



December 16, 2022

Docket Clerk,
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue SW
Washington, DC 20250–3700

RE: Comment on Proposed Framework for Controlling *Salmonella* in Poultry (Docket No. FSIS-2022-0029)

To Whom it May Concern,

The Center for Science in the Public Interest (CSPI)¹ respectfully submits these comments to the United States Department of Agriculture’s Food Safety and Inspection Service (FSIS) on the above-referenced proposed framework for reforming the *Salmonella* poultry food safety program.

We support FSIS moving forward with a substantial reform of the poultry food safety regulatory system that could be consistent with the components of this framework. This reform is needed because, despite FSIS and stakeholders having spent decades investing in *Salmonella* control, the incidence of human *Salmonella* illnesses has been stagnant for over 20 years (approximately 15 confirmed cases per 100,000 people yearly).² Americans failed to make progress towards achieving Health and Human Service’s Healthy People 2010 and 2020 *Salmonella* illness goals of 6.8 and 11.4 confirmed cases per 100,000 people yearly, respectively,^{3,4} and could again be on track to not meet the Health People 2030 goal of reducing *Salmonella* illness incidence to 11.5 confirmed cases per 100,000 people yearly.⁵ Poultry is the leading cause of salmonellosis.⁶ Given the lack of progress under the current *Salmonella* performance standards for poultry slaughter and processing establishments, the time has come for these standards to be reconsidered. The current standards are designed to assess the effectiveness of an establishment’s

¹ CSPI is your food and health watchdog. Since 1971, CSPI has worked to improve the public’s health through better nutrition and food safety. The organization’s work is supported by subscribers to its Nutrition Action Healthletter, one of the nation’s leading health newsletters. CSPI is an independent organization that does not accept government grants or corporate funding.

² Pathogen surveillance - Salmonella. Centers for Disease Control and Prevention. Accessed December 6, 2022. <https://wwwn.cdc.gov/foodnetfast>

³ National Center for Health Statistics. Healthy People 2010 final review. 2012. https://www.cdc.gov/nchs/data/hpdata2010/hp2010_final_review.pdf

⁴ Healthy People 2020 objective FS-1.4: reduce infections caused by Salmonella species transmitted commonly through food. U.S. Department of Health and Human Services. Updated August 27, 2021. Accessed September 10, 2021. <https://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives>

⁵ Healthy People 2030 objective FS-04: reduce infections caused by Salmonella. U.S. Department of Health and Human Services. Accessed September 10, 2021. <https://health.gov/healthypeople/objectives-and-data/browse-objectives/foodborne-illness/reduce-infections-caused-salmonella-fs-04>

⁶ Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2020 for Salmonella, Escherichia coli O157, and Listeria monocytogenes using multi-year outbreak surveillance data, United States. Atlanta, GA and Washington D.C.: U.S. Department of Health and Human Service Centers for Disease Control and Prevention and U.S. Food and Drug Administration, U.S. Department of Agriculture Food Safety and Inspection Service; 2021.

Salmonella controls based on an allowed number of *Salmonella* positive samples from whole carcasses, comminuted poultry, and cuts in a 52-week rolling window.⁷ These standards are unenforceable, meaning an establishment failing the standards does not present sufficient cause, by itself, for FSIS to stop an establishment from producing poultry. Furthermore, product lots found to be contaminated are still allowed to be marketed. These standards also rank all *Salmonella* contamination equally,⁸ even though certain subtypes⁹ and amounts¹⁰ of *Salmonella* can be more harmful to public health than others.

CSPI has long been concerned with *Salmonella* in poultry. We first petitioned USDA to ban certain strains of antibiotic-resistant *Salmonella* in 2011,¹¹ and again in 2014,¹² but the agency denied both petitions without prejudice. Our most recent efforts included petitioning USDA in 2021, along with other consumer advocacy groups and victims of *Salmonella* illness, to reform its poultry *Salmonella* regulations.¹³ The petition asked for enforceable final product standards that would disallow products with concerning types of *Salmonella* contamination from reaching consumers. It also requested that establishments be required by FSIS to ensure they purchase from suppliers they have vetted to ensure the suppliers are controlling risks on farm, as FSIS has long maintained the position that it cannot regulate those suppliers directly.¹⁴

CSPI also joined with consumer groups, leading industry members, food safety scientists, and regulators to form the Coalition for Poultry Safety Reform (the Coalition) in 2021 to push FSIS to modify its regulatory system to better address *Salmonella*.¹⁵ Members of the Coalition are in agreement that the performance standards are not leading to the desired public health outcomes, and are requesting new standards that are objective, risk-based, achievable, enforceable, and flexible enough to adapt to emerging evidence and the latest science.

The proposed FSIS framework describes a regulatory system that could be consistent with reform actions we requested in our most recent petition and with the Coalition. Thus, we applaud FSIS for proposing final product standards in Component 3, which will be the key for an effective regulatory system overhaul. We also support FSIS in ensuring that its proposed framework encompasses food safety from farm to fork, including by requiring establishments to

⁷ 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. February 2, 2016. <https://www.federalregister.gov/documents/2016/02/11/2016-02586/new-performance-standards-for-salmonella-and-campylobacter-in-not-ready-to-eat-comminuted-chicken>

⁸ Ibid.

⁹ Pathogen surveillance – Salmonella, culture confirmed, top 10. Centers for Disease Control and Prevention. Updated October 8, 2022. Accessed May 10, 2022. <https://wwwn.cdc.gov/foodnetfast>

¹⁰ Akil L, Ahmad HA. Quantitative risk assessment model of human Salmonellosis resulting from consumption of broiler chicken. *Diseases*. 2019;7(1):19. Published 2019 Feb 7. doi:10.3390/diseases7010019

¹¹ Petition for an interpretive rule declaring specific strains of antibiotic-resistant Salmonella in ground meat and poultry to be adulterants with the meaning of 21 U.S.C. §601(m)(1) and (2)(A) and 12 U.S.C. §453(g)(1) and (g)(2). May 21, 2011.

https://www.cspinet.org/sites/default/files/media/documents/resource/cspi_petition_to_usda_on_abr_salmonella.pdf

¹² Petition for an interpretive rule declaring antibiotic-resistant Salmonella Heidelberg, Salmonella Hadar, Salmonella Newport, and Salmonella Typhimurium in meat and poultry to be adulterants. October 1, 2014. <https://www.cspinet.org/sites/default/files/media/documents/resource/oct-14-abr-petition.pdf>

¹³ 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://downloads.regulations.gov/FSIS-2021-0003-0001/content.pdf>

¹⁴ 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 Federal Register 7285 (February 11, 2016), pp. 7285-7300.

¹⁵ The coalition for poultry safety reform welcomes the launch of a new USDA effort to reduce Salmonella illnesses associated with poultry products. Center for Science in the Public Interest. Updated October 19, 2021. Accessed December 6, 2022. <https://www.cspinet.org/news/coalition-poultry-safety-reform-welcomes-launch-new-usda-effort-reduce-salmonella-illnesses>

focus on a preharvest component, like what is described in Component 1, and giving inspectors more specific indicators to determine when regulatory action at establishments is needed, as could be provided by Component 2.

We strongly support USDA’s “belt and suspenders” approach to this problem. The prevalence of *Salmonella* contamination is too high and the morbidity and mortality consequences too severe to depend upon reforms to a single component of the production system to realize the desired public health gains. While we support the overall framework, the specific details of each component will determine their efficacy. Our suggestions for the direction FSIS should take to ensure the success of this reform effort are described below.

Component 3

CSPI urges FSIS to prioritize developing and implementing Component 3, as it is the most critical part of the framework. Component 3 describes the potential for FSIS to create an enforceable final product standard or standards to ensure that poultry products contaminated with *Salmonella* that is likely to cause illness are not sold to consumers.

As we have repeatedly emphasized in our advocacy, enforceable final product standards are a critical component of the regulatory system and have the potential to incentivize best practices throughout the production chain. A risk-based, enforceable final product standard would better protect consumers by preventing product known to be most dangerously contaminated with *Salmonella* from reaching store shelves. In addition, such a standard would motivate industry to adequately control *Salmonella* as there will be a more direct financial cost of losing contaminated product (or reprocessing to kill *Salmonella*) if it does not meet an enforceable final product standard.

To conform to FSIS’s legal authority, any enforceable final product standard developed must rely on a finding by FSIS that a product failing to conform to the standard is adulterated under the Poultry Products Inspection Act (PPIA).¹⁶ As discussed in our January 2021 petition,¹⁷ the PPIA states that a product is adulterated “if it bears or contains any poisonous or deleterious substance which may render it injurious to health.”¹⁸ That part of the adulteration definition further states that if the substance is “not an added substance,” the product will not be adulterated “if the quantity of such substance in or on such article does not ordinarily render it injurious to health.” We described in our petition how *Salmonella* may be considered an added substance because it is not normally present in the muscle tissue of healthy animals, but rather is typically deposited through cross-contamination during slaughter and processing.

In addition to developing a standard based on the statute, we urge FSIS to utilize scientifically sound risk assessments when developing this Component (and the entire framework) to determine the expected public health outcome from the policy, such as a X% decrease in the incidence of illnesses. Such an assessment is necessary to ensure the benefits justify its costs, a

¹⁶ 21 U.S.C. §457(a)

¹⁷ 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://downloads.regulations.gov/FSIS-2021-0003-0001/content.pdf>

¹⁸ 21 U.S.C. §453(g)(1),

condition imposed on federal rulemaking.¹⁹ We expect that at a minimum, any application of the statutory standard to *Salmonella* as an adulterant should have a population health impact that will meet or exceed the Healthy People 2030 goal of a 25 percent reduction in illnesses attributable to poultry.²⁰

The current regulatory system fails to sufficiently tie its standards to product risk, and thus efforts to meet the performance standards did not actually improve public health. For example, as FSIS details in the framework proposal, the number of chicken samples in which FSIS detected any *Salmonella* decreased by more than 50% from 2017 to 2021. This decrease may have helped establishments meet the current performance standards. Human illness levels, however, were unaffected. A specific standard more closely aligned with product risk will better ensure that establishments are taking actions that improve public health as they attempt to meet the standard. In addition, by assessing the standard against a measurable public health target outcome, FSIS will be able to evaluate the standard for its success in generating public health improvements and gauge when modifications are necessary.

FSIS's statutory authority does not incorporate attention to feasibility in making the assessment of whether a product is adulterated. As referenced supra, however, each agency is required under presidential order to consider both the costs and benefits of new policies, particularly when engaging in rulemaking that may have large economic effects.²¹ Thus, FSIS should consider the costs of the new standard, paying attention to what is achievable with current best practices and reasonably foreseeable innovation when determining feasibility, keeping in mind that any new proposed standard is likely to drive rapid technological improvements. Such consideration will likely also be necessary in order to avoid unacceptable disruption of the food system, in addition to confirming that the benefits of the rule outweigh its costs.

FSIS should also consider setting stricter standards if there are higher risk poultry products, as risk assessments indicate. Previous risk assessments have examined setting product standards for individual product types, such as ground turkey,²² and the public health impacts from these specific product standards. Risk assessments informing the current reform process could indicate, for example, that comminuted poultry products have a higher prevalence of *Salmonella* contamination,²³ and may generally have more dangerous contamination due to additional establishment handling and the mixing of parts from different carcasses. The assessments could also provide evidence that comminuted products also pose a greater risk of being undercooked by consumers. Consequently, due to comminuted poultry products' increased risk of causing human illness, FSIS should set different final product standards for these products than for other poultry products.

A risk assessment will help determine whether the final product standard should be based on *Salmonella* enumeration, specific serotypes (as current technology enables), or some

¹⁹ Executive Order (E.O.) 12866.

²⁰ Healthy People 2030 objective FS-04: reduce infections caused by Salmonella. U.S. Department of Health and Human Services. Accessed September 10, 2021. <https://health.gov/healthypeople/objectives-and-data/browse-objectives/foodborne-illness/reduce-infections-caused-salmonella-fs-04>

²¹ Ibid.

²² Lambertini E, Ruzante JM, Kowalczyk BB. The public health impact of implementing a concentration-based microbiological criterion for controlling Salmonella in ground turkey. *Risk Anal.* 2021;41(8):1376-1395. doi:10.1111/risa.13635

²³ Quarterly sampling reports on Salmonella and Campylobacter: fiscal year 2022 fourth quarter, Jul 1, 2022–Sept 30, 2022. Food Safety and Inspection Service. https://www.fsis.usda.gov/sites/default/files/media_file/documents/Dataset_QSR_Salmonella_PercentPositive_FY22Q4.xlsx

combination of these factors. However, we encourage FSIS to consider including an element in the initial standards that focuses on serotype or other measures of virulence, as science is quickly evolving to precisely identify the genetic strains and associated factors that account for a strain's virulence. Attention to this element in an initial final product standard will help prepare the agency to target industry efforts towards high-risk strains as our knowledge grows further and advancing science and technology better enables rapid detection and effective control of *Salmonella* subtypes throughout supply chains.

Because strains of *Salmonella* can evolve over time, however, any consideration of virulence into the adulteration standard would necessarily require flexibility. FSIS should therefore account for changes in *Salmonella* populations and advances in science and technology while developing the final product standard and should structure final product standards to be as flexible as possible to allow for modifications without the years of delay frequently required to engage in notice-and-comment rulemaking. This will be especially relevant if FSIS incorporates serotypes or some other form of subtype into the standard, as we recommend. The agency should retain the ability to make adjustments as shifts in genetics, virulence, and prevalence change the *Salmonella* subtypes that are most relevant for public health. Identifying such types via interpretive rulemaking, as FSIS has previously done for STEC *E. coli*,²⁴ could provide a flexible framework that can be more easily adjusted over time.

FSIS should continue to engage with stakeholders to develop an evidence base as it moves forward in implementing the framework into regulatory action. We are encouraged that the agency is already engaged in consultation with the National Advisory Committee on Microbiological Criteria for Foods,²⁵ is developing a quantitative risk assessment,²⁶ and is expanding its exploratory sampling and quantification testing of products.²⁷ We also urge the agency to develop an effective means to collect and utilize data from available sources, including testing data collected by members of industry in the course of business.

Components 1 and 2

We commend FSIS for looking beyond final product standards to consider ways to better incentivize food safety from farm to fork within the framework. While the final product standard described in Component 3 is key to this approach, the verification of such a standard may not be sufficient to detect and address some food safety risks as every individual product leaving establishments cannot feasibly be tested by FSIS to ensure compliance with the standard. Providing additional standards at preharvest and processing therefore has the potential to offer the benefit of allowing FSIS more opportunities to detect and address potential food safety issues.

Component 1 requires incoming flocks to be tested for *Salmonella* before entering an establishment to incentivize the use of preharvest interventions that reduce the level of incoming

²⁴ Texas Food Industry Association n v. Espy, 870 F. Supp. 143 (W.D. Tex. 1994)

²⁵ 2021-2023 National Advisory Committee on Microbiological Criteria For Foods (NACMCF), FSIS charge: enhancing Salmonella control in poultry products. Food Safety and Inspection Service. Updated October 21, 2022. Accessed October 13, 2022. <https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021>

²⁶ Salmonella risk assessments and risk management questions. Food Safety and Inspection Service. Updated July 1, 2022. Accessed December 13, 2022. <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/salmonella-1>

²⁷ Constituent update-July 8, 2022. Food Safety and Inspection Service. July 8, 2022. Accessed December 13, 2022. <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-july-8-2022>

Salmonella. Specifically, incoming flocks would be tested against a predetermined target prior to slaughter, and establishments would be required to maintain documentation of such testing.

The potential benefits of such a testing requirement are, first, that producers would have an incentive to adopt effective preharvest measures, and second, that establishments would take action to further reduce food safety risks from flocks failing the standard, such as diverting the meat from such flocks for cooking or processing a more contaminated flock at the end of the day.

The key challenge for FSIS with this approach is ensuring that a testing program requirement effectively drives preharvest practices that will reduce final product risk. Without such validation, FSIS runs the risk of driving preharvest behaviors that help meet a preharvest testing requirement, but which do not actually further public health goals.

In some circumstances, preharvest flock testing results have correlated to final product risk, which indicates that a preharvest testing requirement could have merit in protecting public health.²⁸ If existing evidence is not sufficient to justify a uniform national testing target, FSIS could consider requiring establishments to develop a tailored testing program that specifies the testing target and actions to be taken if the target is exceeded. The agency could then provide one or two validated methods as a default, while allowing establishments the option to develop and validate methods more tailored to their operation. Such an approach would help build the evidence base for effective preharvest testing while also incentivizing effective preharvest interventions. Providing the flexibility to validate new methods could be especially relevant considering likely advances in science and technology in the future, potentially allowing for greater understanding of effective preharvest *Salmonella* control.

In addition to the preharvest testing requirement, we encourage FSIS to consider additional approaches to promoting preharvest best practices. Our January 2021 petition proposed that FSIS adopt a supply chain verification model and require establishments to verify that suppliers have adopted a set of validated preharvest interventions to reduce *Salmonella* and other food safety risks.²⁹

A third potential model would be to assign establishments to categories stipulating whether the establishment is fully requiring, partially requiring, or not requiring a specific set of FSIS-specified preharvest interventions of its suppliers. These could consist, initially, of the preharvest interventions already described in the FSIS Guideline for Controlling *Salmonella* in Raw Poultry.³⁰ Establishments would then be subject to increased verification testing based on their category status, with more testing for those establishments that have failed to implement preharvest best practices. This would be similar to the approach FSIS has taken with *Listeria* in ready to eat products, where establishments using fewer controls are required to carry out enhanced environmental testing.³¹ Major buyers could also incentivize best practices by selecting

²⁸ Evans NP, Evans RD, Regalado J, et al. Preharvest *Salmonella* Detection for evaluation of fresh ground poultry product contamination. *J Food Prot.* 2015;78(7):1266-1271. doi:10.4315/0362-028X.JFP-14-509

²⁹ 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://downloads.regulations.gov/FSIS-2021-0003-0001/content.pdf>

³⁰ FSIS guideline for controlling *Salmonella* in raw poultry. Food Safety and Inspection Service. June 2021. https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/FSIS-GD-2021-0005.pdf

³¹ FSIS compliance guideline: controlling *Listeria monocytogenes* in post-lethality exposed ready-to-eat meat and poultry products. Food Safety and Inspection Service. January 2014. https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/Controlling-Lm-RTE-Guideline-2014.pdf

only suppliers with the highest category status. Were such a program to be developed, we would also expect and encourage FSIS and industry to coordinate with the National Poultry Improvement Plan (NPIP) in developing a potential certification program to ensure farms were in compliance with category requirements.

In considering such a system, FSIS must bear in mind the burden on smaller producers, who could have less uniform supply chains. Such establishments may account for only a small fraction of the poultry supply and may face a higher economic burden from regulatory compliance.

Component 2 proposes two modifications to the current HACCP model for process control: specifying the location at which sampling will occur within the establishment and requiring a standardized statistical approach to process control. Both changes have the potential to give FSIS inspectors greater insight and control to prevent contamination during slaughter and processing.

Establishments are currently required to sample pre- and post-chill pursuant to current regulations,³² so the change being proposed may simply involve specifying the location at which pre-chill sampling would occur.

Regarding the use of statistical process control, we encourage FSIS to explore requiring a standardized approach to process control. This must necessarily include providing support and technical assistance to establishments that have not had capacity to previously incorporate this approach into their HACCP systems.

Conclusion

The FSIS framework is a laudable step by the agency in reforming poultry food safety. While all of the components of the framework have the potential to be beneficial in protecting public health, Component 3 is certainly the most important. The agency should focus on developing a strong scientific basis for any regulatory requirements and conduct extensive stakeholder engagement as it develops the components of the framework to best ensure the success of this reform effort.

For questions related to these comments, please contact James Kincheloe at jkincheloe@cspinet.org or (202) 777-8316

Sincerely,

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³² FSIS compliance guideline: modernization of poultry slaughter inspection; microbiological sampling of raw poultry. Food Safety and Inspection Service. June 2015. <https://www.fsis.usda.gov/sites/default/files/import/Microbiological-Testing-Raw-Poultry.pdf>