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18 **UNITED STATES DISTRICT COURT**  
19 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**  
20 **OAKLAND DIVISION**

21 CENTER FOR FOOD SAFETY, *et al.*,

22 *Plaintiffs,*

23 v.

24 SONNY PERDUE, in his official capacity as the  
25 Secretary of the U.S. Department of Agriculture,  
*et al.*;

26 *Defendants.*

Case No. 4:20-cv-00256-JSW

**AMICUS CURIAE BRIEF BY  
MARYLAND, ILLINOIS,  
MASSACHUSETTS, AND  
MICHIGAN**

Judge: Honorable Jeffrey S. White  
No hearing has yet been scheduled



1 matter, digestive contents, and milk. A-0052–55; A-0075–76. It is now more difficult to  
2 accomplish this because there are fewer inspectors on the line.

3 This case concerns the FSIS’s deviation from the foundational food-safety principles  
4 embodied in these requirements. The Rule delegates many inspection duties to private plant  
5 employees, who must meet only minimal training requirements, effectively sidelining federal  
6 inspectors and placing the public at a greater risk of consuming suspect products. The Amici States  
7 have a substantial interest in supporting Plaintiffs’ efforts to vacate the challenged Rule and in  
8 protecting the public health and safety of our citizens by insisting that the FSIS adequately regulate  
9 swine-processing facilities. The Rule endangers the health and safety of consumers—dangers that  
10 the FSIS largely disregarded during the rulemaking process. The Amici States file this brief to  
11 inform the court about how the Rule jeopardizes the health of our citizens. The rulemaking is  
12 unlawful under the APA and contrary to the Federal Meat Inspection Act. The Amici States  
13 therefore urge the Court to grant Plaintiffs’ request to vacate the Rule.  
14

## 15 ARGUMENT

### 16 **I. THE RULE JEOPARDIZES THE AMICI STATES’ INTEREST IN ENSURING SAFE PORK** 17 **PRODUCTS FOR OUR CITIZENS.**

18 The Amici States have a significant interest in ensuring the safety of pork and other food  
19 products consumed by our citizens. *See Contreras v. City of Chicago*, 119 F.3d 1286, 1290 (7th  
20 Cir. 1997) (finding a substantial government interest in safety of the food provided in the City of  
21 Chicago). Although the states retain authority to regulate food safety within our borders, the Amici  
22 States must rely on federal regulations to ensure that food produced outside of our jurisdiction is  
23 safe for consumption. *See* National Academy of Sciences, *Enhancing Food Safety: The Role of*  
24 *the Food and Drug Administration* at 205 (2010), available for free download (as guest) at  
25 <https://www.nap.edu/catalog/12892/enhancing-food-safety-the-role-of-the-food-and-drug#stats>  
26 (discussing state-federal division of authority); *see also* The Federal Food Safety System: A  
27  
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1 Primer, Congressional Research Service (Dec. 16, 2016). That reliance on federal safety standards  
2 applies with respect to all meat products sold in commerce and regulated by the USDA.<sup>1</sup> See  
3 Federal Meat Inspection Act, 21 U.S.C. § 603.

4 Foodborne illnesses impose massive costs on the United States health care system  
5 (including, of course, the Amici States' Medicaid programs) and on the well-being of the citizens  
6 of the Amici States. The Centers for Disease Control and Prevention notes that the USDA  
7 estimates that foodborne illnesses cost the United States more than \$15.6 billion each year.<sup>2</sup> See  
8 CDC and Food Safety, <https://www.cdc.gov/foodsafety/cdc-and-food-safety.html>. Contaminated  
9 pork is directly linked to a high incidence of foodborne illnesses. As Defendants themselves have  
10 recognized, “[c]arcasses and parts contaminated with fecal material, ingesta, or milk or that exhibit  
11 signs of septicemia, toxemia, pyemia, or cysticercosis during post-mortem examination are likely  
12 to contain infectious agents, such as bacteria, virus, rickettsia, fungus, protozoa, or helminth  
13 [parasitic-worm] organisms, which can be transmitted to humans. 83 Fed. Reg. at 4793 (preamble  
14 to the Rule).  
15

16  
17 Numerous pork-related pathogens find their way onto the grocery market shelves. A 2013  
18 Consumer Reports survey tested 198 samples of pork chops and ground pork and found *Yersinia*  
19 *enterocolitica*, which can cause gastroenteritis, in 69% of the samples; *Enterococcus*, which can  
20 cause urinary tract infections, in 11%; *Staphylococcus aureus* in 7%; *Salmonella* in 4%; and  
21 *Listeria monocytogenes* in 3%. See *Pork chops and ground pork contaminated with bacteria*,  
22

23  
24 <sup>1</sup> While states can operate inspection authority delegated from FSIS, these programs must  
be at least equivalent to federal requirements. See 21 U.S.C. § 661.

25 <sup>2</sup> One study, however, found that the annual health-related costs of foodborne illness in the  
26 United States may be as high as \$152 billion, when accounting for medical costs (hospital services,  
27 physician services, and drugs) and quality-of-life losses (deaths, pain, suffering, and functional  
28 disability). Scharff, Produce Safety Project, *Health-Related Costs from Foodborne Illnesses in  
the United States* (March 3, 2010), available at [https://www.pewtrusts.org/media/legacy/  
uploadedfiles/phg/content\\_level\\_pages/reports/pspscharff20v9pdf.pdf](https://www.pewtrusts.org/media/legacy/uploadedfiles/phg/content_level_pages/reports/pspscharff20v9pdf.pdf).

1 Consumer Reports (Jan. 2013), <https://www.consumerreports.org/cro/magazine/2013/01/what-s->  
2 [in-that-pork/index.htm](https://www.consumerreports.org/cro/magazine/2013/01/what-s-in-that-pork/index.htm). The Centers for Disease Control and Prevention has noted that  
3 contaminated pork may cause almost one and a half million cases of foodborne illness in the U.S.  
4 each year, leading to approximately 7,000 hospitalizations and 200 deaths. *See* Painter, et al.,  
5 *Attribution of foodborne illnesses, hospitalizations, and deaths to food commodities by using*  
6 *outbreak data, United States, 1998-2008* (2013) (Figure 2), available at [https://wwwnc.cdc.gov/](https://wwwnc.cdc.gov/eid/article/19/3/11-1866_article)  
7 [eid/article/19/3/11-1866\\_article](https://wwwnc.cdc.gov/eid/article/19/3/11-1866_article).

8  
9 Despite these threats to human health, core changes introduced in the Rule increase the  
10 likelihood of unwholesome pork products reaching consumers in the Amici States. First, by  
11 delegating pre-slaughter inspection duties to plant employees, the Rule shields the incoming  
12 supply of hogs from expert federal observation. *See* 9 C.F.R. § 309.19(a)-(b) (2021); 84 Fed. Reg.  
13 52345. This directly contravenes the FMIA’s clear requirement that federal inspectors “examin[e]  
14 and inspect[]” all livestock prior to their entry into a slaughterhouse. 21 U.S.C. § 603(a). The  
15 USDA has traditionally acknowledged the plain intent of this section and required federal  
16 inspectors to observe every head of livestock—both at rest and in motion—prior to slaughter. *See*  
17 *FSIS Directive 6100.1 Rev. 2, X.B.* (July 24, 2014); Doc. 65-2, A0018.

18  
19 The Rule also relaxes the requirements for separating and tagging animals exhibiting  
20 suspicious traits. Rather than requiring federal inspectors to tag *all* such animals as suspect, the  
21 Rule allows plant employees to separate out (rather than tag) the animals exhibiting concerning  
22 behavior and provide further rest and observation before reinspection. If an animal then passes  
23 inspection without further concern, it can be placed back into the general population without  
24 additional tagging for inspection after slaughter. 9 C.F.R. § 309.2(n); A-538. Plant employees  
25 also can remove potentially symptomatic animals from the plant, increasing the risk that—without  
26 federal inspectors personally tagging and segregating—these diseased or injured individuals will  
27 reach the food supply through other means. That diverges from the traditional inspection system  
28

1 whereby federal inspectors tagged all suspect animals prior to slaughter, ensuring their more  
2 thorough examination post-mortem even if they were not ultimately condemned.

3 The Rule's issues continue after slaughter. Delegation of carcass-inspection duties to plant  
4 employees is just as problematic. Traditionally, federal inspectors would examine each carcass,  
5 palpating, feeling, and incising lymph nodes to determine the extent of suspicious conditions and  
6 marking those carcasses that required further evaluation. 9 C.F.R. § 310.3; A-0051-52. Federal  
7 inspectors would also require plant employees to remove problematic parts of carcasses, such as  
8 those showing signs of disease or otherwise contaminated with fecal matter, digestive contents,  
9 and milk. A-0052-55; A-0075-76. Under the Rule, that is no longer the case.  
10

11 These concerns are exacerbated by the potential that the Rule will allow increased line  
12 speeds.<sup>3</sup> Not only are insufficiently trained plant employees<sup>4</sup> being asked to inspect animals and  
13 carcasses, they may also have to do so under line conditions that are more demanding than those  
14 traditionally faced by professionally trained federal inspectors. Faster lines reduce the time that  
15 these minimally trained individuals will have to evaluate each carcass.  
16

17 And it is a near certainty that pork products inspected under the Rule will reach the Amici  
18 States. The USDA expects that each of the nation's 40 high-volume swine-processing facilities  
19 will adopt the Rule, accounting for roughly 93% of total annual pork production in the United  
20 States. 82 Fed. Reg. 52,305 (Oct. 1, 2019). This means that consumers across the country will  
21 receive pork from facilities participating the new system allowed by the Rule. By the time those  
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23 <sup>3</sup> A federal district court upheld a challenge to the line speeds permitted by the Rule.  
24 Although the Defendants did not appeal that ruling, they have announced a trial program that  
25 would allow participating establishments to operate at increased line speeds for up to a year to  
26 gather data measuring the impact of line speeds on workers. *See* Constituent Update - November  
27 12, 2021, Time-Limited Trial for NSIS Establishments, available at [https://www.fsis.usda.gov/  
28 news-events/news-press-releases/constituent-update-november-12-2021](https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-november-12-2021).

<sup>4</sup> Indeed, apart from a reference to distributing a sorting guide, the regulations do not appear  
to specify training requirements or testing to ensure that the employee has developed the necessary  
skills to inspect.

1 products reach consumers in the Amici States, there may be little that state and local food safety  
2 programs can do to prevent exposure to unsanitary products.

3 **II. EXPERIENCES AT PILOT PLANTS SUGGEST THAT THE RULE WILL LEAD TO**  
4 **INCREASED CONTAMINATION AND FOOD SAFETY VIOLATIONS.**

5 Much of the support the USDA offers for the Rule relies on the experiences of plants  
6 adopting similar programs on a pilot basis—the HACCP-Based Inspection Model Project  
7 (“HIMP”)<sup>5</sup>—over the 15 years prior to its rulemaking. But the HIMP pilot program did not yield  
8 the positive results that would justify adoption of its tenets on a wider basis. Rather, the HIMP  
9 program was plagued by poor oversight, resulted in higher rates of contamination and lower rates  
10 of condemnation, and placed plant employees in positions they were unsuited to fulfill.

11 First, the pilot program was managed ineffectively for much of its duration, and the data  
12 produced from studying it is of limited use. For example, the FSIS’s report analyzes data from  
13 2006-2010 and 2012-2013, but the five pilot facilities adopted these HIMP processes as early as  
14 1997. *See* HIMP Report at 5. This means that the FSIS’s analysis missed the first nine years of  
15 pilot program implementation—a highly relevant time that would better reflect the challenges that  
16 plants adopting the new system will face initially.<sup>6</sup>

17  
18 Second, the report itself paints a less than rosy picture of food safety at the HIMP facilities.  
19 Three of the five facilities that participated in the pilot program ranked among the ten facilities  
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<sup>5</sup> HACCP is an acronym for “hazard analysis and critical control points.” The FDA  
23 describes HACCP as “a management system in which food safety is addressed through the analysis  
24 and control of biological, chemical, and physical hazards from raw material production,  
25 procurement and handling, to manufacturing, distribution and consumption of the finished  
product.” <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/hazard-analysis-critical-control-point-haccp>.

26 <sup>6</sup> The experience of the Clemons Food Group plant in Coldwater, Michigan, provides a  
27 useful example. That facility joined the pilot program in September 2017, and the record details  
28 repeated failures to adequately staff lines with employee sorters, difficulties encountered by plant  
employees in incising lymph nodes, and poor employee-training resulting in digestive and fecal  
contamination. A-0302, 0304, A-0310, A-0319-20.

1 nationwide with the worst compliance records during the program's tenure. *See* FSIS – Inspection  
2 and Enforcement at Swine Slaughter Plants, Audit Report 24601-0001-41 (May 2013) at 17-19.  
3 That facilities implementing the pilot program placed among the nation's least safe plants  
4 undermines the FSIS's claims that widespread adoption of NSIS procedures will not pose a risk to  
5 food safety.

6 Third, while the HIMP report notes increases in compliance procedures, like offline  
7 inspections at pilot facilities, the value of those increases to food safety—the FSIS's ultimate  
8 goal—is undermined by the increased records of noncompliance with public health requirements.  
9 *See* USDA, FSIS, *Evaluation of HACCP Inspection Models Project (HIMP) for Market Hogs*,  
10 Nov. 2014, at 5 (describing higher rates of offline verification at HIMP establishments); *id.* at 6  
11 (noting that from 2006-2010 public health related noncompliance rates were 1.2 times higher at  
12 HIMP than non-HIMP establishments). At best, the report provides a mixed review of the pilot  
13 program's impact on food safety.  
14

15 The report's inconsistencies should also be viewed in light of the firsthand accounts of  
16 federal inspectors tasked with performing offline inspection duties at pilot plants. The anonymous  
17 affidavits of four federal inspectors turned whistleblowers in early 2015 show significant concerns  
18 with HIMP implementation. These statements cast doubt on the ability of inspectors to monitor  
19 plant employees at increased line speeds or to correct employee errors during the post-slaughter  
20 inspection process. A-0261-62. Employees had trouble removing contamination and incising  
21 lymph nodes, made efforts to conceal fecal matter contamination, and frequently made errors when  
22 palpating lymph nodes. *Id.*  
23

24 The USDA failed to adequately account for these concerns—the plant-specific reports, the  
25 whistleblower affidavits, and the HIMP report's checkered conclusions—when it finalized the  
26 Rule. That alone should provide adequate grounds to vacate the Rule under the APA.  
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**CONCLUSION**

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2 For the foregoing reasons, the Amici States respectfully request that the Court grant  
3 Plaintiffs' Motion for Summary Judgment and vacate the Rule.  
4

5 Respectfully submitted, this 10th day March, 2022.  
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