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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
OAKLAND DIVISION

CENTER FOR FOOD SAFETY, *et al.*,

Plaintiffs,

v.

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

Defendants.

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

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Judge: Honorable Jeffrey S. White

No hearing has yet been scheduled

NOTICE AND MOTION

PLEASE TAKE NOTICE that Plaintiffs Food & Water Watch, Center for Food Safety, The Humane Farming Association, and Robin Mangini ("Plaintiffs") respectfully request this Court grant Plaintiffs' Motion for Summary Judgment in the above-captioned case. Plaintiffs also request the Court schedule a hearing on this matter.

As detailed in the following brief and set forth in the proposed order, the Court should grant the Plaintiffs' motion and vacate Defendants' New Swine Inspection System rules.

BRIEF IN SUPPORT OF PLAINTIFFS' MOTION

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ABBREVIATIONS USED

APA: Administrative Procedure Act

FMIA: Federal Meat Inspection Act

FS–2: Food Safety Standard 2

FOIA: Freedom of Information Act

FWW: Food & Water Watch

GAO: U.S. Government Accountability Office

HACCP: Hazard Analysis and Critical Control Points

HIMP: HACCP-Based Inspection Model Project

NSIS: New Swine Inspection System

OIG: USDA Office of Inspector General

OMB: Office of Management and Budget

PHV: Public Health Veterinarian

USDA: U.S. Department of Agriculture

INTRODUCTION

Plaintiffs, who are three non-profit consumer organizations and one of their individual members, challenge Defendants' New Swine Inspection System ("NSIS") rules, which radically transform how the federal government inspects live animals, carcasses, and parts in swine slaughter plants under the more-than-a-century-old Federal Meat Inspection Act ("FMIA" or "the Act"). The NSIS inspection system cripples federal inspection under the FMIA, threatening to exacerbate the more than one million annual foodborne illnesses due to *salmonella* alone in the United States. Ex. A-0630.[1]

The NSIS rules are contrary to the FMIA and thus violate the Administrative Procedure Act ("APA"). The FMIA mandates that federal government inspectors give an "examination and inspection" of (1) each and every animal prior to slaughter and (2) every carcass and body part after slaughter. It also requires that those animals showing symptoms of disease be set apart and slaughtered separately. The NSIS rules, however, transfer these crucial federal inspection duties to the slaughter plant employees called "sorters." This prevents federal inspection personnel from "paying close attention to" and giving the required "critical appraisal" of animals, carcasses, and parts, since they cannot perform tasks necessary for the "critical determination whether a product is adulterated or unadulterated." *AFGE v. Glickman (AFGE I)*, 215 F.3d 7, 10–11 (D.C. Cir. 2000). Federal inspectors (1) can inspect no more than 10% of plant-employee-passed animals while they are in motion; (2) are denied the information they need to evaluate symptomatic animals and set them aside for separate slaughter; (3) do not test employee-sorted animals to ensure residues do not taint the plants' animal supply; (4) cannot palpate and incise carcass lymph nodes; and (5) do not evaluate carcasses for more serious or generalized conditions or fecal-matter, digestive-contents, or milk contamination until it is too late to catch these problems. The NSIS rules also reduce the number of federal inspectors on the slaughter lines so that each only has half as much time to perform an inspection.

The NSIS rulemaking also violates the APA because it was arbitrary and capricious. The rules not only irrationally depart from Defendants' existing inspection regulations and practices, but they are also primarily based on a fundamentally flawed pilot project with a small, unrepresentative sample of five

[1] To facilitate review, Plaintiffs have excerpted portions of the administrative record and placed them in Corrigan Ex. A. Hereinafter, they are all cited to as "A-____."

plants. Defendants' 2014 report on the 20-year pilot evaluated only select snapshots of data from a few years. The report also obscured that federal inspectors in NSIS pilot plants did not, in fact, conduct more specific, offline food-safety verifications and that the plants had higher violations for fecal matter, digestive contents, and milk contamination than plants operating under traditional inspection. Defendants also have overlooked persistent pilot-plant problems, including plant employees' repeated failures to perform their newly acquired inspection task of incising lymph nodes. The sole quantifiable public health benefit that Defendants cite for their rules are the reduced *salmonella* illnesses projected by their risk assessment.[2] But Defendants completely disregarded peer reviewers' contentions that the assessment was invalid; they then arbitrarily failed to provide an adequate opportunity to comment on the rules by making peer reviewers' comments publicly available only months *after* the rules' public comment period closed. This, despite that Defendants would ultimately have to walk back their public health claims on the rules in light of this review. Finally, the NSIS rules' transfer of inspection tasks to plant employees was an unlawful subdelegation of authority and contrary to the FMIA's explicit directives. The NSIS rules are thus arbitrary and capricious and otherwise unlawful under the APA and should be vacated.[3]

BACKGROUND

I. STATUTORY AND REGULATORY BACKGROUND

A. A Robust Regulatory Regime Under the Federal Meat Inspection Act

This case is about whether Defendants' NSIS rules are contrary to and frustrate the purposes of FMIA, one of nation's cornerstone food safety laws. Congress passed the Act in 1906 in response to the unsanitary conditions in meatpacking plants detailed in Upton Sinclair's novel "The Jungle." A-0001. Congress declared that "[i]t is essential in the public interest that the health and welfare of consumers be protected by assuring that meat and meat food products distributed to them are wholesome, not adulterated, and properly marked, labeled, and packaged." 21 U.S.C. § 602 .

The Act authorizes Defendants to issue regulations to protect the health and welfare of consumers. *Id.* § 621. Centrally important, Congress required federal *government* employees to inspect meat and meat

[2] "Assessment of the Potential Change in Human Risk of Salmonella Illnesses Associated with Modernizing Inspection of Market Hog Slaughter Establishments" (Sept. 2019).

[3] Vacatur is the presumptive remedy under the APA. *All. for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1121-22 (9th Cir. 2018).

products, as opposed to meat-company employees. *Id.* §§ 603(a), 604, 621.

Federal government inspectors have four primary FMIA duties. First, they must inspect all animals before they are slaughtered—known as "ante-mortem" inspection. *Id.* § 603(a). Second, they must set apart all animals showing symptoms of disease from other animals so that they can be slaughtered separately and receive a "careful examination and inspection" when slaughtered. *Id.* Third, they must provide a "post-mortem" federal inspection of all carcasses and parts after slaughter. *Id.* § 604. Finally, they must condemn carcasses found to be adulterated and supervise the destruction of all condemned carcasses and parts. *Id.*

Pursuant to these general commands, over the more than 100 years since the FMIA was enacted Defendants have established and honed a robust regime—embodied in their regulations, directives, guidance documents, and training materials—aimed at preventing adulterated poultry, pork, and beef products from entering the nation's food supply. For swine, Defendants' directives governing traditional inspection have required trained federal inspectors to examine each and every animal prior to slaughter, both while it is in rest and in motion. A-0018. Federal inspectors were to ear-tag animals showing signs of disease as "U.S. Suspect" so that the hogs received further evaluation or "disposition" by a federal Public Health Veterinarian ("PHV")—both before and after they were slaughtered separately from other animals. 9 C.F.R. §§ 309.18(a), 309.2(a), (m), (n) (2021); A-0018.

After slaughter, federal inspectors were required to examine each and every carcass and part, including by "palpating," or feeling, and "incising," or slicing into, lymph nodes and determining whether there were any localized conditions, or else ear-tag them as "U.S. Retained" for further PHV evaluation. A-0051–52; 9 C.F.R. § 310.3 (2021). Federal inspectors were required to order plant employees to remove and trim the diseased parts of carcasses and those not complying with the Defendants' zero-tolerance standards for fecal matter, digestive contents, and milk. A-0052–55; A-0075–76. Inspectors performed these inspection duties while carcasses moved down the slaughter lines at a speed that Defendants' workplace studies determined was sufficiently slow to perform such tasks. 47 Fed. Reg. 33,673 (Aug. 4, 1982). In addition to these "online" inspections, federal inspectors performed various "offline" spot-checks or "verifications," away from the slaughter lines. A-0077–78.

II. BACKGROUND ON DEFENDANTS' NEW SWINE SLAUGHTER RULES

A. The Push to Replace Traditional Inspection with "HIMP"

Meat packing companies began their push to roll back this regime starting in the 1970s, as Defendants began inspecting more plants. "The driving force behind [Defendant Food Safety and Inspection Service's ("FSIS")] program changes from the 1970s on was the need to keep up with industry's expansion and its productivity gains . . . that increased the rate at which carcasses could move through the slaughter facility (typically referred to as 'line speed')." 60 Fed. Reg. 6774, 6776 (Feb. 3, 1995). In 1976, Defendants' consultants recommended that slaughter plants initially remove or "sort" sick animals, so that federal inspectors would examine only animals that plants deemed healthy. *Id.*; Corrigan Decl. at ¶ 4, Ex. D. But Defendants believed that such proposals were "not permitted by current law." Ex. D-04–05. Defendants also rejected ante-mortem sorting by non-federal employees because it might "materially increase the risk" of federal inspectors overlooking animals with less visible conditions. *Id.* at D-06. Instead, Defendants eliminated a few inspection tasks deemed unnecessary for public health. *Id.* at D-07; 46 Fed. Reg. 43,406 (Aug. 28, 1981).

By the 1990s, however, Defendants reversed course, pushing dramatic new changes with their "HACCP"-Based Inspection Model Project ("HIMP"), A-0065, even though there was little evidence that swine had become any healthier or pork any safer.[4] Under the HIMP pilot, a group of volunteer slaughterhouses were allowed to have their employees "distinguish acceptable from unacceptable carcasses and parts" based on regulatory requirements. A-0071. The purpose was to "change[] the way [Defendants] deploy[ed] . . . resources" because inspections were tied to plant production, and "[o]ccasionally, [inspector] staffing limitations negatively impact plant production rates." A-0067.

The D.C. Circuit would ultimately strike down the purest form of the pilot as contrary to the FMIA and Poultry Products Inspection Act. *AFGE I*, 215 F.3d at 10–11. The court held that neither observing establishment personnel removing unacceptable products, nor random sampling of carcasses, amounted to "inspection." *Id.* at 10. Instead, the ordinary, common meaning of this term requires "paying close attention to" and "critical appraisal," of each carcass and part, and "clearly contemplate[s] that . . . federal inspectors . . . make the critical determination whether a product is adulterated or unadulterated." *Id.* at

[4] 60 Fed. Reg. at 6800 (citing *salmonella* prevalence in carcasses).

10–11.

After remand, Defendants changed the HIMP protocols so that at least one federal inspector was on the slaughter line, and the district court found the program lawful. *AFGE v. Glickman*, 127 F. Supp. 2d 243, 244, 245 (D.D.C. 2001). But in affirming, the D.C. Circuit admonished: "This is a test program . . . intended as an experiment. If the USDA undertakes a rulemaking to adopt [it] as a permanent change, . . . experience with the program's operation and its effectiveness will doubtless play a significant role . . . . [O]ur opinion today may not necessarily foreshadow the outcome of judicial review of such future regulations." *AFGE v. Veneman* (*AFGE II*), 284 F.3d 125, 130 (D.C. Cir. 2002). As detailed below, this modified HIMP program would become the pilot project for Defendants' NSIS rules.

B. The Hog HIMP Pilot Falters.

Defendants' market hog HIMP pilot languished for years after the *AFGE II* decision.[5] In May 2013, nearly 15 years after HIMP's inception, the USDA Office of Inspector General ("OIG") audited the project and concluded that it lacked oversight, with the five voluntarily enrolled plants plagued by persistent regulatory violations, belying the program's supposed food-safety benefits. A-0107. The U.S. Government Accountability Office ("GAO") issued a report the same year echoing these findings and concluding that Defendants' preliminary study had too few pilot plants. A-0147; A-0152–55. It recommended that Defendants collect more information and analyze plants' compliance over time with performance standards established in 2000. A-0147; A-0154–55.

Defendants responded by finalizing their Hog HIMP Report the next year. A-0189. The report evaluated only the same large pilot plants that had previously volunteered, and that the OIG had identified as having compliance problems. *See* Defs.' Answer ¶ 195. The report did not examine how well pilot-plant inspectors could evaluate animals, carcasses, and parts, or whether plant employees or inspectors could perform the tasks required to remove potentially adulterated pork from the production line. Diseased animals and carcasses and online inspection tasks were barely mentioned. *See* A-0189–232. Rather, the report sought to evaluate whether the new system performed comparably to traditional inspection based on several proxies, including the relative number of carcasses that pilot-plant employees and federal

[5] In 2015, the D.C. Circuit dismissed a lawsuit challenging Defendants' rules for poultry plants without reaching the merits. *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905 (D.C. Cir. 2015).

inspectors removed from the lines and the number of the federal inspectors' *offline* verifications. A-0189–90. It only included data from seven years from the pilot, from 2006 to 2010 and 2012 to 2013, *id.*, omitting more years than it included. *See, e.g.*, A-0212–13. The report did not evaluate trends in pilot plants' compliance with the performance standards as GAO had recommended. *Id.*

C. Inspectors Blow the Whistle, But the Pilot Continues.

Defendants did not propose new swine inspection rules immediately after the Hog HIMP Report. The report's sole conclusion was that the program should continue. A-0192. This raised the prospect that Defendants would collect more data. But in early 2015, four inspectors from HIMP plants came forward urging the project's halt. Their anonymous affidavits strongly rebutted the Hog HIMP Report, challenging it as profoundly biased. *See, e.g.*, A-0272. They were additionally concerned that fecal matter contamination had increased (as well as plant employees' attempts to hide it), *id.*; that lines at the plants were moving too fast to allow for inspections; and that plant employees could not effectively remove contamination or incise lymph nodes, a task "critical [for] detecting different diseases that would make product unfit for human consumption, such as septicemia or tuberculosis." A-0260; A-0268. They asserted that due to a lack of training, plant-employee sorters made many errors when palpating and incising lymph nodes. A-0261, A-0280. At increased line speeds, inspectors could not effectively monitor employees, such as whether they could catch abscessed lymph nodes. A-0261–62. Finally, they contended that federal inspectors were too far removed from the lines to correct employee errors. A-0276.

Two years later, in September 2017, Defendants granted a new regulatory waiver to the Clemons Food Group plant in Coldwater, Michigan, so that it could operate similarly to a HIMP plant. A-0285–86. Records of meetings between the company's management and Defendants shows that the plant had only one employee sorter on the lines—and that they were not palpating each carcass's viscera. A-0302. The plant's employees also had trouble incising jaw ("mandibular") lymph nodes. A-0304. Defendant FSIS Administrator Paul Kiecker and District Manager Paul Wolseley expressed concerns about the consistency and thoroughness of sorters' head evaluations. A-0303. Even a year after its waiver, the plant still exhibited the same problems. A-0311–13, A-0322–24. Other problems at this plant included digestive contaminants on carcasses and the lack of process control, *see, e.g.,* A-0310, as well repeated fecal contamination due to a lack of employee training; *see, e.g.,* A-0319–20; A-0309. In terms of ante-mortem inspection, inspectors

wrote the plant up for having a deficient food-safety plan. A-0321.

D. The Public Outcry over the Proposed Rules

Defendants did not let these issues dissuade them from moving forward. They proposed the NSIS rules in February 2018, along with a draft risk assessment and compliance guideline detailing how plant employees were to perform sorting. 83 Fed. Reg. 4780, 4793–94 (Feb. 1, 2018).[6] Defendants pointed to the Hog HIMP Report in support of the rulemaking. *Id.* at 4788. The proposal's preamble cited the draft risk assessment's predicted annual reduction of 2,533 *salmonella* illnesses, about a 3.63% reduction, as its sole public health benefit. *Id.* at 4811–12.

The vast majority of the 83,000 comments submitted on the proposed rules expressed opposition, including more than 60 members of Congress (A-0454–49), five U.S. Senators (A-0461), the European Union (A-0332–37), and numerous consumer, public health, animal-welfare, and worker-safety groups. Commenters challenged the new rules for preventing government inspectors from being able to critically appraise animals and carcasses and parts; A-0234–35; A-0247; A-0447–48; including because plant-employee sorters could remove indicia of disease prior to inspection, A-0325, and because symptomatic animals were no longer tagged for separate PHV inspection. A-0356–57. Commenters also objected to the rules' lifting of existing slaughter-line-speed limits and the lack of mandatory training for plant sorters. A-0343; A-0415. Commenters challenged the Hog HIMP Report's validity, including because it failed to address the GAO's (A-0421; A-0431) and OIG's criticisms (A-0341) and its selective use of stale data (A-0432–33). Commenters also questioned the risk assessment and called for a peer review pursuant to the Office of Management and Budget's ("OMB") and USDA's guidance. A-0346.

E. Defendants Finalize Their New Swine Inspection System Rules.

Nevertheless, the Defendants finalized the rules and guideline for training establishment sorters[7] on October 1, 2019.[8] 84 Fed. Reg. 52,300, 52,313 (Oct. 1, 2019); A-0462. While voluntary, Defendants' cost-benefit analysis for the rules projected that all of the nation's high-volume market hog plants (40 in total), accounting for 93% of the U.S. slaughtered-swine supply, would adopt the new inspection system in five

[6] For ease, this brief cites to the *Federal Register* notices for the proposed and final NSIS rules.

[7] "Guideline for Training Establishment Sorters under the New Swine Slaughter Inspection System."

[8] Defendants' issued four directives on NSIS on December 19, 2019. *See* ECF. No. 62-1 at 4–5.

years. *Id.* at 52,322, Tbl. 4, 52,324, Tbl. 6. In response to the whistleblowers' claims that pilot-plant sorters could not adequately inspect carcasses, the preamble to the final rules pointed to the Hog HIMP Report and the very low rate of carcasses with fecal material, ingesta, and milk contamination. *Id.* at 52,310–12. It further contended that Defendants had addressed all issues raised by the OIG, and there was no reason to revise or update the Hog HIMP Report. *Id.* at 52,305–06, 52,307.

F. The Final NSIS Rules

The new rules codify the HIMP inspection system. They hand over several critical federal inspection duties to under- or un-trained slaughter-plant employee sorters, reduce the number of inspectors on the lines, and lifted slaughter-line-speed limits. The scheme prevents federal inspectors from doing tasks that they otherwise must perform to detect and remove condemnable live animals, carcasses, and parts.

1. Rollbacks that Prevent Ante-mortem Inspection

Under traditional inspection, federal inspectors evaluate the overall condition of *each and every* hog as soon as it arrives at the plant—examining each animal's head, legs, body, alertness, mobility, and breathing, and looking for unusual swellings or other abnormalities. A-0018. And, federal inspectors must evaluate each animal both in rest and in motion,[9] because "certain abnormal signs, such as labored breathing, are easier to detect while the animals are at rest, while other abnormalities, such as lameness, may not be detected until you observe the animals in motion." *Id.*; A-0003. Under the NSIS rules, on the other hand, plant employees initially examine the overall condition of animals and sort those that are diseased and dying according to a written plan. 9 C.F.R. § 309.19(a)–(b) (2021)); 83 Fed. Reg. at 4792; A–0468–69. Of those deemed healthy, federal inspectors evaluate only *five to ten percent* while they are in motion. 84 Fed. Reg. at 52,312; 83 Fed. Reg. at 4788, 4792.

2. Rollbacks that Prevent the Inspection and Separate Slaughter of Potentially Diseased and Drugged Animals

Federal inspectors and PHVs under traditional inspection must tag *all* animals with disease signs as "U.S. Suspect," and place them in "U.S. Suspect pens" so each is slaughtered separately and receives further federal PHV evaluation after slaughter for disease conditions and residue tests. 9 C.F.R §§

[9] A 2014 directive provided an exception that allowed a plant to voluntarily segregate animals showing signs of disease "to facilitate its scheduling of animals for slaughter." A-0018. Nothing in the record indicates the extent to which plants utilized this exception.

309.18(a), 309.2(a), (m), (n); A-0018, A-0021, A-0542. Under NSIS, plant employees can place animals showing signs of disease and other conditions in "Subject" pens, where they can be held "until they have had time to rest and recover." A-0521; A-0469–70; A-0535; A-0538; 83 Fed. Reg. at 4783; 84 Fed. Reg. at 52,312. These animals are not placed in U.S. Suspect pens, tagged as such, and they are not slaughtered separately from others or identified for any further PHV post-mortem evaluation like they would under traditional inspection. A-538 (showing that only animals coming from U.S. Suspect pens get slaughtered separately); 9 C.F.R. § 309.2(n). Nothing in USDA's directives or guideline for training sorters indicates that the animals that plant employees sort and remove from plants ever get tested for drug residues.[10] *See* A-0468–72, A-0521.

3. Rollbacks that Prevent Post-mortem Inspection

Federal inspectors in traditionally inspected plants must evaluate each and every carcass and part for abnormal conditions that are localized; verify that plant employees properly trim such localized tissues for condemnation, A-0052–54; and attach a "U.S. Retained" tag to carcasses with generalized or more serious conditions (*e.g.*, tumors, bruises that show signs of infection, and recent injection sites that would require residue testing) for further PHV evaluation. A-0052–54; A-0584–86; A-0542–43; 9 C.F.R. §§ 310.3, 310.14, 311.14 (2021).

Under NSIS, plant employees are now charged with first "identify[ing], sort[ing], and mark[ing] for disposal market hog carcasses and all associated parts" for food safety issues prior to inspection by the single federal inspector at each slaughter-line station. A-0482 (citing 9 C.F.R. § 310.26); 9 C.F.R. § 310.26(b) (2021).

This changes inspections in two fundamental ways. First, plant employees, not federal inspectors, "must incise mandibular lymph nodes and palpate the viscera to detect the presence of animal diseases." § 310.26(b). Federal inspectors no longer do these tasks to detect abnormalities such as multiple enlarged lymph nodes—a sign of the serious food safety hazard *septicemia*. *See* A-0585; A-0051–52. This also

[10] Plant employees must also make the determination of whether animals have foreign animal diseases under NSIS. 84 Fed. Reg. at 52,300; A-0472; A-0521. Contrary to 9 C.F.R. § 309.2(p) (2021) for traditional plants, NSIS plants need not notify local, state, or federal animal health officials when such animals are removed. A-0521. This will create a secondary market for possibly adulterated animals and allow disease outbreaks that could harm both consumers and non-consumers. A-1142–49. Under NSIS, inspectors do not even track the number of swine sent to other establishments. Defs.' Answer at ¶ 115.

prevents federal inspectors from incising the mandibular lymph nodes so as to detect various conditions, including tuberculosis, as they do under traditional inspection. *See* A-0581.

Second, under NSIS, federal inspectors must rely on plant employees to determine which conditions such as bruises, injection sites, injuries, abscesses, and adhesions are localized, and thus trimmable, and which are generalized or serious, requiring the carcass's disposal. 83 Fed. Reg. at 4792–93; A-0522–23; A-0527; A-0505; *see* Defs.' Answer at ¶ 125. Inspectors do not tag carcasses and parts for generalized or serious conditions requiring PHV evaluation unless they catch these issues at the inspection stations. A-0522–24. Federal inspectors under NSIS must also primarily rely on plant sorters to find and then trim fecal matter, ingesta, and milk, which "are primary avenues for the spread of pathogens[.]" A-0075–76; A-0523–24. Unlike under traditional inspection, federal inspectors can only ensure these contaminants' removal if they spot them at their stations. A-0524; A-0076; A-0583.

4. NSIS's Reduction of Online Inspectors and Lifting of Slaughter-Line-Speed Limits

Defendants' NSIS rules reduce the number of federal inspectors on the slaughter lines, from as many as seven in the largest traditional plants to a total of only three, with one fixed at each inspection station. *Compare* 9 C.F.R. § 310.1(b)(3)(ii), Tbl. 4 (2021), *with* 84 Fed. Reg. at 52,300. The rules also eliminated the 1,106 heads-per-hour line-speed limits,[11] 9 C.F.R. § 310.26(c), which were based on work-measurement studies assessing the speed and effectiveness of inspectors in performing the various required tasks. 47 Fed. Reg. at 33,673. Those limits were removed for NSIS because federal inspectors perform far fewer "time-intensive ante-mortem and post-mortem sorting activities." 83 Fed. Reg. at 4784. The NSIS-pilot plants increased their average line speeds compared to traditional plants, and Defendants anticipate the same under NSIS. A-0196; 84 Fed. Reg. at 52,314, 52,335.

[11] On March 31, 2021, a district court granted summary judgment to the union plaintiffs challenging the NSIS rules' lifting of line speed limits and remanded this provision. *United Food & Commer. Workers Union, Local No. 663 v. U.S. Dep't of Agric.*, 532 F. Supp. 3d 741, 773 (D. Minn. 2021). Several companies have subsequently appealed their denied intervention in order to appeal on the merits. *United Food and Commercial Workers Union, et al., v. Quality Pork Processors, Inc., et al.*, *appeal docketed*, No. 21-2220 (8th Cir. June 6, 2021). Recently, Defendants have announced a "time-limited trial" that would evaluate whether they would again lift line-speed limits. https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-november-12-2021.

5. No Mandatory "Sorter" Training

The NSIS rules do not require training for plant-employee sorters. *Id.* at 52,313. Plants are to instead rely on the guideline for training sorters that USDA issued with the rules, which is based on trainings provided to federal inspection personnel. *Id.*; Defs.' Answer at ¶ 80. Defendants' cost-benefit analysis projects that plants will only provide *four hours per plant-sorter* training. 84 Fed. Reg. at 52,324 (referencing A-0589). In contrast, Defendants dedicate weeks to training federal inspectors, even credentialed PHVs. Defs.' Answer at ¶ 78.

G. No Opportunity to Comment on Revisions to the Final Risk Assessment

Defendants also finalized a risk assessment supporting their NSIS rules. A-0590–774. Defendants had always planned for it to be peer reviewed in April 2018, long after the rules' comment period was initially to close. A-0775. They indicated an earlier review was unnecessary because of their confidence that the risk assessment would not change after the review. A-0287.

On August 8, 2018, more than two months after the close of the extended public comment period on the rules, Defendants posted a summary of peer-reviewer feedback and an updated draft risk assessment on their website. Defs.' Answer at ¶ 280. Defendants made 4,900 changes from the prior draft version, of which approximately 60% were substantive. A-0783. Yet Defendants refused to re-open the comment period on the proposed rules. According to Defendants, "neither the peer review comments nor the revisions to the risk assessment made in response . . . , produced changes to the assessment's conclusions that would require modifications to the proposed rule." A-0784. Instead, Defendants announced a 30-day comment period on the updated risk assessment, which was not published in the *Federal Register* and received just five comments. *Id.*; *see* Defs.' Answer at ¶ 285.

Defendants would change their risk assessment once more, long after this comment period had closed, with the final rules. A-0651. As the preamble would relay, the final assessment modeled a greatly increased range of projected benefits, with the low end actually resulting in an *increase* of 1,719 illnesses, and a 20% chance of *increased* illness. *See* 84 Fed. Reg. at 52,332–34; A-0651. The public obviously could not comment on the rules at this point since they were finalized.

H. Damaging Pilot-Plant Data Released After the Close of the Comment Period

Although Defendants completed the Hog HIMP Report in 2014, previously undisclosed data would subsequently surface that called into question the validity of the new inspection system.

1. Federal Inspectors Did Not Perform More Offline Verifications of "Public Health Regulations" in Pilot Plants.

Defendants have claimed that a primary benefit of the new inspection system would be an increase in federal inspectors' *offline* verifications, and specifically offline checks of plants' compliance with "Public Health Regulations." 84 Fed. Reg. at 52,307–08. Plants' violations of these specific FSIS regulations are statistically linked to pathogenic contamination, and so they are an "important indicator of subsequent food safety issues and loss of process control." *Id.* at 52,308. But Plaintiff Food & Water Watch ("FWW") obtained Defendants' data through a Freedom of Information Act ("FOIA") request that revealed that offline inspectors in the pilot plants were actually *not* able to perform statistically significantly more offline verifications of these important regulations from 2014 to 2017. A-0823. FWW submitted its analysis of this data in May 2019 and requested that Defendants re-open the NSIS comment period. A-0785–87. Defendants never responded.[12]

2. Federal Public Health Veterinarians Evaluated Fewer Animals, Carcasses, and Parts in Pilot Plants

FWW's May 2019 analysis also pointed out that that federal PHVs were able to evaluate far fewer animals tagged as U.S Suspect in pilot plants compared to traditional plants, thus revealing that these inspectors were not critically appraising animals with signs of disease. A-0854. Defendants' initial data turned out to be incorrect, but after months of delay and separate litigation, Corrigan Decl. ¶ 3(a), Defendants released corrected data on February 28, 2020 showing that PHVs did not in fact evaluate as many U.S. Suspect-tagged animals in the pilot plants compared to traditional plants from 2012 through 2015. Indeed, for plants tracking U.S. Suspect-tagged animals, pilot plant inspectors tagged an annual average of *thirty-nine percent fewer* animals for PHV evaluation per plant. *Id.* at ¶ 3(f). On average, federal inspectors in pilot plants tagged *a quarter* of the carcasses as U.S. Retained for PHV evaluation as in traditional plants. *Id.* In total, PHVs in the pilot plants evaluated approximately 3-fold fewer tagged animals

[12] They did submit a "rebuttal" to the New York Times's inquiries about this analysis, however. A-0869. This revealed that that pilot-plant employees and inspectors were actually *not* as effective at removing animals from pilot plants as federal inspectors in traditional plants in the years 2011 to 2019. A-0872.

and their resulting carcasses than in traditional plants. *Id.* at ¶ 3(g).[13]

3. Pilot Plants Actually Had More Violations for Fecal Matter, Digestive Content, and Milk Contamination

Finally, in August 2020, again as the result of a FOIA request, Defendants released data showing that pilot plants had nearly double the regulatory violation rate of traditional plants for fecal matter, digestive content, and milk contamination for calendar years 2014 to 2017. *See* A-0881–82. This undercuts the Hog HIMP Report's finding of a lower pilot-plant violation rate for these contaminants in 2012 and 2013. A-0211–13.

III. THE PLAINTIFFS' PRESENT CHALLENGE

On January 13, 2020, Plaintiffs filed this suit against Defendants, and Plaintiffs filed their Second Amended Complaint on February 18, 2021, alleging that the NSIS rules violate the FMIA's ante-mortem inspection-related requirements under § 603 and the statute's post-mortem inspection, condemnation, and disposal-supervision requirements under § 604. Plaintiffs also contend that the NSIS rules are an unlawful subdelegation of this authority and otherwise arbitrary and capricious, an abuse of discretion, and not in accordance with law, violating the APA, 5 U.S.C. § 706(2).[14]

IV. STANDARD OF REVIEW

This case involves the review of a final agency action under the APA, so "summary judgment is an appropriate mechanism for deciding the legal question of whether the agency could reasonably have found the facts as it did." *Occidental Eng'g Co. v. I.N.S.*, 753 F.2d 766, 770 (9th Cir. 1985). "Agencies cannot exceed the scope of their authority as circumscribed by Congress." *Planned Parenthood of Greater Wash. v. U.S. HHS*, 946 F.3d 1100, 1112 (9th Cir. 2020) (citing *City of Arlington v. FCC*, 569 U.S. 290, 297–98 (2013) and *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 359 (1986)). And they "do[] not have the discretion to misapply

[13] These calculations are derived from 12 pages of raw data in the administrative record. They are proffered as "calculation[s] to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court[,]" under Fed. R. Evidence 1006. Alternatively, they are supplementary information that can be considered under the exception in *Lands Council v. Forester of Region One of the U.S. Forest Serv.*, 395 F.3d 1019, 1030 (9th Cir. 2004), including because they "take technical and complex information from the record and provide it in a more understandable format to the Court." *See Stop B2H Coal. v. BLM*, No. 2:19-cv-1822-SI, 2021 U.S. Dist. LEXIS 145939, at *22 (D. Or. Aug. 4, 2021).

[14] Plaintiffs are no longer pursuing their 4th and 5th claims and will separately move for an order or seek a joint stipulation to voluntarily dismiss these claims.

the law." *Mejia v. Ashcroft*, 298 F.3d 873, 878 (9th Cir. 2002).

The APA additionally provides that a court must reverse an agency decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency's decision is arbitrary and capricious if it "relie[s] on factors which Congress has not intended it to consider, entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The Court must determine "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). Despite the review's narrow scope, a "court must conduct a searching and careful inquiry into the facts." *Nw. Motorcycle Ass'n v. U.S. Dep't of Agric.*, 18 F.3d 1468, 1471 (9th Cir. 1994). To uphold an agency decision, "a court must find that evidence before the agency provided a rational and ample basis for its decision." *Id.*

ARGUMENT

I. PLAINTIFFS HAVE STANDING FOR THEIR CLAIMS.

Plaintiffs have brought forth sufficient evidence demonstrating their standing. The record evidence links the NSIS rules' violations of the FMIA to the credible threat of foodborne illness affecting Plaintiffs' members, as well as the public at large. It shows that Defendants' current regulations and directives defining federal inspectors' responsibilities are aimed at preventing food-safety problems, including *toxemia and septicemia,* and fecal matter, ingesta, or milk contamination. *See* 9 C.F.R. § 311.16 (2021); A-0018; A-0583; A-0585; A-0884–87; A-0051–52; A-0075–76; A-0523–24. These problem are all linked to serious foodborne illnesses. 83 Fed. Reg. at 4793; A-0885; A-0887; A-0889; A-0893.

As described below, the NSIS rules transfer these critical inspection duties from federal inspectors to plant employees. This transfer, along with the reduced numbers of inspectors on the lines, will prevent federal inspection of animals and carcasses and parts and result in fewer federal PHV evaluations of animals and carcasses showing signs of food-safety problems, along with more food-safety violations. Plaintiffs' experts, two former USDA PHVs—one who was the Defendants' Chief PHV with 35 years of experience under multiple administrations—confirm these links. Basu Decl. at ¶¶ 2, 9–20; Martin Decl. at

¶¶ 6–21. Defendants project NSIS-sourced pork to become ubiquitous, accounting for 93% of all domestically slaughtered swine. 84 Fed. Reg. at 52,322, Tbl. 4. Plaintiff Robin Mangini and the other organizations' declarant members, who all have regularly consumed pork, will suffer injury because they will be exposed to the NSIS products should they continue to consume pork, or they will have to spend time and resources to limit their exposure to higher-risk product. Mangini Decl. at ¶¶ 9–14; Samuels Decl. at ¶¶ 6–9; Sperling Decl. at ¶¶ 4–5, 9–17; Rubio Decl. at ¶¶ 3–10; Lapp Decl. at ¶¶ 5–12; Levenbach Decl. at ¶¶ 5–10. All of this establishes the "credible threat of injury" for standing at summary judgment. *See Cent. Delta Water Agency v. United States*, 306 F.3d 938, 950 (9th Cir. 2002). Further, the organizations will suffer injury, including because they must spend more resources to educate their members about the dangers of NSIS product. Jones Decl. at ¶¶ 6–10; Hanson Decl. at ¶¶ 6-8, Eisnitz Decl. at ¶¶ 28-29. These concrete injuries are directly caused by the NSIS rules and would be redressed by vacating them.

II. DEFENDANTS' NSIS RULES ARE CONTRARY TO LAW.

A. The NSIS Rules Violate 21 U.S.C. § 603(a) by Preventing the Ante-Mortem Inspection of Swine.

The NSIS rules are contrary §603(a), as they prevent federal inspectors from performing their required duty to critically appraise all hogs before slaughter. As such, they also violate the APA. 5 U.S.C. § 706(2)(A).

The mandate of the FMIA is clear: "the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of all amenable species before they shall be allowed to enter into any slaughtering . . . establishment . . . ." § 603(a). Employing the common, ordinary meaning of "inspection," as the D.C. Circuit did in *AFGE I,* this means that federal inspectors must "pay[] close attention to" and "critical[ly] apprais[e]" each animal prior to slaughter. 215 F.3d at 11.

The NSIS rules violate this simple edict. Under NSIS, federal inspectors do not pay close attention to all animals prior to slaughter because it is the slaughter–plant employees, not federal inspectors, who are now tasked with "conduct[ing] market hog sorting activities . . . [, including for those] exhibiting signs of moribundity, central nervous system disorders, or pyrexia." 9 C.F.R. § 309.19(a). Under- or un-trained plant employees essentially perform the same duties that highly trained inspectors would do in traditionally inspected plants, observing animals in motion and at rest and evaluating animals' alertness, locomotion,

bodily conditions, bodily functions, and skin color. *Compare* A-0468–69 (the guideline for plant-employee sorters), *with* A-0007–11 (PHV training). And, because plant employees do this sorting "before the animals are presented for ante-mortem inspection" federal inspectors at this point generally do not and cannot inspect the livestock for condemnable conditions. 9 C.F.R. § 309.19(a); 83 Fed. Reg. at 4792. Instead, they only observe plant employees' sorting activities "as scheduled."[15] A-0520. Then, when plant employees do finally present animals that they have deemed normal for inspection, federal inspectors are only allowed inspect 5 to 10% of them while in motion. 83 Fed. Reg. at 4783.

Observing company *sorters* is certainly not inspection of "all animals." Nor can federal inspectors give the FMIA's required "critical appraisal" to the 90 to 95% of animals observed only at rest but not in motion. Federal inspectors cannot examine these animals—as Defendants' training materials instruct—for condemnable conditions or diseases "associated with abnormal body movement," including stiffness, limpness, lameness, restlessness, staggering, circling, abnormal gait, dizziness, loss of balance, and disorientation or running into things, which are all signs the animals are dying, feverish, or have central nervous system conditions. A-0007–08; A-0469–72. Federal inspectors also cannot inspect these animals to see if they have "[c]hanges in locomotion," a textbook symptom of *septicemia*. A-0888. And they cannot effectively evaluate these animals for "[c]ertain poisons and toxic residues that the animal has been exposed to [that] may cause abnormal movement and action, such as staggering or circling." A-0007. NSIS thus precludes federal inspectors from critically appraising 90 to 95% of the plant-employee-evaluated hogs before slaughter, as they cannot observe these animals in motion and make the "critical determination whether a product is adulterated or unadulterated." *AFGE I*, 215 F.3d at 11.

Defendants cannot claim that it is enough that federal inspectors still evaluate all animals while they are at rest or that Defendants are owed deference in determining what constitutes a "critical appraisal." This is just an excuse to avoid this FMIA requirement. In *AFGE II,* the D.C. Circuit did not abjectly defer to Defendants as the district court had. *Compare AFGE II*, 284 F.3d at 128–29, *with* 127 F. Supp. 2d at 248. Instead, in evaluating whether the modified HIMP pilot still allowed federal inspectors to perform their duties on the lines, the court assessed whether the federal inspectors actually could adequately identify

[15] The proposed NSIS rules indicate that this would occur as rarely as twice per shift. 83 Fed. Reg. at 4792. The final rules and final directive do not even require that.

diseases, *i.e.*, *critically* appraise carcasses and parts, and found they could in chicken carcasses without inspecting all parts.[16] *AFGE II*, 284 F.3d at 130.

In the present case, on the other hand, nothing in the administrative record shows that federal inspectors can still identify problems associated with hogs' abnormal movement while only evaluating 10% or fewer in motion.[17] The Defendants' training materials show precisely the opposite. The Defendants are simply misapplying the statute's requirements.

B. The NSIS Rules Violate 21 U.S.C. § 603(a) by Preventing the Inspection and Separate Slaughter of Swine Showing Symptoms of Disease and Careful Examination and Inspection When Slaughtered.

Under NSIS, federal inspectors are unable to set aside and ensure that those animals showing symptoms of disease are slaughtered separately as required by FMIA § 603(a) ("*all* amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other [amenable species], and. . . shall be subject to a careful examination and inspection" (emphasis added). NSIS-plant employees instead place symptomatic animals in "Subject pens" to rest and recover before a PHV's evaluation. 84 Fed. Reg. at 52,312; 83 Fed. Reg. at 4783; A-0469–70; A-0521; A-0535.

This contravenes § 603(a) twice over. First, federal inspectors cannot examine and set aside animals showing symptoms of disease since plant employees are the ones that initially evaluate animals for symptoms and then place them in the Subject pens. Then, federal PHVs also cannot critically appraise the animals since the animals do not have the U.S. Suspect tags and accompanying paperwork detailing the symptoms that landed these animals in the Subject pens and the conditions for which they should be inspected. *Contra* 9 C.F.R. § 309.2(o) (2021) (requiring in traditional plants that each animal identified as U.S. Suspect on ante-mortem inspection, to have a MP 402-2 form (replaced by the 6150-1 form) that "provides a brief description of the animal and of the disease or condition for which the animal was classed as a suspect'); A-0004 (providing that when plant employees ask for an animal to be held for separate treatment, the PHV will have the 6150-1 form to perform the disposition); *see also* A-0006; A-

[16] The court applied *Skidmore* deference. *AFGE II*, 284 F.3d at 129. This Court is of course not bound to follow *AFGE II* and could simply find that transferring inspection responsibilities to plant employees is unlawful, notwithstanding that under NSIS some inspectors remain on the slaughter lines.

[17] It matters little that prior to NSIS some plants adopted voluntary segregation programs in which inspectors inspected fewer than 100% of animals in motion. Without a justification for inspecting less than 100% of animals in motion, these voluntary programs also would be unlawful.

0012 (sample of 6150-1 form). The PHVs are thus denied critical information that they need to evaluate animals showing signs of disease. A-0018; A-0021–22. The record demonstrates that this information is vitally important for conditions such as *septicemia* and *toxemia*, whose symptoms include highly variable body temperatures. A-0885. PHVs are thus flying blind, precluded from being able to discern which animals in the Subject pens have truly "recovered" and unable to evaluate animals showing signs of disease. A-0018; A-0021–22.

That NSIS plant employees can also sort those un-inspected and potentially symptomatic animals placed in Subject pens and remove them from the plant further hamstrings federal inspections. Inspectors cannot test the carcasses of such animals for residues, even if the hogs were set aside because they showed signs of illegal drug or antibiotic use. Without such testing, federal inspectors cannot ensure that the plant's swine supply does not have violative levels of chemicals and antimicrobials, regardless of whether an individual animal or carcass is condemned. *See* Defs.' Answer at ¶ 44. Nothing in the record provides a justification for not doing these tests in NSIS plants, while requiring them when animals are tagged U.S. Suspect in traditional plants. A-0542; A-0544.

Second, the NSIS rules violates § 603(a) because animals set aside in Subject pens are simply not slaughtered separately from other animals, nor are their carcasses identified for further post-mortem PHV evaluation, as they would be if tagged as U.S. Suspect in a traditional plant. A-0538 (showing that only animals coming from U.S. Suspect pens get slaughtered separately in NSIS pilot plants); *contra* 9 C.F.R. § 309.2(n). And, while PHVs evaluating animals in Subject pens can always transfer them to U.S. Suspect pens, Defendants' data demonstrates that they were effectively precluded from doing so in the pilot plants. For those pilot plants tracking U.S. Suspect-tagged animals, inspectors were able to tag 39% fewer animals for PHV evaluation from 2014 to 2017 than in comparably sized traditional plants. Corrigan Decl. at ¶ 3(f); *see also, e.g.*, A-0299 (non-ambulatory animals not tagged as U.S. Suspect for veterinary evaluation).

In short, federal inspectors under NSIS cannot carefully examine and do not have the information they need to critically appraise swine showing symptoms of disease, do not residue test carcasses of animals that plant sorters remove from the plant, and do not tag Subject animals and set them apart for separate slaughter and a careful post-mortem inspection. These deficiencies thus render the NSIS rules contrary to § 603(a).

C. The NSIS Rules Violate 21 U.S.C. § 604 by Preventing the Post-Mortem Inspection of Swine Carcasses and Parts.

The NSIS rules also prevent inspectors from critical appraising carcasses and parts after slaughter. FMIA § 604 is clear: "the Secretary shall cause to be made by inspectors appointed for that purpose a postmortem examination and inspection of the carcasses and parts thereof of all amenable species to be prepared at any slaughtering[] . . . establishment . . . ." When swine are slaughtered and their carcasses and parts are to be prepared, they must all be examined and inspected, *i.e.*, receive a critical appraisal from a federal inspector. *See AFGE I*, 215 F.3d at 11.

The NSIS rules violate this statutory mandate in at least three ways. First, the NSIS rules prevent inspectors' critical appraisal of all carcasses and parts by mandating that only plant employees palpate and incise lymph nodes. Defendants' training materials discuss how critical it is that lymph nodes be *correctly incised* to detect "lesions of certain important diseases" and to permit the evaluation of "both sides of the slice." A-0582; *see also* A-0280. These tasks are essential to detecting serious conditions in swine. *See* A-0581 ("Of *primary importance* in organoleptic detection of disease is the lymphatic system." (emphasis added)). Indeed, numerous conditions are detected through these procedures, including *mycobacterium tuberculosis* and *septicemia,* which is detected by palpating lymph nodes to see if any are enlarged. Defs.' Answer at ¶ 64; A-0888 (indicating a sign of *septicemia* is "[g]eneralized, acute lymphadenitis"); A-0483 (guideline for training sorters stating same).

Defendants might argue that inspectors are still presented lymph nodes for inspection, but a critical appraisal requires more than merely *observing* carcasses and parts. *See AFGE I*, 215 F.3d at 11; 127 F. Supp. 2d 243, 247. And, this says absolutely nothing about *palpating* lymph nodes, since federal online inspectors under NSIS do not, in fact, perform this task. A-0895–96 (indicating that inspectors only visually inspect lymph nodes). Moreover, several whistleblowers attested that inspectors could not catch employee errors while on the lines. A-0261 ("It's almost impossible to recognize problems with both carcasses and plant employees' activities at the high speed of a HIMP line.") *See also* A-0276. The intractable persistence of Coldwater-plant employees' failures to properly incise lymph nodes, moreover, shows federal inspectors could not effectively resolve the plant's failures to properly incise lymph nodes, even when they could catch this problem on the line. A-0301–02; A-0306–07; A-0322. The issue was not limited to this plant, as others had a similar problem. *See, e.g.*, A-0300–01; A-0314.

Second, the NSIS rules violate the FMIA's post-mortem-inspection mandates by preventing federal inspectors from evaluating carcasses and parts for serious or generalized conditions necessitating a federal PHV disposition, as well as fecal matter, digestive contents, and milk contamination. *See* A-0527. Defendants' own guideline for training sorters indicates that determining whether carcasses must be sorted (not simply trimmed) requires expert judgment, as employees must determine if bruises are "extensive," "generalized" or "septic[,]" A-0505, or if "multiple abscesses affect[] the entire carcass." A-0488. Both the whistleblowers and the plants' inspection records indicate that under- or un-trained employees—either in their haste due to fast line speeds or their lack of training—improperly trimmed indicia of more systemic problems or regularly missed problems such as abscesses. *See, e.g.*, A-0275; A-0277; A-0261; A-0315; A-0317–20; Thus, by the time carcasses and parts get to the inspectors, it is simply too late; either the indicia of systematic conditions have been improperly removed, or as discussed further below, the inspectors must catch those problems that plant employees missed—only in half the time.

Defendants may point to their Hog HIMP Report to argue that pilot-plant employees and inspectors removed as many carcasses and parts as inspectors did in traditional plants from 2006 through 2010 and 2012 to 2013. But this merely reflects Defendants' cherry-picking of data for their Hog HIMP Report, as Defendants have admitted that, from 2011 to 2019, pilot plant employees and inspectors actually removed fewer carcasses and parts. A-0872. Moreover, the mere removal of a comparable *number* of carcasses and parts by plant employees, who likely have had as little as four hours of training, is not the same as the critical evaluation of carcasses and parts by credentialled and highly trained PHVs for conditions like *septicemia*. Defendants' own training materials indicate that the retention of carcasses for PHV disposition is critically important, as "[m]ost dispositions require a PHV's professional judgment of the character and distribution of a disease process." A-1141. For example, "[t]he problem of differentiation between septicemia and a localized inflammatory process is often very difficult." A-0885 (italics added). But for those plants that tracked carcasses tagged as U.S. Retained, only a quarter of the carcasses were tagged in pilot plants for PHV evaluation compared to similarly sized traditional plants. Corrigan Decl. at ¶ 3(f). The FMIA demands federal inspectors critically appraise *each and every* carcass *and part*, not a system that *might* be equivalent based solely on the number of carcasses and parts that plant employees remove.

For fecal matter, digestive contents, and milk contaminants, which can be difficult to identify, *see* A-

0082, Defendants regulations and directives require carcasses and parts to be completely free of these contaminants prior to final inspection. A-0076; A-0078. Defendants' data show that the pilot-plant employees and inspectors at the end of the pilot-plants' lines *simply could not catch this contamination*. *See, e.g.*, A-0274; A-0309–10. Specifically, the pilot plants had nearly twice the violation rate as did comparably sized plants under traditional inspection.[18] A-0882; Corrigan Decl. at ¶ 5(a).[19]

Third, the NSIS rules prevent federal inspectors from critically appraising every carcass and part by significantly diminishing the time for federal inspectors to perform their examination. The NSIS rules lifted the plants' line-speed limits and cut online inspection staffing by more than half, eliminating the line-speed and staffing standards that were based on inspectors' abilities to perform "standardized inspection procedures . . . designed to provide assurance that only wholesome and otherwise not adultered [*sic*] carcasses and parts are passed for human food." 46 Fed. Reg. at 43,406. With fewer total federal inspectors on the lines under NSIS, those left at their stations are forced to inspect carcasses and parts at more than double their prior pace, from 2.7 to *6.1 heads per minute*.[20] A-0236. Nothing in the record indicates that inspectors can still perform the tasks required for a critical appraisal of carcasses and parts at this pace. Defendants admit they have never performed such studies, Defs.' Answer at ¶ 146, and, as demonstrated above, the record shows quite the opposite.

III. DEFENDANTS' NSIS RULES ARE ARBITRARY AND CAPRICIOUS, AN ABUSE OF DISCRETION, AND OTHERWISE NOT IN ACCORDANCE WITH LAW, VIOLATING 5 U.S.C. § 706(2).

At its core, Defendants' NSIS rulemaking was about giving the meat industry the gift it has sought since the 1970s: dismantling the inspection system and handing federal inspectors' responsibilities to slaughter plants. To do so, Defendants engaged in quintessential arbitrary and capricious rulemaking.

[18] Such contamination occurs at pilot plants despite inspection personnel's authority to slow lines. *See* 9 C.F.R. § 310.1(b)(1) (2021); *see also, e.g.*, A-0316 (noting increased fecal findings "[e]ven with slower speed").

[19] All calculations are derived from the raw data that Defendants included in the administrative record and can be considered by the Court for the reasons detailed in n.13

[20] Even if the line-speed limits remain in place after *United Food and Commercial Workers Union*, *see* n. 11, *supra*, federal inspectors under NSIS will still have only half the time to inspect heads, carcasses, and viscera (5.4 heads per minute) because of the dramatic reduction in online inspectors. Corrigan Decl. ¶ 6.

A. The NSIS Rules Represent an Irrational Departure from Defendants' Prior Practices and Regulations.

Defendants' NSIS rules are a stark and irrational departure from their existing regulations, directives, and training materials, all of which detail how federal inspectors are to perform the required "critical appraisal" under the FMIA. For NSIS plants, the new rules render nugatory Defendants' rules requiring the ante-mortem inspection of all animals before slaughter, 9 C.F.R. § 309.1 (2021), pertaining to inspectors' duties for the inspection, segregation, and release of animals with disease symptoms, *id.* § 309.2 (a), (m), (n), (o), and (p), and requiring the careful post-mortem inspection of all carcasses and parts, *id.* § 310.1(a) (2021). This is contrary to the APA's dictates that an agency must "display awareness that it *is* changing position" and may not "depart from a prior policy *sub silentio* or simply disregard rules that are still on the books." *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2009).

It matters little that Defendants have not expressly exempted NSIS plants from some of these regulations, directives, and training materials. "[A]n irrational departure from a policy (as opposed to an avowed alteration of it)" can equally violate the APA. *Ins v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1996). And the purpose of the NSIS rules is clearly to ensure that no official "inspection" occurs until after plant-employee sorting, at which point it becomes impossible for inspectors to actually perform their duties.

Defendants have offered no reasoned explanation for why their existing inspection regimen should not be applicable in NSIS plants—instead assuming without support that under-and un-trained plant employees in these plants can somehow perform sorting as well as extensively trained and credentialed federal inspectors and PHVs. This is counter to the rule "that an agency action is arbitrary when the agency *offer[s] insufficient reasons* for treating similar situations differently." *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996) (emphasis added) (citing cases).

Defendants have argued that the NSIS rules merely add employee requirements, rather than arbitrarily deviate from federal-inspection requirements, because plant employee "sorting" is different from and additional to federal "inspection." *See, e.g.*, 84 Fed. Reg. at 52,311 ("FSIS is not privatizing swine slaughter inspection . . . . NSIS simply requires establishments to take additional steps *before* FSIS inspection . . . ."); *id.*, at 52,312; A-0316–17; A-0898–99 (saying that "plant employees will not conduct inspections" because "only federal inspectors do meat inspections"). But this obscures that employee sorting substantially impairs federal inspections. "When an agency gets out the Dictionary of Newspeak

and pronounces that for purposes of its regulation war is peace"—here, that "sorting" is not different from inspection—"it has made a substantive change for which the APA may require procedures." *See Nat'l Family Planning & Reprod. Health Ass'n v. Sullivan*, 979 F.2d 227, 235 (D.C. Cir. 1992). Defendants have failed to adequately explain why they have abandoned their long-standing approach to inspections through plant "sorting," and their rules should thus be vacated and remanded so Defendants can properly do so. *Cf. DOC v. New York*, 139 S. Ct. 2551, 2575–76 (2019) (rejecting an agency's contrived reasons as not meeting "reasoned explanation requirements").

B. Defendants Entirely Failed to Consider Numerous, Significant Problematic Aspects Underlying the New Inspection System.

Defendants also overlooked significant problems with their new inspection system, including that it was based on a small, unrepresentative pilot and their Hog HIMP Report evaluated far too little data. Defendants ignored their own data reflecting poorly on the new system. They also disregarded peer-reviewers' comments challenging the validity of their risk assessment, while they overestimated the likelihood of reducing *salmonella* illnesses, at the expense of the public's ability to comment.

1. Defendants Arbitrarily Evaluated Only a Few, Non-representative Pilot Plants.

Notwithstanding that the pilot project lasted more than 20 years, Defendants rejected repeated calls, including from the GAO and their own peer reviewers and inspectors, to collect and evaluate more of the data that the pilot produced to ensure that the NSIS rules would not harm public health. Instead, Defendants pointed solely to their Hog HIMP Report for the rules' justification.

But this report only underscored the problems recognized by the OIG and GAO, namely that there was insufficient information to demonstrate both that the new system resulted in measurable improvements and that such improvements would be broadly applicable to other plants opting into the system. Case in point, the GAO criticized the pilot for only having five plants and urged it to collect and analyze more pilot plant data to address this shortcoming. A-0153–55. Defendants responded by comparing these plants' performance to 21 comparably sized traditional plants in their Hog HIMP Report. *See id.* But as early as 2015, Defendants knew many more plants—as many as 40, including much smaller plants—would likely opt into the new inspection system. A-0905. Yet Defendants continued to defend their pilot as representative of the broader industry, 84 Fed. Reg. at 52,306—even after the expert peer

reviewers of Defendants' risk assessment voiced serious doubts. A-0907; A-0925; A-0927. Defendants even admit that "the five market . . . HIMP establishments represent a small sample size of establishments." 84 Fed. Reg. at 52,306. And the record is completely devoid of any semblance of support that these plants are "typical," as Defendants have baldly asserted. *See id.*

2. Defendants Arbitrarily Evaluated Only Select Snapshots of Data.

A "primary component" of HIMP was to establish baseline performance standards, A-0071, and evaluate the pilot plants against these standards. A-0963. But the Hog HIMP Report analyzed only seven choice years of pilot-plant data from the 20-year-program and inexplicably failed to include *any* data from the program's early years so as to evaluate the effects from the change in inspection systems. Their limited use of selective snapshots of data ignored GAO's exact criticism about the Defendants' poultry pilot, A-0150, as well as peer reviewers' skepticism that changes in the pilot plants' performance were not actually linked to the inspection system. A-0943. Defendants' use of performance-standards data collected at least six years after the baseline data ignored even the Defendants' own contractors who criticized the poultry pilot for using data collected only two years after the baseline. A-0966. This made it impossible to determine whether the swine pilot plants performed better as a result of the new inspection system. *See id.*

The Defendants' patently indefensible methodology is thus arbitrary and capricious, as it relied on hand-picked data from far too few plants—contrary to the recommendations of the GAO, their own contractors, and peer reviewers. *Cf. Friends of the Boundary Waters Wilderness v. Bosworth*, No. 03-624 (JRT/FLN), 2004 U.S. Dist. LEXIS 18455, at *32–34 (D. Minn. Aug. 26, 2004) (finding a rulemaking arbitrary and capricious for relying on a survey with an underrepresented sample, since "[o]ne does not need to be a statistician to apprehend" that a sample of five interested respondents is "so flawed that reliance on the survey is unreasonable"), *aff'd in parts and rev'd in part on other grounds*, 437 F.3d 815, 826–27 (8th Cir. 2006) (citations omitted).

3. Defendants Failed to Address Unfavorable Evidence About Pilot Plants' Offline Public-Health-Regulation Verifications.

Defendants chose to simply ignore their own data, as analyzed by FWW in May 2019, that showed that federal inspectors performed a statistically significantly *greater* number of offline verifications for *more Public Health Regulations in traditionally inspected* plants than pilot plants in fiscal years 2014 through 2017. A-

0856–57. The data also showed that the Hog HIMP Report's evaluation of pooled verification data for 2012 and 2013 likely masked the differences between the pilot and traditional plants. A-0857–058. This flatly contradicted Defendants' central conclusion that any reduction in online inspection staffing in NSIS plants would be justified because of the greater o*ffline* verifications for Public Health Regulations. *See* 84 Fed. Reg. at 52,308 (saying that comparing the number of Public Health Regulations verifications in HIMP and traditional establishments is "an important indicator of subsequent food safety issues").

Defendants' failure to either take this information into account in the rulemaking or explain why it was inapposite was thus arbitrary and capricious. *Sierra Club v. EPA*, 671 F.3d 955, 965–66 (9th Cir. 2012) (overturning an agency action where it failed to consider newer "data [that] told a different story than . . . earlier data"); *cf. Zen Magnets, LLC v. Consumer Prod. Safety Comm'n*, 841 F.3d 1141, 1149 (10th Cir. 2016) (stating that "where there is a known and significant change or trend in the data underlying an agency decision, the agency must either take that . . . into account, or explain why it relied solely on data pre-dating that change or trend"); *New Life Evangelistic Ctr., Inc. v. Sebelius*, 672 F. Supp. 2d 61, 74 (D.D.C. 2009).

4. Defendants Downplayed the Problem of Fecal Matter, Digestive Contents, and Milk Contamination in Pilot Plants.

Another central justification for NSIS was the Hog HIMP Report's finding that pilot plants had lower violation rates for fecal matter, digestive contents, and milk in 2012 and 2013 than did traditional plants. 84 Fed. Reg. at 52,311; A-0211. This is known as the Food Safety Standard 2 ("FS–2") rate and was "computed as the number of noncompliances citing 9 CFR 310.18 divided by . . . 9 CFR 310.18 verifications performed." *Id.*

But the record demonstrate that this conclusion was incorrect. Applying this formula to Defendants' raw data reveals that pilot plants actually had far *higher* violation rates, in fact *2 times higher*, than comparably sized traditional plants in 2012 to 2013. Corrigan Decl. at ¶ 5(a). Reliance on such an incorrect interpretation of data is arbitrary and capricious, even if simply an honest mistake. *See Resolute Forest Prods. v. U.S. Dep't of Agric.*, 187 F. Supp. 3d 100, 123 (D.D.C. 2016) (finding a decision arbitrary and capricious "where an agency has . . . not made a reasonable effort to ensure that appropriate data was relied upon") (emphasis omitted).

And, here, the mistake was more obfuscation than innocent miscalculation. The Hog HIMP Report

had adjusted the FS–2 rate downwards by more than twofold, factoring in the greater number of swine carcasses that inspectors verify in the pilot plants, but without indicating as much. Corrigan Decl. at ¶ 7, Ex. F. But there is absolutely no valid basis for this "adjustment,"[21] since Defendants' Hog HIMP Report was purporting to use the FS–2 violation rates to compare the two inspection systems as implemented.[22] In short, Defendants unjustifiably discounted pilot plants' FS–2 rates to falsely make them appear smaller than traditional plants' rates, while failing to disclose their assumption for doing so. *See Am. Ass'n of Cosmetology Sch. v. Devos*, 258 F. Supp. 3d 50, 72 (D.D.C. 2017) ("When an agency's reasoning involves a non-obvious, essential factual assumption, the agency must justify [it,] . . . as part of its affirmative duty to engage in rational decisionmaking.") (internal quotation marks and citation omitted)); *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 263 (D.D.C. 2015) (finding arbitrary and capricious an agency's failure to disclose critical assumptions).

5. Defendants Ignored Evidence that Under- or Un-trained Plant Sorters Could Not Perform Critical Inspection Tasks in Pilot Plants.

Defendants' claim that they addressed the OIG audit's findings of poor pilot-plant performance. 84 Fed. Reg. 52,305–06; A-0109. But Defendants have ignored the plethora of evidence showing that pilot-plant employees could or would not actually perform the inspection tasks that they would be required to do under NSIS, such as incising and palpating lymph nodes. The record shows that problems persisted even during the rulemaking and that Defendants' top officials were aware of them. A-0109. Months and even years after switching to the new system, the pilot plants were not even complying with the cornerstone of the new system, which is to design and maintain a plan for sorting. A-0296; A-0308; A-0321. Defendants acted arbitrarily by disregarding this evidence, as they "may not simply disregard without explanation the facts in the record that do not support [their] chosen outcome." *W. Watersheds Project v. Bernhardt*, 428 F. Supp. 3d 327, 352 (D. Or. 2019).

6. Defendants' Approach to Their Risk Assessment Was Fundamentally Flawed.

Defendants' reliance on their risk assessment was arbitrary and capricious for two reasons. First,

[21] After all, inspectors typically issue a single violation per verification when they find contaminants, regardless of the total number of carcasses they evaluate. S*ee, e.g.*, A-0292–95.

[22] Since employee sorters are claimed to be as effective or better at removing contaminants from carcasses, the fact that offline inspectors verify more carcasses in pilot plants should not result in a higher FS–2 violations rate unless there were, in fact, more problems in pilot plants.

Defendants gave short shrift to peer reviewers' comments that questioned whether the assessment's projected *salmonella* reductions were related to the pilot, as opposed to other variables. A-0907; A-0912; A-0943; A-1009. One expert called the risk analysis "invalid," questioning whether there was a causal relationship between *salmonella* reductions and the pilot's inspection system since a pilot plant had low *salmonella* prevalence both before and after plant-employee sorting.[23] A-0921–22; A-0987–88; A-0912; A-0914; *see also* A-0778. This was an issue related to the pilot's very design and was not addressed in the assessment as Defendants claimed. *See* A-0780; A-0976; A-0988. Indeed, Defendants' failure to address comments is precisely why a federal court found their lifting of their line-speed limits unlawful. *Cf. United Food & Commer. Workers Union, Local No. 663.*, 532 F. Supp. 3d at 773; *see also Gresham v. Azar*, 950 F.3d 93, 103 (D.C. Cir. 2020) ("Nodding to concerns . . . only to dismiss them in a conclusory manner is not a hallmark of reasoned decision-making."), *cert. granted,* 141 S. Ct. 890 (2020).

Second, Defendants publicly discounted the tremendous uncertainty over whether NSIS would result in *salmonella*-related-illness reductions and downplayed the likelihood of actually increasing illnesses under the new system, only to later recant after it was too late for public comment. The risk assessment used a complex model that at step one derived a statistical value reflecting the historical relationship between inspectors' performance of offline inspection activities and the prevalence of *salmonella* on carcasses. A-0604. At step two, it then used this value to predict the number of human illnesses that might result from a HIMP-like inspection system that increased the offline inspection tasks at more plants. *Id.* The preamble to the proposed NSIS rules' predicted 2,533 annual avoided illnesses from 35 plants opting into the system, chiefly relying on a model using "simulated data" that assumed inspection tasks would occur on more days in step two than in step one. 83 Fed. Reg. at 4810; A-1034–35.

This use of simulated data was highly problematic. Indeed, the USDA's Office of Risk Assessment and Cost Benefit Analysis strongly opposed the approach, A-1036–39, the results of which were "not included in the FSIS risk assessment at the departmental clearance stage" and just "appeared with the publication of the proposed rule in 2018." A-1039. One of its staffers even filed a report with a Scientific Integrity Officer over his concerns that a staffer had been pressured to shift the results of modeling. A-

[23] In fact, traditional plants had a greater *reduction* in *salmonella* at the "post-chill" stage than pilot plants did after sorting. A-0614.

1036–38. While no formal allegations were lodged, the records related to these allegations reveal that Defendants' use of simulated data was, in fact, outcome-oriented, as Defendants sought to reduce the uncertainty about their projections of avoided illnesses after anticipating far fewer plants would adopt NSIS.[24] A-1037, A-1040. Indeed, Defendants would ultimately *concede* that this approach was improper with their final risk assessment, which did not rely on simulated data. A-0650 (saying the approach "understates the uncertainty").

The public was not privy to this controversy until the peer reviewers' comments were released many months after the close of the comment period. One peer reviewer condemned the use of simulated data: "The impact of this step is that the authors have created an unrealistically precise estimate of the risk. . . . Put bluntly, the authors are stuck with the level of uncertainty inherent in the original data set. No amount of math or statistics is going to make that go away." A-0955–56; A-0959. Yet, in response to the peer reviewer, Defendants failed to discuss the controversy and doubled down, steadfastly defending this approach in the revised risk assessment's new appendix. A-1017; A-1045.

It was only after their assessment was outside public spotlight and the public could not comment that Defendants finally relinquished this outcome-oriented approach after the NSIS rules were finalized. As a result, the final risk assessment asserted a far larger range of potential benefits, estimating that illnesses could decrease by as many as 6,685 (95th percentile) *or increase by as many as 1,719* (5th percentile). 84 Fed. Reg. at 52,333; A-0651. There was also a five-fold greater chance of an increase in illness (20%, compared to the proposed rules' 4% projection), and Defendants' preamble admits that the final rules' benefits were merely "potential," and not "expected," as the proposed rules' preamble had stated. *See* 84 Fed. Reg. at 52,334, n.84; 83 Fed. Reg. at 4791.

Defendants' hide-the-ball approach, offering the unrepentant defense of simulated data that they knew to be controversial inside and outside of the agency while taking public comment, only to jettison it after finalizing the rules, came at great expense to the public's ability to evaluate and comment on the rules' benefits. Defendants were required to at least announce these revisions and then re-open the public

[24] Documents would also suggest that Defendants had used simulated data because "the 5th percentile is above zero," A-1090—in other words, so that range of avoided illnesses would show an *increase* in illnesses. Defendants' economists heralded this as "great news." *Id.*

comment period.[25] *See Harlan Land Co. v. USDA*, 186 F. Supp. 2d 1076, 1095 (E.D. Cal. 2001) (finding a rule arbitrary and capricious for relying on a faulty risk assessment, the correction of which dramatically increased risk, indicating the need for a new assessment); *Shands Jacksonville Med. Ctr.*, 139 F. Supp. 3d at 263 (finding arbitrary and capricious the failure to disclose assumptions until after the comment period); *cf.*, *Serco Inc. v. United States*, 81 Fed. Cl. 463, 488 (Fed. Cl. 2008) (saying that presenting data to make it appear more certain is a "false precision [that] can act like a siren charming the unwary into making arbitrary comparisons"). Their failure to do so was the height of arbitrary and capricious rulemaking.

In sum, Defendants' rulemaking was arbitrary and capricious for failing to consider significant problems underlying their new inspection system. They disregarded their unrepresentative NSIS pilot; their Hog HIMP Report's limited data set; their own unfavorable data pertaining to Public-Health-Regulation verifications and pilot plants' violations for fecal matter, digestive contents, and milk contamination; pilot-plant sorters' inabilities to incise and palpate lymph nodes, and the risk assessment's flaws that were recognized by peer reviewers, but which Defendants either totally ignored or acknowledged only after the public could comment.

C. The NSIS Rules Undermine the Food Safety Purposes of the FMIA and Are an Unlawful Subdelegation Under the Act.

The NSIS rules also undermine the FMIA's chief purpose, which is to protect "the health and welfare of consumers." § 602. The *only* consumer benefits that Defendants estimate are derived from Defendants' flawed risk assessment, and such benefits are at best highly uncertain, as demonstrated above.

Even if the goal of "efficient execution" of inspections would be advanced by the new rules, any increase in efficiency would be achieved through the dramatic curtailing and transfer of federal inspection responsibilities to the meat companies. Congress did not contemplate this under the FMIA. It even expressly rejected an approach of allowing meat companies to pay for inspection because it would "discredit . . . inspection and cast suspicion upon it." Corrigan Decl. ¶ 8, Ex G-003. Defendants are not free to ignore the means Congress set out to accomplish the FMIA, and their rules are arbitrary and

[25] Defendants also erred by failing to have the risk assessment peer reviewed earlier, contrary to the OMB's and USDA guidance. A-1103; A-1138–39. *Cf. Town of Barnstable v. FAA*, 659 F.3d 28, 35 (D.C. Cir. 2011) (finding disregard of agency guidance arbitrary and capricious).

capricious for doing so. *See Gresham*, 950 F.3d at 101 (finding a regulation arbitrary since agencies are "bound, not only by the ultimate purposes Congress has selected, but by the means it has . . . prescribed") (internal quotes and citation omitted).

For similar reasons, Plaintiffs are also entitled to Summary Judgment on their Sixth Claim, as the rules violate the APA's prohibition on subdelegation. The FMIA clearly provides that only federal inspectors may perform inspections. § 621. And there is no affirmative evidence of statutory authority that Defendants can delegate these responsibilities to plant employees. Further evidencing Defendants' improper delegation is their own regulations, which reflect that no one other than an inspector can make the required inspection. *See* 9 C.F.R. §§ 310.1(a), 300.4 (2021) (defining "Inspection program employee, inspection service employee, or program employee" as "an inspector or other government employee who is authorized to conduct any inspection"). Defendants' NSIS rules therefore violate the APA for subdelegating these responsibilities to plant employees. *Cf. Defs. of Wildlife v. Gutierrez*, 532 F.3d 913, 927 (D.C. Cir. 2008) (saying that federal agency officials "may not subdelegate to outside entities—private or sovereign—absent affirmative evidence of authority to do so") (quoting *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 566 (D.C. Cir. 2004)).

CONCLUSION

Defendants' NSIS rules are contrary to the explicit mandates of the FMIA and in violation of the APA. Plaintiffs respectfully request that the Court grant their Motion for Summary Judgment.

Dated: January 14, 2022

Respectfully submitted,

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PROOF OF CONCURRENCE

Pursuant to Civil Local Rule 5-1(i)(3), Plaintiffs through their counsel have concurred in the filing of this motion.

Dated: January 14, 2022

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