

June 2, 2022

Sandra Eskin

Deputy Under Secretary for Food Safety

Food Safety and Inspection Service

U.S. Department of Agriculture

*SUBMITTED VIA REGULATIONS.GOV*

**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)**

Dear Under Secretary Eskin:

The Consumer Federation of America (CFA) appreciates the opportunity to comment on the above-referenced proposed performance standards. CFA is an association of over 250 non-profit consumer organizations that was established in 1968 to advance consumer interest through research, advocacy, and education. Member organizations include local, state, and national consumer advocacy groups, senior citizen associations, consumer cooperatives, trade unions, and food safety organizations.

We commend FSIS for taking this long overdue step to protect consumers from foodborne illness caused by *Salmonella* in pork. The proposed standards will undoubtedly improve food safety by exposing poor performing companies and creating new incentives for investment in reducing pathogen contamination. However, FSIS should go further. In particular, we urge the agency to develop product standards that better protect consumers from dangerous *Salmonella* contamination in pork, with an aim towards building on the proposed standards to create incentives for food safety risk mitigation more closely linked to public health. The agency should also fully enforce existing prohibitions on fecal contamination.

Pork and Foodborne Illness

Foodborne illness caused by pork imposes tremendous personal and economic costs on consumers. According to the Centers for Disease Control and Prevention (CDC) estimates, pork causes over half a million cases of foodborne illness in the U.S. each year, leading to nearly 3,000 hospitalizations, and almost one hundred deaths.[[1]](#footnote-1) *Salmonella* accounts for the bulk of this public health burden. According to USDA estimates, it is the costliest foodborne pathogen, causing an estimated $3.7 billion a year in associated medical costs alone each year.[[2]](#footnote-2)

Pork accounts for a large and growing share of the public health burden caused by *Salmonella*. The most recent analysis of outbreak data by public health authorities—ending in the year 2019—attributes 12.8% of *Salmonella* infections to pork.[[3]](#footnote-3) This figure has grown significantly in just the two years since the estimates cited in the proposed rule, which attribute 10.3% of salmonellosis cases to pork. And pork’s current contribution to *Salmonella* illness is more than double of what it was in the late 1990s. Only chicken (16.8%) and the broad category of fruits (13.5%) are estimated to cause more *Salmonella* infections than pork, which causes more salmonellosis than turkey, eggs, or beef.

 Background

 As noted in the proposed rule, these standards operate to implement FSIS’ 1996 Pathogen Reduction; Hazard Analysis and Critical Control Point Systems (PR/HACCP) rule.[[4]](#footnote-4) According to FSIS’ own characterization, the PR/HACCP rule makes little sense without meaningful microbial performance standards: “microbiological performance standards” are “part of a fundamental shift in FSIS regulatory philosophy and strategy,” away from “intensive ‘command-and-control’ prescription” towards a system that sets objective targets while “provid[ing] industry with the flexibility to devise the optimal means of achieving food safety objectives.”[[5]](#footnote-5) As FSIS explained in 1996, “[p]athogen-specific performance standards for raw products are an essential component of the FSIS food safety strategy because they provide a direct measure of progress in controlling and reducing the most significant hazards associated with raw meat and poultry products.”[[6]](#footnote-6)

 Given the “essential” relationship of microbiological performance standards to the FSIS regulatory scheme, the agency’s decision to operate without a performance standard for pork over the past decade is perplexing. As the proposed rule indicates, the 1996 PR/HACCP rule established a *Salmonella* performance standard for whole pork carcasses. However, by 2012, pork processors had become so adept at using anti-microbial sprays[[7]](#footnote-7) and other strategies to avoid generating positive samples that FSIS decided to abandon its efforts to test against the standard. FSIS declined to replace the discredited whole carcass standard with some other measure of *Salmonella* contamination in pork, even as it sought to overhaul the pork processing inspection system and allow processors to increase line speeds through expansion of the pilot HACCP-based Inspection Models Project (HIMP). As CFA explained in comments on the agency’s proposal to expand HIMP, the absence of microbiological performance standards left the agency unable to meaningfully evaluate the food safety performance of HIMP pilot plants, and of plants that have since sought to join the program.[[8]](#footnote-8)

The proposed performance standards and public disclosure of compliance data are long overdue.

The proposed rule explains that, in the years leading up to 2012, “percent positive findings were very low” in FSIS testing of whole hog carcasses, and so the agency decided to stop testing against that standard. Nevertheless, to this day, *Salmonella* contamination in pork products sold to consumers appears to have remained as high as ever. According to one recent analysis, a baseline study for ground pork reported in 2020 yielded essentially the same (alarmingly high) proportion of *Salmonella* positives (28.9%) as a similar study conducted in 1998, in which 30% of samples tested positive.[[9]](#footnote-9) Pork’s persistently high contamination rates contrast with declining rates for chicken, turkey, and beef. The study authors, three of whom work at FSIS, speculate that “the absence of performance standards,” may account for this “lack of an observable reduction in *Salmonella* prevalence for pork.”[[10]](#footnote-10)

 Performance standards will do little to drive down contamination rates, however, if public disclosure of an establishment’s compliance status does not occur. As discussed below, the Fifth Circuit Court of Appeal’s decision in *Supreme Beef v. USDA* has greatly diminished the effectiveness of *Salmonella* performance standards for meat and poultry. With FSIS unable to enforce the standards, the agency must follow through on its plan to post the category of individual establishments on the FSIS website. As FSIS noted in its recent proposed rule to establish new *Salmonella* performance standards for beef, “web posting delivers greater transparency, thereby providing the public with the tools and information it needs to make informed food safety decisions.”[[11]](#footnote-11) According to USDA’s Economic Research Service, web posting appears to have motivated poultry processors to lower *Salmonella* contamination rates.[[12]](#footnote-12) And the proposed rule’s estimates of associated public health benefits is founded upon an assumption that web posting will take place. According to the risk assessment, “to generate incentives for passing the standards, information about the classification of individual establishments with respect to the performance standards must be available publicly.”[[13]](#footnote-13) FSIS should therefore avoid delays in posting establishments’ classifications.

FSIS should also continue to use compliance with the performance standards as a trigger for greater scrutiny of the establishment’s HACCP plans, follow-up sampling, and more rigorous inspection procedures such as Public Health Risk Evaluations. The experience with poultry processors, however, suggests that these incentives, while important, will not be as important in motivating establishments to comply with the standards.[[14]](#footnote-14)

Even without universal compliance, the proposed performance standards will significantly improve public health. According to the FSIS risk assessment, if just “45 percent of establishments that do not initially meet the standards,” come out of “category 3” within two years, the new standards will help to avert thousands of *Salmonella* infection cases, worth an estimated $107.94 million. These estimates are fraught with uncertainty and, as discussed below, more targeted standards could serve to better protect consumers. However, in the absence of any microbiological criteria, the proposed standards are a welcome step in the right direction.

 FSIS should develop enforceable product standards to build on the proposed performance standards.

The proposed *Salmonella* performance standards for ground pork and pork parts resemble *Salmonella* performance standards that FSIS has recently put in place for ground poultry and poultry parts and standards that the agency has proposed for beef products. These performance standards suffer two weaknesses. First, they are not enforceable. According to the Fifth Circuit Court of Appeal’s decision in *Supreme Beef v. USDA*, FSIS cannot withdraw inspectors from an establishment solely because the establishment fails to meet performance standards for a pathogen, so long as FSIS does not consider that pathogen to be an adulterant. Second, they are less protective to consumers and unnecessarily burdensome to industry, compared to microbiological standards that apply to products rather than an establishment’s performance.

Product standards that prevent companies from selling pork contaminated with dangerous *Salmonella* would be enforceable, and could better protect consumers than the proposed performance standards. First, while FSIS may lack the legal authority to enforce performance standards that measure an establishment’s capacity to minimize the frequency of *Salmonella* contamination, no serious question applies to whether it can enforce a product standard that measures whether a product is adulterated. Indeed, the agency takes just this approach in banning the sale of ground beef contaminated with shiga toxin producing *E.coli* (STEC). While *Salmonella* in pork is more ubiquitous than STECs in beef, FSIS need not apply a zero-tolerance standard for all *Salmonella*. Rather, it can target specific serovars such as *Salmonella* Typhimurium, which represent a particular burden to public health. *S.* Typhimurium is known to be transmitted through pork and it is the second most common serovar isolated from case patients in the United States.[[15]](#footnote-15) Fortunately, hog farmers currently have access to a vaccine against *S.* Typhimurium, administered “in a single oral dose.”[[16]](#footnote-16) However, under the current rules, hog farmers have little incentive to vaccinate pigs against *S.* Typhimurium, as the bacteria causes less harm to the pigs than other serovars, such as *S.* Choleraesuis, which are less frequently implicated in human illness. Were FSIS to consider pork contaminated with *S.* Typhimurium to be adulterated, the new rule would help to facilitate wider adoption of such life-saving technologies.

As an initial step, FSIS might define as adulterated only pork contaminated with a certain level of one or more *Salmonella* serovars. In other words, if the concentration per sampled unit of *S.* Typhimurium or some other designated pathogen exceeds the threshold set by FSIS, the agency disallows sale of the sampled lot without further treatment. Levels of contamination may not correlate with the prevalence of contaminated samples. Indeed, the FSIS risk assessment assumes that these two variables are independent. Nevertheless, “higher levels of *Salmonella* are more likely to cause illness” and so targeting highly contaminated product may benefit public health.[[17]](#footnote-17) The relationship between high bacterial loads and public health outcomes has led New Zealand, for example, to adopt an enumeration limit in tandem with a “prevalence performance target” for *Campylobacter* in chicken.[[18]](#footnote-18) In recent years, testing technologies have evolved such that inspectors would need only a few hours to verify that a sample does not contain a particular microorganism, at a particular concentration.[[19]](#footnote-19)

FSIS should use available fluorescent imaging technology to fully enforce the existing prohibition against contamination of pork with fecal material.

FSIS currently has a product standard for pork insofar as it “enforces a ‘zero tolerance’ standard for visible fecal material, ingesta, or milk on carcasses and parts at the time of inspection.”[[20]](#footnote-20) FSIS regulations require that establishments “prevent contamination with fecal material, urine, bile, hair, dirt, or foreign matter,” and that “if contamination occurs, it shall be promptly removed in a manner satisfactory to the inspector.”[[21]](#footnote-21) This “zero tolerance” policy makes sense because *Salmonella* and other pathogens tend to colonize hogs’ intestinal tracts and fecal material initially on a carcass or released during the slaughter process creates food safety risk.[[22]](#footnote-22) However, FSIS does not pursue “zero tolerance” to the extent that it might.

By relying solely on visual inspection of hog carcasses, FSIS allows some fecal contamination to escape detection. Fluorescent imaging technology is capable of catching many of these oversights.[[23]](#footnote-23) Yet, under the current rules, establishments have little incentive to invest in these technologies or to minimize fecal contamination beyond what an inspector is likely to see. FSIS should integrate fluorescent imaging technology into the “Livestock Zero Tolerance Verification inspection task.” Doing so would make the agency’s “verification” more meaningful, and quite possibly reduce *Salmonella* infections caused by pork as much or more than the proposed performance standards.

Conclusion

The proposed performance standards will provide an important measure of food safety across the pork processing industry, allowing for an “apples-to-apples” comparison of establishments operating under different inspection regimes, and employing different food safety management systems. FSIS should hasten to implement the standards and publish the compliance status of establishments. At the same time, the agency should develop enforceable product standards that are more closely aligned with public health objectives, and incorporate new tools, such as fluorescent imaging, to fully enforce existing inspection standards.

Thank you for your consideration of these comments.

Sincerely,

Thomas Gremillion

 Director of Food Policy

 Consumer Federation of America

1. Painter, J.A., Hoekstra, R.M., Ayers, T., Tauxe, R.V., Braden, C.R., Angulo, F.J., Griffin, P.M., Centers for Disease Control and Prevention (CDC), “Estimates of annual domestically acquired foodborne illnesses attributed

to specific food commodities and commodity groups, by pathogen type, United States, 1998–2008,” (March, 2013)

<https://wwwnc.cdc.gov/eid/article/19/3/11-1866-t1> [↑](#footnote-ref-1)
2. News Desk, “USDA: *Salmonella* Tops List of 15 Most Costly Pathogens,” Food Safety News (Jan. 7, 2015), <http://www.foodsafetynews.com/2015/01/salmonella-costs-the-us-3-7-billion-per-year-among-other-costly-pathogens/#.WtZjA4jwaUk> [↑](#footnote-ref-2)
3. The Interagency Food Safety Analytics Collaboration (IFSAC), Foodborne illness source attribution estimates for 2019 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States (October, 2021), <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf> [↑](#footnote-ref-3)
4. “Pathogen Reduction; Hazard Analysis and Critical Control Point Systems” [“PR/HACCP Rule”], 61 Fed. Reg.

38805 (July 25, 1996), available at: <https://www.govinfo.gov/content/pkg/FR-1996-07-25/pdf/FR-1996-07-25.pdf> [↑](#footnote-ref-4)
5. *Id.*  [↑](#footnote-ref-5)
6. *Id.*  [↑](#footnote-ref-6)
7. *See, e.g.,* Rodriguez, G., Acuff, G., Castillo, A., Department of Animal Science, Texas A&M University, Development of a Carcass Sanitizing Spraying System for Small and Very Small Slaughterhouses, <https://www.fsis.usda.gov/sites/default/files/media_file/2020-09/Coop_Agree_09-2003.pdf>; Richard Mitchell, “Antimicrobial spraying is serious business,” *The National Provisioner* (Dec. 28, 2021), <https://www.provisioneronline.com/articles/111916-antimicrobial-spraying-is-serious-business>. [↑](#footnote-ref-7)
8. *See* CFA Comments on Proposed Hog Slaughter Modernization rule (May 2, 2018), <https://consumerfed.org/testimonial/cfa-opposes-proposed-hog-slaughter-rule/> [↑](#footnote-ref-8)
9. Williams et al. “Changes in Salmonella Contamination in Meat and Poultry Since the Introduction of the Pathogen Reduction and Hazard Analysis and Critical Control Point Rule. *J Food Prot.* 2020 Oct 1;83(10):1707-1717, p.1715. <https://doi.org/10.4315/jfp-20-126>. [↑](#footnote-ref-9)
10. *Id.* at 1716. [↑](#footnote-ref-10)
11. Changes to the *Salmonella* Verification Testing Program: Proposed Performance Standards for *Salmonella* in Raw Ground Beef and Beef Manufacturing Trimmings and Related Agency Verification Procedures, *See* <https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-notices/changes-salmonella-verification-testing> at 57691. [↑](#footnote-ref-11)
12. Ollinger, M., Wilkus, J., Hrdlicka, M., and Bovay, J. “Public Disclosure of Tests for *Salmonella*: The

Effects on Food Safety Performance in Chicken Slaughter Establishments.” Economic Research Report No. (ERR-231), (May, 2017), <https://www.ers.usda.gov/publications/pub-details/?pubid=83660> [↑](#footnote-ref-12)
13. Risk Assessment and Analytics Staff, Office of Public Health Science, Food Safety and Inspection Service, U.S. Department of Agriculture, Public Health Effects of Performance Standards for Comminuted Pork and Pork Cuts, (April, 2020), <https://www.fsis.usda.gov/sites/default/files/media_file/2022-02/Pork_Salmonella_Performance_Standards_Risk_Assessment_April_8_2020_Feb_8_2022.pdf> [↑](#footnote-ref-13)
14. As FSIS data indicates, a sizeable minority of poultry establishments are “category 3.” *See* Performance Categorizations available at: <https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/microbiological-testing-program-rte-meat-and-0> [↑](#footnote-ref-14)
15. [*Salmonella Typhimurium*](https://confluence.cornell.edu/display/FOODSAFETY/Salmonella%2BTyphimurium), [https://confluence.cornell.edu/display/FOODSAFETY/Salmonella+Typhimurium](https://confluence.cornell.edu/display/FOODSAFETY/Salmonella%2BTyphimurium) [↑](#footnote-ref-15)
16. Enterisol® *Salmonella* T/C | Boehringer Ingelheim Vetmedica, <https://www.bi-vetmedica.com/species/swine/products/enterisol_salmonellatc.html> [↑](#footnote-ref-16)
17. McEntire, J., Acheson, D., Siemens, A., Eilert, S., and Robach, M. The Public Health Value of Reducing *Salmonella* Levels in Raw Meat and Poultry, Food Protection Trends, Vol 34, No. 6, p.386-392, (Nov/Dec, 2014), available at: <https://www.foodprotection.org/files/food-protection-trends/NovDec-14-McEntire.pdf> [↑](#footnote-ref-17)
18. Haumaru Kai Aotearoa, New Zealand Food Safety, Review of the *Campylobacter* Regulatory Limits for Meat Chickens (June, 2019), <https://www.mpi.govt.nz/dmsdocument/35265-discussion-paper-review-of-the-campylobacter-regulatory-limits-for-meat-chickens-pdf> [↑](#footnote-ref-18)
19. Hyeon, J., Mann, D.A., Wang, J., Kim, W.K., Deng, X. Rapid detection of *Salmonella* in poultry environmental samples using real-time PCR coupled with immunomagnetic separation and whole genome amplification. [Vol 98, Issue 12](https://www.sciencedirect.com/journal/poultry-science/vol/98/issue/12), (December, 2019), Page 6973-6979. <https://www.sciencedirect.com/science/article/pii/S0032579119580087> [↑](#footnote-ref-19)
20. <https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/6420.2.pdf> [↑](#footnote-ref-20)
21. 9 CFR 310.18(a). [↑](#footnote-ref-21)
22. *See* Baer et al. “Pathogens of Interest to the Pork Industry: A Review of Research on Interventions to Assure Food Safety,” Comprehensive Reviews in Food Science and Food Safety Volume 12, Issue 2 (March 2013),

<https://onlinelibrary.wiley.com/doi/full/10.1111/1541-4337.12001>. [↑](#footnote-ref-22)
23. Gorji, H.T., Shahabi, S.M., Sharma, A. et al. Combining deep learning and fluorescence imaging to automatically identify fecal contamination on meat carcasses. Sci Rep 12, 2392 (2022). <https://doi.org/10.1038/s41598-022-06379-1>. [↑](#footnote-ref-23)