did the reviewers get to review the revisions made by FSIS, as would be done in a peer-review process of a journal article? Did the reviewers have the option to "reject" or "not accept" the risk assessment, or parts of the risk assessment, as would be done in a peer-reviewed journal article? In summary, I do not consider these documents to be "peer-reviewed" in the sense with which many scientists are familiar.

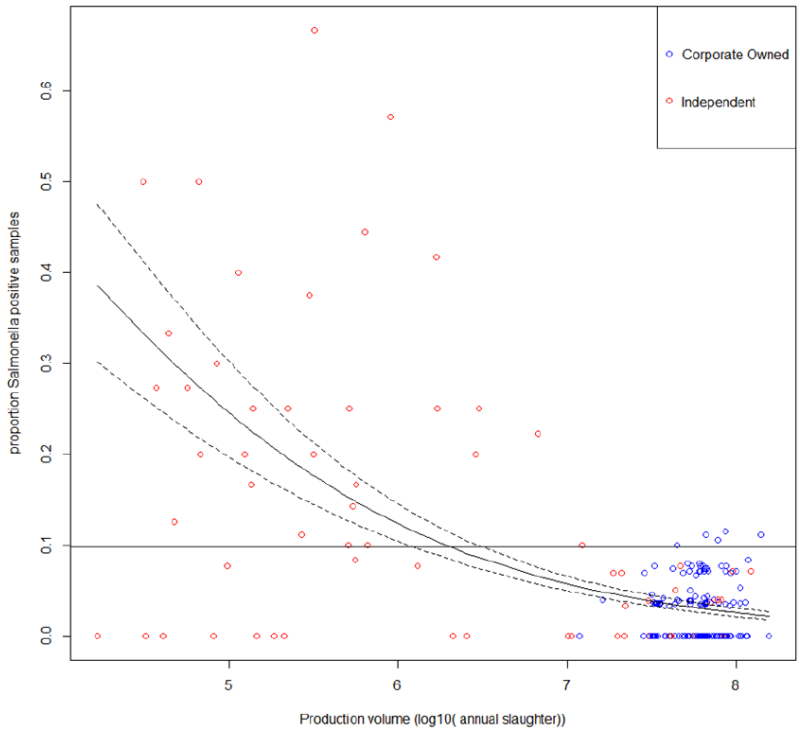


Figure 2: Relationship between establishment production volume, ownership, and presence of *Salmonella* on chicken carcasses.

Salmonella **Framework – Comments Requested by FSIS**

- The proposed timeline for re-evaluating serotypes of public health concern (every 3-5 years).
  Response: As I have written in my Component 1 section, it is concerning that the regulated serotypes of public health significance could be changed at a frequency that is impossible to meet by the industry. It can take 18 months or longer to see downstream effects of vaccine use in breeders. The industry would benefit from being informed of a new serotype signal detected by the public health agencies. The companies could then begin a vaccination program well in advance of a regulatory change in serotypes of public health significance.

- Phasing out performance standards and no longer using *Salmonella* sampling results to categorize establishments and no longer publishing categories on the FSIS website.
  Response: The performance standards for chicken and turkey have been effective at reducing *Salmonella* on tested products, as clearly stated by FSIS in the *Salmonella* Framework documents. Part of the industry's ability and willingness to adapt to the performance standards voluntarily is due to the publishing of establishment results. As stated in my overall assessment of the Framework, a new Performance Standard based on enumeration-based thresholds is a logical and likely effective advancement to poultry inspection. Publishing the establishments' categorization based on the enumeration-based Performance Standards will likely help ensure that the industry adapts to this new standard.

- 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
  Response: The full risk model, while representing a massive effort by many scientists, is not fit nor necessary for determining the serotypes of public health significance.

- Whether 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 US population
  Response: The serotype clustering and dose-response adjustment did not use the best available data. The serotype clustering analysis was more of a phylogenetic tree rather than a clustering based on virulence. The model treated all genes (including putative genes that have no known function within *Salmonella*) to relate isolates. No weighting was performed based on importance of a gene or set of genes. The model does not capture strain variation. Also, the original model was based on beef isolates (Fenske et al., 2023). The issue is that any strain variation within a serotype affects the cluster assignments and subsequent RM estimates. Increasing the number of isolates with non-poultry sources will add these non-poultry genetic arrangements to the algorithm, thereby not reflecting the risk that isolates from poultry possess.

- Potential improvements to the serotype clustering robustness analysis and the risk multiplier sensitivity analysis

Response: The sensitivity analysis on the risk multiplier was useless. It did not address the major concerns I detailed above, including the fact that this RM should never have been used to adjust a dose-response function. What would have happened if a single RM was developed for each serotype, with one serving as a baseline? Where would Infantis fall? Regardless, before the RM can be useful, we must understand how strain differences within serotype affect the RM.

- Possible inclusion of Infantis as a serotype of public health significance
  Response: The clustering algorithm developed by EpiX Analytics and used by FSIS to assign seroclusters and to derive the Risk Multiplier is flawed. Not all strains within a serotype are homogenous, including with respect to virulence. Further, not all serotypes included in a serocluster are homogenous. There are clearly strains of Infantis that are more virulent than others in the serotype. Similar to a paper we published on *Salmonella* Reading, it is necessary to identify the traits that differentiate strains of Infantis and then figure out how to develop a clustering algorithm that can actually account for these intra-serotype inter-strain differences. At this point in time, the use of the serocluster algorithm is unnecessary and highly flawed and leads to inaccurate estimates of illnesses prevented.

- Available technologies and methods for quantification and serotyping
  Response: The current technologies and methods for quantification and serotyping are not currently ready to be used for the Final Product Standard proposed in this Framework. First, the LOQ is too high. As stated in the documents, the LOD of the assay is around 10 cfu/mL(g), which also happens to be the threshold of the Final Product Standard. There is no way that the LOQ can be the same as the LOD. Having an error-prone test for use with a Final Product Standard is inappropriate and problematic. However, this same test might function fine when used in an enumeration-based Performance Standard system. For serotyping, the results take too long. Product cannot be held that long. Regardless, the maximum public health benefit of this program is by using an enumeration-based standard without a serotype criterion, and therefore, the serotyping methods are irrelevant at this time.

- 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 needed when evaluating the effectiveness of the proposed final product standards
  Response: The Agency should phase out the current performance standards and implement an enumeration-based Performance Standard. There is no need to implement a Final Product standard. I have explained this in detail in my report.

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ATTACHMENT 3

Trey Malone, K. Aleks Schaefer, Jada Thompson, Economic Analysis of the FSIS Proposed *Salmonella* Control Measures (January 8, 2025)

Economic Analysis of the FSIS Proposed Salmonella Control Measures

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Abstract

This report examines the economic implications of the FSIS's proposed rule and proposed determination – *Salmonella* Framework for Raw Poultry Products. Through an in-depth assessment of FSIS cost assumptions, an evaluation of overlooked components, and an exploration of long-term industry impacts, the report provides a comprehensive analysis aimed at fostering informed regulatory decision-making.

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Executive Summary

The Food Safety and Inspection Service (FSIS) has issued a proposed rule and determination aimed at reducing Salmonella contamination in raw poultry products, specifically focusing on raw chicken and turkey carcasses, parts, and comminuted products. The proposal introduces enhanced testing requirements, stricter compliance protocols, and a zero-tolerance policy for or certain Salmonella serotypes when contamination levels reach or exceed 10 colony-forming units (CFU) per gram. While the proposal aims to improve public health outcomes by addressing a major source of foodborne illness, its economic ramifications for the poultry industry are extensive and complex, impacting producers, processors, and supply chains.

This report provides an in-depth examination of the FSIS cost assessment, identifying key areas where the analysis falls short. Specifically, it highlights:

- **Unrealistic Assumptions**: FSIS underestimates the costs of initial implementation and compliance, particularly for small and medium-sized processors, and assumes uniform capacity to implement, validate, and verify, advanced testing systems across all establishments.
- **Overlooked Cost Components**: The assessment fails to account for supply chain disruptions, long-term shifts in consumer demand, and potential losses in export markets.
- **Broad Economic Impacts**: Beyond individual processors, the regulation poses risks to rural economies, employment, and industry competitiveness.

Key findings include:

1. Compliance costs will disproportionately burden smaller processors, risking further consolidation in the poultry sector and reducing competition.
2. Increased testing, product disposition protocols, and potential product rejection will lead to higher retail prices, shifting consumer behavior, and potentially decreasing poultry demand.
3. Divergent domestic standards may create barriers for U.S. poultry exporters, undermining their competitive standing in global markets.

To mitigate these risks, this report recommends FSIS reevaluate its cost assessment to incorporate realistic assumptions and a more comprehensive understanding of the economic landscape. Collaboration with industry stakeholders is critical to balancing public health objectives with the economic sustainability of the poultry sector.

As such, this analysis aims to generate informed dialogue with policymakers and industry stakeholders toward developing an appropriate regulatory framework that achieves food safety goals without imposing undue burdens on producers, processors, consumers, rural communities, and the overall U.S. economy.

Contents

I. Introduction

The Food Safety and Inspection Service (FSIS) has issued a proposal to control *Salmonella* contamination in raw poultry products. These requirements detailed in the proposed "*Salmonella* Framework" would constitute a substantial shift in the regulatory landscape for the poultry industry. The proposed measures aim to reduce the prevalence of *Salmonella* infections, a leading cause of foodborne illnesses in the United States. While the overarching goal of enhancing public health is laudable, the proposed *Salmonella* Framework has raised substantial concerns among stakeholders within the poultry industry due to their potential economic implications.

Central to the FSIS proposal is the implementation of new testing and compliance protocols designed to identify and mitigate *Salmonella* contamination at multiple stages of production. Key elements of the proposed testing requirements include:

1. **Pre-Harvest Testing**: Producers would be encouraged, via agency guidance, to adopt pre-harvest interventions. While not mandatory, pre-harvest interventions, such as testing flocks for *Salmonella* before they enter the processing facility, could become an industry expectation to ensure downstream compliance.
2. **Post-Harvest Testing**:
    a) Slaughter facilities will be required to conduct SPC sampling and monitoring for indicator organisms.
    b) FSIS will routinely conduct final product standard sampling of carcasses, parts, and ground products at slaughter and processing facilities.
3. **Testing Frequency**: FSIS proposes routine testing at frequencies determined by product type, production volumes, and historical compliance records. Certain high-volume processors or those with a history of non-compliance may face more frequent testing requirements, potentially increasing costs and operational burdens.
4. **Lot-Specific Testing**: Establishments would be required hold production lots until test results confirm compliance, potentially delaying distribution and increasing storage costs.
5. **Enhanced Record-Keeping**: Facilities will be required to implement additional recording-keeping for document testing procedures, results, and corrective actions in detail. These documents will then be subject to FSIS review.

The proposal also includes proposed enforceable final product standards that deem raw chicken carcasses and parts, as well as ground chicken and turkey, adulterated if testing detects

(1) *Salmonella* at levels of 10 CFU/g; and (2) the presence of at least one *Salmonella* serotype of concern. This policy could result in increased lot rejections, necessitating redirection to fully cooked operations, rendering, or disposal.

This report was commissioned by industry stakeholders to evaluate, in detail, the FSIS's cost assessment and its implications for the poultry sector. It highlights significant deficiencies in the FSIS evaluation, including unrealistic assumptions, overlooked cost components, and failure to account for broader economic impacts. By incorporating industry insights and independent economic analysis, this report provides a comprehensive assessment of the regulation's potential effects on producers, processors, consumers, and rural communities.

The report is structured as follows:

- **Industry Background**: Section II presents a detailed overview of the poultry industry, including its economic importance and operational structure.
- **Critique of FSIS Cost Assumptions**: Section III highlights several unrealistic and arbitrary assumptions underlying the FSIS cost assessment.
- **Ignored Cost Components**: Section IV discusses additional economic costs omitted from FSIS's analysis, such as supply chain adjustments, shifts in consumer demand, and long-term implications for market dynamics.
- **Conclusion**: Section V concludes with some key takeaways and recommendations for policymakers to ensure a balanced approach that achieves public health goals without imposing disproportionate economic burdens.

Through this analysis, we aim to inform stakeholders and regulators of the true economic impact of the proposed framework, including a more balanced and comprehensive evaluation of their potential costs.

II. Industry Background

The poultry industry is a highly integrated supply chain, operating in a hyper-efficient, just-in-time production model, where production occurs close to the time of sale.[1][2] Although products can be

[1] MacDonald, J.M. Technology, Organization, and Financial Performance in U.S. Broiler Production, EIB-126, U.S. Department of Agriculture, Economic Research Service, June 2014.

[2] MacDonald, J. M. (2020). Tracking the consolidation of US agriculture. *Applied Economic Perspectives and Policy*, *42*(3), 361-379.

sold as fresh, frozen, or cooked forms, storage capacity remains constrained by physical space and associated costs. Changes to the supply chain process have multiplicative effects up- and downstream, increasing processing costs and ultimately increasing consumer prices. In terms of processing, however, there is spatial heterogeneity in where these impacts would occur.

The regionalization of production and processing would imply that the costs and burden of increased regulation would disproportionally affect certain parts of the United States more than others.[3] Poultry production typically occurs in rural areas best suited for farming, where land use requirements, availability of resources, and integration with other agricultural activities, such as using poultry litter for fertilizer, make these locations ideal for large-scale operations. As a result, the costs and burden of increased regulation would disproportionately affect these rural communities, where production and processing facilities are concentrated. While the distribution of the costs is beyond the scope of this analysis, it is a salient concern and worth noting. Consider Figure 1, which shows the distribution of USDA-FSIS inspected poultry slaughter facilities.[4] These facilities vary in processing size, whose categories range from small to very large. In summing the expected annual processing volume, a state level of production can be estimated and is presented in state level gradation. The darker the state, the higher the reported volume of poultry processed in that state. This map does not denote the type of poultry processed (i.e., turkey, broiler, or eggs), but generally, broilers have three large concentration regions: the southeast, Delmarva, and California. Turkey production is concentrated in the Midwest and North Carolina. Eggs are processed in hubs throughout the United States, but a large area for egg product production is in the Midwest, including Illinois. In addition to the regional effects, potential changes in processing and standard operating procedure may lead to increased water demand to account for sanitation related to the proposed more stringent measures. These water demands across the production region have varying impacts based on water availability, and in some instances, production and processing facilities are already at their maximum water usage threshold as determined by the local municipality.

[3] Saitone, T. L., Schaefer, K. A., Scheitrum, D., Arita, S., Breneman, V., Nemec Boehm, R., & Maples, J. G. (2024). Consolidation and concentration in US meat processing: Updated measures using plant-level data. *Review of Industrial Organization*, *64*(1), 35-56.

[4] https://www.fsis.usda.gov/inspection/establishments/meat-poultry-and-egg-product-inspection-directory

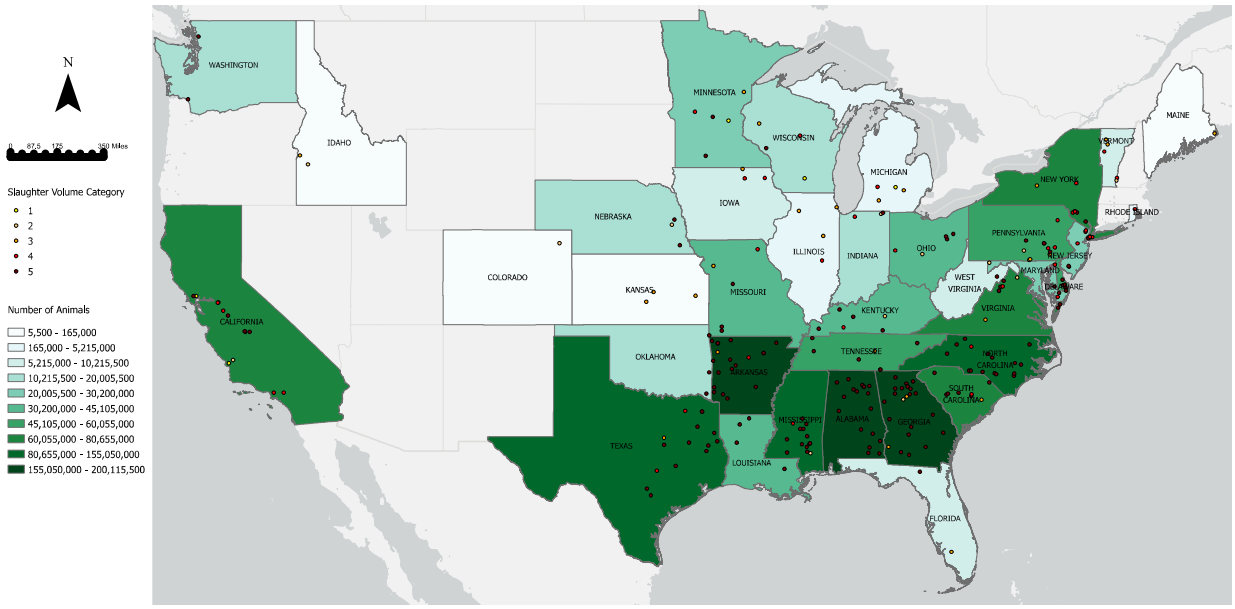

Figure 1: USDA-FSIS Inspected Establishments 2024

Poultry meat processing can be characterized as in Figure 2. This brief overview of poultry processing is described in the following sections. It includes generalizations for each stage in processing with a discussion of where additional costs and testing could occur.

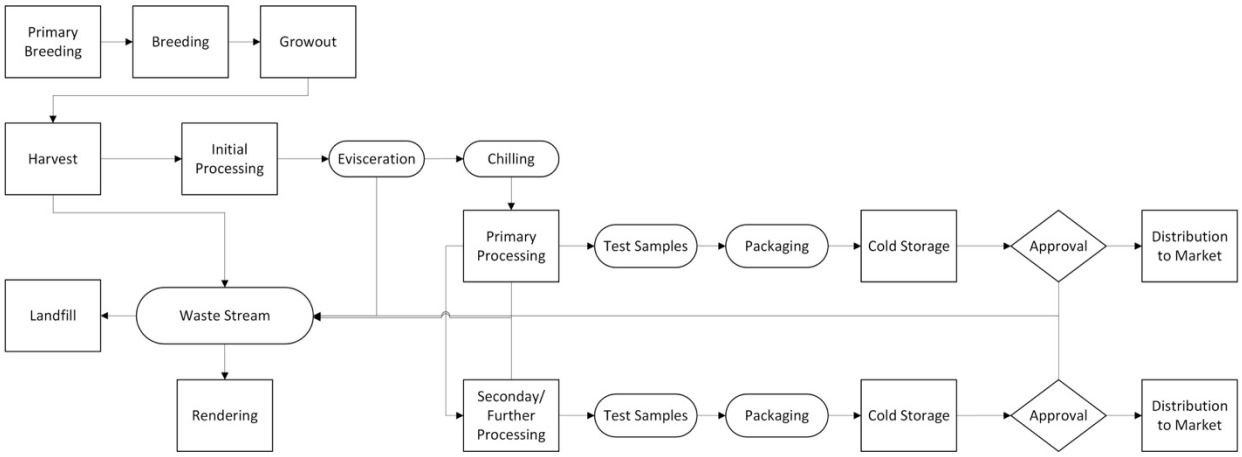

Figure 2: Poultry Processing Flowchart

Poultry are moved to processing at an appropriate age based on desired weight and uniformity. Birds are transported to processing facilities, typically within a reasonable driving distance of the feed mill associated with the processor, as feed hauling costs are the primary

driver of farm location. While farms are often within 50–60 miles of the feed mill, processing facilities may be farther away depending on logistical and operational considerations.[5]

Birds are then moved through initial processing, where birds are humanely stunned and slaughtered following regulatory guidelines to minimize stress and pain to birds or follow specific religious guidelines (e.g., Kosher or Halal). Birds are then sent through a hot water bath for scalding before passing through a feather-picking machine.

After feather picking, birds go through the evisceration stage. Heads and feet are removed and either discarded or sent for further processing. Heads are typically disposed of in compliance with waste management regulations. Feet, or paws, can be marketed domestically but are often exported. Internal organs are removed, with some parts (e.g., liver, gizzards) saved for use as edible byproducts or sent to retail to be marketed on their own. After evisceration each bird is inspected by FSIS for any signs of disease or abnormalities, and the bird and viscera are maintained together during inspection if any portion of the internal organs are for human consumption. Once inspections are passed, birds will proceed into their respective processing stages. Non-compliant carcasses are condemned and moved into a waste stream to be disposed of under appropriate regulatory protocols.

Following evisceration, bird carcasses are rapidly chilled using water immersion or air chilling methods to further reduce potential bacterial contamination and meet temperature safety standards. The rapid chilling ensures the internal temperature falls below 4°C or 40°F within a particular timeframe. This intermediary step has limited capacity for extended storage, as the expectation is that birds will move on to their next processing step to make room for the next flock of birds. If there are delays in the downstream process, this could lead to slower movements of birds, requiring costly or unique solutions to ensure chilling protocols are met for the subsequent flocks. It should be noted that if there becomes a backlog in the processing chain, there would be costly ramifications on the whole chain if production is affected.

After birds reach the appropriate internal temperature, they move into secondary processing. This would include whole ready-to-cook birds for retail or food service, portioning these whole birds into ready-to-cook parts (e.g., breasts, wings, drumsticks, thighs, leg quarters), or completely deboning the bird. Some whole birds or parts would move to food-grade packaging,

[5] Roesler, Kylie, Jada Thompson, Shelby Rider, and Ryan Loy. 2024. “Mapping the Risks for Arkansas Broiler Production.” FSA85. University of Arkansas. https://www.uaex.uada.edu/publications/PDF/FSA85.pdf

typically tray-packed, with any remaining product going to further processing. Those packaged whole birds or parts would be randomly tested by FSIS for *Salmonella* immediately prior to packaging. Post packaging, the lots tested by FSIS would be required to be held in storage. The lot of packaged products will then move into a waste stream if they have unacceptable levels of *Salmonella* as it is cost prohibitive to remove product from packaging, it is not an acceptable food safety practice, and it has the potential to introduce foreign material into the product. Testing by FSIS at this stage requires appropriate storage to maintain the meat at the appropriate temperature to inhibit bacterial growth. The proposed requirement to hold the lot of product sampled by FSIS would require sufficient storage, either onsite in existing coolers or in refrigerated trucks, or off-site at a cold storage facility. The lot of product would be held until sample results indicate that the product is acceptable to enter commerce, which could take up to seven days, but in general, it would be two to three days. Current processing facilities typically only hold these fresh products for a few hours and, therefore, onsite cold storage is extremely limited.

Outside of these ready-to-cook whole birds and parts, the birds go into further processing. This covers a wide range of processing, including deboning, marination, processing, and cooking for ready-to-eat products. These products range from marinated ready-to-cook products for retail and food service to ready-to-eat nuggets and patties. After all further processing is completed, products are packed into their respective food-grade packaging. Random tests for *Salmonella* would be taken before packaging similar to the whole birds and parts discussed above. Additional storage time would incur costs to maintain the product at appropriate temperatures while waiting for the results from the FSIS laboratory.

Once a lot is approved for movement, it is shipped in temperature-controlled environments to wholesales, distributors, or retailers. Refrigeration units must maintain specific temperatures (e.g., below 4°C for fresh and -18°C for frozen products). These products are monitored to ensure the temperature is consistent and are compliant with storage and transportation requirements. Traceability records are maintained throughout storage and distribution.

If the lot of product sampled by FSIS does not meet the proposed *Salmonella* final product standard, it will move into an alternative stream including fully cooking, rendering, or landfills. These routes require transportation infrastructure, drivers, and loading/unloading labor. These additional costs and labor burdens may be cumbersome if the processor’s needs are intermittent or require additional overtime. Many of these products cannot be fully cooked due to limited

capacity, extended transportation distances, and the potential for adulterants from foreign material during an added unpacking step.

Rendering processes carcasses and other non-human-edible parts into meal and fat products, primarily used in animal feed, fertilizers, and other industrial applications.[6] The rendering process involves heat treatment to kill potential bacteria and produce a stable, usable product. Limitations for rendering include processing capacity, market demand for rendered products, and the physical requirements of the process. Rendering facilities are designed to handle raw, unpackaged meat products, so tray-packed or packaged goods would require additional systems to unpack or increased labor to manage, driving up costs and reducing profit margins. These additional steps could also reduce the desirability of such products for rendering. Furthermore, rendering facilities may lack the capacity to process unexpected large lots, leading to logistical challenges and unprocessed supply when demand exceeds available capacity. This would increase the cost of rendering.

Outside of rendering, waste products are moved to landfills following all federal, state, and local regulations for waste disposal. These waste sites may increase fees related to the excess burden of meat recalls or lot disposals. While a landfill is likely able to absorb excess waste, it is possible that landfills refuse products, and alternative arrangements with landfill or waste disposal at greater distances from the processer must be established.

III. The FSIS Cost Assessment Underestimates the Costs Associated with Its Identified Compliance Measures

The FSIS estimates that the proposed *Salmonella* control measures will impose annualized costs on the poultry industry ranging from $3.31 million to $32.25 million, with a central estimate of $16.43 million, as outlined in Table 33 (below) of the regulatory impact analysis. These costs are attributed to compliance activities, including maintaining control of sampled products, HACCP plan reassessments, microbiological sampling and Statistical Process Control (SPC), and electronic data submission. These estimates provide a baseline for understanding the proposal's economic impact. However, FSIS underestimates the actual costs associated with these measures. By underestimating the true financial and operational impacts—particularly for smaller facilities—the FSIS assessment provides an incomplete picture of the economic burden this proposal imposes.

[6] Hamilton, C. R. (2006). An Overview of the Rendering Industry. *Essential Rendering*, 1-16.

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.

A. Maintaining Control of Sampled Products

FSIS estimates the costs for holding sampled products at $2.11 million to $29.26 million annually, as outlined in Table 28 of the regulatory impact analysis. These costs reflect the need to segregate and hold products pending test results. However, FSIS significantly underestimates the financial and logistical burdens this requirement imposes.

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.

FSIS assumes facilities have sufficient existing capacity to hold products without substantial investment. However, most facilities, particularly smaller ones, may require expansions to refrigerated storage, which can cost $150–$170 per square foot only if the physical footprint of the facility could accommodate additional refrigerated storage. Alternatively, facilities may need to lease cold storage space, incurring monthly recurring costs of $15–$20 per pallet. Extended holding times disrupt just-in-time inventory systems, leading to additional labor, transportation, and logistical costs that FSIS does not adequately account for. These delays also increase spoilage risks for fresh poultry, directly impacting product value and marketability, and may negatively impact the safety of the product as well.

For highly perishable products such as chicken parts and comminuted poultry, even short delays during testing reduce shelf life and increase spoilage. These indirect costs, while

significant, are notably absent from FSIS's analysis. In addition, products that fail to meet FSIS standards must often be downgraded, diverted to lower-grade uses such as rendering, or disposed of entirely, with associated costs for transportation or disposal ranging from $50 to $100 per ton. The full extent of these costs also includes environmental impacts, but that is beyond the scope of this analysis.[7]

FSIS's cost methodology also fails to account for cost variability across establishment sizes and product types. Tables 21, 23, and 28 illustrate how high-volume establishments bear the bulk of total costs. However, low- and very low-volume establishments face a disproportionately higher financial burden relative to their production capacity and revenue. These smaller facilities, particularly those in rural or underserved regions, often lack access to affordable capital for infrastructure upgrades, amplifying the operational strain. These low- and very low-volume facilities may also lack access to alternative storage for extended time, further increasing the cost.

B. HACCP Plan Reassessments

FSIS estimates annual costs for revising HACCP plans at $0.09 million to $0.26 million, as outlined in Table 19 of the regulatory impact analysis. These costs are assumed to be manageable for producers, with minimal impact on prices. However, this assumption underestimates the complexity and variability of HACCP updates across facilities, particularly for small and medium establishments with fewer resources.

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.

Facilities with older or less automated processes may require significant modifications to meet updated HACCP requirements, with costs potentially reaching $50,000 to $200,000 for equipment upgrades. Smaller facilities often lack in-house expertise and rely on external

[7] For more information on livestock disposal see: Henry, Chris G, and Larry L Bitney. 2010. "Disposal Methods of Livestock and Poultry Mortality." Extension Report EC727. University of Nebraska, Lincoln.

consultants to revise and validate their HACCP plans. Consultant fees alone can cost $10,000 to $20,000 per facility, representing a significant financial burden.

FSIS also overlooks regional and facility-specific variations in compliance costs. Facilities in rural or remote areas may face higher expenses due to limited access to specialized consultants or training resources. Additionally, the reliance on a uniform 7% discount rate over a 10-year period fails to account for the immediate financial pressures faced by smaller establishments. Many of these facilities operate with limited liquidity, making upfront compliance investments particularly challenging.

Updated HACCP plans also require comprehensive staff training to ensure compliance with new procedures. Training costs, including materials and instructor fees, can range from $5,000 to $10,000 per facility. The time spent on training diverts employees from production activities, further compounding operational disruptions that FSIS's estimates fail to address.

C. Microbiological Sampling for SPC and Final Product Standards

FSIS underestimates annual costs for microbiological sampling and Statistical Process Control (SPC) implementation, as outlined in Table 17 of the regulatory impact analysis. These estimates assume that testing and monitoring requirements will add only marginal costs to production, with minimal effects on retail prices. However, testing for microbiological sampling and SPC monitoring introduces both recurring and fixed investment costs that FSIS significantly underestimates.

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.

Recurring costs for microbial testing reagents and consumables alone can range from $2 to $5 per test for in-house testing and can range from $13 to $20 per test for external testing, quickly accumulating to monthly expenses exceeding $10,000 to $40,000 for high-throughput facilities. Many facilities will require new or upgraded microbial monitoring equipment, with purchase and installation costs ranging from $50,000 to $100,000 per facility. Maintenance and calibration introduce additional recurring costs. Further, establishments with in-house testing

capabilities are at a competitive advantage to those establishments that must send samples to an outside laboratory. In-house sampling capabilities will reduce the time in which sample results are obtained allowing those facilities to make more real-time decisions compared with those that must ship samples offsite for analysis.

Labor costs associated with sampling and SPC monitoring are also underestimated. FSIS assumes that existing staff can integrate these measures without significant changes. In reality, facilities will require additional personnel or retraining to effectively conduct sampling, analyze test results, and manage SPC protocols. These labor-related costs can add $5,000 to $10,000 per month, depending on facility size and throughput.

To minimize the impact of the proposed finished product standards, establishments will need to demonstrate microbial independence between processing lines, *i.e.* thighs vs. wings. Establishing line independence will require the installation of new microbial interventions which also introduces significant costs for poultry processing establishments. Each production line will require a specialized approach, such as antimicrobial spray cabinets, steam pasteurization units, or other targeted control technologies, to ensure compliance with regulatory standards. These interventions necessitate substantial initial investment in equipment and facility modifications, including installation labor and integration with existing systems. Beyond installation, resources must also be allocated to validate the effectiveness of the interventions during initial implementation; requiring microbial testing and quality assurance processes. Ongoing verification adds to operational costs, as establishments must routinely test and monitor the interventions to confirm consistent performance and compliance. These activities demand additional labor, training, and supplies and potential downtime for equipment calibration and maintenance.

D. Electronic Data Submission

FSIS estimates annual industry-wide costs for electronic data submission at $180,000, as outlined in Table 18 of the regulatory impact analysis. These costs are intended to cover the digital reporting of microbial testing results and related compliance information. FSIS assumes that facilities already possess the necessary infrastructure to meet these requirements and that any additional costs will be marginal. However, this assumption fails to account for the significant variability in technological capacity across facilities, particularly for smaller operations.

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.

Smaller facilities, which often lack advanced IT systems, may need to invest between $10,000 and $50,000 to upgrade hardware, software, and network infrastructure. Ongoing costs, such as licensing fees, maintenance, and cybersecurity measures, can add $2,000 to $5,000 annually per facility. FSIS also assumes that existing personnel can manage electronic reporting without additional training. Many facilities will need to hire and train employees on new systems, incurring additional costs of $1,000 to $3,000 per facility.

Moreover, FSIS's cost estimates fail to address the operational inefficiencies during the transition to electronic reporting systems, including potential delays in data submission and reporting. These challenges disproportionately affect smaller facilities, which often have limited technical expertise and financial resources. Tables 18 and 27 highlight how FSIS's assumptions about uniform compliance costs fail to capture the nuances of implementing advanced reporting systems across diverse facility types.

IV. The FSIS Assessment Ignores the Majority of Economic Costs Associated with the Proposed *Salmonella* Framework

The FSIS cost assessment significantly underestimates the economic burden of its proposed *Salmonella* control framework. This section explores several overlooked cost components that substantially impact the poultry industry. First, the analysis neglects critical supply chain adjustments, including pre-harvest controls, contractual renegotiations, and logistical challenges like inventory holding and lot rejections.

Second, the proposal is likely to increase the number of recalls, as seen previously with E. coli being named an adulterant. These recalls could stem from product not properly held pending lab results, or from product tested downstream or by other parties outside of FSIS oversight. The economic assessment fails to account for the ripple effects of increased recalls, including shifts in consumer demand, potential price increases, and erosion of market confidence, which could amplify financial pressures on producers. Finally, the assessment overlooks long-

term implications, such as risks to export competitiveness, threats to small establishment viability, and adverse effects on rural economies heavily reliant on poultry production. These omissions highlight the need for a more comprehensive and realistic economic evaluation.

A. Regulatorily-Induced Supply Chain Adjustments

The proposed regulation will require significant modifications throughout the poultry industry's supply chain, from farm-level operations to processing and distribution. These adjustments will impose new financial and logistical burdens on a protein supply chain already subject to significant regulatory oversight.[8] The added costs are particularly large for smaller establishments, who often operate with tighter margins and fewer resources. Below, we examine the key areas where these supply chain changes will have the most profound impact.

1. Pre-Harvest Controls

Pre-harvest interventions are critical for reducing *Salmonella* loads in poultry, but their implementation carries substantial costs that FSIS's assessment has largely overlooked. These measures include, but are not limited to, vaccination programs, feed additives, litter management, and enhanced biosecurity protocols. Each of these interventions requires significant financial investments and ongoing management, especially for small and medium-sized operations.

Vaccination Programs: Administering a *Salmonella* vaccine to poultry flocks is one method to reduce, but not eliminate, the prevalence of specific *Salmonella* serotypes. The cost of vaccination varies depending on the vaccine type and scale of operation. For instance, the Megan Vac1 Salmonella vaccine is administered at a rate of 5,000 doses per 5,000 chickens, with specific administration protocols. While the exact cost per dose is not specified in the provided source, industry estimates suggest that vaccination costs can range from $0.05 to $0.15 per bird. For a large broiler integrator processing ten million birds per week, this translates to an added expense of $26 million to $78 million per year. Smaller producers may face higher per-unit costs due to limited economies of scale. FSIS's cost assessment does not account for these recurring expenses or the compounded financial burden over time.[9]

[8] Staples, A. J., Chambers, D., Melstrom, R. T., & Malone, T. (2022). Regulatory restrictions across US protein supply chains. *Journal of Agricultural and Applied Economics*, *54*(1), 1-27.

[9] While the rule acknowledges the importance of pre-harvest interventions—like vaccination programs, selective breeding, and enhanced biosecurity protocols—it does not mandate these measures, nor does it provide detailed cost analyses for their implementation. Consequently, the economic burden associated

Production Changes: Feed additives, litter amendments, and water treatments create costly changes for improving disease resistance and microbial control in poultry operations. Implementing feed additives such as probiotics or organic acids can add up significantly for high-volume operations. Litter amendments, including the application of acidifiers or drying agents to control bacterial growth, can vary in cost depending on the facility's size and environmental conditions. Water treatments, such as chlorination or acidification, involve ongoing equipment and chemical supplies expenses. While these interventions are actionable and provide quicker returns, they require regular monitoring and recalibration to ensure efficacy, creating recurring operational costs. FSIS's analysis underestimates these measurable upstream costs, focusing instead on downstream interventions and risks, overlooking the cumulative financial burden of these necessary preventative measures. Furthermore, the adoption process may delay production cycles, affecting contract growers who rely on consistent flows and adding to the economic burden.

Biosecurity Protocols: Strengthening biosecurity measures, such as installing secure perimeters, improving ventilation systems, and upgrading sanitation protocols, entails significant one-time and ongoing expenses.[10,11] Infrastructure improvements can cost between $10,000 and $30,000 per facility, while training and maintenance programs may add an additional $5,000 to $10,000 annually. FSIS's analysis does not incorporate the financial impact of these essential pre-harvest measures. There are approximately 25,000 broiler farms across the United States.

Comparison to FSIS Estimates: FSIS's cost assessment predominantly emphasizes post-harvest testing and enforcement, neglecting the substantial expenses incurred at the farm level. A comprehensive review of pre-harvest measures indicates that cumulative annual costs across the industry could exceed $1 billion, particularly when accounting for operation size and regional cost variations. For example, vaccination and biosecurity measures alone are estimated to cost large integrators upwards of $200 million annually.

with pre-harvest controls is not comprehensively addressed in the FSIS's cost assessment. https://www.meatpoultry.com/articles/30830-keeping-up-with-proposed-emsalmonella-em-rule

[10] Siekkinen, Kirsi-Maarit, et al. "Measuring the costs of biosecurity on poultry farms: a case study in broiler production in Finland." *Acta Veterinaria Scandinavica* 54 (2012): 1-8.

[11] Patyk, Kelly A., Victoria L. Fields, Andrea L. Beam, Matthew A. Branan, Rachel E. McGuigan, Alice Green, Mia K. Torchetti, et al.. "Investigation of Risk Factors for Introduction of Highly Pathogenic Avian Influenza H5N1 Infection among Commercial Turkey Operations in the United States, 2022: A Case-Control Study." Frontiers in Veterinary Science 10 (2023).

2. Inventory Holding

Implementing FSIS's proposed *Salmonella* framework would require establishments to hold products pending test results, leading to increased inventory holding costs. These costs stem from the need for additional storage capacity, extended holding times, and potential disruptions to the supply chain. Below is an expanded discussion of these impacts, including estimated costs and supporting references:

Additional Storage Capacity: To comply with the requirement to hold products until test results confirm the product is not adulterated as defined in the proposal, establishments may need to invest in additional storage facilities or expand existing ones. The cost of cold storage construction varies, but estimates suggest that building a refrigerated warehouse can range from $150 to $170 per square foot. For a facility requiring an additional 10,000 square feet, this translates to an investment of approximately $1.5 to $1.7 million. Alternatively, leasing refrigerated storage space can cost between $15 and $20 per pallet per month, leading to substantial recurring expenses.[12] Further, beyond the rental cost for refrigerated trucks or space would be the cost to maintain these storage spaces. Idling a refrigerated truck uses between 0.4 and 1.1 gallons of diesel an hour to maintain the optimal temperatures which translates to daily costs between $33.50 and $92.14 for one day at $3.49 per gallon of diesel. These additional costs are not insubstantial when factoring the scale needed to store held products.

Extended Holding Times: Holding products pending test results extends the time products remain in storage, increasing energy and labor costs. Energy expenses for refrigeration can amount to $0.10 per cubic foot per month, and additional labor for monitoring and managing held inventory can add $2,000 to $5,000 monthly, depending on the facility's size and volume.[13]

Supply Chain Realignment: The adjustments required by the proposed rule may disrupt existing supply chain dynamics and significantly challenge integrators in sourcing new growers to meet enhanced standards. Contrary to the assumption of a readily available pool of unused capacity, finding new growers may require incentivizing individuals outside the industry. This process could involve substantial costs for securing financing, acquiring land, constructing poultry housing, and navigating regulatory requirements. Additionally, integrators would need to invest heavily in training and verification programs to ensure compliance, with costs likely exceeding the

[12] https://www.conger.com/cold-storage-warehouse/

[13] https://lracking.com/cold-storage-warehouse-cost/

previously estimated $1,000 to $3,000 per grower. These underestimated figures fail to capture the broader economic and logistical challenges of onboarding growers who may need to establish entirely new operations, potentially straining already tight supply chains.

Supply Chain Disruptions: Delays in product release can disrupt just-in-time inventory systems, leading to inefficiencies and potential contractual penalties. While specific cost estimates for these disruptions are not readily available, the cumulative impact can be significant, especially for perishable products like poultry, where timely distribution is critical to maintaining quality and safety.

3. Lot Rejections

Implementing the FSIS's proposed *Salmonella* framework may result in increased lot rejections, creating significant financial and operational challenges for poultry processors. While the FSIS assessment assumes that rejected lots can be redirected to cooked processing or rendering facilities, this assumption overlooks several logistical and economic constraints that complicate such redirection. Below is an expanded discussion of these issues, including estimated costs.

Direct Financial Losses: The immediate financial loss from a rejected lot includes the product's diminished value when diverted to alternative processing streams like cooking or rendering. Cooked product typically commands a lower market price compared to raw poultry, resulting in reduced margins. Rendering, which primarily produces meal and fat for non-human use, further diminishes the product's value. Companies face additional financial strain from processing costs, yield loss, and transportation expenses incurred when diverting product to these streams. For example, rendering facilities often operate near capacity, and transporting products to distant facilities not only increases costs but also risks further quality degradation. These factors significantly erode profitability compared to the margins achievable with raw poultry sales. If neither cooked nor rendering facilities can accommodate the rejected lots, the product must be disposed of, adding further expenses, with disposal costs typically ranging from $50 to $100 per ton, depending on the method (e.g., rendering, composting, or landfilling).

Costs of Redirection: Even when redirection to cooked or rendering processing is possible, it entails additional costs. For packaged lots, unpackaging the product for further processing adds significant labor and handling expenses. These costs can range from $0.10 to $0.20 per pound for unpackaging, with larger facilities incurring higher aggregate costs due to greater volumes. Furthermore, cooking rejected lots require additional energy, labor, and

materials, further increasing expenses and additional monitoring to ensure no foreign materials adulterants enter the supply when unpacking.

Waste Management and Disposal Costs: In cases where redirection is not feasible, rejected lots must be disposed of through landfilling, composting, or rendering. While rendering unusable product may recover some value by converting it into meal or fat for non-human use, this option still incurs transportation, processing, and compliance costs. In contrast, landfilling or composting requires companies to pay for disposal services, with no opportunity to recoup value, and can involve significant logistical expenses. Smaller establishments often face higher disposal costs due to limited access to economies of scale or nearby disposal infrastructure, further exacerbating the financial burden.

Operational Disruptions: Lot rejections disrupt processing schedules, divert resources to manage rejected products and execute corrective actions. This leads to inefficiencies, increased labor costs, and delayed production timelines. For smaller processors, such disruptions may pose existential challenges, particularly if repeated rejections occur.

Supply Chain Implications: Frequent rejections can strain relationships with suppliers and customers, leading to potential contract penalties or loss of business. Delays caused by lot rejections may also result in supply shortages, particularly for time-sensitive orders, further exacerbating financial impacts.

Comparison to FSIS Estimates: The FSIS cost assessment assumes a best-case scenario in which rejected lots are seamlessly redirected to alternative processing. However, this overlooks the practical challenges of facility availability, capacity constraints, and the added costs of unpackaging and transportation. When redirection is not feasible, the FSIS analysis fails to adequately account for the financial burden of disposal. These gaps result in an underestimation of the economic burden of the proposed rule, particularly for small and medium-sized establishments, which are more vulnerable to the costs and logistical challenges of lot rejections.

B. Agency-Induced Changes in Consumer Demand Due to Potential Increased Recalls and Subsequent Price Increases

The proposed *Salmonella* framework is likely to impact consumer demand through increased recalls and price adjustments. These changes could significantly alter market dynamics, affecting both consumer behavior and the economic viability of poultry producers.

1. Increased Consumer Prices

The compliance costs associated with the proposed *Salmonella* framework, such as enhanced testing, monitoring, and facility upgrades, are likely to be passed on to consumers. Retail prices for poultry may increase by an estimated 5–10% to offset these added costs. Such price increases could disproportionately affect low-income households, where poultry is a primary source of affordable protein. Higher prices may also shift consumer preferences away from poultry and toward relatively less expensive proteins. This substitution effect could exacerbate the decline in poultry demand, further reducing revenue across the supply chain.

2. Food Safety Recalls and Consumer Confidence

Recalls stemming from false positives caused by the updated Salmonella testing protocol could erode consumer trust in poultry products. Media coverage of recalls tends to amplify perceived risks, even if the actual threat to public health is minimal. Studies indicate that recalls can lead to a 20–30% reduction in consumer purchasing for affected brands or products within weeks of the announcement.[14] Moreover, repeated recalls across the industry may tarnish the image of poultry as a whole – particularly those companies with well-known, public-facing brands.

The economic implications of diminished market confidence extend beyond immediate sales declines.[15] Retailers may adjust purchasing patterns, reducing order volumes to mitigate the risk of unsold inventory. This cautious behavior can ripple through the supply chain, ultimately reducing production levels and profitability for producers, reduce income to growers, and increase prices to consumers.

E. Potential Long-Term Implications of the Proposed *Salmonella* Framework

FSIS's proposal also carries significant long-term implications for the poultry industry, particularly regarding market structure, international trade, and rural economies. These potential impacts must be considered to ensure the regulation achieves its public health goals without unintended economic consequences.

[14] Lusk, Jayson L., and Susan Murray. "New tool (FooDS) identifies consumers' views on food safety." *Choices* 29.3 (2014): 1-7.

[15] Zhou, P., & Liu, Y. (2023). Recall information heterogeneity and perceived health risk: The impact of food recall on fresh meat market in the US. *Food Policy*, *114*, 102398.

1. Smaller Establishment Viability

Smaller processors face distinct challenges in complying with the proposed *Salmonella* framework due to limited financial resources and economies of scale. Compliance costs for enhanced microbial testing, monitoring, and facility upgrades are disproportionately burdensome for small-scale operations. A USDA Economic Research Service (ERS) study found that small meat and poultry plants spend up to 20% more per unit of production on regulatory compliance compared to larger facilities (ERS, 2021).[16] In this instance, small establishments would face unique challenges in maintaining viability under the new regulatory requirements, particularly with the installation, validation, and ongoing verification of new interventions. Each intervention, such as antimicrobial spray systems, water treatment upgrades, or additional pathogen control mechanisms, demands significant upfront investment in equipment and installation labor. Validation of these interventions requires rigorous testing and quality assurance processes to demonstrate their effectiveness, often necessitating specialized expertise and additional resources. Moreover, these interventions require ongoing verification to ensure consistent performance, involving regular microbial testing, equipment calibration, and maintenance—all of which add to recurring operational costs. Compounding these challenges, any subsequent changes to the processing system, whether driven by regulatory updates or shifts in production methods, would require the entire process of installation, validation, and verification to be repeated. For small establishments operating with limited budgets and staff, these cyclical demands represent a substantial financial and logistical burden, potentially threatening their long-term viability.

The inability to absorb these costs may force smaller processors to exit the market, leading to increased industry consolidation.[17] This shift reduces competition and diversity among producers, potentially driving up prices and limiting innovation. Consolidation also strengthens the market power of larger integrators, which could further disrupt the supply chain.

[16] The analyzed the financial impact of the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) regulation on meat and poultry plants. The study found that compliance costs varied significantly between small and large establishments. Specifically, small plants, which often produce specialized products, incurred higher average costs per unit of production compared to larger plants focusing on commodity products.

[17] Saitone, Tina L., et al. "Consolidation and concentration in US meat processing: Updated measures using plant-level data." *Review of Industrial Organization* 64.1 (2024): 35-56.

2. Export Market Risks

Enhanced domestic standards that diverge from international norms could create compliance challenges for U.S. exporters. Many importing countries rely on *Codex Alimentarius* guidelines for food safety, which differ from FSIS's proposed standards. For example, the Codex thresholds for acceptable *Salmonella* levels in poultry are less stringent than the FSIS's proposed enforceable final product standards, which target *Salmonella* concentration and specific serotypes.

These discrepancies may limit market access for U.S. poultry exporters, particularly in price-sensitive regions like Southeast Asia and Africa. A recent peer-reviewed journal article in the *Review of World Economics* highlighted that non-tariff barriers, including divergent food safety standards, reduce trade volumes by 10–15% for agricultural products.[18] As a major poultry exporter, the U.S. risks losing its competitive edge in these critical markets if compliance costs increase and standards diverge.

This loss of a competitive edge in producing globally affordable chicken is particularly important, as the proposed regulatory changes carry significant export market risks, particularly for lower-income countries that rely heavily on affordable U.S. poultry imports to meet food security needs. Many of these nations depend on consistent supplies of cost-effective chicken to feed their populations, with U.S. exports forming a critical component of their dietary protein sources. However, the additional costs associated with new interventions, validation, and ongoing verification may increase production expenses, leading to higher export prices.

Indeed, this would likely affect low-income importing countries, where even slight price increases can restrict food access for vulnerable populations. As a result, hungry families in these nations may face reduced availability of affordable U.S. chicken, potentially exacerbating food insecurity and malnutrition. Policymakers must consider these downstream impacts when evaluating the broader implications of regulatory changes on global food systems and ensure that measures are taken to mitigate harm to these critical export markets.

[18] Kinzius, Luisa, Alexander Sandkamp, and Erdal Yalcin. "Trade protection and the role of non-tariff barriers." *Review of World Economics* 155.4 (2019): 603-643.

3. Rural Economic Impact

Finally, the poultry industry is a cornerstone of many rural economies, providing employment and economic activity in regions where alternative job opportunities are limited.[19] Closing even small-scale processing facilities or reduced production levels due to compliance costs would have ripple effects across these communities.[20]

According to a National Chicken Council report (2024), each poultry processing job supports an additional 2.5 jobs in related sectors, including transportation, feed production, and retail.[21] The loss of even one small processing facility could result in significant job losses and reduced income for local businesses that rely on the industry.

Additionally, reduced production levels would impact contract growers, many of whom are located in rural areas. Growers depend on the consistent income that comes with contracts with an integrator. Any disruptions could lead to financial hardship and exacerbate existing economic challenges in these regions.[22]

V. Conclusion

The proposed FSIS *Salmonella* framework seeks to improve public health.[23] However, the economic implications of these measures must be thoroughly understood to ensure that the benefits of enhanced food safety do not come at an unsustainable cost to the poultry industry and the broader economy. Our analysis indicates that the proposed Salmonella Framework represents a costly policy shift with financial implications for producers, processors, customers, consumers, and rural America.

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[19] Saitone, Tina L., K. Aleks Schaefer, and Daniel P. Scheitrum. "Leveraging meatpacking ownership concentration and community centrality to improve disease resiliency." *Frontiers in Sustainable Food Systems* 6 (2022): 989876.

[20] Dudensing, R., Guerrero, B., & Amosson, S. (2019). Evaluating the accuracy of regional economic impact estimates: considering a 2013 beef plant closure in Texas. *Journal of Regional Analysis and Policy*, *49*(1), 92-107.

[21] https://www.nationalchickencouncil.org/broiler-industry-provides-1-4-million-jobs-and-450-billion-in-economic-impact-new-study/

[22] Maples, J. G., Thompson, J. M., Anderson, J. D., & Anderson, D. P. (2021). Estimating COVID-19 Impacts on the Broiler Industry. Applied Economic Perspectives and Policy, 43(1), 315–328. https://doi.org/10.1002/aepp.13089

[23] McEntire, J., Acheson, D., Siemens, A., Eilert, S., & Robach, M. (2014). The Public Health Value of Reducing Salmonella Levels in Raw Meat and Poultry. Food Protection Trends, 34(6), 386–392.

This report highlights critical shortcomings in the FSIS cost assessment, including unrealistic assumptions, omitted cost components, and insufficient consideration of long-term impacts. From supply chain adjustments to consumer demand shifts and rural economic vulnerabilities, the proposed framework pose complex challenges that extend far beyond the initial compliance costs. These challenges are particularly acute for small processors, rural communities, and international exporters, all facing unique and disproportionate risks under the proposed framework. The proposal significantly underestimates the cost to the industry and market.

To address these issues, FSIS should:

1. Engage with industry stakeholders to gather comprehensive data on the economic and operational realities of implementing the proposed measures.
2. Reassess cost estimates to include overlooked components such as expanded testing requirements, lot rejection costs, and rural economic impacts.
3. Develop a balanced regulatory approach that maintains high food safety standards while supporting the viability of the poultry industry.

Striking this balance is essential not only for achieving public health objectives but also for preserving the economic sustainability of an industry that plays a critical role in the food system both domestically and internationally. Policymakers must carefully weigh the benefits of all proposed regulations against their potential economic and social costs, ensuring that any final rule is implementable, effective, and equitable.

Through this analysis, we hope to contribute to a more informed dialogue between regulators, industry stakeholders, and policymakers, ultimately fostering a regulatory framework supporting public health and economic resilience.