

SAFE FOOD COALITION

1620 I Street, NW, Suite 200, Washington, DC 20006 202-939-1010

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Roberta Wagner
Assistant Administrator
Office of Policy and Program Development
Food Safety and Inspection Service
U.S. Department of Agriculture
331-E Jamie L. Whitten Federal Bldg.
Washington, DC 20250-3700

RE: Eliminating Unnecessary Requirements for Hog Carcass Cleaning (Docket No. FSIS_FRDOC_0001-0568)

Dear Assistant Administrator Wagner:

The undersigned members of the Safe Food Coalition write to oppose the Food Safety and Inspection Service's (FSIS's) proposal to eliminate rules requiring the cleaning of hog carcasses prior to any incision, codified at 9 C.F.R. 310.11. Contaminated pork represents a serious public health burden in the United States, causing over half a million cases of foodborne illness each year. Consumers deserve better protections against harmful pathogens in pork, from government and industry alike. We acknowledge that shifting from a "command-and-control" approach to more performance-based criteria in regulations could ultimately benefit consumers. However, FSIS has failed to maintain meaningful performance-based criteria for hog slaughter. As a result, the proposed action presents an unacceptable risk of hurting consumers.

Prior to making the proposed changes, FSIS should:

- Implement meaningful *Salmonella* reduction performance standards for pork products;
- Publish the identities of pork processors that fail to meet performance standards, as the agency does for poultry processors;
- Evaluate the impact that removing carcass cleaning requirements has had on pathogen levels in plants that have received waivers from the regulation;
- Develop a plan to evaluate the food safety impact of the proposed action across all plants.

These measures, at a minimum, are needed to support FSIS' claim that the carcass cleaning requirements are "unnecessary," and to ensure that the "more efficient" procedures adopted in the wake of this rulemaking do not compromise food safety.

The burden of foodborne illness transmitted through pork

Contaminated pork sickens hundreds of thousands of people each year in the United States. According to the latest estimates from the Centers for Disease Control and Prevention (CDC), pork causes over half a million cases of foodborne illness in the U.S. annually, leading to nearly 3,000 hospitalizations, and almost one hundred deaths.¹ USDA has identified *Salmonella* as the costliest foodborne pathogen, with an estimated \$3.7 billion a year in associated medical costs alone each year.² According to CDC, the percentage of *Salmonella* outbreaks attributed to contaminated pork has risen steadily in recent years, more than doubling between 1998 and 2008.³ The most recent estimates indicate that pork causes nearly ten percent of *Salmonella* outbreaks each year in the United States.⁴ Effective strategies to reduce *Salmonella* may operate at many different stages of production, from the farm to retail. Controls against fecal contamination at slaughter are particularly critical, however, because *Salmonella* tends to colonize hogs' intestinal tracts, and fecal material initially on a carcass can spread the pathogen.⁵

Food safety standards are a necessary component of HACCP-based regulation

Effective strategies to reduce *Salmonella* and other foodborne pathogens in pork should take place from farm to retail. Through appropriate sampling and increasingly stringent pathogen reduction performance standards, FSIS can create incentives for meatpackers to adopt more effective pathogen reduction strategies inside the slaughterhouse, and to contract with hog farmers that deploy vaccines, improve sanitation, and adopt other proven strategies for reducing pathogen loads on live animals entering the slaughterhouse. To the extent that successful food safety strategies conflict with FSIS regulatory prescriptions, the agency should explore ways to give firms more flexibility. Measurable standards, however, are key to ensuring that “flexibility” does not become an abdication of the agency’s duty to assure food safety.

The past several decades have seen a regulatory shift away from inflexible “command and control” prescriptive regulatory requirements to a more flexible Hazard Analysis and Critical Control Point (HACCP)-based approach. When FSIS first proposed adopting its HACCP rule, the agency

¹ Centers for Disease Control and Prevention, “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>

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>

³ Centers for Disease Control and Prevention, Surveillance for Foodborne Disease Outbreaks — United States, 1998–2008, FIGURE 14. Estimated mean percentage and 95% confidence intervals of foodborne disease outbreaks caused by *Salmonella* attributed to selected food commodities, by year interval — Foodborne Disease Outbreak Surveillance System, United States, 1998–2008,” (June 28, 2013), https://www.cdc.gov/mmwr/preview/mmwrhtml/ss6202a1.htm?s_cid=ss6202a1_w#Fig14

⁴ The Interagency Food Safety Analytics Collaboration, Foodborne illness source attribution estimates for 2013 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States (Dec. 2017), p.7, <https://www.cdc.gov/foodsafety/pdfs/IFSAC-2013FoodborneIllnessSourceEstimates-508.pdf> (estimating the percentage of *Salmonella* illnesses for 2013 attributed to pork, based on multi-year outbreak data, to be 9.3%).

⁵ 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>.

took care to explain that the effectiveness of the approach hinged on the strong connection between HACCP-based process control and appropriate food safety performance standards:

“FSIS has concluded that HACCP-based process control, combined with appropriate food safety performance standards, is the most effective means available for controlling and reducing harmful bacteria on raw meat and poultry products. HACCP provides the framework for industry to set up science-based process controls that establishments can validate as effective for controlling and reducing harmful bacteria. Performance standards tell establishments what degree of effectiveness their HACCP plans will be expected to achieve and provide a necessary tool of accountability for achieving acceptable food safety performance. Science-based process control, as embodied in HACCP, and appropriate performance standards *are inextricably intertwined* in the Agency’s regulatory strategy for improving food safety. Neither is sufficient by itself, but, when combined, they are the basis upon which FSIS expects significant reductions in the incidence and levels of harmful bacteria on raw meat and poultry products and, in turn, significant reductions in foodborne illness.”⁶

The 1996 Final HACCP Rule established a *Salmonella* performance standard for pork carcasses at 8.7 percent—or 6 out of 55 samples—based on industry-wide prevalence levels at that time.⁷ In 2011, however, FSIS stopped testing to ensure compliance with that standard, reasoning that violation rates were too low to justify the effort.⁸

We question the wisdom of that decision, made at a time when the percentage of *Salmonella* outbreaks attributed to contaminated pork had been rising steadily for a decade (as stated above, the CDC estimates that the percentage of *Salmonella* outbreaks attributable to pork more than doubled between 1998 and 2008).⁹ This persistent public health burden suggests that even small rates of *Salmonella* contamination on hog carcasses is cause for concern, and that revised performance standards—targeting pork parts, for example—are needed to address cross-contamination in the evisceration process. Back in 1996, FSIS anticipated that the *Salmonella* performance standards were merely “a first step in what FSIS expects to be a broader reliance in the future on pathogen-specific performance standards.”¹⁰ Consistent with that regulatory design, FSIS should update the whole carcass standards, develop alternative standards for pork parts, or implement other meaningful performance standards to reduce the threat of *Salmonella* contamination in pork products.

Meaningful pathogen performance standards would give FSIS a means to evaluate the food safety impact of policies like the proposed action, and it would also provide an important enforcement

⁶ Food Safety and Inspection Service, “Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,” Proposed Rule, 60 Fed. Reg. 6774, 6786, (February 3, 1995) (emphasis added).

⁷ Food Safety and Inspection Service, “Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems,” Final Rule. 61 Fed. Reg. 38806, 38811 (Jul. 25, 1996). (“Final HACCP Rule”).

⁸ See Food Safety and Inspection Service, “Modernization of Swine Slaughter Inspection,” Proposed Rule, 83 Fed. Reg. 4780, 4786, <https://www.federalregister.gov/d/2018-01256/p-114> (noting that FSIS conducted baseline sampling in 2011 and found that around 1.6% of carcasses tested positive for *Salmonella*).

⁹ Centers for Disease Control and Prevention, Surveillance for Foodborne Disease Outbreaks — United States, 1998–2008, FIGURE 14. Estimated mean percentage and 95% confidence intervals of foodborne disease outbreaks caused by *Salmonella* attributed to selected food commodities, by year interval — Foodborne Disease Outbreak Surveillance System, United States, 1998–2008,” (June 28, 2013), https://www.cdc.gov/mmwr/preview/mmwrhtml/ss6202a1.htm?cid=ss6202a1_w#Fig14

¹⁰ Final HACCP Rule at 38847.

tool. This enforcement power is diminished by the 2001 federal appellate court decision in *Supreme Beef Processors, Inc. v. USDA*,¹¹ but is not extinguished. FSIS can and should use performance standards to target enforcement resources, set criteria for waivers, and inform the marketplace.¹² USDA researchers have attributed significant food safety improvements to FSIS' publishing the names of individual poultry plants that fail to comply with *Salmonella* performance standards.¹³ The agency has recently expanded what it publishes to include compliance with standards for parts and comminuted poultry, in addition to whole carcasses. Yet for pork production, no performance standards are currently in force, and thus the agency has nothing to publish.

The Proposed Action

The rule that FSIS is proposing to eliminate—"Cleaning of hog carcasses before incising," 9 CFR 310.11—provides:

"All hair, scurf, and dirt, including all hoofs and claws, shall be removed from hog carcasses and the carcasses thoroughly washed and cleaned, before any incision is made for inspection or evisceration."

The rationale for this requirement, which goes back to at least 1970,¹⁴ is straightforward. Hair, scurf,¹⁵ and dirt, often containing feces, tend to harbor pathogens like *Salmonella*. Removing this matter and washing a carcass before incision helps to prevent pathogens on the carcass exterior from cross-contaminating cutting blades and, ultimately, the cuts of meat and ground pork that go to consumers.¹⁶ Similar cross-contamination concerns motivate the standard advice to wash fruits and vegetables before cutting into them.¹⁷

FSIS cites one example—removing the hair from the snout—to illustrate how the carcass cleaning rule "may impede the application of alternative, more efficient, procedures." But this proposal clearly goes beyond dehairing snouts. The agency reports that some plants currently dedicate three full-time positions per line, per shift, to comply with the carcass cleaning rule. Removing the rule will allow plants to eliminate several hundred of these positions, and potentially save over \$19 million a year in labor costs, according to FSIS's proposal. How will this reduction in the slaughterhouse workforce affect the safety of pork?

¹¹ 275 F.3d 432 (5th Cir. 2001).

¹² FSIS can also regulate more directly by distinguishing virulent and antibiotic resistant strains of *Salmonella*, and treating them as adulterants, as we have long advocated. See Center for Science in the Public Interest, Petition to the USDA re: Antibiotic-Resistant Salmonella, (Oct. 2015), <https://cspinet.org/resource/petition-usda-re-antibiotic-resistant-salmonella>.

¹³ ERS Study. Public Disclosure of Tests for Salmonella: The Effects on Food Safety Performance in Chicken Slaughter Establishments. available at: <https://www.ers.usda.gov/publications/pub-details/?pubid=83660>

¹⁴ See Department of Agriculture, Consumer and Marketing Service, "Meat Inspection Regulations," 35 Fed. Reg. 15552, 15568 (Oct. 3, 1970), <https://www.gpo.gov/fdsys/pkg/FR-1970-10-03/pdf/FR-1970-10-03.pdf>

¹⁵ Scurf refers to dandruff or flakes on the surface of the skin that form as fresh skin develops below.

¹⁶ See generally Swart et al. "Modeling of Salmonella Contamination in the Pig Slaughterhouse." *Risk Analysis*, Vol. 36, No. 3, 2016, DOI: 10.1111/risa.12514.

¹⁷ See, e.g., Produce Industry Food Safety Initiative, "Commodity Specific Food Safety Guidelines for the Melon Supply Chain," (2005), <https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM168625.pdf> ("While not the only route of possible contamination, edible portions of the melon flesh may be contaminated in the cutting or rind removal process because microbial contamination on the outside rind of the melon may be spread by the knife blade . . . Whole melons used for fresh-cut melon products should be washed thoroughly before cutting or peeling operations begin.")

According to FSIS, it will have no effect at all. The cleaning requirements in 9 CFR 310.11 are unnecessary, it argues, because other rules already require pork processors to control for food safety hazards. Specifically, FSIS cites 9 CFR 310.18, which generally requires that “carcasses, organs, and other parts shall be handled in a sanitary manner to prevent contamination,” and that plants take remedial action “if contamination occurs.” FSIS also cites various sanitation and HACCP regulations that require plants to articulate and follow procedures for maintaining “sanitary conditions,” and to reduce “contamination hazards” to “acceptable levels.”¹⁸

Yet FSIS fails to explain how plants will prevent additional fecal contamination from making its way into the interior of the carcasses if they do not wash animals prior to incision to control for the “contamination hazards” of hair, scruff, and dirt contaminated with feces. It is well-established that these hair, scruff, and dirt serve as a source of potential contamination.¹⁹ FSIS has not cited any studies demonstrating that such hazards can be effectively controlled post-incision. Instead, the agency states, vaguely, that “FSIS has found the performance of establishments using the alternative procedures to be satisfactory.”²⁰ The agency has not explained how it evaluated the performance of these establishments. Certainly it has not evaluated them recently based on their ability to meet *Salmonella* performance standards, as the agency abandoned testing for these standards in 2011. The proposal likewise fails to describe the “alternative procedures” employed by the plants receiving waivers, all of which are apparently operated by one corporation, Tyson Fresh Meats, Inc.²¹ Even assuming these procedures are effective, there is no way to verify that other plants, not operated by Tyson, would employ similarly effective “alternative procedures.” Instead, these plants may simply opt to eliminate cleaning procedures and pocket the savings. FSIS needs to provide better assurance to consumers that this deregulatory action will not increase foodborne illness risks.

More broadly, the complexity of enforcing sanitation and HACCP regulations leaves room for lags in compliance, particularly when performance standards are not in force. Determining whether a plant has removed “hair, scurf and dirt” prior to incision is more readily apparent than whether the plant has conducted an adequate hazard analysis, identified the appropriate critical control points, or set evidence-based critical limits at each of its critical control points. In the context of poultry, there have been cases where FSIS has not taken action to address such deficiencies until after a plant’s failure to comply with a pathogen performance standard attracts regulatory attention. For example, after the Mar Jac Poultry plant in Hattiesburg, Mississippi failed to meet *Salmonella* performance standards, FSIS issued a notice of suspension that cited a litany of recordkeeping, HACCP planning, pest control, microbial sampling, and other violations.²² Would the agency have taken effective

¹⁸ Eliminating Unnecessary Requirements for Hog Carcass Cleaning (Docket No. FSIS_FRDOC_0001-0568)

¹⁹ See, e.g. Warriner et al. “Cross-contamination of carcasses and equipment during pork processing.” *Journal of Applied Microbiology* 2002, 93, 169–177. (“Although there are many opportunities for carcass contamination to occur during slaughter, the initial scalding and singeing steps that are performed to de-hair carcasses have also been demonstrated to remove a substantial proportion of the carcass surface microflora.”)

²⁰ Currently, the FSIS website identifies five Tyson plants as having waivers from the requirements of 9 CFR 310.11. See https://www.fsis.usda.gov/wps/wcm/connect/188bf583-45c9-4837-9205-37e0eb1ba243/Waiver_Table.pdf?MOD=AJPERES

²¹ *Id.*

²² Letter from Larry Davis, District Manager, FSIS Jackson District Office to Joe Colee, Complex Manager, Mar-Jac Poultry regarding “Notice of Suspension,” April 11, 2018, *available at*: https://www.foodandwaterwatch.org/sites/default/files/final_signed_notice_of_suspension_mar_jac_est.517_-_copy.pdf

enforcement action against these violations in the absence of a performance standard? The answer is unclear, but consumers cannot afford to take this risk.

Conclusion

For the reasons discussed above, we urge FSIS not to adopt the proposal to eliminate the rules at 9 CFR 310.11 until it has carried out a better evaluation to assess the food safety impact of this proposed action. In addition, we oppose the elimination of any additional food safety regulatory requirements for swine slaughter until FSIS has implemented effective *Salmonella* performance standards in pork. We therefore urge you to withdraw the current proposal and instead adopt the four steps outlined at the start of this letter.

Sincerely,

Center for Foodborne Illness, Research & Prevention

Center for Food Safety

Center for Science in the Public Interest

Consumer Federation of America

Consumers Union

Government Accountability Project

National Consumers League

Stop Foodborne Illness