



January 17, 2025

Dr José Emilio Esteban
Department of Agriculture
Food Safety and Inspection Service (FSIS)
1400 Independence Avenue SW
Washington, DC 20250–3700
Submitted via Regulations.gov

Re: *Salmonella* Framework for Raw Poultry Products, Proposed Rule and Proposed Determination (Docket No. FSIS-2023-0028)

Dear Dr. Esteban,

The Center for Science in the Public Interest (CSPI) submits these comments regarding the FSIS *Salmonella* Framework for Raw Poultry Products, Proposed Rule and Proposed Determination (hereinafter “the Framework”). We are supportive of the Framework, which marks a positive, groundbreaking shift in the agency’s approach to *Salmonella* in raw poultry by proposing enforceable, risk-based product standards and enhanced statistical process control. As we detail below, the proposal is estimated to prevent between 765 and 4,300 illnesses per year and cost no more than \$0.0005 per pound of chicken produced, about five hundredths of a penny, an amount too small to be detectable in the grocery store. Clearly, the health of American families is worth this much.

While we support the Framework, we are concerned that it fails to include measures to control *Salmonella* *Infantis*, a leading cause of poultry-associated outbreaks that is frequently multidrug resistant. We are also concerned that the standard does not address risk from less common outbreak-causing serotypes. It also fails to regulate activities that take place “preharvest”, e.g. those that take place on the farms that supply poultry to FSIS-regulated establishments.

We therefore urge FSIS to strengthen the Framework by expanding the product standard to cover additional high-risk *Salmonella* contamination and requiring establishments to verify food safety controls preharvest. Finally, we support FSIS’s proposal to take into account slaughter volume in establishing phased-in implementation for verification sampling, and urge the agency to consider further measures to prioritize verification under the new rule.

I. Who We Are

CSPI is a non-profit organization, founded in 1971, that serves as an independent, unbiased voice for consumers in the food system and beyond. Our mission is to advocate for evidence-based and community-informed policies on nutrition, food safety and health; hold government agencies and corporations to account; and empower consumers with independent, unbiased information to live healthier lives.

II. Background

Salmonella is a leading cause of foodborne illness in the United States.¹ Each year, foodborne nontyphoidal *Salmonella*, causes 1.2 million illnesses, according to the most recent estimates from the Centers for Disease Control and Prevention (CDC).² Among these cases, it is estimated that nearly 20,000 lead to hospitalization and 378 end in death, making *Salmonella* the leading cause of hospitalization and death from foodborne pathogens.³

Poultry is the leading source of foodborne *Salmonella*. According to estimates by the Interagency Food Safety Analytics Collaboration (IFSAC), chicken causes nearly one in every five illnesses from *Salmonella*, followed by fruits, seeded vegetables, and pork.⁴ Nontyphoidal *Salmonella* in chicken and turkey has been estimated to cause over 260,000 illnesses and contribute to 3.7 billion in costs annually in the United States.⁵

The FSIS's current standards for *Salmonella* in poultry have not resulted in lower *Salmonella* illness rates. As the Framework notes, these standards, which aim to measure performance by assessing the percentage of products testing positive for *Salmonella* over the course of a year, were initially conceived in 1996 and have never gone into full effect due to a ruling in 2001 by the U.S. Court of Appeals for the Fifth Circuit blocking their enforcement.⁶ However, FSIS continues to test under the standards, and in 2006 began categorizing establishments based on their ability to meet the standards, as well as posting that categorization on a public website.⁷

Unfortunately, this approach has not been associated with any impact on human illness rates. In the 10 years after FSIS began publishing results under the standards, roughly 2006 to 2016, rates of illness have remained largely flat: As described in the Framework, in the period 2006-2008, Americans experienced roughly 15 *Salmonella* illnesses per 100,000 population, and in 2019 the CDC estimated 17.1 illnesses per 100,000, a numeric increase.⁸ These numbers demonstrate that the current regulations have failed to yield the desired benefit for consumers. Americans need a more effective approach.

For regulations to work, they must incorporate standards that are aligned with public health, verified, and enforced. This approach means products that present a high risk of causing illness are diverted from the market and cooked to kill bacteria before being offered to consumers. FSIS adopted one such standard in 1994 when it determined that raw ground beef products

¹ CDC. Estimates of Foodborne Illness in the United States. November 5, 2018.

<https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>. Accessed January 15, 2025. (The CDC attribution estimates have not been updated since 2011)

² Scallan E, et al. Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Diseases*. 2011;17(1):7-15)

³ Scallan E, et al. Foodborne Illness Acquired in the United States—Major Pathogens. *Emerging Infectious Diseases*. 2011;17(1):7-15.

⁴ CDC. Foodborne Illness Source Attribution Estimates – United States, 2022. December 13, 2024.

<https://www.cdc.gov/ifsac/php/data-research/annual-report-2022.html>. Accessed January 15, 2025.

⁵ Scharff RL. Food Attribution and Economic Cost Estimates for Meat and Poultry-Related Illnesses. *J Food Prot*. 2020; 83(6): 959-967.

⁶ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁷ Salmonella Verification Sample Result Reporting, Agency Policy, and Use in Public Health Protection, 71 Fed. Reg. 9875.

⁸ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

contaminated with the pathogen *Escherichia coli* O157:H7 were adulterated, and began testing for that pathogen.⁹ Data gathered in the decade roughly following this determination (1996-2004), show that the incidence of foodborne illness from *E. coli* dropped by more than 40 percent.¹⁰ Likewise, in 2003 the European Union (EU) announced it would require countries to implement a coordinated control program for *Salmonella* that among other things would require that fresh poultry meat test negative for *Salmonella* prior to being marketed to consumers.¹¹ This approach helped reduce cases of salmonellosis in the EU by almost one-half between 2005 and 2009.¹²

Recognizing the lack of progress under the current standards and the potential benefits of enforceable standards, stakeholders have aligned on the need for a new approach. As the Framework describes, two early calls for USDA to adopt this approach came in the form of petitions from consumer advocates: Marler Clark LLP, a law firm representing victims of foodborne illness, submitted a petition in 2020 calling on FSIS to declare all 31 *Salmonella* serotypes that have been associated with foodborne outbreaks to be adulterants in all meat and poultry, expanding on the paradigm of *E coli* in ground beef.¹³ A second petition, submitted by CSPI in 2021, asked for enforceable standards targeting *Salmonella* types of greatest public health concern in poultry.¹⁴

Industry and academic leaders also agree on the need for reform. In 2021 CSPI joined other consumer groups, poultry industry experts, food safety researchers, and current and former state and federal regulators in forming the Coalition for Poultry Safety Reform. Members of the Coalition wrote to USDA Secretary Thomas Vilsack urging reform, stating that: “Modernized standards should be objective, risk-based, achievable, enforceable, and flexible enough to adapt to emerging evidence and the latest science.”¹⁵ Industry groups, consumers, and scientists thus all agree: the time has come for FSIS to rethink its approach to *Salmonella* regulation, creating a new, risk-based, enforceable standard to prevent poultry products from making people sick.

⁹ Beef Products Contaminated With *Escherichia coli* O157:H7. 64 Fed. Reg. 2803.

¹⁰ CDC. Preliminary FoodNet Data on the Incidence of Infection with Pathogens Transmitted Commonly Through Food - 10 Sites, United States, 2004. April 15, 2005.

<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5414a2.htm>. Accessed January 15, 2025.

¹¹ Commission Regulation (EU) 200/2012 of 8 March 2012, Concerning a Union Target for the Reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in Flocks of Broilers, as Provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council Text with EEA relevance.

¹² Commission Regulation (EU) 200/2012 of 8 March 2012, Concerning a Union Target for the Reduction of *Salmonella* Enteritidis and *Salmonella* Typhimurium in Flocks of Broilers, as Provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council Text with EEA relevance.

¹³ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

¹⁴ Center for Science in the Public Interest. Petition to Establish Enforceable Standards Targeting *Salmonella* Types of Greatest Public Health Concern while Reducing all *Salmonella* and *Campylobacter* in Poultry, and to Require Supply Chain Controls. January 25, 2021. https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/21-01-cspi-01252021.pdf. Accessed January 17, 2025.

¹⁵ Baum, MD, et al. RE: Poultry Food Safety Improvements. September 2, 2021.

https://www.fsis.usda.gov/sites/default/files/media_file/2022-06/Salmonella-Letter_FoodSafetyCoalition-9-2-2021.pdf. Accessed January 15, 2025.

III. The Framework Will Advance Food Safety by Creating Enforceable Product Standards and Enhancing Statistical Process Control

The Framework is FSIS's response to those calls for reform. In the Framework, the agency focused not only on end-product standards, but included an even more comprehensive approach, addressing *Salmonella* risks from farm to fork, by looking at preharvest, processing, and end-product standards.

The proposal is well supported by evidence and stakeholder input. In developing the framework, FSIS undertook extensive data collection and analysis that included two peer-reviewed risk assessments and a peer reviewed risk profile, both informed by extensive FSIS sampling data and a literature review.¹⁶ In support of the processing component of the framework, FSIS produced an evidence-based model for statistical process control.¹⁷ The agency also sought feedback in multiple settings, including by sharing an initial outline of the framework in November of 2022, holding a public meeting on the framework, soliciting written comment, and consulting with the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) in November of that year.¹⁸ FSIS also convened a research and science roundtable in February of 2022 to discuss scientific support for various potential components of a revised strategy for *Salmonella* control in poultry.¹⁹ Finally, FSIS sought public feedback through multiple channels hosting an additional public meeting on the Framework in December of 2024²⁰ and allowing more than 160 days for members of the public to submit written comment on the rule, a lengthy comment period.²¹

A key component of the Framework is that it proposes to introduce an enforceable product standard that incorporates both the level of any *Salmonella* (10 cfu per milliliter or gram, depending on the product) and the particular *Salmonella* serotype, opting for three serotypes of concern for chicken and three for turkey. FSIS selected these serotypes of *Salmonella* because the agency determined they were more virulent (i.e. likely to cause harm) than other types of *Salmonella*.²²

Such a product standard implements a common-sense principle: when FSIS or industry identifies a raw poultry product that contains high levels of *Salmonella* serotypes that are likely to cause harm, the product won't be sold to consumers. This approach is both risk-based and enforceable, aligning with CSPI's 2021 petition request. It will also drive positive behavior in food safety best practices; by including serotypes of concern, the rule will encourage innovation in preharvest best practices like vaccination and enhanced biosecurity for the most risky serotypes. The enumeration element of the standard (i.e. targeting contamination above 10 cfu per gram or ml)

¹⁶ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

¹⁷ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

¹⁸ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

¹⁹ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

²⁰ U.S. Department of Agriculture, Food Safety and Inspection Service. FSIS-2023-0028-0335: Hearings, Meetings, Proceedings, etc.: *Salmonella* Framework for Raw Poultry Products. December 13, 2023. Regulations.gov. <https://www.regulations.gov/document/FSIS-2023-0028-0335>. Accessed January 15, 2025.

²¹ U.S. Department of Agriculture, Food Safety and Inspection Service. Constituent Update – October 11, 2024. October 11, 2024. Regulations.gov. <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-october-11-2024>. Accessed January 15, 2025.

²² *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

is also beneficial, as it will incentivize best practices in the plant designed to drive down levels of all *Salmonella*.

The rule also includes new requirements to enhance the use of statistical process control (SPC), applying statistical methods to ensure that food safety controls are leading to the expected results measured through microbiological testing. While both SPC and the end product standard involve microbial testing, they are not interchangeable: SPC complements the product standard by measuring an indicator organism, such as Enterobacteriaceae or aerobic plate counts, to monitor process control.²³ This approach is critical for detecting small changes and initiating corrective action, because levels of *Salmonella* are often too low to assess meaningful reductions between processing steps, an assessment needed for real-time monitoring.²⁴

The new approach to process control is needed because, as FSIS noted in the Framework, establishments often fail to correctly apply best practices for microbial sampling under current rules, frequently because they conduct inadequate sampling or fail to monitor results and perform appropriate follow-up for deviations.²⁵ To address these deficiencies, the Framework will ensure that establishments develop a microbial monitoring plan that incorporates SPC, conduct testing at specific processing points (rehang and post chill), and take corrective actions, including a root cause assessment, when results deviate from the plan's predefined criteria.²⁶

FSIS had initially proposed to incorporate preharvest requirements into the framework by identifying *Salmonella* as a hazard reasonably likely to occur at receiving and requiring incoming flocks to be tested prior to slaughter against a predetermined target for *Salmonella*.²⁷ However, as we critique further below, in the Framework FSIS has failed to follow through on this proposal with a regulatory approach to preharvest, falling back on the status quo, which encourages establishments to voluntarily work with suppliers to implement food safety best practices on the farm.

While improvements are needed, the Framework nonetheless represents progress for public health. FSIS estimates the rule will have net benefits for consumers and industry, preventing between 765 and 4,300 illnesses per year and reducing the number of recalls associated with foodborne outbreaks.²⁸ The rule would also be economically feasible, costing the poultry industry roughly \$3.3 to \$32.3 million annually to implement over a 10-year period.²⁹ For

²³ The National Advisory Committee on Microbiological Criteria in Foods (NACMCF). Response to Questions Posed by the Food Safety and Inspection Service: Enhancing Salmonella Control in Poultry Products. *Journal of Food Protection*. 2024; 87(2).

²⁴ The National Advisory Committee on Microbiological Criteria in Foods (NACMCF). Response to Questions Posed by the Food Safety and Inspection Service: Enhancing Salmonella Control in Poultry Products. *Journal of Food Protection*. 2024; 87(2).

²⁵ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

²⁶ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

²⁷ U.S. Department of Agriculture, Food Safety and Inspection Service. Component 1: Requiring incoming flocks be tested for Salmonella before entering an establishment. October 14, 2022. <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/proposed-0>. Accessed January 15, 2025.

²⁸ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

²⁹ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

context, the United States produced nearly 60 billion pounds of broilers (chicken) in 2020.³⁰ Assuming the full \$32.3 million costs were born exclusively by the chicken industry, these costs amount to just \$0.0005 per pound of chicken, about five hundredths of a penny.³¹ These numbers clearly demonstrate that the rule is a valuable investment in the health of American consumers.

IV. The USDA has Legal Authority to Implement the Framework

FSIS’s legal authority for the Framework is derived from the Poultry Products Inspection Act (PPIA),³² which charges the agency with verifying, through the continuous inspection of slaughter and processing establishments, that poultry products produced in the United States are not adulterated. Poultry may not be slaughtered or processed for human food except in compliance with these requirements.³³

“Adulterated” is defined in 21 U.S.C. 453(g) and requires, among other things, that food not bear or contain “any poisonous or deleterious substance which *may* render it injurious to health” (emphasis added) and that it not be “unhealthful, unwholesome, or otherwise unfit for human food.”³⁴ In the Framework, USDA has tentatively determined that poultry products contaminated with high levels of the serotypes identified in the standard are adulterated because they satisfy both of these elements.

With regard to whether a substance renders product “injurious to health,” the PPIA requires a higher showing of risk if a substance is “not an added substance,” i.e. if it is naturally occurring. In such instances, the substance will not render the food adulterated if the quantity of such substance “does not *ordinarily* render it injurious to health” (emphasis added).³⁵ No court has previously considered whether *Salmonella* in poultry would be an added substance, although in *U.S. v. Anderson Seafoods*, a court interpreted identical language in the federal Food Drug and Cosmetics Act to hold that mercury could be considered an “added substance” in seafood because, while naturally occurring, its levels were increased as a result of human action.³⁶

In the Framework, FSIS does not determine that *Salmonella* is an added substance in poultry, but instead invites comment on this question. We urge FSIS to determine that *Salmonella* is an added substance in raw poultry because, as the agency itself summarized in the Framework, while *Salmonella* is sometimes present in the gastrointestinal tract, skin, liver, and bones of live birds, most contamination on poultry products results from contamination during slaughter and processing, a process controlled and directed by human action. This is supported by the fact that different approaches to processing (e.g., air chilling versus immersion-chilling, or grinding of comminuted chicken using bone-in and skin-on versus deboned and skinless source materials)

³⁰ U.S. Department of Agriculture, National Agricultural Statistics Service. Poultry – Production and Value: 2020 Summary. April 2021. https://www.nass.usda.gov/Publications/Todays_Reports/reports/plva0421.pdf. Accessed January 15, 2025.

³¹ U.S. Department of Agriculture, National Agricultural Statistics Service. Poultry – Production and Value: 2020 Summary. April 2021. https://www.nass.usda.gov/Publications/Todays_Reports/reports/plva0421.pdf. Accessed January 15, 2025.

³² 21 U.S.C. §§ 451 et seq. Poultry Products Inspection Act.

³³ 21 U.S.C. § 458.

³⁴ 21 U.S.C. § 458(g)(1) and (g)(3). (italics added)

³⁵ 21 U.S.C. § 458(g)(1). (italics added)

³⁶ *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir. 1980).

can lead to lower or higher prevalence of contamination. Therefore, FSIS should determine that *Salmonella* is an added substance in raw poultry.

Irrespective of whether *Salmonella* is an “added substance” in raw poultry, FSIS has tentatively determined that products failing the standard are adulterated because there is a high likelihood that these products will result in illness under ordinary consumer cooking practices, where both cross-contamination and inadequate heating are common. We agree. The 2023 chicken risk assessment estimated that 612 illnesses would occur per 100,000 servings of raw chicken carcasses contaminated with a serotype of public health significance at or above 10 cfu/ml, making them 2,000 times more likely to cause illness than average raw chicken carcasses, where only 0.3 illnesses are likely to result from 100,000 servings.³⁷ These numbers quantify and lend further support to the conclusion that such contamination ordinarily renders the poultry product injurious to health, as the statute contemplates.

Finally, we support FSIS’s conclusion that products contaminated in violation of the proposed standard are adulterated because they are “unhealthful, unwholesome, or otherwise unfit for human food.”³⁸ As the Framework notes, FSIS has repeatedly applied this provision in determining that food is adulterated based on risk of illness. This includes by determining that raw, non-intact beef is adulterated if it contains pathogenic *E. coli*, that raw meat or poultry is adulterated if it is associated with an illness outbreak from pathogens; and that beef is adulterated if it is derived from non-ambulatory disabled cattle presenting a risk of bovine spongiform encephalopathy agent (the cause of “mad cow” disease).³⁹ The same provision is applicable here to high-risk poultry product failing the proposed product standard.

V. The Framework Should Be Improved by Expanding the Product Standard to Cover Additional High-Risk Contamination and Incorporating Preharvest Requirements

While the framework as proposed is well supported by science and law, the policy could be improved. The final version of the framework should expand the product standard to include *Salmonella* Infantis, an emerging high-risk serotype, while also addressing risk from serotypes not specifically targeted by the rule. It should also incorporate a regulatory approach to ensuring food safety preharvest.

a. *The Final Rule Should Include Salmonella Infantis as a Serotype of Public Health Significance*

We urge FSIS to include *S. Infantis* as a serotype of public health significance for chicken in the final rule, which currently covers the serotypes Enteritidis, Typhimurium, and I 4,[5],12:i:-, for chicken products, and Hadar, Typhimurium, and Muenchen for raw comminuted turkey.⁴⁰ Under the Framework, samples that fail to test positive for a serotype of public health significance will not be considered adulterated and can be passed into commerce irrespective of the amount of contamination with other *Salmonella* serotypes. This means that companies could sell poultry contaminated with high amounts of harmful *S. Infantis*. In the framework, FSIS cites CDC pilot

³⁷ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

³⁸ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

³⁹ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁴⁰ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

estimates suggesting that including *Infantis* in the rule could increase the percent of outbreak-associated illnesses covered by the rule from 68 percent to 79 percent, a substantial increase.⁴¹

Infantis is now a leading cause of outbreaks in poultry, causing the second highest number of illnesses linked to chicken outbreaks between 2017 and 2021, according to data published by the CDC.⁴² Yet until recently it was a relatively rare cause of human illnesses, associated with only two outbreak cases from 2012 to 2016. Its meteoric rise as a cause of illness was due the emergence of a virulent, multidrug resistant strain that was first detected in travel-associated cases in 2012 but did not receive much attention from regulators or industry until CDC announced a deadly multistate outbreak of this strain in 2018.⁴³ The strain carries a megaplasmid that is associated with increased virulence and can carry mutations that confer resistance to antibiotics commonly used to treat severe *Salmonella* infections.⁴⁴ Because of this, more than 70 percent of patients who have received first-line antibiotic treatment for infection by this strain had an isolate shown to be resistant to that antibiotic.⁴⁵

FSIS included *Infantis*, along with *Enteritidis* and *Typhimurium*, as a part of its “Key Performance Indicator” metrics that the agency developed in October of 2021 to measure progress on *Salmonella* reduction, based on the fact that *Infantis* was one of the top three *Salmonella* serotypes found in chicken and commonly associated with human illness.⁴⁶ The 2024 NACMCF report also identified *Infantis* as one of a small number of serotypes that account for most poultry-associated cases of salmonellosis, along with *Enteritidis*, *Typhimurium*, I:4,5,12:i:-, and Heidelberg.⁴⁷ And FSIS’s 2023 risk profile likewise included *Infantis* among the top seven subtypes associated with chicken.⁴⁸

Yet in the Framework, the agency opted not to include *Infantis* as a serotype of public health significance. This decision appears to have been based on *Infantis* being categorized as a “lower virulence type” in the agency’s 2023 risk assessment, which relied on genomic methods to assess virulence, rather than simply looking at the epidemiological data to determine which strains were causing the most outbreaks attributable to poultry.⁴⁹ FSIS also asserts that “the scientific

⁴¹ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁴² Centers for Disease Control and Prevention (CDC). BEAM (Bacteria, Enterics, Ameba, and Mycotics) Dashboard. U.S. Department of Health and Human Services. www.cdc.gov/ncezid/dfwed/BEAM-dashboard.html. Accessed 1/15/2025.

⁴³ Centers for Disease Control and Prevention (CDC). Data Summary: Persistent Strain of *Salmonella* *Infantis* (REPJFX01). December 16, 2024. <https://www.cdc.gov/salmonella/php/data-research/repjfx01.html>. Accessed January 15, 2025.

⁴⁴ Tyson, GH et al. A Multidrug-Resistant *Salmonella* *Infantis* Clone Is Spreading and Recombining in the United States. *Microb Drug Resist*. 2020;27(6):792-799.

⁴⁵ Centers for Disease Control and Prevention (CDC). Data Summary: Persistent Strain of *Salmonella* *Infantis* (REPJFX01). December 16, 2024. <https://www.cdc.gov/salmonella/php/data-research/repjfx01.html>. Accessed January 15, 2025.

⁴⁶ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁴⁷ The National Advisory Committee on Microbiological Criteria in Foods (NACMCF). Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products. *Journal of Food Protection*. 2024; 87(2).

⁴⁸ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁴⁹ *Salmonella* Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

evidence does not support that the rising trend in Infantis illnesses is associated with chicken consumption” and that data on severity of illness “reinforce it is not a high risk serotype.”⁵⁰

The 2023 risk assessment relied on virulence factors from the *Enterobacteriaceae* family compiled from public databases. Serotypes from this dataset were clustered according to the presence or absence of these virulence factors. Infantis apparently lacked virulence factors in the dataset, as it was placed in a “lower virulence” cluster based on this analysis.⁵¹

While the overall approach to considering genetic virulence has merit, the method may fall short in capturing Infantis as an emerging risk. As FSIS acknowledged in the framework, “current bioinformatics methods are based on the serotypes that have been the consistently highest illness causes (Enteritidis and Typhimurium) across time rather than the full genetic landscape of *Salmonella*.”⁵² Essentially, the database is weighted towards *Salmonella* serotypes that have historically caused illness, not emerging, novel threats. Unfortunately, the rise of Infantis has been so swift that the databases used by FSIS to understand virulence may not include the virulence factors specific to this new emerging Infantis strain. We urge FSIS to consult with CDC and ensure that it adequately incorporates virulence factors from the emerging *Salmonella* Infantis strain into its model prior to finalizing the rule. If FSIS does not have assurance that the genomic databases upon which it is relying adequately incorporate virulence factors from Infantis, it should consider incorporating Infantis based on epidemiological evidence, rather than genomic data.

We also urge FSIS to reconsider its argument that the rise in Infantis is not caused by chicken. Chicken is the predicted source for 55 percent of all Infantis cases, according to genome modeling source attribution pilot estimates presented by the CDC at the 2023 National Advisory Committee on Microbiological Criteria for Foods meeting.⁵³ Nevertheless, the FSIS 2024 risk assessment hypothesized that “other reservoirs and modes of transmission (other than broilers)” were responsible for a rise in human cases of Infantis, because human Infantis cases began to increase in 2005, whereas the proportion of broilers testing positive did not begin to rise until 2012, with that proportion rising steeply following identification of the first multidrug resistant Infantis variant in poultry samples in 2014.⁵⁴ This approach may have obscured the effects of chicken as a source of the emerging Infantis strain because it looked at Infantis overall, rather than focusing on the new, virulent, multidrug resistant strain. That strain, specifically, did not lead to a substantial number of human cases until 2015, the year after it was first identified and

⁵⁰ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁵¹ U.S. Department of Agriculture, Food Safety and Inspection Service. Quantitative Risk Assessment for Salmonella in Raw Chicken and Raw Chicken Products. July 2024. https://www.fsis.usda.gov/sites/default/files/media_file/documents/Chicken_SRA_July2024.pdf. Accessed January 15, 2025.

⁵² Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁵³ NACMCF final report “Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products.” March 13, 2023. https://www.fsis.usda.gov/sites/default/files/media_file/documents/NACMCF_Salmonella_2023.pdf. Accessed January 17, 2023.

⁵⁴ U.S. Department of Agriculture, Food Safety and Inspection Service. Quantitative Risk Assessment for Salmonella in Raw Chicken and Raw Chicken Products. July 2024. https://www.fsis.usda.gov/sites/default/files/media_file/documents/Chicken_SRA_July2024.pdf. Accessed January 15, 2025.

began its steep ascent in broiler chickens.⁵⁵ We urge USDA to repeat its analysis with a specific focus on this emerging strain, which appears to have charted a similar trajectory in humans and poultry.

Moreover, FSIS has failed to support its conclusion that Infantis is a “lower virulence” serotype using epidemiological evidence. As stated above, Infantis is now a leading and rising cause of chicken-associated outbreaks. And while the framework suggests that epidemiological studies “reinforce [that Infantis] is not a high risk serotype,” its only support for this statement is a study published by CDC researchers in 2018 indicating that patients infected with the multidrug resistant Infantis strain had a higher hospitalization rate than comparison cases with other serotypes (44% versus 29%).⁵⁶ The virulence of this strain was reiterated by CDC in a study published in 2021, which also noted that a plasmid associated with the strain confers increased adhesion and invasion in cell culture models and increased virulence in mouse models of infection.⁵⁷ Thus, FSIS has failed to propose epidemiological evidence suggesting that infection with the new Infantis strain is less likely to result in severe illness.

Finally, FSIS appears not to have considered antimicrobial resistance in identifying serotypes of public health significance. Such resistance is an important factor in assessing risk, because it can limit or remove treatment options for severe salmonellosis. We urge the agency take into account antimicrobial resistance as a factor for prioritization in the final rule, and to consider the multidrug resistant nature of the emerging Infantis strain.

While FSIS has committed to update the serotypes of public health significance in the future, such updates typically occur only slowly (for example, it has now been two years since FSIS announced plans to develop the framework, which is only now at the proposed rule stage). If FSIS does not include Infantis in its final rule, the serotype likely will be left unchecked for years, even as birds are more consistently monitored and vaccinated for other high-risk serotypes. We urge the USDA not to allow this dangerous strain to grow and spread further across our food system, when a framework is available and could be deployed today to mitigate the threat.

b. FSIS Should Extend the Standard to Address Contamination with Other Serotypes

Even with Infantis included, not all illness potentially caused by chicken is covered under the current rule. As noted above, even if Infantis is included in the rule it will cover only 79 percent of all outbreak-associated illnesses, leaving a substantial proportion excluded. These include outbreaks caused by additional strains like Blockley, Braenderup, and Heidelberg, which were all causes of chicken-associated outbreaks in recent years.⁵⁸

⁵⁵ Centers for Disease Control and Prevention (CDC). Data Summary: Persistent Strain of Salmonella Infantis (REPJFX01). December 16, 2024. <https://www.cdc.gov/salmonella/php/data-research/repjfx01.html>. Accessed January 15, 2025.

⁵⁶ Brown AC et al. CTX-M-65 Extended-Spectrum β -Lactamase–Producing Salmonella enterica Serotype Infantis, United States. *Emerg Infect Dis*. 2018 Dec;24(12):2284–2291.

⁵⁷ Tyson, GH et al. A Multidrug-Resistant Salmonella Infantis Clone Is Spreading and Recombining in the United States. *Microb Drug Resist*. 2020;27(6):792-799.

⁵⁸ Centers for Disease Control and Prevention (CDC). BEAM (Bacteria, Enterics, Ameba, and Mycotics) Dashboard. U.S. Department of Health and Human Services. www.cdc.gov/ncezid/dfwed/BEAM-dashboard.html. Accessed 1/15/2025.

We urge USDA to extend the standard to cover additional risk from these serotypes. One approach would be to consider shifting the current product standard requirement, which relies on finding a serotype of concern AND high levels of *Salmonella*, to requiring either the presence of a serotype of concern OR high levels of *Salmonella*. Such an approach will ensure that risk from both high amounts and high-risk types is captured. It will also help account for the inevitable lag as new serotypes emerge, because the rule will cover high-risk contamination regardless of the serotypes present.

c. The Final Rule Should Incorporate Preharvest Requirements

Food safety experts have long endorsed employing a multi-hurdle approach to reducing food safety risks prior to harvest, addressing food safety from farm to fork. Many of these practices are captured in the agency's June 2021 Guidance for Controlling *Salmonella* in Raw Poultry and include vaccinating breeder flocks, obtaining chicks from pathogen-free hatchery flocks, appropriate management and treatment of litter, feed, and water, and biosecurity (e.g. limiting uncontrolled exposure to humans, animals and insects that can spread bacteria).⁵⁹

The European Union approach noted above, which has been so effective in reducing illness from *Salmonella*, requires national control programs to address *Salmonella* on farms by testing for priority serotypes at various stages of the animal life cycle and requiring compulsory slaughter of flocks testing positive for such priority serotypes (meat from such slaughtered flocks can still be consumed, provided it is cooked or otherwise processed to be free of *Salmonella*).⁶⁰

In our 2021 petition, CSPI urged that FSIS address preharvest practices by adopting an approach that encompasses supplier verification, extending regulatory review of slaughter establishment's Hazard Analysis and Critical Control Point (HACCP) plans to include preharvest controls and requiring microbial testing programs to verify program effectiveness.⁶¹ When FSIS initially sought feedback on the framework through a public meeting in 2022, the agency indicated it was considering the testing approach recommended by CSPI, incentivizing preharvest interventions by requiring incoming flocks to be tested prior to slaughter against a predetermined target for *Salmonella*.⁶² In a risk assessment published in 2023, FSIS estimated that if such an approach could drive effective preharvest interventions and management, it would eliminate high risk serotypes and thereby avoid between 27,000 and 55,000 cases of

⁵⁹ U.S. Department of Agriculture, Food Safety and Inspection Service. FSIS Guidance for Controlling Salmonella in Raw Poultry. June 2021. https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/FSIS-GD-2021-0005.pdf. Accessed January 16, 2025.

⁶⁰ Commission Regulation (EU) 200/2012 of 8 March 2012, Concerning a Union Target for the Reduction of Salmonella Enteritidis and Salmonella Typhimurium in Flocks of Broilers, as Provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council Text with EEA relevance.

⁶¹ Center for Science in the Public Interest et al. Petition to Establish Enforceable Standards Targeting Salmonella Types of Greatest Public Health Concern while Reducing all Salmonella and Campylobacter in Poultry, and to Require Supply Chain Controls. January 2025. https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/21-01-cspi-01252021.pdf. Accessed January 16, 2025.

⁶² U.S. Department of Agriculture, Food Safety and Inspection Service. *Component 1: Requiring incoming flocks be tested for Salmonella before entering an establishment*. October 14, 2022. <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/proposed-0>. Accessed January 15, 2025.

salmonellosis annually (a much higher number of prevented illnesses than the 765 and 4,300 illnesses per year FSIS has estimated will be prevented by the Framework as-proposed).

In the proposed Framework, the agency affirmed that “[t]esting results at or before the receiving step may have a substantial public health impact.” However, as noted above, the agency did not propose conducting such verification testing, stating “the requirements associated with... verification of pre-harvest *Salmonella* control strategies... would require substantial industry resources.”⁶³ The agency was also advised by NACMCF that such on-farm testing was inadequately predictive of contamination at the end of processing.⁶⁴ In lieu of testing, FSIS declared that it intends to rely on voluntary guidance to promote best practices pre-harvest.

We urge FSIS to reverse this decision and include a stronger regulatory approach to preharvest conditions in its final rule. FSIS could develop a testing approach that is adequately predictive of contamination at the end of processing. Moreover, irrespective of how the program is verified, FSIS should include a requirement that HACCP plans ensure that establishments have verified the use of appropriate pre-harvest interventions.

The agency also indicated in the Framework that it is exploring “non-regulatory” approaches to controlling *Salmonella* at preharvest, and lists work with the U.S. Animal and Plant Health and Inspection Service’s (APHIS’s) National Poultry Improvement Plan (NPIP) as one such approach. NPIP is a cooperative industry, state, and federal program that offers voluntary certification to verify that minimum requirements for disease control are met by participating companies. It currently has programs for primary and multiplier breeders, but none of these programs offer to verify that such flocks are free of all *Salmonella* of public health significance.^{65,66}

We encourage FSIS to work with NPIP to develop a program for primary and multiplier breeders verifying that flocks are certified free of the *Salmonella* serotypes identified by the rule, and that FSIS consider how it can incentivize the purchase of chicks from such suppliers.

VI. FSIS Should Engage in Risk-Based Verification Testing Under the Framework

In order for the new Framework to prove effective, FSIS must proceed with plans to independently verify the standards by testing product using a statistically valid sampling approach. Industry stakeholders at the December 2024 public meeting on the framework expressed the concern that companies would be discouraged from conducting their own testing for fear of having to dispose of violative product. While there is no evidence that this behavior occurred following USDA’s determination that E coli O157:H7 is an adulterant in ground beef, USDA has also been consistent in testing to verify the product standard. Such verification testing appears to have driven companies to test extensively and invest in control measures, leading to

⁶³ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁶⁴ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁶⁵ Salmonella Framework for Raw Poultry Products. 89 Fed. Reg. 64678 (proposed August 7, 2024).

⁶⁶ The “U.S. Salmonella Monitored Program” is intended only to reduce the incidence of Salmonella and the “U.S. S. Enteritidis Clean Program” verifies only that chicks are free of Salmonella Enteritidis, only one of three of the serotypes.

less contamination. Testing is important because without it, there would be an incentive for companies to avoid testing as a means to effectively conceal violative product.

While such testing is essential, it should be directed in a manner that produces the greatest benefit for human health. One way to tailor testing based on risk is for FSIS to consider reduced testing for slaughter establishments purchasing chick exclusively from suppliers participating in an NPIP program that could be developed to ensure flocks are free of serotypes of public health significance. In addition, given the very low production of meat by very small and very low volume establishments, and thus very low contribution to human illness, we support FSIS's plans, proposed in the Framework, to roll out verification testing on a staggered basis and take into account volume. This approach will help ensure agency resources are directed towards establishments in which testing will have a greater public health impact.

VII. Conclusion

The Framework has the potential to be one of the greatest advances in food safety in a generation and will help ensure that when a poultry product is stamped "USDA inspected," it means it is free of harmful contamination likely to make consumers sick. We urge the agency to move forward with this important effort and make improvements to strengthen the proposal for the benefit of public health.