The Honorable George "Sonny" Perdue III Secretary of Agriculture U.S. Department of Agriculture 1400 Independence Avenue, SW Washington, DC 20250

Carmen Rottenberg
Acting Deputy Under Secretary for Food Safety
Food Safety and Inspection Service
U.S. Department of Agriculture
331-E Jamie L. Whitten Federal Bldg.
Washington, DC 20250-3700

RE: Modernization of Swine Slaughter Inspection Proposed Rule (Docket No. FSIS-2016-0017)

Dear Secretary Perdue and Acting Deputy Undersecretary Rottenberg:

Consumer Federation of America writes to oppose the Food Safety and Inspection Service's (FSIS) proposed rule to overhaul swine slaughter inspection. The proposed rule would expand a pilot program—the Hazard Analysis and Critical Control Point (HACCP)-based Inspection Models Project (HIMP)—that the agency has carried out in five establishments for over a decade. Despite that long history, FSIS has failed to marshal evidence that the program actually improves food safety. Rather, the HIMP program's track record indicates that the proposed rule lacks adequate safeguards to protect consumers from foodborne illness threats that are likely to emerge as a result of higher line speeds, a reduced inspection force, and the elimination of microbiological testing standards. We urge FSIS to withdraw this rule, and to seek out instead evidence-based reforms that will improve food safety, and not simply boost pork processors' profits.

<u>Contaminated pork sickens hundreds of thousands of people each year in the United</u> States

More effective pathogen controls in swine slaughter would improve public health and literally save lives. 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. each year, leading to

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

nearly 3,000 hospitalizations,² and almost one hundred deaths.³ USDA has identified *Salmonella* as the costliest foodborne pathogen, with an estimated \$3.7 billion a year in associated medical costs alone each year.⁴ According to CDC, the percentage of *Salmonella* outbreaks attributed to contaminated pork has risen steadily in recent years, more than doubling between 1998 and 2008.⁵ The most recent estimates indicate that pork may cause as much as 12.36% of *Salmonella* outbreaks each year in the United States.⁶ Effective strategies to reduce *Salmonella* may take place 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 or released during the slaughter process can spread the pathogen.⁷

The foodborne illness threat of pork goes beyond just *Salmonella*. In recent years, pork consumption has been linked to major outbreaks of *Staphylococcus aureus*, E. coli O157:H7, and trichinellosis. Other significant sources of foodborne illness—including *Listeria monocytogenes, Campylobacter*, and *Toxoplasma gondii*—are commonly found in pigs or pork products. One pathogen, *Yersinia enterocolitica*, is almost exclusively associated with pork, and causes almost 117,000 illnesses, 640 hospitalizations, and 35 deaths each year, according to CDC.

Unfortunately, the U.S. has made very little progress in reducing illnesses from foodborne pathogens in recent years. According to the latest CDC data, diagnosed *Yersinia* infections more than

² Centers for Disease Control and Prevention, "Estimates of annual hospitalizations for 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-t2

³ Centers for Disease Control and Prevention, "Estimates of annual deaths resulting from 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-t3

⁴ 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

⁵ 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

⁶ 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), https://www.cdc.gov/foodsafety/pdfs/IFSAC-2013FoodborneillnessSourceEstimates-508.pdf

⁷ 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.

⁸ See Foodborne Illness Outbreak Database, http://www.outbreakdatabase.com/details/2016-outbreak-of-staphylococcus-aureus-wise-county-virginia/?vehicle=pork;

⁹ Honish et al. "Escherichia coli O157:H7 Infections Associated with Contaminated Pork Products - Alberta, Canada, July-October 2014." MMWR Morb Mortal Wkly Rep. 2017 Jan 6;65(52):1477-1481, doi: 10.15585/mmwr.mm6552a5. https://www.ncbi.nlm.nih.gov/pubmed/28056011

¹⁰ Heaton et al. "Trichinellosis Outbreak Linked to Consumption of Privately Raised Raw Boar Meat — California, 2017," Morbidity and Mortality Weekly Report (MMWR), (Mar. 2, 2018), https://www.cdc.gov/mmwr/volumes/67/wr/mm6708a3.htm?scid=mm6708a3.w

¹¹ Baer el al. *supra* note 7.

¹² See Centers for Disease Control and Prevention, Yersinia enterocolitica (Yersiniosis), https://www.cdc.gov/yersinia/

quadrupled from 2014 to 2017.¹³ The incidence of other foodborne illness has increased as well. Some of these increases reflect more accurate testing. Nevertheless, CDC concludes that overall "incidence of infections transmitted commonly through food has remained largely unchanged for many years." In other words, despite advances in technology and scientific understanding of the causes of foodborne illness, progress in reducing foodborne illness has stalled. Not surprisingly, retail sampling has uncovered a high level of contamination in pork products. A recent Consumer Reports analysis of 198 pork-chop and ground-pork samples found *Yersinia* in 69% of the samples, enterococcus—which has been linked to urinary tract infections—in 11% of samples, and *Salmonella*, *Staphylococcus aureus*, or *Listeria monocytogenes* in 3% to 7% of samples. ¹⁵ Clearly, FSIS and industry can do more to protect the public from contaminated pork. But while the proposed rule purports to "facilitate pathogen reduction in pork products," scant evidence supports that claim.

FSIS has conducted this rulemaking with inadequate public involvement

The proposed rule would significantly reform the country's meat inspection system. FSIS estimates that industry would spend tens of millions of dollars to come into compliance with the new rule. As a result of its potential repercussions for consumers, federal meat inspectors, plant workers, and even international trade, the proposal has attracted intense interest. As of today, over 61,000 comments have been filed on this rule. Given the magnitude of the proposed changes, the agency's approach to crafting this new proposal was extremely flawed.

Previous agency proposals seeking to substantially change parts of the federal inspection program have been debated and discussed in public forums, so that stakeholders could provide input before the agency is wedded to a formal proposal. Indeed, FSIS has a dedicated body—the National Advisory Committee for Meat and Poultry Inspection (NACMPI)—to help it consider a broad range of stakeholder perspectives. Established by Congress in 1971, the NACMPI "provides advice and recommendations to the Secretary on meat and poultry inspection programs." Following passage of the 1996 Farm Bill, Congress pressured USDA to include a more diverse body of stakeholders on the NACMPI, and as a result, the committee came to include "representatives of state and local governments; industry and trade associations; public health, scientific, and academic communities; and consumers and consumer organizations." Since Donald Trump became president, however, the committee has not met, nor has any meeting been scheduled, nor has FSIS even taken any action on

¹³ Marder et al., "Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food — Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2006–2017," Morbidity and Mortality Weekly Report (MMWR) (March 23, 2018),

https://www.cdc.gov/mmwr/volumes/67/wr/mm6711a3.htm?s_cid=mm6711a3_w 14 Id

¹⁵ "Pork chops and ground pork contaminated with bacteria," Consumer Reports magazine (Jan. 2013), https://www.consumerreports.org/cro/magazine/2013/01/what-s-in-that-pork/index.htm

¹⁶ Food Safety and Inspection Service. "National Advisory Committee on Meat and Poultry Inspection; Nominations for Membership." 81 Federal Register 84548, (Nov. 23, 2016),

https://www.federalregister.gov/documents/2016/11/23/2016-28237/national-advisory-committee-on-meat-and-poultry-inspection-nominations-for-membership

¹⁷ Balla, Steven J. and John R. Wright. "Can Advisory Committees Facilitate Congressional Oversight of the Bureaucracy?" in Congress on Display, Congress at Work. Ann Arbor: University of Michigan Press. William T. Bianco. ed. Ann Arbor, MI: University of Michigan Press.; see also FSIS. "National Advisory Committee on Meat and Poultry Inspection Charter," https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/advisory-committees/nacmpi/nacmpi-charter

the request for nominations that it issued under the previous administration. As a result, the substantial changes announced in this rule do not reflect the committee's consideration or feedback.

Nor does the proposed rule reflect stakeholder perspectives that may have been gleaned from one or more public meetings. Given the number of substantial changes to hog slaughter inspection that the agency is proposing, a series of public meetings to discuss the agency's thinking and solicit stakeholder input should have preceded formal publication of the agency's proposal. The agency's failure to hold a single public meeting is shocking. After FSIS published the proposed rule, consumer groups requested a public meeting to discuss the proposal but the agency refused to grant even that request.

Perhaps most troubling, FSIS has denied requests for additional time to comment, and in particular, the opportunity for the public to consider the findings of an external peer review of its risk assessment. The risk assessment, entitled "Assessment of the Potential Change in Human Risk of Salmonella Illnesses Associated with Modernizing Inspection of Market Hog Slaughter Establishments," or just "the market hog risk assessment," to use agency's shorthand, offers critical support for the agency's contention that the proposed rule would improve food safety. It also exhibits glaring flaws. An external peer review should have enabled the public to better understand the significance of the risk assessment. Instead, FSIS recently announced that it had selected a contractor to perform the peer review on Monday, April 16 of this year, and that it expects its contractor to complete the review after the public comment period on the proposed rule has closed.

Given these plans, the agency's insistence on a 90-day comment period is indefensible. Recently, FSIS set the comment period for a comparatively uncontroversial proposed rule to amend egg products inspection regulations at 120 days. Yet for this rule, it set the comment period for 60 days, and extended that period to 90 days only after widespread public outcry. Agency officials have indicated that, if the risk assessment's untimely peer review identifies any significant problems, the agency may issue a separate request for public comments—on just the risk assessment and its review. By all indications, FSIS is seeking to rush its hog slaughter modernization proposal to become a final rule, and the haphazard process does not bode well for consumers.

The proposed rule lacks evidentiary support and would increase food safety risks

FSIS seeks to make a number of significant changes to hog slaughter inspection with this rule. The proposal would eliminate limits on line speeds, reduce inspector staffing at large plants by nearly half (from 11 to 6 inspectors), shift responsibility for detecting diseases in live animals and carcasses from government inspectors to company employees, eliminate mandatory pathogen performance standards, replace microbiological testing requirements with voluntary measures, and establish an ambiguous "process control" standard. Conceivably, these changes could be part of a comprehensive reform package that leads to food safety improvements, but on their face, they pose obvious hazards.

FSIS has failed to adequately address those hazards. All else equal, faster line speeds increase the likelihood that a plant employee handles a carcass in a way that creates fecal contamination, or that an inspector fails to detect a diseased carcass. FSIS itself has concluded that "in the absence of compensating measures," higher line speeds result in higher *Salmonella* contamination in poultry

plants.¹⁸ Similarly, the risk assessment for this rule indicates that contamination rates are worse at plants that are not "fully staffed" with inspectors,¹⁹ and FSIS has credited the application of concrete, numeric pathogen performance standards with significant improvements in the poultry industry.²⁰

These documented causal relationships create a reasonable presumption that many of the proposed changes—increasing line speeds, reducing the number of inspectors, eliminating microbiological testing standards—would hurt food safety. FSIS could overcome this presumption with clear and compelling evidence that the HIMP program as a whole improves food safety, but it has not done so. Rather, the agency has largely neglected to gather the data needed to evaluate HIMP, and has settled instead on the unnerving conclusion that "the new system is unlikely to result" in worse food safety outcomes.

The scant record of support for this proposal is indefensible given the history of the HIMP program. As the proposed rule recounts, the original HIMP pilot dates back to 1996. The Federal Court of Appeals for the D.C. Circuit prevented FSIS from implementing HIMP in its original incarnation, because the program put FSIS personnel in the position of "inspecting people not carcasses," in violation of the Federal Meat Inspection Act.²¹ FSIS made adjustments, and the D.C. Circuit approved "the modified inspection model" that remains today.²² However, the court qualified its approval of HIMP, warning that "our opinion today may not necessarily foreshadow the outcome of judicial review of such future regulations [to make the program permanent]." The court explained that the HIMP pilot "is a test program, a temporary measure intended as an experiment. If the USDA undertakes a rulemaking to adopt as a permanent change something along the lines of the modified program, experience with the program's operation and its effectiveness will doubtless play a significant role."²³

The "experiment" has now persisted for over a decade-and-a-half at five large slaughter facilities. Yet despite the federal court's pronouncement, and criticism early on from federal oversight authorities, ²⁴ FSIS has failed to document the HIMP program's effectiveness in protecting food safety.

¹⁸ See FSIS. "Reply to Peer Review Comments for FSIS Risk Assessment for Guiding Public Health Risk-Based Poultry Slaugther Inspection," (Dec. 27, 2012) ["2012 Peer Review"], available at:

https://www.fsis.usda.gov/wps/wcm/connect/ff8b2373-697f-4c5a-bbc6-

c57e404b7c09/PSRA+REPLY+TO+PEER+REVIEW+12-27-12.pdf?MOD=AJPERES (noting that the risk assessment modeling results indicate that "in the absence of compensating measures, increased nominal line speed is predicted to result in higher [Salmonella] prevalence of poultry carcasses.").

¹⁹ FSIS. "Assessment of the Potential Change in Human Risk of Salmonella Illnesses Associated with Modernizing Inspection of Market Hog Slaughter Establishments," p. 22, (Jan. 2018), [Market Hog Risk Assessment] https://www.fsis.usda.gov/wps/wcm/connect/0c03ed4d-68bf-4bd9-80e0-b8f3aa6ff16e/ModernizationSwineSlaughterRiskAssessment.pdf?MOD=AJPERES

²⁰ FSIS. "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. 7288. (Feb. 11, 2016).

²¹ AFGE v. Glickman, 215 F.3d 7, 11 (D.C. Circ. 2000).

²² AFGE v. Veneman, 284 F.3d 125, 130 (D.C. Cir. 2002).

²³ *Id.* (emphasis added).

²⁴ See GAO. "Weaknesses in Meat and Poultry Inspection Pilot Should Be Addressed Before Implementation," (Dec. 2001) ["2001 GAO Report"], https://www.gao.gov/assets/240/233016.pdf (noting "several design and methodology limitations that compromise the overall validity and reliability of [the HIMP pilot's] results" including lack of a control group and self-selection bias.).

The lack of rigor has not gone unnoticed. In 2013, the U.S. Government Accountability Office (GAO) and the USDA Office of Inspector General (OIG) issued separate reports questioning the efficacy of hog HIMP, and the adequacy of USDA's evaluation of the program. The OIG report describes how three of the five HIMP plants were among the worst food safety offenders in the industry, and recommends that FSIS take steps to "determine what measurable improvement the HIMP program achieved." The GAO report similarly declares that the agency "has not thoroughly evaluated the performance of each of the pilot projects over time even though the agency stated it would do so when it announced the pilot projects." Contrary to what FSIS indicated that it would do in response to these reports, and to what it claims to have done in this proposed rule, the agency still has not thoroughly evaluated the hog HIMP pilot project.

As a preliminary matter, the HIMP pilot program consisted of plants which were self-selected and likely higher performing plants than others in the industry, and so the data from the HIMP pilot program may not represent what FSIS is likely to see when the vast majority of hog slaughterhouses take part in the proposed program. Moreover, the proposed rule differs from the HIMP pilot in important respects, raising further concerns about whether results from the HIMP pilot program can be extrapolated to the new program. Nevertheless, FSIS has relied on data from the HIMP pilot to justify this rule and so further examination of that data is warranted.

In particular, FSIS claims that it responded to the OIG and GAO reports with "a thorough evaluation of the models tested," which it documented in the 2014 "Hog HIMP Report." The Hog HIMP Report, however, does not support even the proposed rule's tepid conclusion that "market hog slaughter establishments participating in HIMP were performing as well as comparable large non-HIMP market hog establishments." Rather, the report relies on indirect indicators—counts of inspection tasks performed and carcasses condemned—without demonstrating the relationship of those indicators to food safety performance in the plants. Where the report identifies more relevant indicators, such as the incidence of fecal contamination and other "food safety defects," or *Salmonella* testing results, it fails to marshal compelling evidence in support of HIMP. In particular, the report acknowledges that the *Salmonella* dataset is too small to demonstrate a statistically significant correlation, while it compares 2013 data for HIMP plants on "food safety defects," such as fecal contamination, with "baseline" data for non-HIMP plants collected in 1998, *twenty years ago*. These deficiencies were documented in a January 19, 2016 letter to then Secretary Vilsack signed by 64 members of Congress.²⁹

²

²⁵ See GAO. "More Disclosure and Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections GAO-13-775: Published: Aug 22, 2013. Publicly Released: Sep 4, 2013 ["2013 GAO Report"], available at: http://gao.gov/products/GAO-13-775; USDA OIG. "Inspection and Enforcement Activities at Swine Slaughter Plants" ["OIG Swine Slaughter Report"] available at: http://www.usda.gov/oig/webdocs/24601-0001-41.pdf
²⁶ OIG Swine Slaughter Report at 17 ("Although HIMP was intended to improve food safety, we found that 3 of the 10 plants with the most [non-compliance reports] NRs from FYs 2008 to 2011 were HIMP plants. In fact, the swine plant with the most NRs during this timeframe was a HIMP plant – with nearly 50 percent more NRs than the plant with the next highest number.").

²⁷ 2013 GAO Report at 5.

²⁸ See FSIS. "Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs," Final Report (Nov. 2014), https://www.fsis.usda.gov/wps/wcm/connect/f7be3e74-552f-4239-ac4c-59a024fd0ec2/Evaluation-HIMP-Market-Hogs.pdf?MOD=AIPERES

²⁹ Letter available at: https://delauro.house.gov/sites/delauro.house.gov/files/Hog-HIMP-Letter-1-19-16.pdf (arguing that the FSIS' report's comparison of fecal contamination and other food safety and consumer protection defects at HIMP plants in recent years with findings from a baseline study conducted in 1998 "assumes that non-HIMP hog slaughter facilities failed to make any improvement in reducing food safety defects over a 14-year period.").

The proposed rulemaking and its supporting materials do nothing to address those members' objections. In particular, the agency continues to cite the 2014 Hog HIMP report as evidence of HIMP plants' "exceptional" performance without disclosing that it is comparing HIMP plant data from 2013 with non-HIMP plant data from 1998. For its part, the agency's latest assessment of the hog HIMP pilot—the "market hog risk assessment"—presents an oversimplified and misleading analysis of how the rules' changes would affect public health.

The agency's 2018 risk assessment exhibits glaring flaws

According to the proposed rule, the market hog risk assessment supports the conclusion that converting more establishments to HIMP would result in a "decline on average from an initial prevalence of 0.9407% to a final prevalence of 0.9066%" in *Salmonella* positive rates. The risk assessment, however, fails to explain the basic logic behind these findings. On the one hand, it acknowledges "no statistically significant difference in the prevalence of Salmonella-positive samples observed in HIMP establishments compared to non-HIMP establishments." That finding comes from the analysis of a slightly larger data set in the 2014 Hog HIMP Report. On the other hand, the risk assessment claims that the increased offline inspection tasks associated with HIMP plants are correlated with significant reductions in *Salmonella*-positive samples, and so expanding HIMP would result in less *Salmonella*. In other words, HIMP has not reduced *Salmonella* rates yet, but it will.

What is driving this counter-intuitive result? Again, FSIS has not collected sufficient data to detect a difference between HIMP and non-HIMP plants' performance in controlling *Salmonella* contamination. The risk assessment, however, lumps together the test results for the HIMP and non-HIMP plants, and pairs it with data on inspection tasks conducted at those plants. In particular, it models how differences in the number of "unscheduled" versus "scheduled" versus "scheduled but not performed" tasks correlate with the prevalence of *Salmonella* contamination in a plant. The model shows that more offline tasks at a given plant, and in particular more unscheduled tasks, are correlated with fewer positive *Salmonella* samples. Because "HIMP establishments have demonstrated the capacity for FSIS inspectors to conduct up to 50% more offline procedures than in non-HIMP establishments," FSIS concludes that converting more plants to HIMP would drive down *Salmonella*.

This conclusion, however, raises an obvious question: if conducting extra offline procedures at HIMP plants reduces *Salmonella* contamination, why are the contamination rates at the HIMP plants no better than average?

One explanation may be that inspector staffing vacancies, rather than the number of offline tasks performed, best account for poor food safety outcomes. Inspector vacancies are a real problem at FSIS. According to a 2015 Food & Water Watch analysis of USDA records, more than half of FSIS districts were running double-digit vacancy rates for permanent full-time inspectors. The market hog risk assessment observes that unscheduled and other offline tasks are performed more frequently both at HIMP plants, *and* at plants that are "fully staffed." Presumably, adequate staffing at a given plant

³⁰ Market Hog Risk Assessment at 19.

³¹ Id. at 12.

³² Food & Water Watch. "USDA Records Reveal Staffing Shortages Undermining Food Safety," (Feb. 26, 2015), https://www.foodandwaterwatch.org/news/usda-records-reveal-staffing-shortages-undermining-food-safety

generates benefits other than simply the capacity to perform more offline and unscheduled inspection tasks. In almost any work context, chronic understaffing tends to undermine morale. Conversely, inadequate staffing could reflect poor working conditions at a plant, and even intimidation by a plant's management.³³

The risk assessment, however, does not control for the possibility that staffing generally may be driving the differences in controlling *Salmonella* contamination. In other words, *Salmonella* rates may go down when off-line inspection tasks go up *not* so much because the number of offline or unscheduled inspection tasks matters so much, but because those numbers serve as a proxy for adequate staffing. If this is the case, expanding the HIMP model would seem destined to exacerbate *Salmonella* contamination problems, since it would reduce the inspection force at large plants by nearly half. Nevertheless, the risk assessment does not control for the impact of having a "fully staffed" plant. The closest it appears to come is a continuous "structural variable" to control for "the number of establishment inspectors." But because not all plants have the same number of inspectors, which is influenced by plant size, production volume, and other factors, this variable does not provide a control for the impact of staffing vacancies.

The risk assessment raises several other concerns. First, it relies on results of the very *Salmonella* testing regime that the agency discontinued in 2011 because it "was not an effective use of resources for verifying process control." This is problematic because the test results, and the corresponding data on inspection tasks from 2010 and 2011, are out-of-date. Moreover, by FSIS' own estimation, the data are an ineffectual measure of food safety risks. This is particularly unfortunate because more up-to-date, relevant data were available for this risk assessment. Since 2011, when FSIS "discontinued its *Salmonella* verification sampling program for market hogs to make better use of its resources," the agency has conducted an exploratory parts sampling program. For calendar year 2017, FSIS tested 718 samples of intact pork cuts (68 positive), 707 non-intact cuts (52 positive), and 927 comminuted pork products (210 positive) for *Salmonella*. That is 2,352 total samples with 330 positives. By contrast, the risk assessment considers 3,625 samples with just 99 positives. When asked why they did not compare *Salmonella* test results for pork parts from HIMP and non-HIMP plants, FSIS officials have responded that parts processing is far removed from slaughter, and sometimes even takes place at separate facilities. But most large slaughter facilities also run processing operations, ³⁴ and the contamination rates of their products would seem highly relevant to assessments of their "process control."

Second, the risk assessment neglects to control for line speed. According to the Risk Assessment, "[d]ata describing establishments' line speeds were incomplete and not included in the

³³ See, e.g., Government Accountability Project, "Inspectors Warn Against USDA's High-Speed Hog Inspection Program," (Jan. 30, 2015), https://www.bodwhistleblower.org/wp-content/uploads/2015/01/Affidavit-2-Redacted .pdf ("When we try to point out problems in the slaughter process, we are berated by company management. Our upper-management no longer backs up those inspectors who are actually trying to do their jobs."); Affidavit of USDA Inspector Joe Ferguson,

https://www.foodwhistleblower.org/wp-content/uploads/2015/01/Affidavit-4-%E2%80%93-Joe-Ferguson.pdf ("When the inspectors try to take corrective action at the [HIMP pilot] plant, we get no support from our supervisors. I tell them that I am working for the consumers, not the company. There is no stopping the industry.").

³⁴ Cates et al. RTI International. "Survey of Meat and Poultry Slaughter and Processing Plants: Final Report," (June 2005), https://www.fsis.usda.gov/shared/PDF/SRM_Survey_Slaughter_&_Processing_Plants.pdf ("More than 80 percent of meat plants also perform processing activities.").

model."³⁵ This marks an important distinction with the poultry risk assessment, on which this analysis is purportedly based. ³⁶ In response to an external peer review of the poultry study, FSIS acknowledged that "in the absence of compensating measures, increased nominal line speed is predicted to result in higher [*Salmonella*] prevalence of poultry carcasses."³⁷ Presumably, the same is true for pork. Does this deleterious effect of increased line speeds outweigh the benefits of increased unscheduled inspection tasks? The risk assessment offers no insight.

Third, the risk assessment lacks transparency. As noted above, FSIS has not completed an independent peer review of this analysis. This omission is inexcusable given the role that this analysis plays in justifying the proposed rule, including through its cost benefit analysis, which pegs the "value of health benefits" associated with the proposed rule to fall in the range of "\$0.19 million to \$18.97 million, with a mean of \$9.33 million." FSIS claims that the market hog risk assessment model is "the same as the peer reviewed risk model used for the 2014 risk assessment supporting Modernization of Poultry Slaughter Inspection." But that is true only to the extent that inspecting chickens and pigs is "the same." It also glosses over relevant distinctions between the risk assessments, such as the absence of a line speed variable.

Moreover, the last peer review to which FSIS submitted its poultry risk assessment was apparently in the summer of 2012, while it issued the latest version of its poultry risk assessment in July 2014.³⁹ That 2012 peer review raised significant concerns. For example, one reviewer asserted that "the implementation of the logistic regression component is incorrect because it does not anchor the comparison between current and alternative states to the observed current state." In its response, FSIS claimed to have addressed this error in a later version of the model, albeit with a different approach than that recommended by the reviewer. The validity of that fix, however, remains shielded from further technical scrutiny, as does a number of questionable assumptions in the market hog risk assessment, such as the assumption that in each plant that converts to a HIMP-style inspection system, inspectors would conduct precisely 25% more unscheduled tasks, and reduce the number of scheduled but not performed tasks by 50%.

Beyond the lack of an independent external peer review, the risk assessment's cryptic language, highly technical presentation, and in some cases outright errors, make it ill-suited to inform the public, or to facilitate meaningful comment on this rule. What is the significance of the risk assessment's assumption that non-compliance records would fall by 46.67% under the projected scenarios? Does this assumption raise endogeneity concerns about the projections? The risk assessment offers little guidance. The risk assessment's description of "structural variables" provides another illustration. Apparently, these 15 variables serve as controls; their inclusion "significantly reduces the model deviance." Yet there is no explanation of why, only perfunctory descriptions. A footnote superscript

³⁵ Market Hog Risk Assessment at 35.

³⁶ See FSIS. FSIS Risk Assessment for Guiding Public Health-Based Poultry Slaughter Inspection (Aug. 2012), https://www.fsis.usda.gov/wps/wcm/connect/8f374626-ee06-49d3-9d41-6eb65ad32cbb/Poultry Slaughter Risk Assess Aug2012.pdf?MOD=AJPERES

³⁷ 2012 Peer Review at 46.

³⁸ Id. at 12.

³⁹ See FSIS. Risk Assessments, https://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments

^{40 2012} Peer Review at 3.

⁴¹ Market Hog Risk Assessment at 97-98.

⁴² *Id*.

accompanies the variable "number of establishment inspectors," but the footnote itself appears to be missing.⁴³ The same is true for the footnote following the sentence: "Fourteen structural variables were tested and several eliminated providing the best model."⁴⁴

FSIS has violated Office of Management and Budget peer review requirements

During the George W. Bush Administration, the Office of Management and Budget (OMB) issued a bulletin, after providing opportunity for public comment, which requires peer review of documents like the market hog risk assessment. Specifically, the bulletin provides that "important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the federal government." The peer review process must be transparent and provide "the public with the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' report(s), and the agency's response to the peer reviewers' report(s)."

The OMB requirements make clear that the FSIS risk assessment is just the sort of document that should undergo peer review. The OMB guidelines explain that "in the context of risk assessments, it is valuable to have the choice of input data and the specification of the model reviewed by peers before the agency invests time and resources in implementing the model and interpreting the results." And if a risk assessment "is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options." The OMB policy allows an agency to "waive or defer some or all of the peer review requirements," but only "where warranted by a compelling rationale." Here, FSIS has offered no such rationale.

FSIS should develop and codify pathogen reduction performance standards for pork before it implements sweeping reforms to hog slaughter inspection

As already mentioned, in addition to eliminating line speed caps and reducing the number of inspectors at hog slaughter facilities, FSIS is proposing to remove the codified *Salmonella* pathogen reduction performance standards for swine and replace them with a requirement that plants conduct microbiological testing of their choice. The new requirements do not specify any particular test, nor any concrete standard to meet, e.g. 'no more than 8 of 52 samples may test positive for *Salmonella*.'⁴⁷ Rather, FSIS would require plants' testing results to support a generalized showing that they are "maintaining process control." For larger plants, the proposed rule prescribes a minimum frequency for sampling—one pre-evisceration sample and one post-chill sample per one thousand carcasses—but plants may substitute alternative sampling locations and frequencies if they can demonstrate that the changes would "provide a definite improvement in monitoring process control."

⁴³ Id.

⁴⁴ Id.

⁴⁵ Office of Management and Budget. Final Information Quality Bulletin for Peer Review (Dec. 16, 2004), http://www.cio.noaa.gov/services-programs/pdfs/OMB Peer Review Bulletin m05-03.pdf.

⁴⁶ See id. OMB goes on to explain that early review is desirable in part because "[i]f review occurs too late, it is unlikely to contribute to the course of a rulemaking," and in part because an early peer review may "provide net benefit by reducing the prospect of challenges to a regulation that later may trigger time consuming and resource draining litigation."

⁴⁷ This is the standard for chicken parts that FSIS finalized in 2016. See FSIS. "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. 7288. (Feb. 11, 2016).

The absence in the proposed rule of concrete, numerical pathogen reduction performance standards tied to a standardized testing regime raises serious food safety concerns. FSIS has failed to define "process control" in any meaningful way. Inevitably, this failure would result in pressure on inspectors to sign off on a plant's controls, regardless of what the microbiological testing indicates. Pathogen reduction performance standards have limitations. No amount of testing can replace a well-designed food safety program and provide the assurance of rigorous government inspection. As the experience with *Salmonella* performance standards for market hogs demonstrates, standards must be updated, and that process may involve difficult questions. In recent years, for example, some researchers have argued that enumeration, rather than prevalence-based *Salmonella* standards, would better align with public health goals.⁴⁸ But even an imperfect pathogen performance standard offers an objective, consistently applied check on how a plant's food safety controls are operating, and a measure of how its performance compares to other plants. Under the proposed rule, FSIS would not have *any* comparable data across the industry to determine whether pathogen contamination is actually being reduced.

The proposed rule intimates that FSIS might develop pathogen reduction performance standards for pork parts in 2019, but the agency's track record suggests otherwise. Back in 2013, in response to OIG's recommendation that FSIS "determine what measurable improvement the HIMP program achieved," FSIS responded that it would "complete an evaluation of HIMP . . . with respect to performance standards established by an independent consulting firm contractor." Neither a contractor nor the agency itself, however, established pathogen performance standards for pork, or compared HIMP and non-HIMP plants against them, in the years following. ⁵⁰

To its credit, the agency launched an exploratory sampling program for pork parts in 2014, and that testing supports the feasibility of updated performance standards. In particular, the initial round of testing has revealed a very significant *Salmonella* contamination rate of 16.7% in pork products. FSIS has already implemented *Salmonella* performance standards for chicken parts, and it should do the same for the pork. It should also address dangerous shiga-toxin producing *E. coli* (STECs) in pork. The exploratory testing has shown that an alarming 5% of pork products harbor STECs. In 2011, FSIS declared STECs to be adulterants on beef products, and implemented testing to enforce that decision.⁵¹ That declaration came in the wake of several high-profile outbreaks linking STECs to ground beef. Already, several outbreaks of STECs in pork have been documented in

⁴⁸ McEntire et al. "The Public Health Value of Reducing *Salmonella* Levels in Raw Meat and Poultry," *Food Protection Trends*, Vol 34, No. 6, p.386-392 http://www.foodprotection.org/files/food-protection-trends/NovDec-14-McEntire.pdf

⁴⁹ 2013 OIG report at 37-38 (emphasis added).

⁵⁰ The agency has been similarly dragging its feet in updating *Salmonella* performance standards for ground beef.

⁵¹ See, e.g., Dennis Johnson. "FSIS declares top six non-O157 STEC adulterants," The National Provisioner, (Oct. 26, 2011), https://www.provisioneronline.com/articles/97307-fsis-declares-top-six-nono157-stec-adulterants

Canada,⁵² with one ongoing as of this writing.⁵³ FSIS should not wait for an STEC outbreak to strike the United States before taking action to protect consumers from these deadly pathogens.

FSIS needs specific authority to set and enforce performance standards

FSIS points out that the Fifth Circuit Court of Appeals 2001 decision in *Supreme Beef Processors, Inc. v. USDA* limits the agency's ability to enforce pathogen reduction standards. This poses a legitimate problem, and FSIS should actively seek authority from Congress to set and enforce pathogen reduction performance standards. FSIS now addresses the failure of plants to meet *Salmonella* and other pathogen reduction performance standards by sending in staff to conduct Food Safety Assessments. This staff is in addition to the inspection staff already in the plant. The result is taxpayer money spent to support expensive efforts by FSIS to provide technical assistance to meat and poultry plants that are unable or unwilling to meet the current standards. Taxpayer dollars should not continue to subsidize the operation of these poor performing plants. Instead, FSIS should seek, and Congress should provide, the agency with the specific authority to fully enforce its pathogen reduction performance standards.

Performance standards are a critical component of poultry inspection

Despite the limitations on FSIS' enforcement capacity, in the context of poultry inspection, meaningful pathogen reduction performance standards have provided for accountability. This experience underscores the folly of rolling out sweeping inspection reforms without *any* applicable standards. After the *Supreme Beef* decision, poultry plants' compliance with *Salmonella* performance standards began to slip in the mid-2000s. During the George W. Bush Administration, FSIS responded by publishing on its website which poultry establishments were failing to meet performance standards. FSIS has credited this policy with a steep decline in *Salmonella* contamination rates in poultry during the years following.⁵⁴

The application of performance standards has also operated to expose weaknesses in the HIMP inspection approach, and to serve as a backstop against industry bottom dwellers. For example, FSIS recently reported that one of the original enrollees in the poultry HIMP pilot—the Mar Jac Poultry plant in Hattiesburg, Mississippi—had failed to meet *Salmonella* performance standards for chicken parts. Information in response to a Freedom of Information Act request from Food & Water Watch later revealed a litany of food safety deficiencies at the plant, including an inadequate food

⁵² See Honish et al., supra note 9, https://www.ncbi.nlm.nih.gov/pubmed/28056011; Trotz-Williams et al. "Pork implicated in a Shiga toxin-producing Escherichia coli O157:H7 outbreak in Ontario, Canada." Can J Public Health. 2012 Jul 18;103(5):e322-6 (July 2012), https://www.ncbi.nlm.nih.gov/pubmed/23617981

⁵³Canadian Food Inspection Agency. "Updated Food Recall Warning - Certain Irvings Farm Fresh brand pork products recalled due to E. coli O157:H7," (April 25, 2018), http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recall-warnings/complete-listing/2018-04-25/eng/1524717992218/1524717994965

⁵⁴ After the Fifth Circuit Court of Appeals' 2001 decision in *Supreme Beef v. USDA*, which severely restricted USDA's ability to enforce performance standards, compliance with 1996 Salmonella performance standards began to slip in the mid-2000s. As FSIS itself has noted, "this rise was because there were rarely significant consequences to failing a Salmonella set." However, "[i]n 2006, this trend of rising Salmonella positive carcasses was reversed when FSIS instituted categorization and web-posting of Category 2 and 3 establishments. In fact, the number of establishments not meeting the standard fell by 50 percent in the 2-year period following the time FSIS started posting category information." FSIS. "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.* 7288. (Feb. 11, 2016).

safety plan and deficient procedures for diverting carcasses contaminated with feces and ingesta.⁵⁵ The public records disclosed that FSIS even went so far as to shut down the plant for a shift.

Astoundingly, FSIS has not revoked the Mar Jac Poultry plant's permission to operate at the higher line speeds allowed under the New Poultry Inspection System, the avian analogue to the New Swine Inspection System being proposed in this rule. However, web-posting of the plant's compliance with the performance standards provides a check, albeit an imperfect one. Wholesale purchasers that value food safety can avoid buying from the plant if it is out of compliance. And many do just that. As a recent research report from USDA's Economic Research Service (ERS) explains, web-posting compliance with performance standards lets "buyers determine the appropriate level of food safety and costs," while avoiding "costly regulatory oversight and labor devoted to compliance." Of course, for the individual consumer, who may be unsure of the local grocers' or restaurants' procurement policies and whether they buy chicken from plants like Mar Jac, this approach offers incomplete assurance.

The absence of a standardized testing regime would further confound efforts to curb food safety abuses.

In addition to *Salmonella* performance standards, FSIS proposes to get rid of generic *E. coli* testing requirements. According to the agency, this would give plants "more flexibility in monitoring their process control" and make pork inspection regulations "more consistent with the Federal poultry products inspection regulations." Consistency with poultry regulations is a suspect objective, for the reasons CFA gave in our comments on the expansion of the poultry HIMP program. ⁵⁷ Moreover, this rule does not deliver consistency because it lacks key safeguards found in the poultry rules: most critically, as discussed above, meaningful pathogen performance standards. It also fails to provide for *any* line speed limit. Plants would operate at whatever speed allows for "process control," and the agency has not defined what that term means.

Uniform microbiological testing requirements—whether for generic *E. voli*, aerobic plate count, total plate count, total coliforms, *Salmonella*, or some other indicator of "process control"—would facilitate more decisive action from inspectors. Under the proposed rule, plants have enormous leeway in defining when the results of microbiological testing signal a problem. Plants need only "provide scientific or technical documentation to support the judgments made in designing their sampling plans." The rule's vast "definite improvement" exception for the location and frequency of sampling compounds the problem. If some plants choose to abuse this "flexibility" to avoid meaningful checks on how well they are maintaining "process control," inspectors would lack clearly

⁵⁵ See Food & Water Watch. "Suspension of New Poultry Inspection System Plant Shows that Privatized Inspection is a Failure," (April 23, 2018), https://www.commondreams.org/newswire/2018/04/23/suspension-new-poultry-inspection-system-plant-shows-privatized-inspection#

⁵⁶ See Michael Ollinger, James Wilkus, Megan Hrdlicka, and John Bovay. "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 ["ERS Report"]

⁵⁷ Comments of Chris Waldrop, Consumer Federation of America, re FSIS proposed rule regarding Modernization of Poultry Slaughter Inspection (Docket No. FSIS–2011-0012), (May 29, 2012), https://consumerfed.org/pdfs/Comments poultry slaughter proposal 5.29.12.pdf

defined standards to enforce compliance. FSIS has provided no justification for allowing every plant to develop its own sampling program.

FSIS should set specific standards for OCP defects

FSIS is proposing to allow each plant to design and implement its own measures to address non-food safety "Other Consumer Protection" (OCP) defects, and to assure that the plant is producing ready-to-cook pork. FSIS has not set specific acceptable OCP defect levels that plants must meet. Rather, the proposed rule provides that if inspectors observe "persistent, unattended defects," FSIS would require the plant to take appropriate actions. This approach gives consumers little assurance that hog slaughterhouses would produce pork in a uniform manner and adequately remove defective carcasses.

According to FSIS, "OCP standards are non-food safety standards concerned primarily with diseases of no public health significance and carcass processing defects." Failing to control for OCP defects, however, has implications for public health. For example, as the rule explains, under the current OCP standards, hog carcasses may not show signs of erysipelas. Erysipelas is "an infectious disease caused by the bacterium Erysipelothrix rhusiopathiae seen mainly in growing pigs and characterised clinically by sudden death, fever, skin lesions and arthritis." The most common treatment for the disease is antibiotics, and contact with the disease poses an occupational hazard to slaughterhouse workers, who may become infected and develop a skin lesion called erysipeloid. Thus, ensuring that plants control for erysipelas may help to avoid increased reliance on antibiotics, and reduce occupational hazards for workers. Both of these factors affect food safety, albeit indirectly.

Of course, FSIS claims that it does not need to establish standards because HIMP plants have such a strong record of controlling OCP defect, but that assertion lacks support. The proposed rule claims:

Data collected from market hog establishments operating under HIMP show that from CY 2012 through 2013, HIMP establishments maintained OCP defect levels that average about half the corresponding OCP performance standards derived from the performance of non-HIMP establishments. Thus, the data show that establishments operating under the HIMP system do exceptionally well in controlling OCP defects.

This is an apples to oranges comparison. What the rule does not mention is that the "OCP performance standards" are derived from a baseline study conducted in 1998. A lot changes in twenty years. Technological advances in animal breeding and transport, for example, are likely to have made a significant impact on the rates of OCP defects in hog slaughterhouses. A timely "baseline" survey of non-HIMP plants might very well show that HIMP plants are not so exceptional, or even that they are exposing consumers to more OCP defects than comparable plants under traditional inspection.

FSIS should set minimum training and certification requirements for establishment employees that take over inspection tasks

⁵⁸ New South Wales Department of Primary Industries, "Swine erysipelas", (Aug. 2017), https://www.dpi.nsw.gov.au/ data/assets/pdf file/0003/436440/Swine-erysipelas.pdf ⁵⁹ Id.

Currently, FSIS inspectors who conduct sorting activities in pork plants receive formal training. FSIS Public Health Veterinarians charged with inspecting live hogs have, as their name suggests, a veterinary degree. The proposed rule would shift the inspection duties of FSIS employees to company employees, and the FSIS personnel that remain would have to review a much larger number of animals, moving at higher speeds, to detect any diseases that the company employees miss. If the company "sorters" do not perform their function well, food safety hazards are more likely to make their way to the consumer. To avoid that outcome, training and certifying sorters is essential.

The proposed rule recognizes that training company sorters is necessary for them "to make accurate decisions on how to address animal disease conditions and trim and dressing defects." Yet the agency has declined to actually require that plants train or certify sorters. According to the proposed rule, this approach would "give establishments operating under the NSIS the flexibility to select the training program that would best assist them to meet the requirements of this proposed rule." The rule fails to justify the need for such "flexibility."

Critics of the HIMP program have pointed to the need for training and certification requirements since the pilots began. In 2001, the Government Accountability Office issued a report on the HIMP pilot program that criticized FSIS for not requiring that plant employees complete training before assuming carcass sorting activities. GAO also criticized the agency for not establishing a way to measure plant employee's knowledge and competence. The oversight body pointed out that HIMP like programs in Australia and Canada required training and certification for company sorters, and that FSIS requires training and certification of plant sorters in these foreign poultry slaughter programs as a condition of equivalency determination.

FSIS responded to those concerns in a similar fashion to the proposed rule's treatment of the subject now, acknowledging the "vitally important" nature of training, and going on to dismiss the need for any requirements. The absence of training requirements, coupled with higher line speeds, means increasing the burden on FSIS inspectors to stop production lines and take regulatory actions to address problems with carcass defects going down the line. Evidence from the HIMP program bears this out. Comparing the noncompliance records from the five HIMP plants with a comparable control group, a recent Food & Water Watch study reveals significant oversights on the part of company sorters, including 32 instances "in which a USDA on-line inspector discovered that a plant employee failed to identify a carcass so infected that consumption of the meat could cause food poisoning." Training and certification requirements would help to avoid such incidents, but of course, they would also require plants to invest more in their employees.

Poor working conditions affect food safety

The proposed rule correctly "recognizes that evaluation of the effects of line speed on food safety should include the effects of line speed on establishment employee safety." A company's ability

⁶⁰ GAO, "Food Safety: Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation." GAO-02-59, December 2001.

⁶¹ Food & Water Watch. "New Documents Show Privatized Hog Inspection Scheme Rife with Food Safety Violations," (Feb. 21, 2018), https://www.foodandwaterwatch.org/news/new-documents-show-privatized-hog-inspection-scheme-rife-food-safety-violations

to effectively protect consumers from food safety risks depends in part on having a stable, skilled workforce. New workers are more likely to make mistakes, such as perforating intestines, that lead to contamination and food safety problems. The prevailing labor conditions in the meatpacking industry, however, breed instability.

According to the Bureau of Labor Statistics, meatpacking workers suffer more occupational illnesses—tendonitis, carpal tunnel syndrome, skin diseases, respiratory conditions, hearing loss, among others—than workers in any other private industry. Serious injury rates among meatpacking workers are three times the average rate in other private industry. The high illness and injury rates contribute to high turnover in the industry. In 2005, GAO observed: "Labor turnover in meat and poultry plants is quite high, and in some worksites can exceed 100 percent in a year as workers move to other employers or return to their native countries." A panel discussion at a recent industry conference touted the potential benefits of seeking out veterans, workers with disabilities, and refugees, to fill vacancies at slaughterhouses.

The available evidence indicates that high line speeds contribute to the undesirable working conditions at slaughterhouses. According to the National Institute for Occupational Safety and Health, "[l]ine speed affects the periodicity of repetitive and forceful movements, which are key causes of musculoskeletal disorders." In a GAO study published in November 2017, federal regulators told interviewers that "line speed—in conjunction with forceful exertions, awkward postures, and other factors—affects the risk of [musculoskeletal discorders]." And the same study reported that "[w]orkers we interviewed in all five states said increased line speed is an issue of concern to them, for reasons such as increased pain or injuries, not having time to sharpen knives, and not being able to keep up with the pace of work."

Given the preoccupation with existing line speeds, the proposed rule's reported findings that "HIMP establishments had lower mean injury rates than non-HIMP establishments" is surprising, and the unavailability of the underlying study is perplexing. Does the study exhibit the same sorts of irregularities that plague the market hog risk assessment? FSIS should not raise line speed caps at hog slaughter facilities until it provides the data and analysis to facilitate meaningful public comment. The impact of increase line speeds on worker illness and injury rates should also factor into the agency's cost-benefit analysis.

FSIS should create more incentives for on-farm controls

⁶² See Bureau of Labor Statistics, Supplemental News Release Table, SNR8. Illness rates by category of illness - detailed industry, https://www.bls.gov/web/osh.supp.toc.htm
⁶³ See id.

 $^{^{64}}$ GAO, "Safety in the Meat and Poultry Industry, while Improving, Could Be Further Strengthened." (Jan. 2005), $\underline{\text{https://www.gao.gov/new.items/d0596.pdf}}$

⁶⁵ Rita Jane Gabbett, "Panel points to three labor sources for meat plants," *Meatingplace*, (Apr.19, 2018), http://www.meatingplace.com/Industry/News/Details/79160

⁶⁶ John Howard, Director, National Institute for Occupational Safety and Health. "Letter to Food Safety Inspection Service: NIOSH Health Hazard Evaluation at a South Carolina Poultry Plant, 2014," (Apr. 7, 2014), https://www.cdc.gov/niosh/topics/poultry/letterapril72014.html

⁶⁷ GAO. "Better Outreach, Collaboration, and Information Needed to Help Protect Workers at Meat and Poultry Plants," (Nov. 2017), https://www.gao.gov/assets/690/688294.pdf

The proposed rule correctly observes that the "traditional inspection model needs to be updated. . . ." Any update, however, should include incentives for on-farm controls of pathogens that cause foodborne illness.

In addition to "significant advances . . . in the control or eradication of many animal diseases that were more prevalent and were considered to present a greater concern when the existing inspection systems were designed," there have been significant advances in understanding how onfarm or "pre-harvest" controls may reduce the incidence of foodborne illness. For example, in Denmark, farmers regularly test pigs for *Salmonella* and "animals from herds with high levels of Salmonella are slaughtered under special hygiene conditions." As a result of these "pre-harvest" strategies, that country "estimates that *Salmonella* infections in the population from 1994 to 2005 have been reduced by up to 600,000 and that 600 premature human deaths may have been avoided."

FSIS should encourage the pork industry to undertake on-farm controls as well. The proposed rule raises the possibility that FSIS may accept a plant's "records documenting their on-farm controls" of M. Avium to justify an exemption of requirements to incise mandibular lymph nodes and palpate the viscera. The agency could take a similar approach to encourage industry on-farm testing for *Salmonella*, instead of simply eliminating food safety protections without any countervailing measures.

Poor-performing establishments should be dropped from the program

FSIS indicates that its new swine slaughter inspection program would be a voluntary program operating under a waiver through the Salmonella Initiative Program. By deciding to take part in this new swine inspection program, plants would be granted certain benefits, such as the ability to increase their line speeds, which would likely provide plants with an economic advantage in the marketplace. FSIS officials have said that poor-performing plants would be addressed through the agency's regular enforcement process.

The experience of HIMP cries out for a mechanism to eject poor performing plants. As noted earlier, the OIG found in 2013 that "the swine plant with the most NRs during [FYs 2008 to 2011] was a HIMP plant—with nearly 50 percent more NRs than the plant with the next highest." More recently, undercover footage at the Quality Pork Processors HIMP plant in Austin, Minnesota, revealed humane handling and food safety violations that further called into question the adequacy of controls under HIMP. And in the poultry HIMP program, the Mar Jac Poultry plant provides another salient example of the agency's rule: once a HIMP plant, always a HIMP plant.

Poor-performing plants should not be "rewarded" for their poor performance by being allowed to take part in a program and increase their line speeds, which could further exacerbate performance and worker safety problems. If a plant in the new program repeatedly violates agency regulations or is unable to produce product that meets microbial performance standards, the plant should not be allowed to continue accruing the benefits of the program and should be returned to traditional inspection. FSIS should develop procedures for addressing how plants with repeated violations, repeated NRs, or microbial testing failures would be removed from the program and transitioned to traditional inspection. This approach would provide a very strong incentive for plants

⁶⁸ The Pew Charitable Trusts. *Food Safety From Farm to Fork*. (July 2017), at 83, http://www.pewtrusts.org/~/media/assets/2017/07/food-safety-from-farm-to-fork-final.pdf

to maintain their processes and achieve acceptable levels of performance.

Thank you for your consideration of these comments.

Sincerely,

Thomas Gremillion
Director, Food Policy Institute
Consumer Federation of America