

24-382-CV

United States Court of Appeals
for the
Second Circuit

FARM SANCTUARY, ANIMAL EQUALITY, ANIMAL OUTLOOK,
Plaintiffs-Appellants,

– and –

CENTER FOR BIOLOGICAL DIVERSITY, COMPASSION OVER KILLING,
MERCY FOR ANIMALS, INC., NORTH CAROLINA FARMED ANIMAL
SAVE, ANIMAL LEGAL DEFENSE FUND,
Plaintiffs-Plaintiffs,

(For Continuation of Caption See Inside Cover)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

**BRIEF AND SPECIAL APPENDIX
FOR PLAINTIFFS-APPELLANTS**

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– v. –

UNITED STATES DEPARTMENT OF AGRICULTURE,
FOOD SAFETY AND INSPECTION SERVICE,

Defendant-Appellee.

DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Plaintiffs-Appellants Farm Sanctuary, Animal Equality, and Animal Outlook, by and through their undersigned counsel, each hereby certifies that it has no parent corporation and that no publicly held corporation owns 10% or more of its stock.

/s/ Piper Hoffman
PIPER HOFFMAN
ANIMAL OUTLOOK

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PRELIMINARY STATEMENT

Highly-trained government inspectors are the only safeguard of the public's interests at privately-owned slaughterhouses: Congress appointed them to protect Americans from diseased pork and protect animals from inhumane treatment. But the U.S. Department of Agriculture (USDA) has adopted new regulations that sharply cut back those inspectors' roles while increasing the roles of the regulated entities and their employees. 9 C.F.R. § 309.19(a)–(d) (hereinafter the Regulations). The result, as the former chief veterinarian of USDA's Food Safety and Inspection Service warned in condemning the Regulations, is to jeopardize public health, harm animals, and risk an "outbreak all over the country."¹

The Regulations violate Congress's explicit mandates, unlawfully delegate agency responsibility to regulated parties, and are not grounded in reasoned decision-making. Because the court below erroneously upheld them, this Court must correct that error and set the Regulations aside under the Administrative Procedure Act. 5 U.S.C. § 706.

JURISDICTIONAL STATEMENT

The district court had subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 because it arises under the Administrative Procedure Act, 5

¹ A985–86 (Kimberly Kindy, *Pork Industry Soon Will Have More Power Over Meat Inspections*, Wash. Post, Apr. 3, 2019). (Citations beginning with "A" followed by numbers refer to pages in the Joint Appendix filed with this brief.)

U.S.C. § 706, and the federal regulations promulgated under the Federal Meat Inspection Act, 21 U.S.C. § 601 *et. seq.* The district court’s order was entered on December 12, 2023, and Appellant timely filed a notice of appeal on February 12, 2024. This Court has appellate jurisdiction pursuant to 28 U.S.C. § 1291 because this appeal is from a final order of the district court denying all claims by granting Appellee’s motion for summary judgment and denying Appellants’ motion for summary judgment.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. Do 9 C.F.R. § 309.19(a)–(d), the provisions of the New Swine Inspection System (the NSIS or the Rule) that revised antemortem inspection practices for participating slaughterhouses (the Regulations), violate Section 603 of the Federal Meat Inspection Act (FMIA), and therefore the Administrative Procedure Act (APA), because they are not in accordance with law, and did the district court err in holding to the contrary?
 - a. Do the Regulations violate Section 603(a) because they require employees of establishments that opt into the NSIS (Slaughterhouse Employees) to dispose of “unfit” animals without inspection by USDA-appointed and -trained inspectors (Inspectors), contrary to the FMIA’s mandate that the USDA “shall cause to be made, by inspectors appointed for that purpose, an examination and inspection

of all amenable species” (the Amenable Species Provision), and contrary to the Supreme Court’s holding in *National Meat Ass’n v. Harris*, 565 U.S. 452 (2011), that the FMIA governs the inspection of *all* animals that arrive at a slaughter establishment?

- b. Do the Regulations violate Section 603(a)’s requirement that antemortem inspections must occur “before [animals] shall be allowed to enter into any slaughter establishment” (the Pre-Entry Provision), and not just before they are slaughtered, by giving Slaughterhouse Employees decision-making responsibilities regarding animals before Inspectors see them?
- c. Do the Regulations violate Section 603(a)’s requirement that “inspectors appointed for that purpose” must determine which animals “show symptoms of disease” and therefore must be “set apart” for slaughter (the Sorting Provision) by requiring Slaughterhouse Employees to perform this task (Sorting)?
- d. Do the Regulations violate Section 603(b)’s requirement that the USDA “shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which amenable species are slaughtered and handled in connection with

slaughter” because Slaughterhouse Employees dispose of animals particularly susceptible to inhumane handling without Inspectors examining the methods by which they are handled?

2. Do the Regulations violate the APA by subdelegating government duties to regulated entities in violation of separation-of-powers principles and in excess of the agency’s statutory authority under the FMIA, and did the district court err in holding to the contrary?
3. Are the Regulations arbitrary and capricious in violation of the APA, 5 U.S.C. § 706, because the USDA cherry-picked data, failed to address important considerations, and therefore incorrectly claimed, contrary to the record evidence, that the Regulations would improve humane handling and public health, and did the district court err in reaching the contrary holding as it erroneously applied a standard of review “akin to non-reviewability”?

STATEMENT OF THE CASE

This action challenges the Regulations, which the USDA promulgated unlawfully as part of the NSIS, subrogating the enabling statute, the FMIA, and violating the APA. 9 C.F.R. § 309.19(a)–(d); A431–480 (Modernization of Swine Slaughter Inspection, 84 Fed. Reg. 52300 (Oct. 1, 2019)) (codified at 9 C.F.R. pts. 301, 309, 310) (hereinafter Final Rule). By order dated December 12, 2023, Chief

Judge Elizabeth A. Wolford of the U.S. District Court for the Western District of New York erroneously granted Appellee’s motion for summary judgment and denied Appellants’ motion, holding that the Regulations do not violate the APA. SPA-1–38, 38 (Decision and Order, *Farm Sanctuary v. USDA*, No. 19-cv-6910 at 38 (W.D.N.Y. Dec. 12, 2023) (hereinafter Order). Appellants appeal that judgment.

As a whole, the Regulations reduce the role of Inspectors in antemortem inspections and increase the role of Slaughterhouse Employees. Inspectors, appointed to conduct inspections pursuant to statute, must have college degrees and undergo extensive mandatory training. 21 U.S.C. § 603; A668–782 (FSIS Public Health Veterinarian Training: Multi-species Disposition Basics with a Public Health Focus); *see also* AR100539–891 (FSIS Compliance Guide for a Systematic Approach to the Humane Handling of Livestock);² AR101491–94 (FSIS Notice 15-18, Public Health Regulations and Alerts for Use in Determining Inspection Program Personnel Actions and Public Health Risk Evaluation Scheduling in Meat and Poultry Establishments). In contrast, the Regulations do not require any certifications or training for Slaughterhouse Employees, and USDA’s guidelines for training them are paltry. *See* A444 (Final Rule at 52313)

² Citations beginning with “AR” refer to the administrative record, filed in the district court below. *Farm Sanctuary v. USDA*, No. 19-cv-6910 (W.D.N.Y. Nov. 10, 2021), ECF No. 58.

(“FSIS is not prescribing specific sorter training or certification”); A613–667 (FSIS Guideline for Training Establishment Sorters under the New Swine Slaughter Inspection System, September 2019) (hereinafter 2019 Training) (only six pages discuss antemortem sorting).

The sections below detail the changes to antemortem inspections and the roles of Inspectors and Slaughterhouse Employees under the Regulations.

I. Comparison of Traditional Antemortem Inspection and Antemortem Inspection under the Regulations

A. Traditional Antemortem Inspection

In traditional antemortem inspections, USDA inspectors “appointed for that purpose” (Inspectors) conduct thorough inspections of every animal upon the animals’ arrival at a slaughter establishment, examining each animal both at rest and in motion for symptoms of disease. 21 U.S.C. § 603; A387, 390 (Modernization of Swine Slaughter Inspection, 83 Fed. Reg. 4780, 4783 (proposed Feb. 1, 2018)) (hereinafter Proposed Rule). To conduct at-rest observations, Inspectors observe all the animals and note their general behavior. A1084 (FSIS, Entry Training for PHV: Ante-mortem Inspection (Sept. 21, 2016) at 6) (hereinafter 2016 Training). In-motion inspections are more thorough: Inspectors examine all animals individually as they walk “by viewing the visible side of the head, neck, shoulder, flank, legs, and rump.” *Id.* Inspectors conduct in-motion

inspections from both sides of the animal if they observe signs of disease or distress. *Id.*

Animals deemed healthy based on Inspectors' observations are sent to be slaughtered for human consumption. A532 (Ante-Mortem Livestock Inspection, FSIS Directive 6100.1, Rev. 2 (July 24, 2014) at 6) (hereinafter Directive 6100.1, Rev. 2). Inspectors "set apart" animals showing signs of abnormalities or disease and send them to a "Suspect Pen," with tags and notes that inform the public health veterinarian's (PHV) subsequent evaluation. A530, 532–34 (*id.* at 4, 6–8); A1083, 1090 (2016 Training at 5, 12) (when Inspectors find animals during antemortem inspection exhibiting signs of disease, they must record the signs on FSIS Form 6150-1, including the animal's symptoms, temperature, and weight). For example, when Inspectors determine that an animal has a raised temperature, they notify PHVs to hold the animal in the Suspect pen long enough to observe temperature fluctuations, even if the animal appears asymptomatic when the PHV first checks. *See* A1087–89 (2016 Training at 9–11) (listing antemortem conditions with variable temperatures). PHVs then tag animals as "Condemned" to be killed separately if slaughtering them for human consumption would pose a risk to public health. 9 C.F.R. § 309.13; Ante-Mortem Livestock Inspection, FSIS Directive 6100.1, Rev. 3 at 4 (2019) (hereinafter Directive 6100.1, Rev. 3).

B. Antemortem Inspections under the Regulations

The new Regulations change Inspectors' roles with respect to antemortem inspections by (1) requiring Slaughterhouse Employees to make decisions about which animals should be slaughtered, both before and in place of Inspectors, and (2) reducing critical in-motion inspections by 90–95%. 9 C.F.R. § 309.19; A443 (Final Rule at 52312).

After animals arrive at a slaughter establishment, the Slaughterhouse Employees observe them for symptoms of disease and perform Sorting, segregating the healthy from diseased animals. *Id.* Establishments devise their own plans for Slaughterhouse Employee Sorting, and USDA's directives provide just two pages of guidance for such establishment plans. 9 C.F.R. § 309.19(b), (c); *see also* A619–620 (2019 Training at 7–8).

Employee Sorting under the Regulations sends animals down one of three paths. First, if Slaughterhouse Employees do not see signs of disease or distress in certain pigs, Slaughterhouse Employees sort these animals into “Normal” pens. A549 (New Swine Slaughter Inspection System, FSIS Directive 6600.1, Rev. 2 (Dec. 19, 2019) at 5) (hereinafter Directive 6600.1, Rev. 2). Inspectors observe all the animals in the Normal pen at rest but need never see 90–95% of these animals in motion, though in-motion inspections are more thorough and are often the only way to detect significant symptoms and abnormalities, such as lameness. A443

(Final Rule at 52312) (“Inspectors examine all animals found by the establishment to be normal at rest and five to ten percent of those animals in motion”).

Second, if Slaughterhouse Employees notice that an animal has certain symptoms of disease or distress, such as fatigue, overheating, abnormal body swellings, or lameness, they sort the animal into a “Subject” pen—which does not exist under the traditional system. A620–21 (2019 Training at 8–9) (hereinafter 2019 Training). Animals in the Subject pen are given “time to rest and recover” before they are observed by PHVs. A549 (Directive 6600.1, Rev. 2 at 5). Importantly, Slaughterhouse Employees, unlike Inspectors under the traditional system, do not tag these animals or document the symptoms they observed or the diseases they suspect. *Id.* Therefore, unlike in the traditional system where the animals PHVs inspect have always been pre-tagged by Inspectors, in slaughterhouses that opt into the NSIS (NSIS Establishments), when PHVs inspect animals in Subject pens, they have no indication as to the symptoms they need to look for in evaluating these animals.

Third, if Slaughterhouse Employees deem animals to be dead, moribund, suffering from central nervous system disorders, or experiencing extreme fevers called pyrexia, and therefore to be unfit for slaughter (Unfit), they dispose of them without an Inspector or PHV ever performing an inspection or observing how the animals are handled. A476 (Final Rule at 52345). Unfit animals are especially

likely to carry dangerous diseases like classical swine fever (hog cholera), foot-and-mouth disease, and African swine fever,³ which can cause severe disease outbreaks. *See* A521–526 (FSIS Directive 6000.1, Rev. 1 (Aug. 3, 2006)) (hereinafter Disease Directive 6000.1, Rev. 1) (describing disruptions and costs associated with such diseases). Some, like moribund animals, are also more susceptible to inhumane handling. *See* 9 C.F.R. § 313.2 (special methods required for handling nonambulatory animals); A107–108 (Comment from American Society for the Prevention of Cruelty to Animals and Compassion Over Killing, dated May 1, 2018) (hereinafter ASPCA & COK Comment) (detailing inhumane handling of nonambulatory animals in HIMP facilities). Nevertheless, neither Inspectors nor PHVs ever inspect these animals, nor does the Rule provide for Inspectors to observe how these animals are handled. *See* 9 C.F.R. § 309.19. Rather, the establishment develops, implements, and maintains its own procedures to oversee this process, ensure Unfit animals are not slaughtered for human consumption, and identify animals with dangerous diseases to prevent outbreaks.

Id.

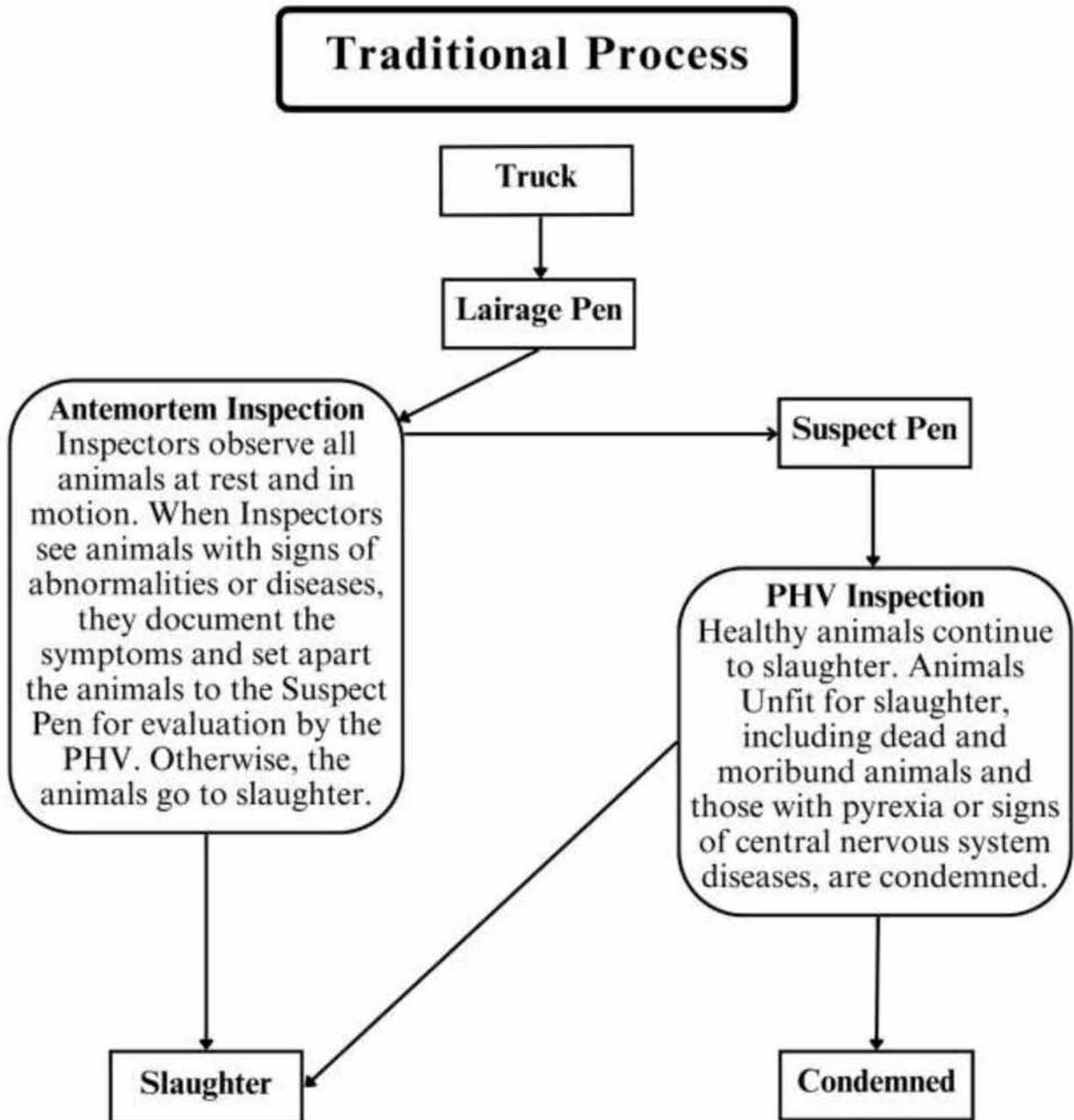
³ In China, outbreaks of African swine fever since 2018 have resulted in an estimated 43.6 million pigs dying or being culled, with a total economic loss of an estimated \$111.2 billion. Shibing You et al., *African Swine Fever Outbreaks in China Led to Gross Domestic Product and Economic Losses*, 2 NATURE FOOD 802, 803 (2021). African Swine Fever has not yet been detected in the United States.

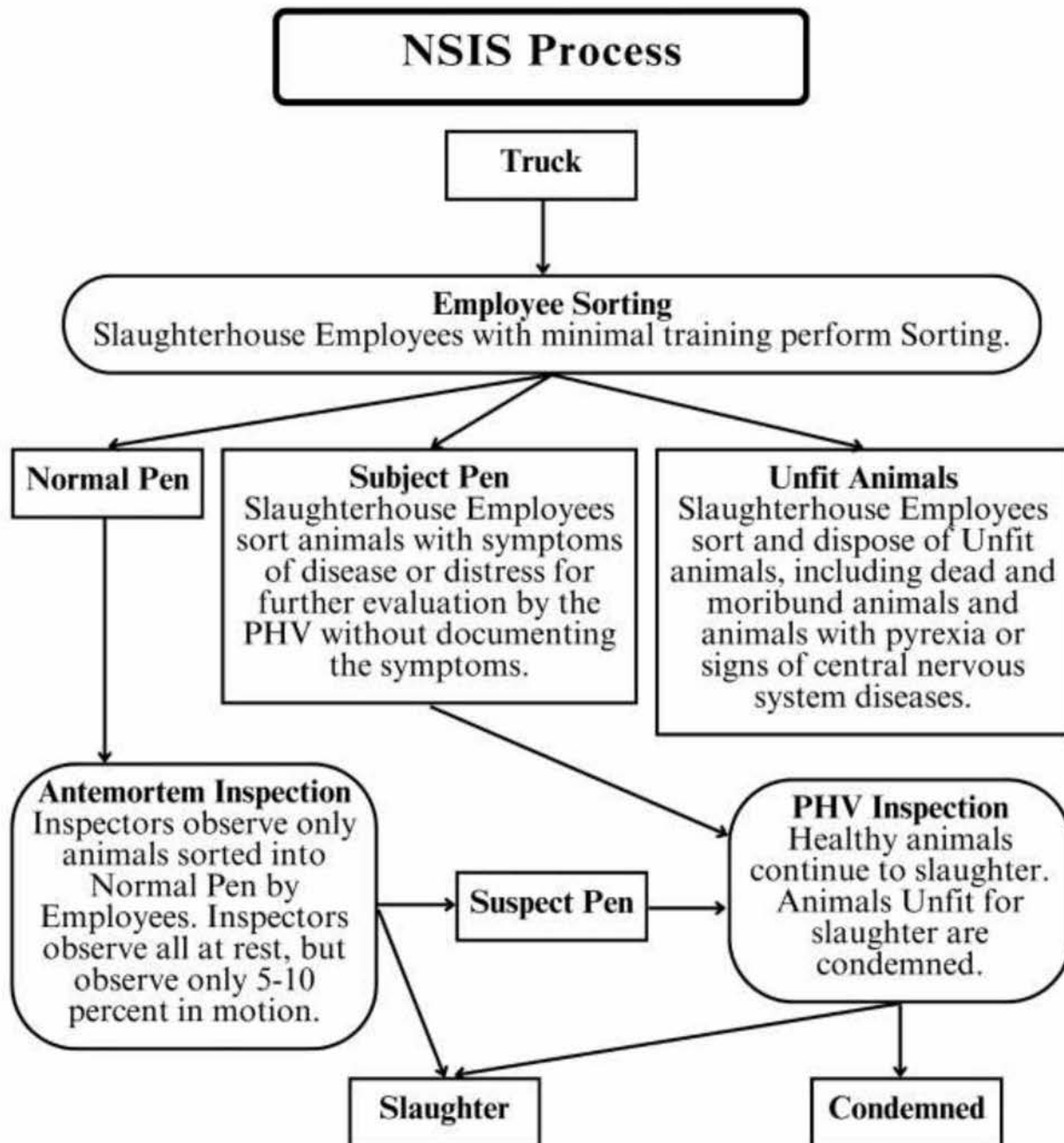
C. Side-by-Side Comparisons of Traditional Antemortem Inspection and Antemortem Inspection under the Regulations

The flowcharts below illustrate the differences between traditional antemortem inspections⁴ and those conducted under the Regulations.⁵

⁴ **Traditional Process.** *Antemortem Inspection:* 21 U.S.C. § 603; A1083–1084 (2016 Training at 5–6); A532–534 (Directive 6100.1, Rev. 2). *PHV Inspection:* 9 CFR § 309.13; A532 (Directive 6100.1, Rev. 2); Directive 6100.1, Rev. 3 at 4.

⁵ **NSIS Process.** *Employee Sorting:* SPA-19; A476 (Final Rule at 52345). *Subject Pen:* A613–667 (2019 Training at 8–9); A549 (Directive 6600.1, Rev. 2 at 5). *Unfit Animals:* A476 (Final Rule at 52345) (Inspectors never inspect these animals.). *Antemortem Inspection:* A549 (Directive 6600.1, Rev. 2 at 5); *compare* A1084 (2016 Training (observing 5-10% of animals in motion under the Regulations)) *with* A532 (Directive 6100.1, Rev. 2 at 6 (observing 100% of animals in motion under traditional system)). *PHV Inspection:* AR104019 (FSIS Webinar, Proposed Rule: Modernization of Swine Slaughter Inspection at 13 (2018)).





As a result of these changes from the traditional system, diseased animals can enter the food supply more easily under the Regulations, jeopardizing public

health. The following hypothetical scenarios illustrate two examples of how this could occur:

Scenario 1: Pig with Fever

Under the traditional system, an Inspector would tag an animal with a fever with a U.S. Suspect tag, document her symptoms for the PHV, and sort her into the Suspect pen. A622–624 (2019 Training at 10–12). There, the PHV would know what to look for to further evaluate the animal, even if the signs of fever had diminished after she rested and drank water. *Id.* For example, the PHV would hold the animal long enough to observe another spike in fever, mark her “condemned,” and ensure the animal was not slaughtered for human consumption. 9 C.F.R. § 309.13; Directive 6100.1, Rev. 3 at 4.

Under the Regulations, by contrast, this animal may enter the food supply in two ways. First, a Slaughterhouse Employee, due to lack of training, pressure to work quickly, fear of management retaliation, or any other reason, does not notice the animal has a fever and sorts her into the Normal Pen. Because she has rested, drunk water, and possibly eaten before inspection, her fever temporarily subsides before Inspectors observe her at rest. A567 (Humane Handling and Slaughter of Livestock, FSIS Directive 6900.2, Rev. 2) (hereinafter Handling Directive 6900.2, Rev. 2). Inspectors do not detect other symptoms, such as lethargy, because they do not observe her in motion. A443 (Final Rule at 52312). The animal is therefore

sent to slaughter and into the human food supply, creating a potential public health hazard.

Alternatively, a Slaughterhouse Employee does notice the animal's fever and sorts her into the Subject pen. A620–21 (2019 Training at 8–9). By the time a PHV evaluates her, however, her signs of fever have diminished due to resting and drinking water. 9 C.F.R. § 313.2(e). The PHV has no information about the reason the animal is in the Subject Pen, and seeing no signs of illness, sends her to slaughter and into the public food supply, again creating a potential health hazard. A620–21 (2019 Training at 8–9).

Scenario 2: Pig with Central Nervous System (CNS) Disorder

Under the traditional system, an Inspector would identify this disorder by observing the animal in motion, tag the animal with a Suspect tag, and send her to the Suspect pen with documentation noting the condition. A1083, 1090 (2016 Training at 5, 12). There, a PHV would verify the symptoms and mark the animal “Condemned,” and she would not be slaughtered for human consumption. 9 C.F.R. § 309.13; Directive 6100.1, Rev. 3 at 4.

In contrast, the Regulations could generate one of two hazardous outcomes. First, the Slaughterhouse Employee may not identify the symptoms, for the reasons discussed above, and sort the animal into the Normal pen. There, because Inspectors do not observe the animal in motion, they also do not observe her

lameness and send her for slaughter for human consumption. A443 (Final Rule at 52312).

Alternatively, if the Slaughterhouse Employee notices the symptoms of CNS disorder, the Employee will determine the animal is Unfit and dispose of the animal pursuant to the establishment plan. 9 C.F.R. § 309.19(a). Inspectors will never inspect this animal for signs of transmissible disease (unless a Slaughterhouse Employee brings it to their attention) or alert other officials in a timely manner, diminishing chances to prevent an outbreak. 9 C.F.R. § 309.19(e). Inspectors may also never observe how the animal is handled. *Id.*

II. Procedural History

Appellants filed this action in the Western District of New York with one cause of action challenging the Regulations, and two others challenging the revocation of caps on line speeds in the NSIS. A12–13 (First Am. Compl. at 3–4). Appellants voluntarily dismissed the line speed causes of action as moot after a different federal district court vacated that portion of the NSIS. A1105 (Stipulation for Dismissal of Plaintiffs’ Second and Third Causes of Action); *United Food & Com. Workers Union, Local No. 663 v. U.S. Dep’t of Agric.*, No. 19-cv-2660, 2021 U.S. Dist. LEXIS 95595 (D. Minn. May 20, 2021), *aff’d* 36 F.4th 77 (8th Cir. 2022). The district court denied Defendants’ motion to dismiss for lack of standing. *Farm Sanctuary v. U.S. Dep’t of Agric.*, 706 F. Supp. 3d 381, 389

(W.D.N.Y 2020). The parties subsequently filed cross-motions for summary judgment. By order dated December 12, 2023, the district court granted Appellee’s motion for summary judgment and denied Appellants’ motion, holding that the Regulations do not violate the APA. SPA-38. Appellants appeal that judgment.

ARGUMENT SUMMARY

The Regulations, codified at 9 C.F.R. § 309.19, violate the APA for several reasons: they are not in accordance with law because they subvert the FMIA; they are not in accordance with law and are in excess of the agency’s authority because they unlawfully delegate agency responsibilities to regulated establishments; and they are arbitrary and capricious because the USDA acted contrary to the evidence, ignored important aspects of the problem, and did not engage in reasoned decision-making in adopting them. 5 U.S.C. § 706.

The Regulations violate FMIA Section 603 in several ways, beginning with Section 603(a), which Congress enacted to protect public health. It specifies:

- *who* must perform antemortem inspections—inspectors “appointed for that purpose” (Inspectors);
- *which animals* they must inspect—“all amenable species” (the Amenable Species Provision);
- *when/where* inspections must take place—before animals “enter into” any slaughter establishment, not any time before they are slaughtered (the Pre-Entry Provision); and

- *what* inspections must accomplish and *how*—identifying animals showing symptoms of disease, and setting them apart to be slaughtered separately from healthy animals (the Sorting Provision).

The Regulations subvert each of these provisions:

The Amenable Species Provision. The Regulations violate Section 603(a)'s plain text—and Supreme Court precedent interpreting the FMIA's scope—which make clear that Inspectors must inspect all animals arriving at an establishment, regardless of whether they are ultimately slaughtered for human consumption. *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 466 (2012). The Regulations, contrary to this mandate, require Slaughterhouse Employees to dispose of animals they deem Unfit for slaughter before Inspectors can inspect them. This unlawful elimination of government oversight jeopardizes public health because animals deemed Unfit can be suffering from especially dangerous diseases, like African Swine Fever—yet under the Regulations, it falls on untrained and uncertified Slaughterhouse Employees to identify and report such diseases to prevent outbreaks, and to ensure these animals are never slaughtered for human consumption.

The Pre-Entry Provision. Section 603(a) also requires antemortem inspections to occur before animals “enter into” any slaughter establishment, and not just before they are slaughtered. The original meaning of and intent behind this provision was that inspections must occur before Slaughterhouse Employees could come in contact with, let alone make decisions regarding, diseased animals, to

reduce the risk of establishments selling adulterated meat to consumers. The Regulations vitiate this provision by creating an “additional step[]” during which Slaughterhouse Employees sort animals before Inspectors inspect or even see them. A442 (Final Rule at 52311).

The Sorting Provision. The Regulations violate Section 603(a)’s mandate that diseased animals must be identified and set apart from healthy animals “by inspectors appointed for that purpose.” The Regulations prescribe a different means of segregating healthy from diseased animals, requiring untrained and uncertified Slaughterhouse Employees to perform this task *ultra vires*.

The Regulations also violate Section 603(b) of the FMIA, which incorporates the Humane Methods of Slaughter Act (HMSA), 7 U.S.C. § 1901, and requires that Inspectors examine whether the methods for handling all animals at slaughter establishments are humane. Under the Regulations, however, Inspectors need not inspect the methods that establishments employ to handle Unfit animals apart from during Sorting once a month—though Unfit animals require special handling methods, and are especially susceptible to inhumane handling, because many are unable to move on their own.

In addition to these violations of the FMIA, the Regulations unlawfully subdelegate government responsibilities to the regulated industry, violating separation-of-powers principles. Agencies cannot subdelegate powers to private

entities absent Congressional authorization, unless the delegations are limited to ministerial tasks. But the Regulations, without statutory authorization—and, indeed, contrary to Congressional intent—require NSIS Establishments and their employees to carry out tasks like distinguishing healthy and diseased animals, identifying animals with dangerous diseases, overseeing the segregation of Unfit animals, and designing systems to ensure that Unfit animals do not enter the food supply. These tasks require not only discretion but expertise, and are the core public health inspection activities of the FMIA.

Finally, the Regulations are arbitrary and capricious, and the district court afforded the USDA too much deference by applying the incorrect legal standard. Properly scrutinized, the USDA's relevant justifications for the Regulations—that they would improve humane handling and better protect public health—lack reasoned judgment and run counter to the evidence. The USDA's supporting data comes from just a few years cherry-picked out of a 20-year study that was not designed to assess humane handling, was improperly analyzed according to a selected peer reviewer, is insufficient on its face to support the agency's conclusions, fails to address important considerations, and is belied by the other evidence in the record.

Appellants respectfully ask this Court to reverse the decision below and set aside the Regulations as unlawful. 5 U.S.C. § 706(2).

STANDARD OF REVIEW

“On appeal from a district court’s review of an APA claim, an appellate court accords no deference to the lower court’s decision.” *Ward v. Brown*, 22 F.3d 516, 521 (2d Cir. 1994). Instead, the appellate court must conduct *de novo* review of both the law and the administrative record. *Id.* The reviewing court must “hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; [or] (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.” 5 U.S.C § 706(2).

ARGUMENT

I. The NSIS Violates Section 603(a)’s Amenable Species Provision, Pre-Entry Provision, and Sorting Provision.

In Section 603(a) of the FMIA, Congress spelled out the mandatory requirements of an antemortem inspection:

[**Clause 1**] [T]he 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, packing, meat-canning, rendering, or similar establishment*, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; [**Clause 2**] and *all amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine . . .*

(Emphasis and “Clause” labels added.) Clause 1 includes the Amenable Species Provision, which provides *who* must conduct antemortem inspections, and *which animals* they must inspect: federal Inspectors “appointed for that purpose” must inspect “all” amenable species. It also includes the Pre-Entry Provision, which provides *when* and *where* Inspectors must perform antemortem inspections: before animals *enter* a slaughter establishment (not any time before they are slaughtered). Clause 2 is the Sorting Provision, which provides *what* the Inspectors must accomplish through antemortem inspections: the segregation of healthy animals who can safely be slaughtered for human consumption from diseased animals who cannot. It also provides *how* Inspectors must accomplish Sorting: by identifying animals “found on such inspection to show symptoms of disease.” The Regulations violate each of these clear mandates.

A. The Regulations Violate Section 603(a)’s Amenable Species Provision Because Inspectors Do Not Inspect All Animals.

The Regulations violate Section 603(a)’s requirement that Inspectors inspect *all* animals arriving at a slaughterhouse by ensuring that Inspectors never inspect the animals Slaughterhouse Employees deem Unfit.

Section 603(a)’s Amenable Species Provision requires that Inspectors examine and inspect “*all* amenable species⁶ before they shall be allowed to enter

⁶ “The term ‘amenable species’ means . . . (1) those species subject to the provisions of this chapter. . . .” 21 U.S.C. § 601(w). “Species” refers to individual

into any . . . establishment,” not just *some* animals, as decided by Slaughterhouse Employees. This requirement is both clear on its face and has been affirmed by the U.S. Supreme Court. In *National Meat Association v. Harris*, the Supreme Court directly addressed the scope of the FMIA’s antemortem inspection provisions, ruling that they apply from the moment animals arrive on a slaughterhouse’s premises, and that they apply to every animal who was sent there for the purpose of slaughter, including animals who ultimately are not slaughtered for human consumption. *Nat’l Meat Ass’n v. Harris*, 565 U.S. 452, 465–66 (2012) (“[A]n animal is on a slaughterhouse’s premises[] from the moment a delivery truck pulls up to the gate.”); *id.* (the “FMIA’s scope includes not only animals that are going to be turned into meat, but animals on a slaughterhouse’s premises that will never suffer that fate.”); *see also* Humane Handling and Slaughtering of Livestock, Directive 6900.2, Rev. 3 at 5 (Sept. 24, 2020) (hereinafter Handling Directive 6900.2, Rev. 3) (“Once a vehicle carrying livestock enters, or is in line to enter, an official slaughter establishment’s premises, the vehicle is considered to be a part of that establishment’s premises.”). Indeed, the idea that the antemortem inspection mandate includes all animals “intended for slaughter,” not just those actually

animals. *See* 21 U.S.C. § 603(a) (“[A]ll amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine . . .”).

slaughtered for human consumption, dates back to 1906 when the FMIA was enacted. *See The So-Called "Beveridge Amendment" to the Agricultural Appropriation Bill: Hearings on H.R. 18537 before the H. Comm. on Agric., 59th Cong. 277 (1906) (hereinafter *Beveridge Amend. Hr'g*) (antemortem inspections required for all animals "*intended for slaughter*") (emphasis added).*

Congress requires Inspectors to inspect *all* animals, not just those ultimately slaughtered for human consumption, at least in part because many symptoms that render an animal Unfit are symptoms of "notifiable" diseases which "can cause considerable economic and social disruption." A521–526 (Disease Directive 6000.1, Rev. 1) (costs of "controlling the spread . . . by animal quarantine, depopulation, the cleaning and disinfecting of livestock environments, and the mass disposal of animal carcasses" are significant). Such diseases need to be identified and reported immediately to regional command centers to prevent outbreaks. *See, e.g.,* A523 (*id.* at 3) ("PHVs are to notify the [District Office] as soon as possible"). In short, the antemortem inspection provisions of the FMIA apply to every animal that arrives at a slaughterhouse, and do not exempt Unfit animals. *Id.*

Under the Regulations, however, Inspectors do not inspect the animals Slaughterhouse Employees deem to be moribund, or to have symptoms of CNS disorders or pyrexia, and therefore to be Unfit for slaughter. 9 C.F.R. § 309.19(b);

see also A431 (Final Rule at 52300) (“[T]his final rule requires establishment personnel in NSIS establishments to sort and remove unfit animals before ante-mortem inspection by FSIS inspectors”); A546 (Directive 6600.1 at 2) (“Requiring establishment personnel to sort and remove unfit animals before FSIS conducts antemortem inspection” is a “key element[] of the NSIS”). Excluding these animals from federal oversight violates the plain text of the FMIA and the Supreme Court’s explicit ruling that they are covered by the FMIA’s antemortem inspection provisions. *Nat’l Meat Ass’n*, 565 U.S. at 466.

By violating the FMIA, moreover, the Regulations jeopardize public health. Since Inspectors do not observe the animals Slaughterhouse Employees deem Unfit, it is up to these untrained and uncertified Slaughterhouse Employees to ensure they are not slaughtered for human consumption and to report signs of the dangerous diseases that Unfit animals may carry, at the risk of pandemic outbreaks. *See* 9 C.F.R. § 309.19(e) (“The establishment must immediately notify FSIS inspectors if the establishment has reason to believe that market hogs may have a notifiable animal disease”).

Despite the clear requirement of antemortem inspections for all animals at slaughterhouses, the district court erroneously held that “dead, moribund, or otherwise unfit hogs that Slaughterhouse Employees remove and dispose of prior to ante-mortem inspection” do not require inspection, on the grounds that they are

not “offered for slaughter” under 9 C.F.R. § 309.1. SPA-23, n.5. The reliance on this regulation is misplaced for two reasons. First, assuming *arguendo* the regulation applies only to animals who actually are slaughtered, the statute, as interpreted by the Supreme Court, still requires inspection of all animals at the premises, not just the subset covered by the regulation. Second and regardless, the Supreme Court’s holding that the FMIA requires inspections of all animals that arrive at a slaughter establishment supersedes any conflicting regulation. *See Nat’l Meat Ass’n*, 565 U.S. at 466.

Accordingly, because Inspectors do not inspect entire groups of animals that arrive at slaughter establishments pursuant to the Regulations, these Regulations violate the FMIA and must be set aside as unlawful under the APA.

B. The Regulations Gut Section 603(a)’s Pre-Entry Provision by Allowing Establishments to Take Possession and Control of Animals Before Inspectors Perform Antemortem Inspections.

The Regulations also gut Section 603(a)’s Pre-Entry Provision, which requires that Inspectors inspect animals “before they shall be allowed to enter into any . . . establishment,” not just before they are slaughtered, like the district court erroneously held. Compare 21 U.S.C § 603(a) with SPA-19 (holding Regulations are lawful if “all swine sent for slaughter are *ultimately* inspected by FSIS inspectors”) (emphasis added).

As originally understood by the enacting Congress and by industry, mandating a pre-entry inspection, not just a pre-slaughter inspection, served to bar regulated slaughter establishments from possessing animals, or even coming in contact with animals, until Inspectors had independently determined they were healthy. At that time, after breeders raised animals for slaughter, shipping companies transported them to stockyards in major cities, where slaughter establishments bought the animals, then conveyed them to their premises. *See Beveridge Amend. Hr'g* at 6–7, 36; *see also* Symposium, *Recent Inspection of Meat Supply*, 28 *Annals Am. Acad. Pol. & Soc. Sci.* 317–323 (1906). The Pre-Entry Provision, enacted against this backdrop, caused antemortem inspections to occur at stockyards before slaughter establishments ever purchased animals, let alone before their employees could possess and make decisions about the animals. *Id.*

The Legislature and industry shared an understanding that this complete separation of inspections, conducted by expert government personnel, from processing, controlled by the slaughter establishments, was at the heart of the FMIA. Testimony before the 1906 Agriculture Committee highlights that shared understanding, and makes clear Congress's intent that, due to pre-entry inspections, diseased animals would not only be separated for slaughter, but would not fall into the possession of slaughter establishments until after an independent

government inspection with which establishments could not interfere. *See, e.g., Beveridge Amend. Hr'g* at 8–9, 36 (questioning of an industry representative about whether slaughter establishments could buy condemned animals under any circumstances). As industry representative Thomas E. Wilson expounded to the Committee:

If [animals] are inspected in the yards, and tagged, we have nothing to do with them. That is before we come in contact with them at all, and they never reach our hands, and they are never in our possession, and we have nothing to do with them, absolutely.

Id. at 36. Indeed, far from allowing establishments to take part in inspections, Congress rejected a proposal to “require[] those who are to be inspected to pay the cost of the inspection” because “the [public’s] knowledge of this fact would discredit the inspection and cast suspicion upon it.” *Id.* at 363; *see also id.* at 186 (statement of Judge Edgar D. Crumpacker) (asking rhetorically, “[d]o you desire a system of inspection that depends upon the favor or sufferance of the meat packers for its enforcement, or do you want one that can be enforced by the officers of the law?”); *id.* at 200 (statement of Congressman Edgar C. Ellis) (“The only kind of inspection that will satisfy the people under ordinary circumstances is Government inspection; but under the extraordinary circumstances that now exist, they would be far from accepting inspection of any other sort”); 21 U.S.C. § 622 (prohibiting gifts to Inspectors). In short, in light of then-existing infrastructure, Congress drafted the Pre-Entry Provision to guarantee that regulated

establishments never had access to diseased animals and could not interfere with, or even appear to interfere with, inspections.

The historical context further illuminates why Congress drafted the FMIA to require pre-entry inspections, not just pre-slaughter inspections, guaranteeing that regulated establishments would not possess diseased animals. In the late nineteenth and early twentieth centuries, slaughter establishments had been slaughtering diseased animals for human consumption and selling adulterated meat, defrauding consumers and endangering public health. *See generally Beveridge Amend. Hr'g* (transcribing extensive hearings and interviews with experts and Slaughterhouse Employees). U.S. soldiers had died from eating “impure” meats during the Spanish-American War, stoking public outrage. Kristen L. Rouse, *Meat Inspection Act of 1906*, Encyclopedia Britannica (June 23, 2024), <https://www.britannica.com/topic/Meat-Inspection-Act>. On top of that, exposés like Upton Sinclair’s *The Jungle* revealed the cruel slaughtering practices and unsanitary conditions in slaughter establishments. *Id.* By prohibiting regulated slaughter establishments from possessing animals unless Inspectors first deemed them healthy, Congress stopped these establishments from slaughtering diseased animals and selling the products as food.

In later years, when stockyards disappeared as advancements in trucking enabled breeders to ship animals directly to slaughter establishments, antemortem

inspections had to relocate. To preserve Congress’s intent and the integrity of federal oversight, a legal fiction—that animals kept in holding pens immediately after delivery to a slaughter establishment had not yet “entered” the establishment for purposes of antemortem inspection and Sorting—enabled Inspectors to continue conducting antemortem inspections before the animals were ever in Slaughterhouse Employees’ possession.⁷ *Beveridge Amend. Hr’g* at 36 (statement of Thomas E. Wilson); *Union Stock Yard & Transit Co.*, Encyclopedia of Chicago, <http://www.encyclopedia.chicagohistory.org/pages/2883.html> (last visited Aug. 16, 2024).

But the Regulations deal a death blow to Congress’s intent and to the original understanding of the Pre-Entry Provision, gutting it in both form and function. Now Slaughterhouse Employees can, and must, make decisions about which animals are slaughtered—under the authority of their employer, the slaughter establishment—*before* Inspectors conduct antemortem inspections. 9 C.F.R. § 309.19(a). This additional step vitiates Congress’s purposeful separation of inspections, conducted by expert government personnel, from processing, controlled by the slaughter establishments. A442 (Final Rule at 52311). Put

⁷ The idea that animals in holding pens have not “entered” a slaughter establishment is a legal fiction because, as both the Supreme Court and USDA have made clear, “an animal is on a slaughterhouse’s premises[] from the moment a delivery truck pulls up to the gate.” *Nat’l Meat Ass’n v. Harris*, 565 U.S. 452, 466 (2012); *accord* Handling Directive 6900.2, Rev. 3.

differently, under the Regulations, the legal fiction that animals in holding pens have not yet “entered” an establishment for inspection purposes collapses.⁸

As the 1906 Congress understood, giving Slaughterhouse Employees such “pre-inspection” access to diseased animals, which the Regulations require, increases opportunities for companies to sell adulterated products to consumers. *See Beveridge Amend. Hr’g* at 363. For example, because Slaughterhouse Employees dispose of Unfit animals, it falls primarily on slaughter establishments to ensure these animals are not sold to consumers, and Inspectors may not become aware that especially dangerous and contagious diseases, like African swine fever, are present and spreading. *See* 9 C.F.R. § 309.19(b), (e); A521–22 (Disease Directive 6000.1, Rev. 1 at 1–2) (such diseases cause significant disruption and

⁸ Requiring employees to sort animals before Inspectors’ antemortem inspections also undermines enforcement of the FMIA’s sister statute, the 28-Hour Law, which was re-enacted alongside the FMIA and states that carriers “may not confine animals in a vehicle or vessel for more than 28 consecutive hours without unloading the animals for feeding, water, and rest.” 49 U.S.C § 80502. The 28-Hour Law regulates transport to slaughter establishments, and the FMIA picks up “the moment a delivery truck pulls up to the gate.” *Nat’l Meat Ass’n v. Harris*, 565 U.S. 452, 466 (2012). Because Inspectors traditionally have inspected all animals promptly upon their arrival from a long journey to the slaughterhouse, they could use antemortem inspections to detect signs of 28-Hour Law violations. A530 (Directive 6100.1, Rev. 2 at 4) (requiring Inspectors to report such evidence of legal violations). Under the new Regulations, however, employees sort animals and put them into pens where they can rest and drink water, so by the time Inspectors see the animals to perform antemortem inspections, the evanescent signs of “exhaust[ion] and dehydrat[ion]” may be gone. 9 C.F.R. § 313.2(e). This erases a key opportunity Inspectors had for enforcement of the 28-Hour Law.

expense). Slaughterhouse Employees, moreover, are not incentivized to flag animals that cannot be slaughtered for human consumption, or to report diseases that could require establishments to shut down operations, since their livelihoods depend on profit-driven employers that seek to process the greatest number of animals for human consumption. Even assuming Slaughterhouse Employees' best intentions, they may miss symptoms because they do not complete any required training or certification. A444 (Final Rule at 52313) ("FSIS is not prescribing specific sorter training or certification"). "[I]n such an environment the opportunity for illegitimate operators to traffic in dead, dying, disabled, or diseased animals has been found to be all too readily prevalent and inviting." Legis. Hist. Wholesome Meat Act, Pub. L. 90-201 at 20: 81 Stat. 584 (Dec. 15, 1967).⁹

The district court's opinion wrote the Pre-Entry Provision out of the FMIA, re-conceptualizing the statute to require "an 'examination and inspection' by federal inspectors of all market hogs *prior to slaughter*." SPA-18 (emphasis added). But that court erred in finding the Regulations would be lawful merely because "all swine sent for slaughter are *ultimately* inspected by FSIS inspectors." SPA-19 (emphasis added). Section 603(a) does not just mandate that FSIS Inspectors "ultimately" inspect all pigs "prior to slaughter"—it mandates that

⁹ In 1967, Congress enacted the Wholesome Meat Act to strengthen the FMIA, reiterating the goals of the 1906 Congress. *See* Legis. Hist., Pub. L. 90-201.

Inspectors inspect all pigs “before they shall be allowed to enter into any . . . establishment” so that they can be sorted according to “such inspection,” and the district court’s relaxation of that requirement amounts to improper judicial policymaking. This Court must therefore reverse the district court’s ruling and hold that the Regulations are contrary to law in violation of the APA, 5 U.S.C. § 706, because they violate the Legislature’s plain statement of intent in the FMIA’s Pre-Entry Provision.

C. The Regulations Unlawfully Require Employees at NSIS Establishments to Perform Sorting.

The Regulations violate another straightforward mandate in Section 603: the Sorting Provision, which prescribes *how* diseased and healthy animals are to be “set apart” for slaughter. Section 603(a) specifies that: (1) Inspectors “appointed for that purpose” (2) must inspect all animals to determine which “show symptoms of disease,” and (3) based on these symptoms, determine which animals “shall be set apart and slaughtered separately” (*i.e.*, perform Sorting) so that diseased animals do not enter the food supply. The Regulations create a system in which this simply does not happen.

The FMIA’s instructions are binding upon the USDA. “When a statute limits a thing to be done in a particular mode, it includes the negative of any other mode.” *Raleigh & G. R. Co. v. Reid*, 80 U.S. 269, 270 (1871); *accord Botany Worsted Mills v. United States*, 278 U.S. 282, 288–89 (1929); *Conboy v. AT&T*

Corp., 241 F.3d 242, 255 (2d Cir. 2001). “This principle of statutory construction reflects an ancient maxim – *expressio unius est exclusio alterius*.” *Nat’l R.R. Passenger Corp. v. Nat’l Ass’n of R.R. Passengers*, 414 U.S. 453, 458 (1974). “Accordingly, administrative agencies and the courts are ‘bound, not only by the ultimate purposes Congress has selected but by the means it has deemed appropriate, and prescribed, for the pursuit of those purposes.’” *MCI Telecomms. Corp. v. AT&T Co.*, 512 U.S. 218, 231 (1994). It is therefore unlawful for the USDA to promulgate a different mode or means of Sorting than the FMIA specifies. But this is what the USDA did in the Regulations, tasking Slaughterhouse Employees with inspecting and setting apart animals showing symptoms of disease. 9 C.F.R. § 309.19(a); *see also* SPA-19 (“establishment employees may conduct ante-mortem sorting procedures”).

The district court accepted, erroneously, that as long as Inspectors “ultimately” inspect animals who are slaughtered for human consumption, Slaughterhouse Employees can perform Sorting as an additional step. SPA-19. But the questions of whether, under the Regulations, Inspectors still inspect all the animals Congress required, and do so at the time Congress required, are distinct¹⁰

¹⁰ Slaughterhouse Employees performing Sorting raises an additional legal concern: it is one of several ways in which the Regulations unlawfully subdelegate government power to private employees, violating separation-of-powers principles. *See pp. 38–40, infra*.

from the problem of employees of the regulated industry playing a role in the antemortem inspection process that is unauthorized and *ultra vires*. Congress deliberately excluded Slaughterhouse Employees from antemortem inspections and Sorting to foreclose opportunities for slaughter establishments to sell adulterated products and jeopardize public health, and to avoid undermining public confidence. *See* Scenarios 1 and 2 at pp.14–16, *supra* (illustrating ways diseased animals can enter the meat supply given Slaughterhouse Employee involvement in antemortem inspections); *see also, e.g., Beveridge Amend. Hr’g* at 6–7, 36, 186, 200. The USDA does not have the authority to enact its own, conflicting policy choices.

Because the Regulations require Slaughterhouse Employees to conduct *ultra vires* Sorting, the Regulations violate APA Section 706 as contrary to law and must be set aside, and the holding below reversed.

II. The Regulations Violate FMIA Section 603(b)’s Humane Handling Requirement Because Inspectors Do Not Inspect the Methods Slaughterhouse Employees Use to Handle Animals Uniquely Susceptible to Inhumane Handling.

The Regulations also violate FMIA Section 603(b), which incorporates the HMSA to enforce the humane handling of animals at slaughter establishments.

Section 603(b) states:

[T]he Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which amenable

species are slaughtered and handled in connection with slaughter in the slaughtering establishments . . .

Animals “handled in connection with slaughter” include all those delivered to a slaughter establishment, including moribund animals who will never be slaughtered for human consumption. *See* pp. 23–24, *supra* (discussing *Nat’l Meat Assoc. v. Harris*, 565 U.S. 452, 466, which held that “an animal is on a slaughterhouse’s premises[] from the moment a delivery truck pulls up to the gate,” and the “FMIA’s scope includes not only animals that are going to be turned into meat, but animals on a slaughterhouse’s premises that will never suffer that fate”). Therefore, Inspectors must inspect and examine an establishment’s handling methods, even if these methods impact only Unfit animals.

Certain handling methods at an establishment will, indeed, be specific to Unfit animals, who are especially susceptible to inhumane handling by nature of being Unfit and often unable to move on their own. *See* 9 C.F.R. § 313.2 (special methods required for handling nonambulatory animals); *see also* A107–109, 129–157 (ASPCA & COK Comment) (describing Animal Outlook’s undercover videos at HIMP plant capturing fully conscious, moribund pigs being dragged to slaughter with a metal hook); A61–62 (Leahy Decl. ¶ 15) (same); 147 Cong. Rec. H6367 (daily ed. Oct. 4, 2001) (statement of Rep. Ackerman) (“These animals, known as downers, suffer beyond belief as they are kicked, dragged, and prodded with electric shocks in an effort to move them”). Still, the Regulations require

Slaughterhouse Employees to identify and dispose of Unfit animals outside the inspection process, such that Inspectors may never see these animals or observe the special methods for handling them at the establishment. 9 C.F.R. § 309.19(b). By keeping Inspectors from protecting these animals under federal law, the Regulations leave them with no protection whatsoever. *Nat'l Meat Ass'n.*, 565 U.S. at 459–60 (holding the FMIA preempts state laws regulating the handling of nonambulatory animals).

The district court held incorrectly that, under the Regulations, Inspectors fulfill their Section 603(b) mandates because they “will verify that animals that are intended to be disposed of are humanely euthanized and that animals that are intended to be diverted to another official establishment are eligible for transport.” SPA-22–23 (citing Final Rule at 52312). Even taking this finding at face value, however, such verification by Inspectors is less than the statute requires: Section 603(b) mandates that Inspectors examine and inspect the methods by which all animals are handled, and overseeing their euthanasia and confirming eligibility for transport falls far short of observing the methods by which Slaughterhouse Employees maneuver them, often with large, specialized equipment. *See* 9 C.F.R. § 313.2.

Because the Regulations read Section 603(b)'s protections, and therefore the HMSA, out of the FMIA with respect to Unfit animals, the Regulations are not in accordance with law and must be set aside, and the order below reversed.

III. The Regulations Unlawfully Subdelegate Government Duties to Regulated Entities.

The Regulations also violate the APA because they unlawfully subdelegate non-ministerial government responsibilities to the slaughter establishments the government is regulating, violating separation-of-powers principles. This subdelegation is not only unauthorized but is contrary to Congressional intent.

When Congress delegates powers to agencies, the agencies cannot subdelegate those powers to private entities absent Congressional authorization. *See Fund for Animals v. Kempthorne*, 538 F.3d 124, 132 (2d Cir. 2008); *see also Consumers' Rsch. v. Fed. Commc'ns Comm'n*, 109 F.4th 743, 774 (5th Cir. 2024) (noting “the *only* Supreme Court cases blessing private delegations involved explicit statutory authorizations,” and discussing founding-era history); *U.S. Telecom Ass'n v. FCC*, 359 F.3d 554, 566 (D.C. Cir. 2004), *cert. denied*, 543 U.S. 925 (2004). The only exception is that a subdelegation may be permissible when it involves no more than ministerial tasks. *See Yaretsky v. Blum*, 592 F.2d 65, 70 (2d Cir. 1979) (Lumbard, J., concurring in part) (discussing “the familiar distinction between discretionary, managerial, and policy-making tasks, which clearly cannot be delegated, and ministerial tasks, involving little or no exercise of discretionary

judgment”). “A ministerial duty. . . is one in respect to which nothing is left to discretion.” *Gaines v. Thompson*, 74 U.S. 347, 353 (1868).

Here, Congress has not authorized the USDA to subdelegate its powers under the FMIA to private entities. To the contrary, Congress passed the FMIA to “restore the public confidence” in the meat supply by creating a federal inspection system with which specific private parties, the regulated slaughter establishments, could not interfere—the same private parties whom the Regulations now *require* to be involved with inspections at NSIS Establishments. *See* pp. 26–33, *supra* (discussing the history of the FMIA, including historical evidence that the enacting Congress took measures to prevent even the appearance that establishments could influence inspections); *Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023, 1032 (Fed. Cir. 2016) (stating the “unremarkable proposition that congressional intent to preclude delegation can sometimes be found in the legislative history”). Any subdelegation of the USDA’s powers under the FMIA, especially to the regulated businesses, is thus unlawful unless those powers are strictly ministerial.

Nevertheless, the Regulations unlawfully subdelegate broad, non-ministerial responsibilities to NSIS Establishments and their untrained, uncertified employees, whose incentives are to serve the establishments’ interests so they can keep their jobs. These responsibilities include Sorting healthy and symptomatic animals (Final Rule at 52312); identifying, handling, and disposing of Unfit animals

without oversight (9 C.F.R. § 309.19); identifying symptoms of disease in Unfit animals that can presage pandemic outbreaks (Final Rule at 52345); and tracking Unfit animals to ensure their products do not enter the food supply (Final Rule at 52312). All these tasks are non-ministerial because they require discretion and expertise. Sorting, for instance, requires Slaughterhouse Employees to exercise discretion in deciding which animals “show symptoms of disease” and therefore “shall be set apart.” 21 U.S.C. § 603(a).

In short, the Regulations are built on the unauthorized subdelegation of non-ministerial powers to private regulated parties, contrary to Congress’s intent. They are therefore in excess of the agency’s statutory authority and not in accordance with law, in violation of the APA. 5 U.S.C. § 706. The district court’s holding to the contrary must be reversed.

IV. The Regulations Are Arbitrary, Capricious, and an Abuse of Discretion.

This Court must also reverse the district court’s opinion and set aside the Regulations because their adoption was arbitrary, capricious, and an abuse of discretion in violation of the APA, and because the district court, in reaching a contrary holding, applied an incorrect standard of review that was overly deferential. 5 U.S.C. § 706(2)(A). An agency’s adoption of a rule is arbitrary and capricious if the agency “failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before” it.

Motor Vehicle Mfrs. Ass'n v. State Farm, 463 U.S. 29, 43 (1983). The agency must “examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choice made.” *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (internal citation omitted). An agency must also provide a reasoned explanation for “depart[ing] from its own precedent.” *N.Y. & Atl. Ry. Co. v. Surface Transp. Bd.*, 635 F.3d 66, 71 (2d Cir. 2011) (internal quotations omitted); *see also Encino Motorcars*, 579 U.S. at 221–22. In evaluating an agency’s decision-making, courts are “not required to exhibit a naiveté from which ordinary citizens are free,” because “[t]he reasoned explanation requirement of administrative law is meant to ensure that agencies offer genuine justifications for important decisions,” and “[a]ccepting contrived reasons would defeat the purpose of the enterprise.” *DOC v. New York*, 588 U.S. 752, 785 (2019) (quoting *United States v. Stanchich*, 550 F. 2d 1294, 1300 (CA2 1977) (Friendly, J.)).

The district court erroneously applied the legal standard, writing: “[t]his standard is applied at the high end of the range of deference and an agency refusal is overturned only in the rarest and most compelling of circumstances . . . and has been said to be so high as to be akin to non-reviewability.” SPA-25 (citations omitted). The court took this “akin to non-reviewability” standard from two opinions addressing a different kind of case—challenges to agency decisions to

deny rulemaking petitions—and review of such denials requires significantly more deference than is required where, as here, the Court is reviewing the agency’s promulgation of a rule. *New York v. U.S. Nuclear Regul. Comm’n*, 589 F.3d 551, 554 (2d Cir. 2009) (quoting *Cellnet Comm’n, Inc. v. FCC*, 965 F.2d 1106, 1111 (D.C. Cir. 1992)).

Here, applying the standard of review correctly, this Court should hold that the USDA’s justifications for the Regulations, namely that they would (1) improve humane handling and (2) better protect the public health, are lacking in reasoned judgment and run counter to the evidence. *State Farm*, 463 U.S. at 43. The entirety of the USDA’s supporting data is unreliable, as it comes from just a few years it cherry-picked out of a 20-year study which was never designed to address animal welfare; that, according to a peer reviewer, improperly analyzed health data; that is not representative of the pilot data as a whole; that, on its face, is insufficient to support the agency’s conclusions; that fails to address important considerations; and that is belied by the other evidence in the record. Such failure to adequately examine the relevant data and articulate a satisfactory explanation for its conclusions is textbook arbitrary and capricious agency action, and the district court’s contrary holding must be reversed and the Regulations set aside. *Encino Motorcars*, 579 U.S. at 221; *see also Am. Radio Relay League, Inc. v. FCC*, 524

F.3d 227, 237 (D.C. Cir. 2008) (cherry-picking data ground for finding agency action arbitrary and capricious).

A. The USDA’s Conclusion that the Regulations Would Improve Humane Handling Relied on Insufficient Cherry-Picked Data, Is Contrary to the Record Evidence, and Failed to Consider Important Aspects of the Problem.

In concluding that the Regulations would improve humane handling, the USDA cherry-picked data from the record which, as a whole, demonstrates that the Regulations will harm animals; failed to consider the implications of removing oversight of Unfit animals; and failed to consider how the Regulations would impede enforcement of the 28-Hour Law. A398 (Proposed Rule at 4791); 49 U.S.C. § 80502. Indeed, in offering the conclusory rationalization that the Regulations would give Inspectors more flexibility to look for humane handling violations, it cherry-picked data from HIMP,¹¹ a study it designed without consideration of humane handling, then ran for 20 years without correcting this oversight. A397 (Proposed Rule at 4790) (“The Hog HIMP Report did not address compliance with the HMSA”). The district court credited this data, applying an incorrect and overly deferential standard of review. SPA-25. Analyzed under the

¹¹ The Hazard Analysis and Critical Control Point (HACCP)-Based Inspection Models Project (HIMP) Pilot was an experiment to collect data on the reduced-inspection system it eventually implemented via the NSIS. The USDA started HIMP in 1997, granting five pig slaughterhouses waivers from traditional inspection requirements. A376–85 (HACCP-Based Meat and Poultry Inspection Concepts, 62 Fed. Reg. 31553 (Jun. 10, 1997)).

correct legal standard, the USDA’s reasoning for promulgating the Regulations was arbitrary and capricious.

1. The USDA’s Conclusion That the Regulations Would Improve Humane Handling Relied on Insufficient Cherry-Picked Data, Is Not Based on Reasoned Decision-Making, and Runs Counter to the Evidence Before It.

In the FMIA (which incorporates the HMSA), Congress requires Inspectors to ensure that all pigs are handled humanely in connection with slaughter. 21 U.S.C. § 603(b). But for over two decades, as the USDA worked to “modernize” antemortem inspections—culminating in the NSIS—the agency ignored the ramifications of the changes for humane handling. It ignored the issue in 1997, when first calling for reconsideration of “[e]very aspect of traditional FSIS methods of inspection for slaughter”—limited only by “its responsibilities to ensure ... safe, wholesome, unadulterated and properly labeled meat ... products,” but not by humane handling considerations. A376–385 (HACCP-Based Meat and Poultry Inspection Concepts, 62 Fed. Reg. at 31553–63). By its own admission, it also ignored the issue in the HIMP Pilot it conducted to develop and justify NSIS. *See, e.g.*, A397 (Proposed Rule at 4790) (“The Hog HIMP Report did not address compliance with the HMSA”); *see also* A889–936 (FSIS’s HIMP report); A968 (USDA’s Response to Compassion in World Farming, dated September 26, 2019) (evaluating HIMP’s potential impact only as to food safety and product wholesomeness). Then in 2018, the USDA brazenly asserted that it was proposing

the NSIS, *inter alia*, to “improve compliance with the HMSA,” supporting this claim with cherry-picked data from the very HIMP Pilot whose design failed to address this question—and counter to all other evidence in the record. A398 (Proposed Rule at 4791).

As reports by the federal Government Accountability Office (GAO) and the USDA Office of the Inspector General (OIG) demonstrate, the USDA is a repeat offender in misrepresenting HIMP data in this manner, and the APA does not allow it.¹² See A839 (GAO, *More Disclosure Data Needed to Clarify Impact of Changes to Poultry and Hog Inspections* (Aug. 2013)) (hereinafter GAO Report 2013) (examining USDA HIMP reports and raising concerns that the agency relied on “snapshots of data for two 2-year periods instead of data for the duration of the pilot project, which has been ongoing for more than a decade”); A813–15 (FSIS, *Inspection and Enforcement Activities at Swine Slaughter Plants*, Audit Report No. 24601-0001-41 (May 2013) at 17) (hereinafter OIG Report 2013) (explaining that the USDA “did not adequately oversee” the HIMP pilot program because its “focus was on other issues, and it did not consider the swine HIMP program a priority,” and therefore USDA “could not determine whether [its] goals were

¹² The USDA has never indicated that the 2.5-year period it cherry-picked from the HIMP Pilot for its humane handling data is representative of the full 20-year sample. See A485–86 (*Tables of Inspection Records and HATS Hours for HIMP and 21 Non-HIMP Establishments from January 1, 2013 through September 30, 2015*) (providing HATS data for 2.5-year period).

met”).¹³ “[T]here is no APA precedent allowing an agency to cherry-pick a study on which it has chosen to rely in part.” *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008) (collecting cases); accord *Water Quality Ins. Syndicate v. United States*, 225 F. Supp. 3d 41, 68 (D.D.C. 2016) (reversing an agency decision that “cherry-pick[ed] . . . evidence”).

Even if the HIMP data were representative and relevant, the USDA’s assertion that the Regulations improve handling by freeing time for Inspectors to verify humane-handling practices hinges on two HIMP data points that are highly unreliable in their own right: (1) that Inspectors in HIMP establishments reported spending more time per shift (5.33 hours) on humane handling verification activities in the Humane Activities Tracking System (HATS) than did Inspectors in traditional Establishments (4.29 hours); and (2) that Inspectors in HIMP facilities filed fewer humane handling non-compliance reports (NRs) than Inspectors in traditional establishments. A397 (Proposed Rule at 4790).

Regarding the first point, the OIG has raised substantial concerns about HATS data, reiterating in a 2017 audit that USDA “still . . . cannot ensure that the

¹³ The administrative record also includes numerous expert analyses concluding that HIMP data is unreliable in general. *See, e.g.*, A963–67 (Public Comment by Compassion in World Farming (July 17, 2019)) (“several groups – including the House of Representatives and Office of the Inspector General – have raised concerns whether the NSIS’s regulatory changes are based on representative data and appropriate analysis”).

time recorded in its system of record accurately represents time spent on humane handling inspection activities.”¹⁴ A296–97 (Comment from Mercy for Animals *et al.*, dated May 2, 2018) (hereinafter MFA Comment) (citing OIG, *Food Safety and Inspection Service Followup on the 2007 and 2008 Audit Initiatives*, Audit Report 24016-0001-23 (June 2017), available at <https://usdaoig.oversight.gov/reports/audit/food-safety-and-inspection-followup-2007-and-2008-audit-initiatives> (hereinafter OIG Report 2017)). According to this audit, veterinary “specialists at multiple locations expressed concerns with the accuracy of the time reported in HATS,” and OIG could not verify “the total time spent on humane handling activities because of errors [it] found in the HATS reports.” OIG Report 2017 at 48. Additionally, the HATS data is not only generally unreliable; it also is collected differently in, and therefore not comparable between, HIMP and non-HIMP establishments. *Id.* In HIMP establishments, all Inspectors have access to the HATS system and can input their humane handling tracking times themselves, but in traditional establishments, only

¹⁴ The hours spent verifying humane handling are not properly in the record in the first place: the Final Rule cites to the Hog HIMP Report, but the numbers are not in that report. A467 (Final Rule at 52336). Rather, they are allegedly based on HIMP data that the agency examined *after* issuing that report. A397 (Proposed Rule, 83 Fed. Reg. at 4790). USDA’s failure to provide its analysis for public review is one more reason to suspect the reliability of its data and the veracity of its explanation. *See* A296, (Mercy for Animals *et al.*, Public Comment (May 2, 2018)) (“FSIS’s findings . . . [are] suspect because the analysis was not provided for public review”).

a few people—their supervisors—have access to the HATS system, and while they must input the Inspectors’ time, there is no “formal process for entering this information” and there are “no controls to verify . . . or ensure that the time was actually entered.” *Id.* at 49. The USDA is *not* comparing apples to apples when the HIMP numbers are reported directly by every person who worked the time, but the traditional numbers are funneled through a few reporters who are a step removed from the people who worked the time. *Id.* In fact, it is reasonable to deduce that the HIMP numbers would be higher due solely to this extra step in data reporting at non-HIMP establishments. *Id.* Finally, under the traditional system, Inspectors spent more time Sorting animals. Therefore, even if it were true that Inspectors spent less time *verifying* humane handling under the traditional system than under HIMP, they spent more time inspecting the animals themselves, necessarily decreasing the opportunities for inhumane conduct by Slaughterhouse Employees.

The slender slice of data in the second point—the number of NRs filed—cannot support the enormous presumption the USDA builds upon it. Even if these numbers were reliable, they do not make the USDA’s chosen rationalization any more likely to be true. It is possible that Inspectors in HIMP facilities filed fewer NRs because HIMP establishments are more compliant with laws, as the USDA proclaimed. But it is more plausible that Inspectors in HIMP facilities filed fewer humane handling NRs because there was less effective oversight of handling in

HIMP establishments. There is even record evidence indicating that one HIMP plant “threaten[ed] and retaliate[d] against USDA inspectors who actually ma[de] efforts to do their jobs to the best of their abilities.” A347 (Affidavit of USDA-FSIS Inspector, sworn to September 29, 2014) (“I know this because it has happened to me. In fact, the company has made it extremely difficult for me to do my job each and every day. They have also managed to push out veterinarians and other inspectors who performed high quality inspection.”).

Contrary to the USDA’s limited and unreliable data, the remainder of the record evidence, not to mention common sense, demonstrates that the Regulations will adversely impact animal welfare. Under the traditional inspection system, Inspectors inspected all animals antemortem, including Unfit animals; under NSIS, Slaughterhouse Employees “dispose[] of” these animals before antemortem inspections begin. 9 C.F.R. § 309.19(a). Under the traditional inspection system, Inspectors sorted all animals and observed how Slaughterhouse Employees handled every animal in connection with this Sorting; under the NSIS, Slaughterhouse Employees sort animals instead, and Inspectors need observe this process only once a month. FSIS Directive 6100.1, Rev. 3 at 8. Therefore, because of the Regulations, Inspectors no longer oversee the handling of entire groups of animals, and handling during Sorting can go unobserved all but one day of the month—up to 97% of the time. *Id.*

Unfit animals are especially susceptible to inhumane handling, and in the absence of Inspectors, there is every reason to expect it to happen. *See* pp. 36–37, *supra*. But even healthy animals are at high risk for inhumane handling when they are being sorted, because Slaughterhouse Employees often struggle to maneuver 250-pound animals, who are scared and exhausted, across a slaughterhouse. A131 (ASPCA & COK Comment) (describing excessive force used in handling animals at HIMP establishment). Slaughterhouse Employees are untrained or undertrained, in what tend to be low-wage, high-turnover jobs with no protection from retaliation by their employers or their colleagues for slowing down production by handling animals humanely. *See* A400 (Proposed Rule at 4793) (FSIS won’t “prescribe specific sorter training or certification”); A937 (Costs of Training) (estimating that new Slaughterhouse Employees would get only four to twelve hours of training on humane handling). Furthermore, even if Slaughterhouse Employees witness inhumane handling by others and want to take action, they do not have the authority to call a halt to inhumane handling or protection from retaliation by their employers for doing so. 9 C.F.R. §§ 500.2(a)(4), 500.3(b), 500.4 (detailing USDA enforcement protocols); *see also* A562 (Handling Directive 6900.2, Rev. 2) (directing Inspectors to ensure compliance with handling requirements); A343 (Affidavit of USDA-FSIS Inspector, sworn to September 29, 2014) (“Unlike USDA personnel, I don’t feel that [Slaughterhouse Employees] truly have the

authority to shut off the line. Obviously their employer will terminate them if they do it too many times. This alone is reason enough to show that HIMP is a bad idea.”). Appellant Animal Outlook’s 2015 undercover investigation inside a HIMP slaughterhouse, which provides the only footage, or even detailed report, of a facility operating under the new system, revealed pervasive humane handling violations, including the dragging of fully conscious, moribund pigs with metal hooks—the exact category of Unfit animals that is no longer subject to antemortem inspection or handling oversight under the Regulations. A107–109, 129–157, (ASPCA & COK Comment); A61–62 (Leahy Decl. ¶ 15).

In short, the evidence that was before the USDA showed that the Regulations would jeopardize humane handling. The USDA’s cherry-picked rationalizations that NSIS would *improve* humane handling should not be credited and run contrary to the evidence that was before the agency—and the district court erred in crediting it under a standard of review “akin to non-reviewability.” SPA-25. This Court must therefore correct the district court’s error and set the Regulations aside as arbitrary and capricious under the APA.

2. The Regulations' Impact on Humane Handling of Unfit Animals Is an Important Aspect of the Problem that the USDA Failed to Consider.

In promulgating the Regulations, the USDA failed to consider an important aspect of the problem—the impact on the handling of Unfit animals—even though it removed oversight for exactly these animals. Moreover, comments and evidence in the record highlighted the concern because such animals, who struggle to move, are especially susceptible to inhumane treatment. *See pp. 36–37, supra*. This failure is an independent reason the Regulations are arbitrary and capricious and must be set aside.

The Regulations remove the only oversight of the handling of Unfit animals, like those who are dying and cannot make it through to slaughter for human consumption, by requiring Slaughterhouse Employees to sort and dispose of them before Inspectors conduct antemortem inspections. 9 C.F.R. § 309.19(b); A431 (Final Rule at 52300); *see Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 455 (the FMIA preempts state oversight). Accordingly, the Rule's impact on the humane handling of Unfit animals was “an important aspect of the problem” that the USDA was required to consider, including by “examin[ing] the relevant data and articulat[ing] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs.*

Ass'n v. State Farm, 463 U.S. 29, 43 (1983); *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016).

Many public comments drew the USDA's attention to this problem. *See, e.g.*, A281–88 (MFA Comment); A107, 113 (ASPCA & COK Comment). The only notable direct evidence before the USDA on this issue, Appellant Animal Outlook's 2015 undercover investigation inside a HIMP slaughterhouse, raised significant alarms about the treatment of Unfit animals under NSIS. A113–15, 129–67 (ASPCA & COK Comment); A61–62 (Leahy Decl. ¶ 15). The investigation documented inhumane handling of moribund pigs, including the dragging of fully conscious pigs with metal hooks. *Id.* Nevertheless, the USDA entirely failed to address this issue in promulgating the Rule, noting only that Inspectors would verify the humane *killing* of non-ambulatory animals. A443 (Final Rule at 52312) (“FSIS inspectors will verify that animals that are intended to be disposed of are humanely euthanized”); A447 (*id.* at 52316) (claiming that Inspectors will ensure that [non-ambulatory] pigs are handled humanely at slaughter). Regarding AO's evidence in particular, the USDA did not even analyze the role of the HIMP program in these violations. A446 (*id.* at 52315) (addressing undercover video but failing to discuss implications of HIMP for Unfit animals).

Because the USDA failed to consider such an important aspect of the Rule, the Court must find its promulgation of the Regulations to be arbitrary and

capricious in violation of the APA for this additional reason. *State Farm*, 463 U.S. at 43.

3. The Regulations' Impact on the USDA's Statutory Obligation to Enforce the Twenty-Eight Hour Law is Another Important Aspect of the Problem that the USDA Failed to Consider.

The USDA failed to consider the impact of the Regulations on an additional, important aspect of its responsibility for ensuring animal welfare: enforcement of the 28-Hour Law, which provides that animals confined in a vehicle for 28 hours must be allowed a five-hour break to rest and have food and water. 49 U.S.C. § 80502.

When Congress re-enacted the 28-Hour Law simultaneously with its enactment of the FMIA, it created a scheme of continuous regulation, with the FMIA (and its incorporation of the HMSA) picking up precisely where the 28-Hour Law leaves off. *See* 28-Hour Law, Pub. L. No. 59-340, 34 Stat. 607-8 (re-enacted June 29, 1906); FMIA 21 U.S.C. § 601 *et seq.* (enacted June 30, 1906). The 28-Hour Law regulates transport to a slaughter establishment, and the FMIA picks up “the moment a delivery truck pulls up to the gate.” *Nat'l Meat Ass'n v. Harris*, 565 U.S. 452, 466 (2012). The USDA is responsible for enforcing both statutes, with the same Inspectors who conduct antemortem inspections on the front line to enforce the 28-Hour Law too. *Id.*

To enforce the 28-Hour Law, Inspectors are responsible for determining whether the animals “appear exhausted or dehydrated” upon arrival at a slaughter establishment, and if they do, must question the truck driver about compliance with the law. A567 (Handling Directive 6900.2, Rev. 2 at 6). The enforcement of the 28-Hour Law relies wholly on Inspectors’ observing animals as close to arrival as possible, and before Slaughterhouse Employees can interfere with them. *See id.* (describing steps Inspectors must take if livestock arriving on a transport vehicle appear exhausted or dehydrated). Directives lay out enforcement steps in detail:

If the truck driver or establishment is unwilling to provide information, or if [the Inspector] believe[s] the condition of the animals could be the result of being deprived of rest, food, and water for over 28 hours, [Inspectors] are to contact...APHIS...via their FSIS chain of command, so that APHIS can conduct an investigation. A Memorandum of Interview (MOI) should be prepared to document what the [Inspector] observed and all actions taken.

Id.

Because Inspectors traditionally have been the first to inspect animals arriving at slaughter establishments, examined all animals, and did so promptly after these animals arrived from what were often long journeys to the slaughter establishment, they could use antemortem inspections to detect signs of 28-Hour Law violations. A530 (Directive 6100.1, Rev. 2 at 4). Under the Regulations, however, Slaughterhouse Employees sort animals and put them into pens where they can rest and drink water, so by the time Inspectors see the animals to perform antemortem inspections, the evanescent signs of “exhaust[ion] and dehydrat[ion]”

may be gone. A567 (Handling Directive 6900.2, Rev. 2 at 6). The Regulations do not even attempt to compensate for erasing this inspection by assigning Slaughterhouse Employees to do the job instead.¹⁵

In short, the Regulations frustrate enforcement of the 28-Hour Law, for which the USDA has sole responsibility, and the agency's failure to consider this important issue provides additional grounds for this Court to set the Regulations aside as arbitrary and capricious. 5 U.S.C. § 706.

B. The USDA's Conclusion that the Regulations Would Improve Public Health and Safety Likewise Relied on Insufficient Cherry-Picked Data and is Contrary to the Record Evidence.

In promulgating the Regulations, the USDA upheaved multiple longstanding practices that were designed to protect the public health. Rather than pointing to record evidence explaining why such protections are no longer necessary, the USDA vaguely asserted that the Regulations “may . . . facilitate pathogen reduction in pork products,” providing, as its primary support, another highly-contested analysis of cherry-picked HIMP data, this one suggesting that the NSIS is “unlikely to result in a higher prevalence of *Salmonella*.” A431 (Final Rule at 52300). This does not satisfy the legal requirement that agencies provide a more

¹⁵ Even if they did, Slaughterhouse Employees would not have the same expertise to spot the signs of exhaustion and dehydration, or the job security and access to initiate investigation and enforcement by informing the “FSIS chain of command” if they did see these signs. *Id.*

detailed justification for a change in policy, let alone a reasoned explanation as is required anytime an agency promulgates a rule. *See State Farm*, 463 U.S. at 42; *FCC v. Fox*, 556 U.S. 502, 515 (2009).

Regarding USDA's reliance on salmonella data, an anonymous peer reviewer that the USDA selected (Reviewer A) explained, in detail, why the USDA's analysis was invalid. A1017–30 (Response to Peer Reviewer Comments (2018) at 9–22). Reviewer A explained that the production volume in HIMP establishments was a confounding variable that would impact the relative salmonella rates between HIMP and non-HIMP establishments (in other words, the HIMP establishments are larger and kill many more pigs than non-HIMP establishments as a whole, and that alone can affect salmonella rates, outside of any differences related to HIMP itself) and that the USDA's statistical analysis was unreliable both because it did not control for this variable and because of its very small sample size (only five HIMP establishments). *Id.* The USDA claims that it responded to Reviewer A's concerns in Appendix H of its response, but this is simply untrue: Appendix H contains nothing to show that the analysis would be the same if it controlled for production volume. A1031–76 (Appendix H – Alternative Model Considerations). An agency is entitled to disagree with a peer reviewer, but in attempting to mask these disagreements by stating “no response necessary” and failing to address the reviewer's comment, the USDA has not satisfied its burden

of explaining how its decision-making is supported by accurate and sufficient evidence in the record. A1017 (Response to Peer Reviewer Comments at 9); *see 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.”); *New Orleans v. SEC*, 969 F.2d 1163, 1167 (D.C. Cir. 1992) (“An agency’s reliance on a report or study without ascertaining the accuracy of the data contained in the study . . . is arbitrary agency action, and the findings based on [such a] study are unsupported by substantial evidence.”) (internal quotations omitted).

What is more, salmonella is just one of many public health hazards that USDA should have addressed in evaluating the Regulations, but failed to. Ample record evidence identifies these risks. For example, the OIG’s audit found, because of lack of oversight, “that 3 of the 10 plants cited with the most NRs [for food safety] from FYs 2008 to 2011 were HIMP plants. In fact, the swine plant with the most NRs during this timeframe was a HIMP plant—with nearly 50 percent more NRs than the plant with the next highest number.” A813 (OIG Audit 2013 at 17). And when nonprofit organization Food and Water Watch obtained additional HIMP data through public records requests and analyzed it, the data overwhelmingly confirmed heightened health risks in HIMP establishments. A991–1007 (Letter from Food & Water Watch with Addendum). This analysis

showed, *inter alia*, that at non-HIMP establishments, where Inspectors perform initial Sorting, 0.43 percent of pigs were flagged as potentially diseased and sent to Suspect pens; in HIMP establishments, by contrast, where Slaughterhouse Employees perform initial Sorting, this number dropped almost in half—0.25 percent of pigs were segregated and removed to Suspect pens as showing symptoms of disease, suggesting that Slaughterhouse Employees missed signs of disease. *Id.* The analysis further showed that the USDA could not correct for such problems with increased offline verification tasks because Inspectors in HIMP establishments consistently performed fewer Public Health Regulation verification tasks than those in non-HIMP establishments. *Id.* And between 2012 and 2018, HIMP establishments had more noncompliance reports than non-HIMP establishments. *Id.* As Dr. Pat Basu, the chief veterinarian with the USDA’s Food Safety and Inspection Service from 2016 to 2018, explained after refusing to sign off on the NSIS due to concerns about safety for consumers and livestock, “[t]his [Rule] could pass, and everything could be okay for a while, until some disease is missed, and we have an outbreak all over the country.” A985–86 (Kimberly Kindy, *Pork Industry Soon Will Have More Power Over Meat Inspections*, Wash. Post, Apr. 3, 2019).

In addition to the data, numerous Inspectors’ testimonies in the administrative record attest to HIMP slaughterhouses posing heightened safety

risks. Inspectors found that contamination increased under HIMP and attested that they were unable to engage in real oversight to stop HIMP-establishment violations without criticism from company personnel. A341–54 (Affidavits of USDA-FSIS Inspectors). For example, one Inspector attested that they witnessed HIMP-establishment employees fail to spot “abscesses, lesions, fecal matter, and other defects” on numerous occasions. A355 (Affidavit of USDA-FSIS Inspector, sworn to September 29, 2014 [Affidavit 1]). The testimony of another Inspector confirmed that in HIMP establishments, “[s]ick pigs are routinely getting into the system.” A353 (Affidavit of USDA-FSIS Inspector, sworn to April 30, 2018 [Affidavit 5]).

The fact that the record evidence demonstrates, contrary to the USDA’s assertions, that the Regulations will jeopardize public health, is unsurprising given how many protections the USDA removed without explaining why they are no longer needed. As examples, first, Inspectors under the traditional system inspect Unfit animals who may carry highly contagious diseases, and it was essential that trained Inspectors inspect for these signs—both to ensure specific diseased animals do not enter the food supply, and so they could alert other officials to prevent outbreaks. *See* A521–26 (Disease Directive 6000.1, Rev. 1). The USDA has not explained why Slaughterhouse Employees can suddenly perform this monumental task without training. Second, under the traditional system, trained Inspectors

inspected all animals in motion, because in-motion inspections are the only way to detect many abnormalities that indicate hazardous conditions.¹⁶ *See* pp. 6–8, *supra* (describing at-rest versus in-motion inspections). This is the reason the USDA has such extensive explanation of, and training for inspection personnel who conduct, in-motion inspections, and the reason the USDA has not budged from its requirement that Inspectors perform in-motion inspections of 100% of animals for the vast majority of species intended for slaughter under the FMIA. *See* A532 (Directive 6100.1 Rev. 2 at 6). But the USDA does not explain why Inspectors no longer need to conduct in-motion inspections of more than five to ten percent of animals in NSIS Establishments, and why this change will not significantly increase public health risks.

¹⁶ *See, e.g.*, A1084 (2016 Training); A619–20 (2019 Training (listing abnormal body issues to look for when the pigs are in motion); A697–98 (FSIS, Multi-species Disposition Basics with a Public Health Focus (Jan. 29, 2012)) (including changes in locomotion as an antemortem finding); A684–707 (*id.*) (various diseases that must be reported and/or require condemning the animal have symptoms that must be observed while animal is in motion); A790 (*id.*) (a sign of swine flu is a pig “not wanting to get up and move around”; thus observation while the animal in motion is necessary for diagnosis); A786 (*id.*) (Swine Brucellosis, a zoonotic disease, “may also localize in joints, leading to lameness[,]” which can only be identified when observing animals in motion); AR119092, Beltran-Alcrudo *et. al.*, African Swine Fever: Detection and Diagnosis Manual for Veterinarians, United Nations Food & Agric. Org. at 839 (2017) (one symptom of Porcine Reproductive and Respiratory Syndrome (PRRS) is lameness, which can only be identified when observing animals in motion); A1092–93 (2016 Training) (detailing 11 examples of antemortem signs to look for when observing an animal’s body movement).

In short, the USDA did not provide rational support for a sweeping policy change, refused to explain why specific protections are no longer required, and pointed to a single, cherry-picked data point that is (1) highly contested in its own right, and (2) belied by the record evidence in its entirety. This is exactly the kind of arbitrary and capricious action that jeopardizes the health and safety of American families, and that judicial review is meant to guard against. Because the district court, nevertheless, signed off on the Regulations under a standard “akin to non-reviewability,” this Court must correct that error and set aside the Regulations as violating the APA.

CONCLUSION

For the foregoing reasons, Appellants respectfully ask this Court to reverse the district court's order granting Appellee's motion for summary judgment and denying Appellants' motion, and to set aside the Regulations for violating the APA, 5 U.S.C. § 706.

Respectfully submitted,

/s/ Piper Hoffman

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Attorney for Appellants

Dated: January 6, 2025

SPECIAL APPENDIX

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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

FARM SANCTUARY, ANIMAL EQUITY,
ANIMAL LEGAL DEFENSE FUND,
CENTER FOR BIOLOGICAL DIVERSITY,
MERCY FOR ANIMALS, INC.,
NORTH CAROLINA FARMED ANIMAL SAVE,
ANIMAL OUTLOOK,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF
AGRICULTURE, FOOD SAFETY AND
INSPECTION SERVICE, PAUL
KIECKER, in his official capacity as
Food Safety and Inspection Service
Administrator,

Defendants.

DECISION AND ORDER

6:19-cv-06910 EAW

INTRODUCTION

Plaintiffs are nonprofit organizations working to protect animals, people, and environments from industrial animal agriculture, and to ensure that laws intended to regulate industrial animal agriculture are properly implemented. They challenge the implementation of the Modernization of Swine Slaughter Inspection, 84 Fed. Reg. 52300, promulgated by defendants the United States Department of Agriculture (“USDA”) and the Food Safety and Inspection Service (“FSIS”), which Plaintiffs allege “will allow nearly all of the pigs slaughtered in the United States to be slaughtered at unlimited speeds with

very little federal oversight, posing serious risks to animal welfare, consumer health and safety, and the environment.” (See Dkt. 22 at ¶ 1).

Presently pending before the Court are the parties’ cross-motions for summary judgment, and responses thereto. (Dkt. 92; Dkt. 93; Dkt. 94; Dkt. 95). For the following reasons, Defendants’ motion (Dkt. 93) is granted, Plaintiffs’ motion (Dkt. 92) is denied, and the amended complaint is dismissed.

BACKGROUND¹

Plaintiffs challenge a Final Rule addressing pig slaughter at swine slaughter establishments in the United States through the New Swine Inspection System (hereinafter, the “NSIS” or the “Final Rule”). The NSIS, which is a voluntary system, has three elements: (1) it requires establishment employees to perform ante-mortem and post-mortem sorting activities before federal inspection; (2) it requires establishment employees

¹ Neither Plaintiffs nor Defendants have included a Statement of Undisputed Facts with their motion papers. “When a party seeks review of agency action under the APA, the ‘entire case on review is a question of law’ such that ‘[j]udicial review of agency action is often accomplished by filing cross-motions for summary judgment.’” *Am. Steamship Owners Mut. Prot. and Indem. Assoc., Inc. v. United States*, 489 F. Supp. 3d 106, 128 (E.D.N.Y. 2020) (quoting *Conn. v. U.S. Dep’t of Commerce*, No. 04 Civ. 1271(SRU), 2007 WL 2349894, at *1 (D. Conn. Aug. 15, 2007)). “In an APA case, the court relies on the administrative record for the material facts to determine if the agency’s decision exceeds the agency’s statutory authority or is arbitrary and capricious or an abuse of discretion.” *Id.* Under these circumstances, a Rule 56 Statement of Undisputed Facts is “not necessary as the case on review presents only a question of law.” *Just Bagels Mfg., Inc. v. Mayorkas*, 900 F. Supp. 2d 363, 372 n.7 (S.D.N.Y. 2012); see also *Vt. Pub. Interest Rsch. Grp. V. U.S. Fish & Wildlife Serv.*, 247 F. Supp. 2d 495, 516 (D. Vt. 2002) (recognizing that Rule 56 Statement is of “limited use” in APA cases, but declining to strike entire statement since “in complicated cases with voluminous records . . . the statement can serve the useful purpose of highlighting areas of agreement and disagreement,” but concluding it would not consider portions of the statement that are “argumentative and conclusory or includes information the Court has concluded is outside the record rule”).

to trim and identify defects on animal carcasses and parts before post-mortem inspection by FSIS inspectors, reducing the number of online FSIS inspectors to a maximum of three per line; and (3) it revokes maximum line speeds and allows establishments to set their own speeds based on their ability to maintain process control. *See* USDA, *Modernization of Swine Slaughter Inspection*, 84 Fed. Reg. 52300 (Oct. 1, 2019) (“The [FSIS] . . . is amending the Federal meat inspection regulations to establish an optional new inspection system for market hog slaughter establishments that has been demonstrated to provide public health protection at least equivalent to the existing inspection system.”). Plaintiffs’ challenge focuses on the first provision identified; that is, participating establishments’ employees sorting hogs before presenting them for federal ante-mortem inspection.

A. Statutory Background

Under the Humane Methods of Slaughter Act (HMSA), 7 U.S.C. § 1901, the USDA is required to ensure the humane handling of all animals at slaughterhouses. The HMSA is incorporated by reference into the Federal Meat Inspection Act (FMIA), which is a comprehensive statutory inspection scheme that regulates meat from covered species, including swine, entering interstate commerce. *See* 21 U.S.C. § 602. The FMIA has authorized the FSIS to appoint inspectors and public health veterinarians (PHVs) to conduct ante-mortem and post-mortem inspections of carcasses intended for use as human food. *Id.* at §§ 602-604. Consistent with the FMIA, FSIS has promulgated regulations governing ante-mortem and post-mortem examinations at swine slaughter establishments. *See, e.g.*, 9 C.F.R. 309 & 9 C.F.R. 310.

B. The Traditional System

Prior to the institution of the NSIS, swine establishments operated under the “traditional system,” pursuant to which, as relevant to this case, federal inspectors conducted ante-mortem inspections of all livestock offered for slaughter. During these ante-mortem inspections, federal inspectors examined the livestock, and any animals with visible signs of disease or other condemnable conditions were set apart for slaughter separately. *See* 9 C.F.R. §§ 309.1, 309.2. Defendants contend that, even prior to the institution of the NSIS and while establishments operated under the traditional system, most market hog slaughter establishments operating under the traditional system voluntarily segregated animals and set apart those showing visible adverse signs before federal inspection occurred. *See* USDA, *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4780, at 4783 (Feb. 1, 2018) (“Most establishments under traditional inspection that slaughter only market hogs voluntarily segregate animals that show signs of diseases or conditions from healthy animals before the Agency performs ante-mortem inspection.” (citing FSIS Directive 6100.1)).

C. HACCP-Based Inspection Models Project

Prior to the institution of the NSIS, the USDA developed a pilot project, termed the HACCP-Based Inspection Models Project (hereinafter, the “HIMP”), to test new inspection models in five volunteer swine slaughter establishments. *See* USDA, *HACCP-Based Meat and Poultry Inspection Concepts*, 62 Fed. Reg. 31553-02 (June 10, 1997). Among other objectives, the pilot project focused on the “need for resource redeployment,” to reduce slaughter establishments’ overreliance on federal inspectors to sort acceptable

from unacceptable products, which caused the USDA to expend resources inefficiently. *See id.* at 31555 (“FSIS will be unable to meet its food safety goal and other regulatory objectives unless it changes the way it deploys its resources.”). Specifically, under the HIMP:

Similar to the voluntary segregation procedures described above in establishments that slaughter only market hogs under traditional inspection, establishment personnel sort animals before they are presented to FSIS ante-mortem inspectors under HIMP. Establishment personnel sort animals that appear to be healthy into “Normal” pens and animals that appear to have condemnable diseases or conditions into “Subject” pens. Establishment personnel remove and dispose of dead and moribund animals and animals suspected of having central nervous system disorders (CNS) or pyrexia. Under HIMP, FSIS inspectors examine all animals found by the establishment to be normal at rest, and five to ten percent of those animals in motion. If any animals exhibit signs of condemnable conditions, FSIS inspectors direct establishment employees to move the animals to the “U.S. Suspect” pens for final disposition by the FSIS PHV. FSIS PHVs examine all animals in the establishment’s “Subject” pens, and direct establishment employees to move animals to “U.S. Suspect” pens for final disposition by the FSIS PHV. The FSIS PHV determines if any animals must be identified as “U.S. Condemned” and disposed of in accordance with 9 CFR 309.13 (9 CFR 309.2). While establishment personnel sort and remove animals unfit for slaughter, only FSIS inspectors have the authority to condemn an animal. FSIS inspectors observe establishment employees performing sorting procedures at least twice per shift under HIMP compared to at least once per month under the voluntary segregation procedures permitted under traditional inspection of market hogs.

83 Fed. Reg. at 4787-88.

In 2014, USDA analyzed data from establishments participating in the HIMP from 2006 to 2013, and published a HIMP Report, which compared the performance of HIMP participants with comparable establishments operating under the traditional inspection system. *See id.* at 4788-89. USDA found that federal inspectors performed more offline verification activities for the HIMP participants, and those participants had no more

incidents of food-safety defects—and in some cases had fewer food safety defects—than establishments operating under the traditional system. *Id.* at 4789 (“The HIMP Report concluded that this increased level of offline inspection activities provides increased assurance that HIMP establishments are maintaining OCP and food safety defects at levels that are to or less than the levels in non-HIMP establishments.”). USDA also conducted a risk assessment, which indicated that as federal inspectors increased offline procedures, the prevalence of *salmonella* in market hog carcasses decreased. *Id.* at 4791. In terms of humane handling, USDA analyzed the data collected by participating HIMP establishments from 2013 through 2015 and, based on its Humane Activities Tracking System (HATS), the USDA “found that FSIS inspectors spent more time verifying that specific humane handling and slaughter requirements were met in HIMP market hog establishments than in non-HIMP market hog establishments.” *Id.* at 4790.

D. The NSIS

Based on the results of the HIMP, in February 2018, USDA published a notice of proposed rulemaking, to amend the system for inspecting market hogs offered for slaughter by allowing qualifying establishments to operate under a new optional inspection system, called the NSIS. *Id.* at 4780; *see also* Administrative Record (AR) 100207-50. As noted above, the key elements of NSIS include the following, which were tested during the HIMP: (1) requiring establishment employees to perform ante-mortem and post-mortem sorting activities before federal ante-mortem and post-mortem inspection; (2) requiring establishment employees to trim and identify defects on animal carcasses and parts before post-mortem inspection by FSIS inspectors, reducing the number of online FSIS inspectors

to a maximum of three per line, and enabling the USDA to shift some resources from online inspection to offline inspection activities; and (3) revoking maximum line speeds and allowing establishments to set their own speeds based on their ability to maintain process control. 83 Fed. Reg. at 4781. In October 2019, the USDA published the Final Rule, effective December 2, 2019, which adopted the three key elements set out in the Proposed Rule. *See* 84 Fed. Reg. 52300; *see also* AR100251.

Under the NSIS, establishment personnel sort animals appearing to be healthy into “Normal” pens, and animals with diseases or abnormal conditions into “Subject” pens. 83 Fed. Reg. at 4792. Establishment personnel also sort and remove animals with localized conditions (such as arthritis or abscesses), or animals that do not meet establishment specifications (such as swine that were the wrong size or underweight), to be diverted to another official establishment for slaughter. *Id.* FSIS inspectors then inspect all animals in the “Normal” pens at rest, and five to ten percent of those animals in motion. *Id.* If any animals exhibit signs of condemnable conditions, FSIS inspectors direct establishment employees to move the animals to the “U.S. Suspect” pens for final disposition by the FSIS PHV. *Id.* The FSIS PHV inspects all animals in the “Subject” and “U.S. Suspect” pens to render a final disposition decision. *Id.*

USDA considered how many qualifying establishments might opt-in to the NSIS. 84 Fed. Reg. at 52322. It expected that, due to economic constraints associated with an establishment’s training and costs, only large and small high-volume establishments that exclusively slaughter market hogs would choose to participate in the optional NSIS. *Id.*

PROCEDURAL HISTORY

Plaintiffs filed their complaint on December 18, 2019. (Dkt. 1). On February 18, 2020, the Court granted Plaintiffs' consent motion to file an amended complaint (Dkt. 20; Dkt. 21), which Plaintiffs filed that same day (Dkt. 22). Plaintiffs' amended complaint alleged three causes of action, including: (1) violation of the FMIA, the HMSA and the Administrative Procedures Act (APA), for Defendants' failure to conduct an ante-mortem inspection; (2) violation of the HMSA, FMIA, and APA, for Defendants' revocation of maximum line speeds; and (3) violation of the National Environmental Policy Act and the APA, for Defendants' failure to prepare an Environmental Impact Statement or an Environmental Assessment. (*Id.* at 43-47). After the Court denied Defendants' motion to dismiss (*see* Dkt. 50), Plaintiffs voluntarily dismissed their second and third causes of action by stipulation (Dkt. 80).²

The AR was filed on November 10, 2021. (Dkt. 58; Dkt. 59; Dkt. 60; *see also* Dkt. 65 (additions to AR filed on January 26, 2022)). Thereafter, the parties filed cross-motions for summary judgment (Dkt. 92; Dkt. 93), and responses to the motions (Dkt. 94; Dkt. 95).³

² Plaintiffs originally challenged the portion of the NSIS which eliminated the limit on how many swine could be slaughtered per minute at slaughterhouses. Plaintiffs voluntarily dismissed their second and third claims, which related to that portion of the NSIS, after the District of Minnesota vacated that portion of the Final Rule, concluding that the decision to eliminate line speed caps was arbitrary and capricious because it failed to consider impacts to worker safety. *See, e.g., United Food & Commercial Workers Union, Local No. 663 v. USDA*, 532 F. Supp. 3d 741, 766 (D. Minn. 2021).

³ The motion papers were first exchanged by the parties and then bundled to be received by the Court within five days of the motions becoming fully briefed. (*See* Dkt. 88).

On April 17, 2023, following its ruling in *Farm Sanctuary v. U.S. Dep't of Agric.*, No. 6:20-cv-06081 EAW, ___ F. Supp. 3d ___, 2023 WL 2673141 (W.D.N.Y. Mar. 28, 2023) (hereinafter, “the downed pigs case”), the Court directed the parties to provide further briefing on the issue of whether Plaintiffs had standing to bring their claims. (See Dkt. 101). The parties submitted supplemental briefing on the issue of standing. (Dkt. 102; Dkt. 103; Dkt. 104).

Plaintiffs raise three arguments in support of their motion for summary judgment. They contend that the NSIS violates the FMIA and the HMSA, which require that government inspectors examine all animals before slaughter, for both animal welfare and food safety purposes. Plaintiffs further argue that under the NSIS, Defendants are handing over their oversight authority to establishment employees, which they are tasked with regulating. Finally, Plaintiffs argue that in promulgating the Final Rule, Defendants acted arbitrarily and capriciously by departing from decades-long policy emphasizing the need for stringent oversight of ante-mortem inspection, and ignoring voluminous record evidence demonstrating how animals will suffer under the NSIS. (Dkt. 92-1 at 8-9). Defendants oppose each of these arguments, and they also argue that Plaintiffs lack standing to bring their claims. (See Dkt. 93-1; Dkt. 103).

DISCUSSION

I. Standard on Motion for Summary Judgment

Rule 56 of the Federal Rules of Civil Procedure provides that summary judgment should be granted if the moving party establishes “that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ.

P. 56(a). The Court should grant summary judgment if, after considering the evidence in the light most favorable to the nonmoving party, the court finds that no rational jury could find in favor of that party. *Scott v. Harris*, 550 U.S. 372, 380 (2007) (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986)). Once the moving party has met its burden, the opposing party “must do more than simply show that there is some metaphysical doubt as to the material facts. . . . [T]he nonmoving party must come forward with specific facts showing that there is a *genuine issue for trial*.” *Caldarola v. Calabrese*, 298 F.3d 156, 160 (2d Cir. 2002) (quoting *Matsushita Elec.*, 475 U.S. at 586-87). “[T]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986).

II. Standing

The Court turns first to the issue of standing.⁴ Defendants contend that Plaintiffs lack both organizational and associational standing because their “assertions of injury-in-fact hinge on their misunderstanding of the final rule”—namely, that contrary to Plaintiffs’ assertion, the NSIS does not subdelegate authority for conducting ante-mortem inspections to establishment employees—and that it is “not possible to be harmed by a program that does not exist.” (Dkt. 103 at 9). Defendants further argue that even if the Court took Plaintiffs’ allegations about the NSIS at face value, Plaintiffs still lack organizational

⁴ Defendants did not initially move for summary judgment on the issue of standing; however, after reviewing the positions of the parties, the Court determined that supplemental briefing was warranted and ordered that the parties submit supplemental briefing on that issue. (See Dkt. 96; Dkt. 97; Dkt. 98; Dkt. 99).

standing under Second Circuit precedent—including this Court’s decision in the downed pigs case—because “a decision by an advocacy group to voluntarily re-order their spending priorities is not an ‘involuntary material burden.’” (Dkt. 103 at 10 (“Plaintiffs are advocacy groups: they exist to advocate for their cause. Although Plaintiffs must prioritize some issues over others, they are not actually injured in a particular way when they decide to advocate for one issue at the expense of another.”)). With respect to associational standing, Defendants similarly argue that Plaintiffs misconceive that the NSIS subdelegates authority for conducting ante-mortem inspections to establishment employees, and therefore their concerns about food safety risks are unfounded. (*Id.* at 10-11). Defendants further argue that even if Plaintiffs’ arguments about the NSIS were accurate, they would still lack standing because their members’ claims about food safety are too speculative. (*Id.* at 11-12).

“The law of Article III standing, which is built on separation-of-powers principles, serves to prevent the judicial process from being used to usurp the powers of the political branches.” *Clapper v. Amnesty Int’l USA*, 568 U.S. 398, 408 (2013) (citations omitted). “To satisfy the requirements of Article III standing, plaintiffs must demonstrate ‘(1) [an] injury-in-fact, which is a concrete and particularized harm to a legally protected interest; (2) causation in the form of a fairly traceable connection between the asserted injury-in-fact and the alleged actions of the defendant; and (3) redressability, or a non-speculative likelihood that the injury can be remedied by the requested relief.’” *Hu v. City of New York*, 927 F.3d 81, 89 (2d Cir. 2019) (alteration in original) (quoting *Selevan v. N.Y. Thruway Auth.*, 711 F.3d 253, 257 (2d Cir. 2013)).

Plaintiffs in this case are organizations, and “[a]n organization can have standing to sue in one of two ways. It may sue on behalf of its members, in which case it must show, *inter alia*, that some particular member of the organization would have had standing to bring the suit individually.” *N.Y. Civil Liberties Union v. N.Y.C. Trans. Auth.*, 684 F.3d 286, 294 (2d Cir. 2012). This is often referred to as “associational” standing. *Id.* An organization may show associational standing by demonstrating “(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization’s purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.” *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977); *see also Irish Lesbian & Gay Org. v. Giuliani*, 143 F.3d 638, 649 (2d Cir. 1998) (same).

“In addition, an organization can ‘have standing in its own right to seek judicial relief from injury to itself and to vindicate whatever rights and immunities the association itself may enjoy.’” *N.Y. Civil Liberties Union*, 684 F.3d at 294 (quoting *Warth v. Seldin*, 422 U.S. 490, 511 (1975)). “Under this theory of ‘organizational’ standing, the organization is just another person—albeit a legal person—seeking to vindicate a right. To qualify, the organization itself must meet the same standing test that applies to individuals.” *Id.* (quotations and alteration omitted); *see also Irish Lesbian & Gay Org.*, 143 F.3d at 649 (explaining that it is “well established that organizations are entitled to sue on their own behalf for injuries they have sustained,” and to make such a showing, “the organization must meet the same standing test that applies to individuals . . . by showing actual or threatened injury in fact that is fairly traceable to the alleged illegal action and likely to be

redressed by a favorable court decision.” (quotations, citation, and alterations omitted)). Finally, “standing is not dispensed in gross” and “a plaintiff must demonstrate standing for each claim [it] seeks to press and for each form of relief that is sought.” *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 581 U.S. 433, 439 (2017) (quotations omitted).

Defendants’ first argument—that Plaintiffs’ allegations about NSIS are incorrect—does not support a finding that Plaintiffs lack standing. That argument goes to the merits of the case; specifically, whether Defendants are in compliance with the FMIA and HSMA by permitting establishment employees to sort swine once they arrive at a slaughter establishment, and the Court does not consider the merits when deciding standing. *See Dubuisson v. Stonebridge Life Ins. Co.*, 887 F.3d 567, 574 (2d Cir. 2018) (“we must avoid conflating the requirement for an injury in fact with the validity of [a plaintiff’s] claim”) (citation omitted); *Knife Rights, Inc. v. Vance*, 802 F.3d 377, 380 (2d Cir. 2015) (“On this appeal, we do not consider the merits of plaintiffs’ vagueness claim, but only their standing to pursue it.”); *Ctr. for Food Safety v. Perdue*, No. 20-cv-00256-JSW, 2022 WL 4793438, at *7 (N.D. Cal. Sept. 30, 2022) (explaining that the defendants’ argument that “Plaintiffs’ declarations rest on the erroneous assertion that NSIS-produced pork is ‘higher risk’ than pork produced under the traditional inspection system,” was “effectively an argument on the merits, and ‘the Court cannot consider the merits when deciding standing’” (citation omitted)).

In the downed pigs case, which involved almost all of the same parties, the Court found that the plaintiffs lacked both organizational and associational standing to bring their claims. Plaintiffs there challenged the alleged failure of the USDA and the FSIS to prohibit

the slaughter of downed pigs, which plaintiffs alleged contributed to increased levels of inhumane handling during the slaughter process, as well as increased levels of food-borne illness. With respect to organizational standing, the Court noted that “an organization cannot show a ‘perceptible impairment’ to its activities where the defendant’s actions ‘merely perpetuated the *status quo*.’” *Farm Sanctuary*, 2023 WL 2673141, at *9 (quoting *Animal Welfare Inst. v. Vilsack*, No. 20-CV-6595 (CJS), 2022 WL 16553395, at *6 (W.D.N.Y. Oct. 31, 2022)). Relying on the Second Circuit’s decision in *Connecticut Parents Union v. Russel-Tucker*, 8 F.4th 167 (2d Cir. 2021), where the Second Circuit rejected an expansive concept of an organizational injury for standing purposes, this Court concluded that the plaintiffs’ expending funds to investigate and report on downed pigs, which amounted to no more than a decision to embark on new activities, “is precisely what *Connecticut Parents Union* says is insufficient to establish organizational standing.” *Id.* at *10. In other words, the downed pigs defendants’ failure to take some action that the plaintiffs wanted them to take did not give the plaintiffs standing to pursue their claims.

Plaintiffs distinguish the downed pigs case, arguing that they are challenging agency-initiated rulemaking that modified the *status quo* between the parties—in other words, that Plaintiffs were “already engaged in core programmatic activities to advance the humane treatment of pigs and strengthen the HMSA *before* the challenged rulemaking.” (Dkt. 102 at 13). Defendants do not address this argument, or the distinction Plaintiffs draw between the instant case and the downed pigs case. (*See generally* Dkt. 103).

Unlike in the downed pigs case, Defendants in this case have not merely perpetuated the *status quo*. Rather, Defendants have implemented the NSIS, which expands the HIMP

from five slaughterhouses to an industrywide standard—and Plaintiffs claim that they are injured by this new system. In support of this claim, Plaintiffs submit declarations from their members demonstrating that they had already engaged in efforts to combat the impacts of the HIMP, which were subsequently burdened by the passage of the NSIS. (*See, e.g.*, Declaration of Mark Walden, Dkt. 30-11 at ¶ 15 (“ALDF began advocating against the HIMP pilot program in 2017, drafting communications pieces condemning it as inhumane, unsafe, and violative of federal law. In 2018, when the FSIS announced the proposed Rule, threatening to expand the disastrous pilot program across the country, ALDF was forced to expend further resources drafting additional communications pieces and detailed regulatory comments opposing the Rule, shifting staff time and funding away from our existing work to fight the expansion of the pilot program.”)); *see also* Declaration of Cheryl Leahy, Dkt. 30-2 at ¶¶ 14-15, 19-20 (discussing Animal Outlook’s 2015 investigation at Quality Pork Processors, one of the five slaughterhouses operating under the HIMP, and that the subsequent decision by Defendants to expand the HIMP would frustrate and impede Animal Outlook’s mission)); *see also* Dkt. 104 at 11 (“Before the Rule was promulgated, each Plaintiff had already established core programs and activities to advance the humane treatment of pigs, strengthen the HMSA, or oppose the HIMP pilot project. The Rule directly impairs these established programs because it weakens federal inspections that monitor the humane treatment of pigs, weakens the HMSA, and proliferates HIMP.” (citations omitted)).

In *Connecticut Parents Union*, the Second Circuit noted that “the injury-in-fact inquiry should focus on the *involuntary* and *material* impacts on *core activities* by which

the organizational mission has historically been carried out.” 8 F.4th at 174-75. It found that the plaintiff in that case did not have standing because it failed “to identify any restrictions on its ability to perform the core activities . . . by which it pursued its mission prior to the 2017 RIS” (emphasis added)). Here, Plaintiffs did not commence activities in response to the NSIS, which expanded the deregulation that occurred under the HIMP program. Rather, Plaintiffs had already established core programs and activities which were subsequently burdened by the NSIS.

Because Plaintiffs have demonstrated a change to the *status quo* which burdens their core activities, and in the absence of any argument by Defendants on this point to the contrary, the Court concludes that Plaintiffs have organizational standing to bring their claim, and it need not reach the associational standing issue.

III. Whether the NSIS Violates the FMIA and the HMSA

Plaintiffs’ first argument is that the FMIA and the HMSA require FSIS inspectors to carry out ante-mortem inspection duties for all animals, and that the delegation of this authority under the NSIS is unlawful under *Chevron, U.S.A., Inc. v. Natural Resource Defense Council, Inc.*, 467 U.S. 837 (1984). (Dkt. 92-1 at 18-31). According to Plaintiffs, the NSIS shifts ante-mortem inspection of swine to establishment employees, and this shifting violates the FMIA and the HMSA, which require federal inspectors to perform these processes—not establishment employees. Plaintiffs cite to language in the FMIA stating that FSIS inspectors must make “an examination and inspection of all amenable species before they shall be allowed to enter” into an establishment in which they are to be slaughtered. (*Id.* at 20; *see also* 21 U.S.C. § 603(a)).

Defendants respond that Plaintiffs are incorrect, because the NSIS does not delegate inspection duties to establishment employees—rather, it simply allows establishment employees, on a voluntary basis, to conduct pre-inspection sorting activities prior to federal ante-mortem inspection. (Dkt. 93-1 at 6, 17-21). Accordingly, because federal inspectors continue to conduct the ante-mortem inspection of swine sent for slaughter, the NSIS is in compliance with the FMIA and the HMSA.

The Court turns first to the language of the FMIA which states, in relevant part:

For the purpose of preventing the use in commerce of meat and meat food products which are adulterated, 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, packing, meat-canning, rendering, or similar establishment, in which they are to be slaughtered and the meat and meat food products thereof are to be used in commerce; and all amenable species found on such inspection to show symptoms of disease shall be set apart and slaughtered separately from all other cattle, sheep, swine, goats, horses, mules, or other equines, and when so slaughtered the carcasses of said cattle, sheep, swine, goats, horses, mules, or other equines shall be subject to a careful examination and inspection, all as provided by the rules and regulations to be prescribed by the Secretary, as provided for in this subchapter.

21 U.S.C. § 603(a). Further, the FMIA requires that “[f]or the purpose of preventing the inhumane slaughtering of livestock, the Secretary shall cause to be made, by inspectors appointed for that purpose, an examination and inspection of the method by which amenable species are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter.” *Id.* § 603(b)

Plaintiffs’ arguments with respect to the alleged delegation of authority by Defendants is premised on their belief that, under the NSIS, slaughterhouse establishment employees—rather than federal inspectors—are performing the ante-mortem inspection

required by the FMIA and the HMSA. A court in the Northern District of California recently addressed this issue, *see Ctr. for Food Safety*, 2022 WL 4793438, and concluded that the NSIS does not violate the FMIA with respect to the tasks performed by establishment employees, *id.* at *8-13. In that case, the plaintiffs challenged both the ante-mortem and post-mortem sorting and inspection procedures established by the NSIS, arguing that they were in contravention of 21 U.S.C. §§ 603 and 604. *Id.* In evaluating the plaintiffs' challenge to the ante-mortem sorting procedures, the court noted that, under the NSIS, federal inspectors still inspect each pig before it is slaughtered. *Id.* at *9. After discussing the process by which establishment employees sort the animals, the court concluded that "the pre-inspection sorting process does not replace federal inspection," and "federal inspectors still inspect the animals 'before they shall be allowed to enter into any slaughtering . . . establishment, in which they are to be slaughtered. . .'" *Id.* (quoting 21 U.S.C. § 603(a)).

Section 603(a) requires an "examination and inspection" by federal inspectors of all market hogs prior to slaughter. The NSIS does not contravene this requirement. Under the NSIS, establishment employees sort healthy animals into "Normal" pens, and animals that appear to have diseases or abnormalities into "Subject" pens. 83 Fed. Reg. at 4792. Establishment personnel may also sort and remove animals with localized conditions, such as animals with arthritis or abscesses, or animals that do not meet establishment specifications, such as swine that are underweight, to be diverted to another official establishment for slaughter. *Id.* Critically, FSIS inspectors then inspect all animals in the "Normal" pens at rest, and five to ten percent of those animals in motion. *Id.* If the

inspectors determine any of the “Normal” animals have condemnable conditions, they direct establishment employees to move the animals to “U.S. Suspect” pens for final disposition by the FSIS PHV, with the PHV inspecting all animals in the “Subject” and “U.S. Suspect” pens to render a final disposition decision. *Id.*; *see also* 84 Fed. Reg. at 52312 (“FSIS inspectors still conduct 100 percent ante-mortem inspection. If any animals exhibit signs of condemnable conditions, FSIS inspectors direct establishment employees to move the animals to the ‘U.S. Suspect’ pens for final disposition by the FSIS PHV. The FSIS PHV examines all animals in the ‘subject’ and ‘U.S. Suspect’ pens.”). In other words, although establishment employees may conduct ante-mortem sorting procedures, all swine sent for slaughter are ultimately inspected by FSIS inspectors. The NSIS does not replace federal inspection—rather, it adds an additional step (the pre-inspection sorting) to the process. *See* 84 Fed. Reg. at 52311 (“FSIS is not privatizing swine slaughter inspection. The new inspection system will not eliminate FSIS inspection. NSIS simply requires establishments to take additional steps before FSIS inspection to ensure that their products are safe and wholesome.”).

Both Plaintiffs and Defendants cite to *Am. Fed’n of Gov’t Emps., AFL-CIO v. Veneman*, 284 F.3d 125 (D.C. Cir. 2002) (“*AFGE II*”), in support of their arguments with respect to the NSIS and whether it complies with the HMSA and the FMIA. (*See* Dkt. 92-1 at 25-26; Dkt. 93-1 at 20-21). In that case, the D.C. Circuit considered whether post-mortem inspection of poultry carcasses under the HIMP program violated those statutes. The court first concluded that the initial program, which did not require federal inspectors to examine each carcass, violated the FMIA and the HMSA, since federal inspectors’ roles

were limited to oversight and verification, and not actual inspection of carcasses. *See Am. Fed'n of Gov't Emps. v. Glickman*, 215 F.3d 7, 11 (D.C. Cir. 2000) (“*AFGE I*”) (“To the extent federal employees are doing any systematic inspecting under the Models Project, they are inspecting people not carcasses. Delegating the task of inspecting carcasses to plant employees violates the clear mandates of the FMIA and PPIA.”). The defendants thereafter implemented a modified inspection program, and on the second appeal, the court considered whether federal inspectors were properly performing “inspections” under the modified program. *AFGE II*, 284 F.3d at 129-30. The court found that they were, despite that federal inspectors examined poultry carcasses only after industry employees had eviscerated, sorted, trimmed and rinsed the carcasses. *Id.* at 130. The court explained that the statute required that “federal inspectors must conduct a ‘post mortem inspection of the carcass of each bird processed,’” and “[b]ecause the modified program calls for federal inspectors in participating poultry plants to personally examine each poultry carcass leaving the slaughter line, the USDA is complying with the PPIA’s requirement that ‘the carcass of each bird processed’ be inspected for adulteration.” *Id.* (quoting 21 U.S.C. § 455(b)). Although Plaintiffs contend that the court limited its holding to the post-mortem inspection of the HIMP pilot program (*see* Dkt. 92-1 at 26), the reasoning is equally applicable here—the FMIA and the HMSA require that federal inspectors inspect all swine sent for slaughter, and the NSIS complies with this requirement.

Plaintiffs next argue that the NSIS limits FSIS inspectors to examining only five to ten percent of animals in motion. (*Id.* at 22; *see also id.* at 27 (“Without observing animals in motion, the inspectors do not carry out the critical appraisal to determine whether

animals are dying or feverish, have central nervous system conditions, or have been treated with drugs or contaminated with poisons.”)). Contrary to Plaintiffs’ implication, 21 U.S.C. § 603(a) requires only that federal inspectors conduct an “examination and inspection” of swine—not that they observe all swine both at rest and in motion. The Court does not find this five to ten percent observation requirement to be contrary to the FMIA and, in any event, that figure is simply a floor, and there is nothing preventing federal inspectors from observing a higher percentage of swine in motion. Plaintiffs have failed to point to evidence conclusively demonstrating that the NSIS does not allow federal inspectors to make a “critical appraisal” of all swine sent for slaughter. *AFGE II*, 284 F.3d at 130; *see also Ctr. for Food Safety*, 2022 WL 4793438, at *10 (noting that, under NSIS, federal inspectors inspect “Normal” animals at rest, including an assessment of the “[t]he overall condition of each animal, including the head, with attention to the eyes, the legs, and the body of the animal,” “[t]he degree of alertness, mobility, and breathing,” and “[w]hether there are any unusual swellings or any other abnormalities,” and noting that, “although it is true that NSIS requires federal inspectors to observe only five to ten percent of the animals sorted as ‘Normal’ in motion, the Final Rule does not preclude federal inspectors from examining a larger percentage of swine in motion if they deem necessary,” and concluding that these procedures satisfy the requirements of Section 603(a)).

Plaintiffs further argue that the NSIS reduces the presence of FSIS inspectors at slaughterhouses, thereby reducing humane handling verification at the ante-mortem inspection stage. (Dkt. 92-1 at 22, 28). Plaintiffs contend that the FMIA requires that federal inspectors examine and inspect the humane handling of all swine at a slaughtering

establishment, and not just the swine that are offered for slaughter. (*See id.* at 28 (arguing that 21 U.S.C. § 603(b) “broadly covers all animals handled anywhere on the premises at a federally inspected facility”)); *see also* Dkt. 94 at 19 (arguing that the language of 21 U.S.C. § 603(b) “is extremely broad, governing not just handling directly at slaughter, but handling of all animals anywhere on the premises at a federally inspected facility”). According to Plaintiffs, the presorting portion of the NSIS therefore conflicts with § 603(b) since it requires slaughterhouse personnel to handle swine out of view of FSIS personnel.

Contrary to Plaintiffs’ suggestion, there is no requirement in § 603(b) that FSIS inspectors conduct an examination and inspection of the humane handling of each hog. Rather, federal inspectors are required to examine and inspect “*the method* by which amenable species are slaughtered and handled in connection with slaughter in the slaughtering establishments inspected under this chapter.” 21 U.S.C. § 603(b) (emphasis added). Under the NSIS, FSIS inspectors observe establishment employees during the sorting process, including to verify that hogs are humanely handled, and therefore they are examining the method by which they are handled with respect to humane handling requirements. *See* 84 Fed. Reg. at 52312 (explaining that “the key difference, as compared to traditional inspection, is that sorting procedures are mandatory under NSIS,” and “[u]nder the NSIS, FSIS inspectors will observe establishment employees performing sorting procedures,” and “[d]uring this time, FSIS inspectors will verify that animals that

are intended to be disposed of are humanely euthanized and that animals that are intended to be diverted to another official establishment are eligible for transport”).⁵

For those reasons, the Court concludes that the NSIS does not run afoul of the provisions of the HMIA or the HMSA, and Defendants are entitled to summary judgment on this issue. Because the Court concludes that the NSIS does not unlawfully delegate ante-mortem inspection duties, it need not undertake a *Chevron* analysis.⁶

IV. Whether the NSIS Unlawfully Delegates to an Outside Party

Plaintiffs’ second argument is that the Final Rule violates the APA and should be set aside because it is not in accordance with the FMIA and HMSA, since it subdelegates

⁵ To the extent Plaintiffs argue that the NSIS violates the FMIA because during the sorting process establishment employees may discard unfit hogs without an inspection, the Court rejects that argument, since those hogs are not sent for slaughter. *See Ctr. for Food Safety*, 2022 WL 4793438, at *10 n.5 (rejecting argument that 9 C.F.R. § 309.1(b) requires inspection of all swine on the premises of the establishment, including dead, moribund, or otherwise unfit hogs; “Because the dead, moribund, or otherwise unfit hogs were never to be ‘offered for slaughter,’ the FMIA does not require their federal inspection.”).

⁶ 21 U.S.C. § 603(a), which requires an “examination and inspection” of all hogs presented for slaughter, is unambiguous and therefore the analysis ends at the first step of the *Chevron* framework. *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842-43 (1984) (“If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”). Accordingly, Plaintiffs’ reliance on other steps in the *Chevron* analysis is misplaced. Further, even if the statute was ambiguous, Plaintiffs have failed to demonstrate why the NSIS is not a “permissible construction of the statute,” since their argument in that respect is premised on their erroneous belief that establishment employees are performing ante-mortem inspections, when the NSIS continues to require federal inspectors to perform ante-mortem inspections of swine. *Id.* at 843 (even if the movant satisfies the first step of the *Chevron* analysis by demonstrating that Congress has not directly addressed the precise question at issue, “the court does not simply impose its own construction on the statute, as would be necessary in the absence of an administrative interpretation. Rather, if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency’s answer is based on a permissible construction of the statute.”).

ante-mortem inspection duties to establishment employees. (Dkt. 92-1 at 31-32). Plaintiffs' argument that the NSIS "contravenes [the FMIA and HMSA] by . . . delegating inspection duties to slaughterhouse employees with only occasional oversight by FSIS" (*see id.* at 32), is inherently tied to their first argument that the NSIS violates the FMIA and the HMSA by allowing establishment employees to conduct ante-mortem inspection. For the reasons explained above, the Court concludes that the NSIS does not violate the FMIA and the HMSA. Rather, the NSIS simply permits establishment employees to voluntarily engage in pre-inspection sorting. Accordingly, Plaintiffs' motion for summary judgment on this basis is denied. *See Ctr. for Food Safety*, 2022 WL 4793438, at *18 (summarily rejecting the plaintiffs' assertion that the NSIS improperly subdelegates inspections to third-party plant employees, explaining that "as discussed above, the Court has concluded that federal inspectors still perform their statutorily required inspection duties under the FMIA and have not impermissibly delegated those tasks to plant employees").

V. Whether the NSIS violates the APA

Plaintiffs' third and final argument is that Defendants, in finalizing the NSIS, acted in an arbitrary and capricious manner, including because they failed to consider the record evidence showing that the delegation of ante-mortem inspection duties to slaughterhouse employees would increase the inhumane handling of pigs, and also because it constitutes an unjustified departure from longstanding agency policy. (Dkt. 92-1 at 33). In response, Defendants contend that they considered all record evidence when adopting the NSIS, reasonably concluded that the ante-mortem inspection provisions would not have an adverse effect on humane handling, and that they provided adequate responses to those

who commented with humane handling concerns. (Dkt. 93-1 at 22). Defendants further argue that the NSIS is not a departure from longstanding agency policy, and even if it was, the USDA offered a sufficient explanation to withstand scrutiny under the APA. (*Id.*).

Section 706(2) of the APA gives a reviewing court authority to “hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). “The standard of review under 5 U.S.C. § 706(2)(A) is highly deferential and presumes the agency’s action to be valid.” *Yu v. U.S. Dep’t of Transp.*, 440 F. Supp. 3d 183, 195 (E.D.N.Y. 2020) (citation and quotation omitted). This standard “is applied at the high end of the range of deference and an agency refusal is overturned only in the rarest and most compelling of circumstances,” *New York v. U.S. Nuclear Regul. Comm’n*, 589 F.3d 551, 554 (2d Cir. 2009) (quotations and citation omitted), and “has been said to be so high as to be ‘akin to non-reviewability,’” *id.* at 554 (quoting *Cellnet Comm’n, Inc. v. FCC*, 965 F.2d 1106, 1111 (D.C. Cir. 1992)).

In reviewing an APA claim, “[t]he Court’s task is not to engage in an independent evaluation of the cold record, nor to substitute its judgment for that of the agency. Instead, it is for the Court to determine whether the agency has considered the pertinent evidence, examined the relevant factors, and articulated a satisfactory explanation for its action.” *Noroozi v. Napolitano*, 905 F. Supp. 2d 535, 541 (S.D.N.Y. 2012) (internal citations and quotations omitted). In other words, “a court is not to substitute its judgment for that of the agency and should uphold a decision of less than ideal clarity if the agency’s path may reasonably be discerned.” *Saget v. Trump*, 345 F. Supp. 3d 287, 298 (E.D.N.Y. 2018)

(citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 513-14 (2009)); *see also WildEarth Guardians v. EPA*, 751 F.3d 649, 653 (D.C. Cir. 2014) (court must determine whether agency “adequately explained the facts and policy concerns it relied on” and whether “those facts have some basis in the record” (citation omitted)); *New York*, 589 F.3d at 554 (“To deny review of a rulemaking petition, a court typically need do no more than assure itself that an agency’s decision was ‘reasoned,’ meaning that it considered the relevant factors.” (citation omitted)).

“[A]n agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered 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. Assn. cf United States, Inc. v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 43 (1983). To that end, “[o]ne of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions. The agency ‘must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made.’” *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (citation omitted). “[W]here the agency has failed to provide even that minimal level of analysis, its action is arbitrary and capricious and so cannot carry the force of law.” *Id.* Bearing these principles in mind, the Court turns to Plaintiffs’ claim that Defendants’ denial of the Petition was arbitrary and capricious.

A. Consideration of Impact on Humane Handling

Plaintiffs first argue that the adoption of the Final Rule was arbitrary and capricious because Defendants failed to consider evidence that the NSIS would increase inhumane handling violations. (Dkt. 92-1 at 34). Specifically, Plaintiffs argue that the HIMP pilot program and the resulting HIMP Report (*see* AR101990-2037) did not evaluate animal welfare impacts, citing to a 2015 undercover investigation at one of the HIMP slaughterhouses and a 2013 Office of Inspector General (OIG) audit, which demonstrated inhumane handling problems. Plaintiffs also cite a laundry list of other complaints and comments of which Defendants were aware. (Dkt. 92-1 at 34-38). In response, Defendants contend that the USDA adequately considered humane handling when promulgating the Final Rule—and that this is apparent from the Final Rule itself—and the fact that noncompliance episodes occurred at HIMP-participating establishments does not mean that the USDA did not consider humane handling impacts. (Dkt. 93-1 at 22-26).

Plaintiffs' contention that Defendants did not adequately address humane handling concerns in promulgating the Final Rule is not supported by the record. For example, in the notice of proposed rulemaking, there is a section specifically entitled "Verification of Humane Handling." 83 Fed. Reg. at 4790. While noting that the HIMP Report⁷ did not specifically address compliance with the HMSA, that section discusses that FSIS reviewed data from the HATS, which provides FSIS with data on the amount of time inspectors

⁷ The Court finds that Plaintiffs' focus on the HIMP Report's lack of analysis on the humane handling issue is irrelevant. Plaintiffs' challenge in this litigation is to Defendants' promulgation of the Final Rule—not the conclusions of the HIMP Report.

spend verifying whether swine are humanely handled at slaughter establishments. *Id.* FSIS found that inspectors spent more time verifying that specific humane handling and slaughter requirements were met in HIMP market hog establishments than in non-HIMP market hog establishments. *Id.*

FSIS inspectors devoted approximately 5.33 hours per shift to verifying humane handling activities for the HATS categories in HIMP market hog establishments compared to approximately 4.29 hours per shift in the 21 non-HIMP market hog comparison establishments. FSIS also compared the rate of humane handling NRs issued in HIMP market hog establishments and non-HIMP market hog establishments. FSIS inspectors documented fewer humane handling NRs in HIMP market hog establishments than in non-HIMP market hog establishments. From January 2013 through September 2015, FSIS recorded 11 humane handling NRs in five HIMP market hog establishments and 117 NRs in the 21 non-HIMP market hog comparison establishments. It should be noted that none of the 11 NRs recorded in the HIMP establishments documented market hogs being forced to move faster than normal walking speeds to keep up with faster evisceration line speeds.

Id. at 4790-91. USDA concluded that “[t]he data demonstrate that HIMP establishments have higher compliance with humane handling regulations than non-HIMP establishments, and that increased offline inspection may improve compliance with the HMSA.” *Id.* at 4791.

The Final Rule also demonstrates that FSIS considered humane handling concerns. The Final Rule states that Defendants expected that NSIS would “improve animal welfare and compliance with the HMSA,” including because “more FSIS resources will be available to verify the humane handling of animals.” 84 Fed. Reg. at 52300; *see also id.* (“under NSIS, FSIS can assign fewer inspectors to online inspection, freeing up Agency resources to conduct more offline inspection activities that are more effective in ensuring food safety, such as verifying compliance with sanitation and HACCP, as well as humane

handling requirements”); *id.* at 52315 (responding to comment regarding concerns from animal welfare advocacy organizations that revoking line speeds under the NSIS would have adverse effects on the humane handling of swine, that “FSIS was able to conduct more offline humane handling verification tasks under HIMP as compared to traditional inspection,” and that “more inspection resources will be available to verify whether establishments meet humane handling requirements as an offline activity under NSIS”); *id.* at 52336 (“NSIS increases the Agency’s ability to conduct more process and product verification and to increase monitoring of humane handling procedures, which is expected to improve animal welfare. . . . Under the NSIS, establishments sort, remove, and identify swine unfit for slaughter before FSIS ante-mortem inspection. More FSIS resources can be devoted to offline inspection activities because initial sorting and tagging functions are performed by establishment personnel. This change will provide Agency personnel with more time to conduct offline inspection activities.”).

Plaintiffs cite a 2015 investigation conducted by Plaintiff Animal Outlook, as well as a 2013 OIG audit as evidence that the HIMP had negative effects on animal welfare. (*See* Dkt. 92-1 at 35-37). The Final Rule includes a discussion of the 2013 OIG audit and its responses thereto, including (1) required supplemental training on humane handling and slaughter of livestock, including situation-based training modules which teach inspectors how to interpret an egregious or non-egregious inhumane handling event objectively, and to take appropriate enforcement actions, and (2) hiring a Humane Handling Enforcement Coordinator, to conduct ongoing reviews of relevant noncompliance reports, suspensions, and Notices of Intended Enforcement, and to conduct correlations with inspectors to help

them improve their objective analysis when enforcing the HMSA and related regulations. 84 Fed. Reg. at 52306. The 2015 undercover investigation, and a video associated with that investigation, were also discussed in the Final Rule. *See id.* at 52315 (discussing undercover video that was taken at a HIMP establishment in 2015). Specifically, the Final Report explained, “[r]egarding the undercover video, multiple FSIS experts—including trained veterinarians and humane handling experts—reviewed the video and determined that there was unacceptable rough handling and inappropriate use of a rattle paddle to drive animals. FSIS took immediate regulatory action against the establishment and required it to respond with acceptable corrective actions to prevent a recurrence.” *Id.* In other words, Defendants specifically responded to these concerns and, contrary to Plaintiffs’ contentions, they also considered NSIS’s effect on humane handling at slaughter establishments. The fact that noncompliance reports existed does not render Defendants’ decision arbitrary and capricious. *See, e.g., Ctr. for Food Safety*, 2022 WL 4793438, at *16 (discussing that non-compliance reports relating to plant employee performance did not render NSIS arbitrary and capricious, explaining that a failure to address every specific instance of non-compliance does not render a rule arbitrary and capricious, and further explaining that “FSIS addressed commenters’ concerns about the ability of plant employees to identify food safety defects and cited data from the Hog HIMP Report supporting the conclusion that the NSIS system would effectively protect food safety” (citing 84 Fed. Reg. at 52312)).

In sum, Plaintiffs’ contention that Defendants failed to consider the impacts of humane handling when adopting the Final Rule is not supported by the record. Simply

because Plaintiffs disagree with the adoption of the NSIS based on animal welfare concerns does not make Defendants' adopting of the Final Rule arbitrary and capricious. It is clear to the Court that Defendants considered this issue in connection with promulgating the Final Rule, including by responding to comments raising animal welfare concerns. Defendants gave adequate explanations for the choices made, and that is all that is required.

B. Training for Establishment Employees

Plaintiffs next contend that Defendants' decision was arbitrary and capricious because they ignored evidence that inadequately trained slaughterhouse employees cannot perform the same inspection duties as FSIS inspectors. (Dkt. 92-1 at 38). Specifically, Plaintiffs argue that there is no mandatory training for slaughterhouse employees—rather, FSIS provides slaughterhouse establishments with a guideline for training, of which only 6 of 55 pages discuss ante-mortem sorting. (*Id.* at 38-39). Further, establishment employees receive only 4 to 12 hours of humane handling training per year—while FSIS inspectors undergo extensive training—and slaughterhouse employees cannot address humane handling violations in the same way as FSIS inspectors. (*Id.* at 39-41). In response, Defendants contend that establishment employees do not perform the same inspection duties as FSIS inspectors under the NSIS, and therefore they are not required to undergo the more extensive training prescribed for FSIS inspectors. (Dkt. 93-1 at 27). Defendants further argue that the record demonstrates that they considered whether training for establishment employees was necessary under the Final Rule. (*Id.*).

Plaintiffs' argument in this respect is partially premised on the notion that the NSIS delegates inspection duties to slaughterhouse employees which, as explained above, is not

accurate. Establishment employees are not assuming the duties of FSIS inspectors by performing the additional task of pre-inspection sorting, for all the reasons articulated above.

Further, the record demonstrates that Defendants considered whether training for establishment employees was necessary under the Final Rule. Specifically, the Final Rule includes a discussion on various comments received on this topic, including from consumer advocacy and public health groups which “recommended that FSIS establish training for establishment employees performing sorting activities and require sorters to prove proficiency in performing their duties.” *See* 84 Fed. Reg. at 52313 (discussing comments from the pork industry, which stated that “establishments operating under HIMP have been successful at training employees to sort for food safety and non-food safety defects,” and “commended the Agency for creating its sorter guide” but noted that it “could be improved by defining several pathological conditions and veterinary terms not well-known to industry personnel, as well as updating photos and diagrams”); *see also id.* at 52312 (“A few commenters referenced affidavits from three FSIS inspectors who worked in HIMP establishments who stated that because of excessive line speeds and lack of training, establishment sorters routinely miss many food safety and wholesomeness defects.”). The USDA considered these viewpoints and sufficiently addressed the issues raised by these comments in its response:

FSIS is not prescribing specific sorter training or certification. FSIS made some editorial changes to its sorter guide to simplify the guideline. The Agency did not make any significant changes to its sorter guide in response to comments. FSIS did not think it was necessary to add the pathological conditions, veterinary terms, or pictures mentioned in the comments because

they are not commonly found or used. However, FSIS PHVs will be available to discuss conditions and terms if an establishment has any questions. The guide is available on the FSIS website at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatorycompliance/compliance-guides-index>. As FSIS explained in the proposed rule, the guide that the Agency has developed is based on the training that FSIS provides to its online inspection personnel that are responsible for sorting carcasses under the existing inspection systems.

(*Id.* at 52313). Accordingly, Defendants did not ignore concerns with respect to training for establishment employees, and they provided a reasoned response as to why they did not adopt additional training. Accordingly, their determination in this respect was not arbitrary and capricious.

C. Evidence of Decreased Staffing on Humane Handling Verification

Plaintiffs next argue that Defendants' decision in promulgating the Final Rule was arbitrary and capricious because they failed to consider that there would be fewer humane handling verification inspections under the Rule. (Dkt. 92-1 at 41). Plaintiffs note that as part of the Final Rule, the number of FSIS staff are reduced from 365 to 218, and the data collected by Defendants in the HATS system fails to distinguish ante-mortem inspection verifications from the other eight categories of verifications. (*Id.* at 41-42). Defendants respond that this argument "misunderstands the import of the time recorded by FSIS inspectors in HATS," that an FSIS inspector need not enter time in HATS under the "ante-mortem inspection" activity category to monitor establishments' conduct for humane handling compliance, and that FSIS inspectors in HIMP establishments devote additional time to verifying humane handling activities relative to their non-HIMP counterparts which

reinforces the efficiency of the ante-mortem inspection process under NSIS. (Dkt. 93-1 at 30-31).

Plaintiffs appear to agree that the HATS data demonstrated that FSIS inspectors at HIMP establishments were able to devote additional time to verifying humane handling activities. Whether this verification is concentrated at ante-mortem inspection, or is spread over the other categories of the slaughter process, the HATS data leads to the reasonable conclusion that there are humane handling benefits flowing from the NSIS, including its pre-inspection sorting procedure.

In any event, the record before the Court indicates that the HATS system does break down time spent by activity category. *See* AR100818-19 (“The HATS component provides FSIS with data on the time that FSIS PHVs and other IPP spend verifying that specific humane handling and slaughter requirements are met. To the maximum extent possible, multiple IPP are routinely to conduct HATS related activities. IPP are to accurately and completely report the time that they spend on these activities and to separate that time into nine specific categories.”). Plaintiffs have not presented data demonstrating that humane handling verifications in the ante-mortem inspection category are lower in HIMP establishments than in non-HIMP establishments.

Even putting the HATS data aside, the record before the Court establishes that Defendants considered that inspection staff would be reduced with the institution of the NSIS. The Final Rule includes a section on “Agency Staffing,” which discusses in detail the impacts of the NSIS on staffing. *See, e.g.*, 84 Fed. Reg. at 52336-37 (discussing changes in staffing, and referring to Table 20, comparing impact of number of

establishments converting to NSIS on staffing). However, as explained above, the Final Rule explains that this reduction in staffing would not result in a decrease in humane handling verifications, including because NSIS allows for federal inspectors to more efficiently spend their time on-site at slaughter establishments. *See, e.g., id.* at 52300 (“FSIS expects that the new inspection system will improve animal welfare and compliance with the HMSA because more FSIS resources will be available to verify the humane handling of animals”); 83 Fed. Reg. at 4790 (explaining that inspectors spent more time verifying that specific humane handling and slaughter requirements were met in HIMP market hog establishments, than in non-HIMP market hog establishments). For those reasons, the Court does not find that Defendants ignored evidence concerning the impact of staffing on humane handling verification under the NSIS.

D. Failure to Explain Reversal of Position

Finally, Plaintiffs contend that Defendants disregarded decades of prior agency positions and statements emphasizing the importance of FSIS-conducted ante-mortem inspections, and failed to adequately explain the reversal of their position. (Dkt. 92-1 at 42-45). In response, Defendants argue that Plaintiffs’ misreading of the Final Rule nullifies this argument, since the NSIS does not delegate ante-mortem inspection responsibility to establishment employees, and therefore Defendants are not “changing position” on agency policy. (Dkt. 93-1 at 33).

Where an agency departs from prior agency practice or policies, the APA requires the agency to provide a ‘reasoned explanation’ for such departure. The Supreme Court has made clear that an ‘unexplained inconsistency in agency policy is a reason for holding an

interpretation to be an arbitrary and capricious change from agency practice.” *Saget*, 345 F. Supp. 3d at 298 (citations omitted). “To survive arbitrary and capricious review when changing a policy, an agency must ‘at least display awareness that it is changing position,’ ‘show that there are good reasons for the new policy,’ and ‘be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.’” *Id.* at 298-99 (quoting *Encino Motorcars, LLC*, 579 U.S. at 222).

Plaintiffs’ argument that the agency reversed its position by delegating ante-mortem inspection duties to slaughterhouse establishment personnel is fundamentally flawed for the same reasons that many of their other arguments fail—that is, because the NSIS does not delegate ante-mortem inspection duties to establishment personnel. Rather, the NSIS creates a pre-inspection sorting procedure conducted by establishment personnel, which serves as an additional step in the process. All hogs that are actually sent for slaughter are inspected by an FSIS inspector.

To the extent Plaintiffs argue that Defendants have failed to justify the change from the traditional inspection system to the NSIS, any such contention is not even remotely supported by the record, which is voluminous and more than sufficiently articulates the basis for the change to the NSIS, including to improve the effectiveness of swine slaughter inspection and make better use of USDA and FSIS resources. 84 Fed. Reg. at 52300; *see also Ctr. for Food Safety*, 2022 WL 4793438, at *13 (concluding that the defendants explained why they abandoned the traditional inspection process in favor of the NSIS, including because FSIS has “provided good reasons for the change—it believes the new policy will improve the effectiveness of market hog slaughter inspection while ‘provid[ing]

public health protection at least equivalent to the existing inspection system” (quoting 84 Fed. Reg. at 52300)). Accordingly, the Court finds that Defendants’ adoption of the NSIS was not arbitrary and capricious because they have more than sufficiently displayed awareness of their changing position from the traditional system, and further that they have articulated that there are good reasons for this new policy.⁸

In sum, Plaintiffs face a heavy burden in succeeding on their APA claim, and they have failed to sustain this burden. The record before the Court demonstrates that Defendants considered pertinent evidence, examined the relevant factors, and articulated a satisfactory explanation when they adopted the Final Rule. Accordingly, Defendants are entitled to summary judgment in their favor on Plaintiffs’ APA claim.

⁸ In their reply papers, Plaintiffs argue that “the agency failed to consider the alternative of using the pre-existing regulatory waiver system, which ‘allows slaughter facilities, on a case-by-case basis, to experiment with innovations designed to improve food safety outcomes.’” (Dkt. 94 at 44-45). This claim does not appear in Plaintiffs’ complaint, nor does it appear in their motion for summary judgment. Rather, Plaintiffs appear to have raised this issue for the first time in their reply papers, and therefore the Court will not consider it. *See Keefe v. Shalala*, 71 F.3d 1060, 1066 n.2 (2d Cir.1995) (“Normally, we will not consider arguments raised for the first time in a reply brief . . .”); *Zirotiannis v. Seterus, Inc.*, 221 F. Supp. 3d 292, 298 (E.D.N.Y. 2016) (“It is well-established that arguments may not be made for the first time in a reply brief. Therefore, new arguments first raised in reply papers in support of a motion will not be considered.” (quotations, citations, and alterations omitted)), *cf. id.*, 707 F. App’x 724 (2d Cir. 2017).

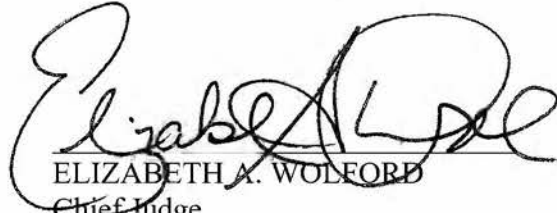
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CONCLUSION

For the foregoing reasons, Defendants' motion for summary judgment (Dkt. 93) is granted, and Plaintiffs' motion for summary judgment (Dkt. 92) is denied. The Clerk of Court is directed to enter judgment in favor of Defendants and to close this case.

SO ORDERED.


ELIZABETH A. WOLFORD
Chief Judge
United States District Court

Dated: December 12, 2023
Rochester, New York

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Judgment in a Civil Case

United States District Court
WESTERN DISTRICT OF NEW YORK

JUDGMENT IN A CIVIL CASE
CASE NUMBER: 19-CV-6910

FARM SANCTUARY, ANIMAL EQUITY,
ANIMAL LEGAL DEFENSE FUND,
CENTER FOR BIOLOGICAL DIVERSITY,
MERCY FOR ANIMALS, INC.,
NORTH CAROLINA FARMED ANIMAL SAVE,
ANIMAL OUTLOOK,

Plaintiffs,

v.

UNITED STATES DEPARTMENT OF
AGRICULTURE, FOOD SAFETY AND
INSPECTION SERVICE, PAUL
KIECKER, in his official capacity as
Food Safety and Inspection Service
Administrator,

Defendants.

Jury Verdict. This action came before the Court for a trial by jury. The issues have been tried and the jury has rendered its verdict.

Decision by Court. This action came to trial or hearing before the Court. The issues have been tried or heard and a decision has been rendered.

IT IS ORDERED AND ADJUDGED that judgment is entered in favor of Defendants and the case is closed.

Date: December 13, 2023

MARY C. LOEWENGUTH
CLERK OF COURT

By: s/Rosemarie M. Eby-Collom
Deputy Clerk