CENTER FOR Science IN THE Public Interest
Your Food and Health Watchdog

June 2, 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 Performance Standards for Salmonella in Raw Comminuted Pork and Intact or Non-Intact Pork Cuts and Related Agency Verification Procedures (Docket No. FSIS–2019–0023).

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 pork *Salmonella* performance standards.

We support the FSIS proposed performance standards because they will encourage pork establishments to prioritize reducing *Salmonella* contamination of pork products. With these standards, establishments will have a constant measure of their performance that they can refer to and aim to improve.[2] The proposed public posting of establishment performance could also create market pressure to decrease *Salmonella* contamination, as retailers may prioritize purchasing products from establishments that are meeting the performance standards.[3] In addition, the performance standards will be a useful supplemental resource to indicate to FSIS which establishments should receive additional regulatory attention and will better enable the agency to take action to ensure that establishment food safety programs are addressing foodborne illness risk.

While these performance standards will likely be beneficial in reducing pork *Salmonella* contamination and are a good first step in protecting consumers, similar performance standards for the poultry sector have not to date had the desired effect of reducing foodborne illnesses.[4] Accordingly, FSIS should proceed with these proposed pork performance standards, but should work quickly to develop new standards that more directly target the most dangerous *Salmonella* contamination types, similar to the standards that consumer advocates, scientists and industry are

[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 donations or corporate funding.
[2] "Changes to the Salmonella Verification Testing Program: Proposed Performance Standards for Salmonella in Raw Comminuted Pork and Intact or Non-Intact Pork Cuts and Related Agency Verification Procedures," 87 Federal Register 32 (February 16, 2022), pp. 8744-8780.
[3] Ibid.
[4] See 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.

advocating for in the poultry sector.[5]

I. Background on the Proposed Pork Performance Standards

Salmonellosis remains a key public health issue in the United States, sickening over 1.3 million people a year.[6] The salmonellosis rate has remained steady since 1996.[7] Contaminated pork causes an estimated 12.8 percent of these illnesses and is the third largest product category causing salmonellosis, behind chicken (16.8 percent) and fruits (13.5 percent).[8]

In 1996, FSIS first promulgated performance standards for pork establishments that set acceptable levels of pork carcass *Salmonella* contamination.[9] In 2011, the agency suspended sampling and testing pork carcasses, essentially discontinuing the original pork performance standards, due to the low positivity rate (2.7 percent) of targeted carcasses, stating that the standards "were not a good use of Agency resources."[10] The agency conducted exploratory sampling in establishments to help determine a new direction for *Salmonella* reduction efforts and standards and fully eliminated the previous standards in 2019.[11,12]

While the relatively low *Salmonella* carcass contamination rate led to the discontinuation of the previous carcass standards, the agency's exploratory sampling showed substantially more contamination of pork products that had undergone further processing into comminuted (ground or similar) pork, intact cuts, and nonintact cuts (16.4, 9.4, and 6.3 percent *Salmonella* positive, respectively).[13] Thus, FSIS developed the proposed performance standards to target these specific products. Though there are no standards for some products like the primal cuts of ham or loin, the targeted products represent the majority of the pork consumed in the United States.[14]

The proposed standards are based on a moving window of weekly *Salmonella* sampling of establishment products and allow for a maximum number of positive samples in the most recent 52-week period: 13 of 52 for raw comminuted pork and 6 of 52 for the raw intact or non-intact pork cuts.[15] The different standards for the product classes are due to differences in *Salmonella* prevalence between the product classes found by FSIS in sampling.[16] Establishments will be placed in categories based on how far their *Salmonella* prevalence falls below or exceeds the

[5] 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 May 19, 2011. https://www.cspinet.org/news/coalition-poultry-safety-reform-welcomes-launch-new-usda-effort-reduce-salmonella-illnesses.
[6] Salmonella. Centers for Disease Control and Prevention. Updated February 2, 2022. Accessed May 19, 2022. https://www.cdc.gov/salmonella/index.html.
[7] Pathogen surveillance - *Salmonella*. Centers for Disease Control and Prevention. Accessed May 10, 2022. https://wwwn.cdc.gov/foodnetfast.
[8] Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2019 for Salmonella, Escherichia coli O157, Listeria monocytogenes and Campylobacter using multi-year outbreak surveillance data. 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.
[9] "Changes to the Salmonella Verification Testing Program: Proposed Performance Standards for Salmonella in Raw Comminuted Pork and Intact or Non-Intact Pork Cuts and Related Agency Verification Procedures," 87 Federal Register 32 (February 16, 2022), pp. 8744-8780.
[10] "Modernization of Swine Slaughter Inspection," 83 Federal Register 22 (February 1, 2018), pp. 4780-4823.
[11] "Modernization of Swine Slaughter Inspection," 83 Federal Register 22 (February 1, 2018), pp. 4780-4823.
[12] "Modernization of Swine Slaughter Inspection," 84 Federal Register 190 (October 1, 2019), pp. 52300-52349.
[13] Public health effects of performance standards for comminuted pork and pork cuts. Washington D.C.: U.S. Department of Agriculture Food Safety and Inspection Service; 2020.
[14] Ibid.
[15] "Changes to the Salmonella Verification Testing Program: Proposed Performance Standards for Salmonella in Raw Comminuted Pork and Intact or Non-Intact Pork Cuts and Related Agency Verification Procedures," 87 Federal Register 32 (February 16, 2022), pp. 8744-8780.
[16] Ibid.

applicable standard, and establishment categorization will be publicly posted.[17]

II. The Proposed Standards Will Motivate Pork Establishments to Reduce *Salmonella* Contamination of Pork Products

The proposed *Salmonella* performance standards will establish a regulatory testing standard for *Salmonella*, which is lacking in the current regulatory system, encouraging establishments to critically assess their *Salmonella* policies.

Establishment practices can play a large role in causing pork products to be contaminated with *Salmonella*. Some *Salmonella* in the final product can enter from the slaughter environment due to improper slaughter plant cleanliness practices.[18] Cross-contamination between swine herds in holding pens, inadequate holding pen cleaning practices, and stressful swine holding pen conditions can result in a greater prevalence and level of *Salmonella* shedding in swine entering the slaughter line.[19] During and after slaughter, *Salmonella* can be spread between carcasses along the same slaughter line due to inadequate worker sanitation practices or poor evisceration techniques that pierce the intestinal tract.[20,21] Harrison et al (2022) inoculated swine with *Salmonella* 4,[5],12:i, one of the more common pork strains causing human salmonellosis and commonly found in pork.[22] They identified no *Salmonella* colonization of skeletal muscle at slaughter and concluded that "contamination in pork products most likely results from cross-contamination of meat by digesta or lymph node tissue during processing."

Pork establishments should have policies to reduce many of these opportunities for *Salmonella* contamination, and the proposed standards will encourage them to evaluate their food safety systems. The weekly testing required by the standards will provide a measure of *Salmonella* control that plants can refer to and use to compare themselves to other plants.

In addition, the proposed public posting of an establishment's performance standard status may add market pressure to ensure that their *Salmonella* controls are sufficient, as major purchasers may assess establishment food safety performance when making purchasing decisions. This factor likely contributed to the benefits of performance standards in poultry: FSIS began posting the performance categorization of poultry establishments in 2006, and in the four years following that move, *Salmonella* rates in poultry dropped 60%.[23]

Thus, we support the agency's performance standard proposal for pork, as the additional pressure on establishments to prioritize *Salmonella* control should cause a reduction in *Salmonella* contamination of pork products and may substantially benefit public health.

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[17] Ibid.
[18] Arguello H, Alvarez-Ordoñez A, Carvajal A, et al. Role of slaughtering in Salmonella spreading and control in pork production. *J Food Prot*. 2013;76(5):899-911.
[19] Ibid.
[20] Ibid.
[21] Marin C, Chinillac MC, Cerdà-Cuéllar M, et al. Contamination of pig carcass with Salmonella enterica serovar Typhimurium monophasic variant 1,4[5],12:i:- originates mainly in live animals. *Sci Total Environ* 2020;703:134609.
[22] Harrison OL, Gebhardt JT, Paulk CB, et al. Inoculation of weaned pigs by feed, water, and airborne transmission of Salmonella enterica serotype 4,[5],12:i. *Journal of food protection* 2022;85:693-700.
[23] Food safety: USDA should take further action to reduce pathogens in meat and poultry products. Washington D.C.: United States Government Accountability Office; 2018.

III. The Proposed Standards Will Better Enable FSIS to Target Establishments with Poor *Salmonella* Control Practices

The performance standards can play an important role in allowing FSIS to focus attention on establishments that represent the greatest risk to consumers.

While performance standards alone are not grounds for FSIS regulatory enforcement action due to a 2001 judicial decision,[24] they can provide substantial evidence that action is warranted. For example, FSIS issued a notice of suspension to Mar-Jac Poultry on April 11, 2018, shortly after the establishment was reclassified for failing to meet poultry microbial performance standards. In the notice, the agency cited failure to meet microbial performance standards as part of the body of evidence indicating that the establishment's food safety measures were inadequate.[25]

The proposed performance standards will enable similar actions in pork establishments. In the federal register notice announcing the proposed standards, FSIS emphasized that the agency could collect additional samples at a failing establishment and conduct establishment assessments like Public Health Risk Evaluations and Food Safety Analyses based on failures to meet the performance standards. According to the agency, "If, after 120 days from not meeting the standard, the establishment has not been able to demonstrate reduced variability of process control…FSIS would likely take an enforcement action, such as issuing a Notice of Intended Enforcement or suspending inspection."[26]

We support providing FSIS with these additional means to target problematic food safety practices and consequently urge the agency to implement these standards and fully utilize them.

IV. We Urge FSIS to Begin Development of More Risk-Based Pork *Salmonella* Standards

While the agency's proposed standards are a good first step in better protecting public health from *Salmonella*-contaminated pork products, the inability to date of the poultry *Salmonella* performance standards to reduce human illness rates indicates that FSIS should also begin to develop risk-based pork *Salmonella* standards that may be more beneficial to public health.

A form of poultry *Salmonella* performance standards has been in existence since 1996.[27] Since then, the rate of *Salmonella* contamination in poultry products has decreased substantially.[28] There has been no corresponding decrease, however, in the salmonellosis rate in the United States in the same time period, which has hovered around 15 cases per 100,000 population a year[29] despite an estimated 23 percent of these cases being attributed to poultry products.[30]

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[24] *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432 (5th Cir. 2001)
[25] Notice of Suspension from USDA to Mr. Joe Colee, Complex Manager, Mar-Jac Poultry, LLC; Est P517; 1301 James Street; Hattiesburg, MS 39401. April 11, 2018.
[26] "Changes to the Salmonella Verification Testing Program: Proposed Performance Standards for Salmonella in Raw Comminuted Pork and Intact or Non-Intact Pork Cuts and Related Agency Verification Procedures," 87 Federal Register 32 (February 16, 2022), pp. 8744-8780.
[27] Ibid.
[28] Hale KR. Salmonella Trends –What the Science Tells Us. Oral presentation at: USDA FSIS Virtual Public Meeting: Salmonella-State of the Science; September 2020.
[29] Pathogen surveillance - *Salmonella*. Centers for Disease Control and Prevention. Accessed May 10, 2022. https://wwwn.cdc.gov/foodnetfast.
[30] Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2019 for Salmonella, Escherichia coli O157, Listeria monocytogenes and Campylobacter using multi-year outbreak surveillance data. 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.

This discrepancy between decreased *Salmonella* poultry carcass contamination and the unchanged human salmonellosis rate may be due to a variety of factors, including the lack of regulatory enforceability, an initially limited scope to a minority of poultry products, and the fact that the standards allow for substantial prevalence of contamination in many products. But an important potential opportunity for reform stems from the fact that the standards are not currently tailored based on risk. Specifically, they fail to account for bacterial levels in contaminated products and differences in pathogenicity of individual *Salmonella* serotypes.[31] For example, recent modeling of possible poultry *Salmonella* microbial standards indicated that eliminating chicken part lots with a high concentration of *Salmonella* would reduce illness counts by 60.2 percent.[32] In addition, one of the most common *Salmonella* serotypes found on chicken products, *Salmonella* Kentucky (30 percent of FSIS chicken *Salmonella* positives in the last quarter of 2021), causes very few illnesses, meaning its pathogenicity is relatively low compared to other, less common serotypes.[33,34]

Pork product *Salmonella* sampling by FSIS indicates a similar pattern. One of the consistently most common serotypes in pork is *Salmonella* Anatum, representing about 10 percent of samples in 2021.[35] Considering the total number of serotype-identified *Salmonella* cases detected in 2020 in the subset of the population in the Foodborne Diseases Active Surveillance Network in the United States (5895) and the most recent salmonellosis attribution estimate for pork (12.8 percent), the *Salmonella* Anatum salmonellosis case count should have been about 75 (.10* 0.128*5895).[36,37] Instead, the case count was only 23, indicating that the case rate for *Salmonella* Anatum was 3 times lower than it would have been if all *Salmonella* were equally pathogenic.[38] Other common pork *Salmonella* serotypes like Derby and Johannesburg follow similar patterns.[39,40,41,42]

Some *Salmonella* mitigation factors can be serotype-specific. These include vaccination (which already exist for some serotypes like *Salmonella* Typhimurium and *Salmonella* Choleraesuis)

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[31] See 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.

[32] Lambertini E, Ruzante JM, Chew R, et al. The public health impact of different microbiological criteria approaches for Salmonella in chicken parts. *Microbial Risk Analysis* 2019;12:44-59.

[33] Food Safety and Inspection Service. Quarterly sampling reports on Salmonella: fiscal year 2021, Oct 1, 2020–Sep 30, 2022. Updated April 29, 2022. Accessed May 20, 2022. https://www.fsis.usda.gov/sites/default/files/media_file/2022-04/Salmonella-Serotype-QSR-FY22.xlsx.

[34] Pathogen surveillance. Centers for Disease Control and Prevention. Accessed May 10, 2022. https://wwwn.cdc.gov/foodnetfast.

[35] Food Safety and Inspection Service. Quarterly sampling reports on Salmonella: fiscal year 2021, Oct 1, 2020–Sep 30, 2021. Updated April 29, 2022. Accessed May 20, 2022. https://www.fsis.usda.gov/sites/default/files/media_file/2022-01/Salmonella-Serotype-QSR-FY21Q4.xlsx.

[36] Pathogen surveillance. Centers for Disease Control and Prevention. Accessed May 10, 2022. https://wwwn.cdc.gov/foodnetfast.

[37] Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2019 for Salmonella, Escherichia coli O157, Listeria monocytogenes and Campylobacter using multi-year outbreak surveillance data. 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.

[38] Pathogen surveillance. Centers for Disease Control and Prevention. Accessed May 10, 2022. https://wwwn.cdc.gov/foodnetfast.

[39] Food Safety and Inspection Service. Quarterly sampling reports on Salmonella: fiscal year 2021, Oct 1, 2020–Sep 30, 2021. Updated April 29, 2022. Accessed May 20, 2022. https://www.fsis.usda.gov/sites/default/files/media_file/2022-01/Salmonella-Serotype-QSR-FY21Q4.xlsx.

[40] Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2019 for Salmonella, Escherichia coli O157, Listeria monocytogenes and Campylobacter using multi-year outbreak surveillance data. 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.

[41] Pathogen surveillance. Centers for Disease Control and Prevention. Accessed May 10, 2022. https://wwwn.cdc.gov/foodnetfast.

[42] Salmonella Derby Theoretical Case Count: .07*.128*5895=52.8 Actual Case Count: 10
Salmonella Johannesburg Theoretical Case Count: .07*.128*5895=52.8 Actual Case Count: 4

and other production chain-wide efforts against a specific harmful serotypes.[43] Such measures have been effective in achieving reduction of specific harmful serotypes in poultry in the United States.[44]

Consequently, CSPI and other consumer groups petitioned FSIS in 2021 to create enforceable poultry product standards that target the most dangerous types of *Salmonella* contamination.[45] The consumer groups also joined leading poultry industry members, scientists, and other advocates in a coalition to request that FSIS create enforceable risk-based standards for poultry that would be focused on the more dangerous types of *Salmonella* contamination.[46]

Thus, while we believe the current FSIS proposal will have benefits for consumers and should be implemented in the near term, we urge FSIS to expeditiously develop standards that will encourage the pork production system to focus on action against the highest-risk *Salmonella* serotypes that have the greatest impact on public health.

V. Conclusion

The proposed standards are a laudable step by the agency in working to ensure the safety of the pork reaching consumers. We support their implementation as proposed, though we look forward to working with the agency to develop additional risk-based pork standards tailored to specific serotypes and levels of contamination.

Sincerely,

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[43] de la Cruz ML, Conrado I, Nault A, Perez A, Dominguez L, Alvarez J. Vaccination as a control strategy against Salmonella infection in pigs: A systematic review and meta-analysis of the literature. *Res Vet Sci*. 2017;114:86-94.
[44] Tauxe R. Public Health Challenge of Salmonellosis in the 21st Century. Presentation at: Salmonella: State of the Science; September 22, 2020; virtual.
[45] 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.
[46] 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 May 19, 2011. https://www.cspinet.org/news/coalition-poultry-safety-reform-welcomes-launch-new-usda-effort-reduce-salmonella-illnesses.