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,

DECISION AND ORDER

6:19-cv-06910 EAW

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.

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 \P 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 postmortem sorting activities before federal inspection; (2) it requires establishment employees

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").

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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

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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 antemortem 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

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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." *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

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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.

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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-infact 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-infact 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 of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm in*, 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 or threatened injury in fact that is fairly traceable to the alleged illegal action and likely to be

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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 incorrectdoes 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

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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 antemortem 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 postmortem 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.").

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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

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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. of 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/comp liance-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 "antemortem 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 polices, 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

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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]

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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 . . ."); *Zirogiannis 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)), *aff'd*, 707 F. App'x 724 (2d Cir. 2017).

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.

FORP

Chief Hudge United States District Court

Dated: December 12, 2023 Rochester, New York