

United States District Court
Northern District of California

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CENTER FOR FOOD SAFETY, et al.,
Plaintiffs,
v.
SONNY PERDUE, et al.,
Defendants.

Case No. 20-cv-00256-JSW

**ORDER RESOLVING CROSS-
MOTIONS FOR SUMMARY
JUDGMENT**

Re: Dkt. Nos. 65, 68

Now before the Court for consideration are the motion for summary judgment filed by Plaintiffs Food & Water Watch (“FWW”), Center for Food Safety (“CFS”), the Humane Farming Association (“HFA”), and Robin Mangini (“Mangini”) (collectively, “Plaintiffs”) and the cross-motion for summary judgment filed by the U.S. Department of Agriculture (“USDA”), Secretary of Agriculture Thomas Vilsack, the Food Safety and Inspection Service (“FSIS”), and Deputy Under Secretary for Food Safety Sandra Eskin (collectively, “Defendants”). The Court has reviewed the parties’ papers, relevant legal authority, and the record in the case, and it finds this matter suitable for disposition without oral argument.¹ *See* N.D. Civ. L.R. 7-1(b). For the following reasons, the Court DENIES Plaintiffs’ motion for summary judgment and GRANTS Defendants’ cross-motion for summary judgment.

BACKGROUND

Plaintiffs are three non-profit consumer organizations and one of their individual members who bring this challenge to the USDA’s Modernization of Swine Slaughter Inspection Rule. *See* 84 Fed. Reg. 52,300 (Oct. 1, 2019) (“Final Rule”). Plaintiffs allege that the new rule, which

¹ The Court has also considered the amicus brief in support of Plaintiffs filed by the American Federation of Government Employees. (Dkt. No. 76.)

1 implements a new inspection system for swine slaughter, is contrary to the Federal Meat
2 Inspection Act (“FMIA”) and violates the Administrative Procedure Act (“APA”).

3 Plaintiffs allege that the FMIA requires federal government inspectors to examine and
4 inspect every animal prior to slaughter and every carcass and body part after slaughter. Plaintiffs
5 contend, however, that the new inspection system established by the Final Rule transfers these
6 federal inspection duties to the slaughter plant employees, which prevents federal inspectors from
7 conducting an adequate appraisal of animals, carcasses, and parts as required by the FMIA.

8 Plaintiffs also allege that the rulemaking process was arbitrary and capricious in violation
9 of the APA because the Final Rule (1) irrationally departs from prior inspection regulations and
10 practices; (2) is based on a flawed pilot project; and (3) relies on a flawed risk assessment for
11 which the public was not provided adequate time to provide notice and comment.

12 **A. The Federal Meat Inspection Act.**

13 Congress enacted the FMIA in response to unsanitary conditions in meatpacking plants.
14 The FMIA authorizes the FSIS, a component of USDA, with protecting consumer health and
15 welfare by ensuring that meat products are safe and unadulterated. 21 U.S.C. § 602. The FMIA
16 authorizes FSIS to appoint inspectors and public health veterinarians (“PHVs”) to conduct ante-
17 mortem and post-mortem inspections of carcasses intended for use as human food. *Id.* §§ 603-
18 604.

19 In furtherance of its mission of protecting consumer health and welfare, FSIS has
20 promulgated regulations that govern ante- and post-mortem examinations at swine slaughter
21 establishments. *See, e.g.*, 9 C.F.R. pts 309 & 310; Swine Post-Mortem Inspection Procedures and
22 Staffing Standards, 50 Fed. Reg. 19,900 (May 13, 1985); Cattle & Swine Post-Mortem Inspection
23 Procedures and Staffing Standards, 47 Fed. Reg. 33,673 (Aug. 4, 1982).

24 **B. The Traditional Inspection System.**

25 The traditional inspection system established by the FSIS requires federal inspectors to
26 inspect all swine before and after slaughter. During ante-mortem inspections, federal inspectors
27 examine all livestock offered for slaughter while at rest and in motion and direct establishment
28 employees to tag animals showing visible signs of disease or other condemnable conditions for

1 further inspection by a PHV. *See* 9 C.F.R. § 309.1. During post-mortem inspections,
2 establishments present the head, viscera, and carcass of each animal for inspection by FSIS. 9
3 C.F.R. § 310.1(b)(3). Federal inspectors look for disease through “organoleptic inspections” and
4 by incising and palpating certain lymph nodes. Modernization of Swine Slaughter Inspection, 83
5 Fed. Reg. at 4780, 4783 (Feb. 1, 2018) (“Proposed Rule”). The traditional inspection system
6 requires up to seven FSIS inspectors per evisceration line. *Id.* Under the traditional inspection
7 system, establishment employees are not required to sort carcasses before the post-mortem
8 inspection to identify or remove contamination or to flag potentially condemnable carcasses or
9 parts for further scrutiny by FSIS. *Id.*

10 **C. The HIMP Pilot Program.**

11 In the 1990s, FSIS proposed changes to the inspection process. FSIS acknowledged that
12 the FSIS’s inspection procedure had not kept up with advancements in the control and eradication
13 of animal diseases. *See* HACCP-Based Meat and Poultry Inspection Concepts, 62 Fed. Reg.
14 31,553 (June 10, 1997). FSIS also found that the traditional inspection method failed to efficiently
15 use its resources, including failing to adequately target foodborne pathogens such as *Salmonella*
16 and *E. coli*. *Id.*

17 As a result, FSIS began to look for ways to modernize and increase the efficiency of the
18 inspection process. As a first step, FSIS required establishments to develop a system of
19 preventative controls designed to ensure their products are safe. *See* Pathogen Reduction/Hazard
20 Analysis and Critical Control Point (“HACCP”) Systems, 61 Fed. Reg. 38,806 (1996). With these
21 measures, FSIS adopted a new approach that required establishments to play a larger role in
22 ensuring product safety. *See* 83 Fed. Reg. at 4787; 61 Fed. Reg. at 38,808.

23 To assess the efficacy of the new approach, FSIS developed the HACCP-Based Inspection
24 Models Project (“HIMP”) pilot, which was designed to test the new inspection models in
25 volunteer meat and poultry slaughter establishments. *See* HACCP-Based Meat and Poultry
26 Inspection Concepts, 62 Fed. Reg. 31,553 (June 10, 1997). Under the HIMP pilot, plant
27 employees performed the task of separating normal from abnormal carcasses and parts; federal
28 inspectors monitored the plant’s performance and verified the plant’s compliance with

1 performance standards and regulatory requirements.

2 The D.C. Circuit struck down the initial HIMP pilot program as contrary to 21 U.S.C.
3 section 604 (“Section 604”) of the FMIA, finding that the proposed model impermissibly
4 “[d]elegat[ed] the task of inspecting carcasses to plant employees” and relegated federal inspectors
5 to an oversight and verification role in violation of the clear mandate of the FMIA. *Am. Fed’n of*
6 *Gov’t Emps., AFL-CIO v. Glickman*, 215 F.3d 7, 11 (D.C. Cir. 2000) (“*AFGE I*”).

7 Following *AFGE I*, FSIS modified the HIMP pilot to comply with the D.C. Circuit’s
8 ruling. The modified pilot program placed federal inspectors at up to three fixed locations along
9 the slaughter lines with the responsibility of examining the head, carcass, and viscera of all hogs;
10 other federal inspectors would be assigned to plants to verify the effectiveness of the plant’s
11 process control systems. The D.C. Circuit held that the modified HIMP pilot program satisfied the
12 FMIA because it required “federal inspectors in participating hog plants to inspect all hog
13 carcasses, heads and viscera, as the statute demands.” *Am. Fed’n of Gov’t Emps., AFL-CIO v.*
14 *Veneman*, 284 F.3d 125, 130 (D.C. Cir. 2002) (“*AFGE II*”). However, the court noted that
15 because the program was a test program, were Defendants to undertake rulemaking “to adopt [it]
16 as a permanent change,” the opinion in that case “may not necessarily foreshadow the outcome of
17 judicial review of such future regulations.” *Id.* at 130-31.

18 In 2000, the revised HIMP pilot program was initiated in five large, high-volume hog
19 slaughter establishments. *See* 83 Fed. Reg. at 4787-88. Under the HIMP pilot, establishment
20 employees remove and dispose of animals that are dead, moribund, or display condemnable
21 conditions before federal inspectors conduct ante-mortem inspection. *Id.* at 4788. The
22 establishment employees also sort animals that appear to be healthy into “Normal” pens and sort
23 animals that appear to have condemnable diseases or conditions into “Subject” pens. *Id.* Federal
24 inspectors then examine, at rest, all animals deemed “Normal”, and they examine five to ten
25 percent of those animals in motion. *Id.* If any of the animals exhibit signs of condemnable
26 conditions, federal inspectors direct establishment employees to move the animals to “U.S.
27 Suspect” pens for final disposition by a federal PHV. *Id.* The federal PHVs examine all animals
28 in the “Subject” pen and direct the plant employees to move the animals to the “U.S. Suspect”

1 pens for final disposition by a federal PHV. *Id.* The federal PHV determines if any animals must
 2 be identified as “U.S. Condemned” and disposed of in accordance with 9 C.F.R. section 309.13.
 3 *Id.*

4 During post-mortem inspection, establishment personnel sort carcasses and parts and trim
 5 dressing defects and contamination (*e.g.*, hair, bruises, feces, ingesta, and milk), mark with ink
 6 localized pathology defects intended for removal under FSIS supervision, and identify carcasses
 7 and parts intended for disposal under FSIS supervision. *Id.* Subsequently, FSIS online inspectors
 8 visually inspect the head, viscera, and carcass of each hog at fixed locations on the evisceration
 9 line. *Id.* FSIS represents that the plant employees’ pre-sorting permits the federal online
 10 inspection to occur much more efficiently under HIMP than under the traditional inspection
 11 system. *Id.* As a result of the increase in online efficiency, FSIS states federal inspectors conduct
 12 more offline, food safety related verification inspection activities under HIMP than under the
 13 traditional inspection system. *Id.*

14 In 2013, the U.S. General Accountability Office (“GAO”) and the USDA’s Office of the
 15 Inspector General (“OIG”) evaluated the HIMP pilot program. 83 Fed. Reg. at 4781. The GAO
 16 report identified certain strengths in the HIMP pilot but also recommended that FSIS collect and
 17 analyze additional information to determine the plants’ compliance with the performance
 18 standards. AR_101756-806. The OIG report concluded that FSIS did not adequately oversee the
 19 HIMP program and made several recommendations related to HIMP procedures. AR_101706-
 20 755.

21 **D. The Hog HIMP Report.**

22 In 2014, FSIS finalized a report detailing and evaluating the results of the HIMP pilot
 23 program (“Hog HIMP Report”). 83 Fed. Reg. at 4787-88; *see also* AR_101990-102037. The Hog
 24 HIMP Report assessed the performance of five HIMP market hog slaughter establishments
 25 between 2006 through 2010 and 2012 through 2013.² *Id.* The five HIMP establishments were

26
 27 ² The results from 2006 to 2010 were based on data from the Performance Based Inspection
 28 System (“PBIS”) database. In 2011, FSIS began transitioning establishments to the new Public
 Health Information System (“PHIS”) database. The period from April 2011 to December 2011
 was a transitional period during which some inspection results were record under PBIS and others

1 compared to twenty-one (21) non-HIMP market hog slaughter establishments “of comparable
2 production volume, line speed, and days of operation.” *Id.*

3 The report evaluated whether the new system performed comparably to traditional
4 inspection by evaluating several proxies including the relative number of carcasses that plant
5 employees and federal inspectors removed from the slaughter lines and the number of federal
6 inspectors’ offline verifications. The report concluded that HIMP establishments “receiv[ed] more
7 off-line food safety related inspection verification checks than the traditional non-HIMP market
8 hog establishments” and that HIMP establishments “have higher compliance with Sanitation SOP
9 and HACCP regulations, lower levels of non-food safety defects, equivalent or better *Salmonella*
10 verification testing positive rates” than traditional plants. AR_102023. In addition, the report
11 evaluated data from plants for two periods, 2009 through 2010 and 2012 through 2013, to assess
12 HIMP establishments’ compliance with FSIS’s Food Safety and Other Consumer Protection
13 performance standards. *Id.* The results suggested that the HIMP establishments were performing
14 as well as comparable large non-HIMP market hog establishments. AR_102024.

15 The Hog HIMP Report concluded that market hog slaughter establishments participating in
16 the HIMP pilot were performing as well as comparable large non-HIMP market hog
17 establishments and meeting FSIS requirements for operating under waivers through the HIMP
18 projects. 83 Fed. Reg. at 4788-4789.

19 **E. Proposed Rule.**

20 In February 2018, FSIS published a notice of proposed rulemaking creating a new,
21 optional inspection system, NSIS, for market hog establishments based on the HIMP pilot
22 program. *See* 83 Fed. Reg. at 4780. The goals of the Proposed Rule included reducing pathogens
23 in pork products, improving the effectiveness of FSIS inspection, increasing the efficiency of FSIS
24 resources, and allowing establishments flexibility to innovate. *Id.* FSIS released a draft risk
25 assessment and compliance guidelines regarding plant employee sorting. *Id.* at 4793-94. FSIS
26 relied on the findings in the Hog HIMP Report and adopted the HIMP pilot’s key features

27 _____
28 under PHIS. Thus, the transitional 2011 data is not included in the Hog HIMP Report, and the
analysis of the 2006 through 2010 data is separate from the 2012 through 2013 data. *Id.*

1 regarding plant employee ante- and post-mortem sorting. The Proposed Rule cited the draft risk
 2 assessment's predicted annual reduction of 2,533 *Salmonella* illnesses as a main public benefit of
 3 the new rule. *Id.* at 4811-12.

4 The proposed rule received 83,000 comments. 84 Fed. Reg. at 52,300. Several comments
 5 challenged the rule for preventing federal inspectors from critically appraising animals, failing to
 6 provide training to plant sorters. Commenters also questioned the validity of the Hog HIMP
 7 Report and the risk assessment. *Id.*

8 **F. The Final Rule.**

9 On October 1, 2019, FSIS published the Final Rule, which became effective on December
 10 2, 2019. 84 Fed. Reg. at 52,300. The Final Rule adopted the key parts of the Proposed Rule,
 11 including that plant employees would engage in pre-inspection sorting.³ *Id.* The NSIS system
 12 established in the Final Rule is voluntary, and FSIS predicted that only high-volume market hog
 13 establishments would opt in to NSIS. *Id.* at 52,322. In 2016, there were 40 high-volume, market-
 14 hog-only establishments. *Id.* FSIS predicted the Final Rule would result in \$62 million in savings
 15 over the next two years, increase establishments' compliance with sanitation regulations, and
 16 improve welfare by increasing monitoring of humane handling procedures by FSIS inspectors. *Id.*
 17 at 52,335-36. Unlike in the Proposed Rule, which predicted an annual reduction in *Salmonella*
 18 illnesses, the Final Rule stated that the Final Rule may lead to lower prevalence of *Salmonella* on
 19 hog carcasses and thus fewer illnesses. *Id.* at 52,332.

20 **G. The Risk Assessment.**

21 In January 2018, FSIS published a risk assessment that assessed the potential change in
 22 human risk of *Salmonella* in HIMP establishments. *See* AR_104395-104523. The risk assessment
 23 found a statistically significant correlation between increased offline inspection procedures and a
 24

25 ³ The Final Rule also eliminated line speed limits. *See* 9 C.F.R. § 310.26. A federal district court
 26 granted summary judgment in favor of union plaintiffs who challenged the Final Rule's lifting of
 27 line speed limits as arbitrary and capricious. The court found FSIS did not adequately consider the
 28 comments it received regarding the effects of eliminating line speeds on worker safety. The court
 vacated that portion of the Final Rule but did not set aside any other aspect of the Final Rule. *See*
United Food & Com. Workers Union, Loc. No. 663 v. U.S. Dep't of Agric., 532 F. Supp. 3d 741
 (D. Minn. 2021).

1 reduction in the prevalence of *Salmonella* on market hog carcasses at HIMP establishments.
2 Specifically, the risk assessment concluded that establishments operating under HIMP would lead
3 to an expected reduction in market hog attributable *Salmonella* illnesses to 2,533 cases. The risk
4 assessment concluded that shifting FSIS resources from online inspections to offline inspections
5 would likely result in a decrease in human illnesses from contaminated pork. AR_104410.

6 FSIS published the risk assessment along with the Proposed Rule before it underwent peer
7 review. The risk assessment's peer review occurred in April 2018 after the public comment period
8 on the Proposed Rule closed. AR_104524. In August 2018, FSIS posted a summary of peer-
9 reviewer feedback and an updated draft risk assessment on its website. See AR_104692-104756;
10 AR_104757-104933. FSIS provided thirty days for comments on the revised risk assessment.
11 AR_103790. FSIS did not reopen comments for the Final Rule because it stated that the revised
12 risk assessment did not change the conclusions in the risk assessment, and FSIS advised that it
13 would respond to the risk assessment comments in the final rule.

14 When FSIS published the Final Rule, it included another updated version of the risk
15 assessment, updated in September 2019. AR_104934-105118. The September 2019 version of
16 the risk assessment projected that the potential benefits reflected increased uncertainty around the
17 human risk from *Salmonella*, with a potential annual increase of 1,719 cases and a potential
18 decrease of 6,685 cases. See 84 Fed. Reg. at 52,333. However, FSIS maintained that *Salmonella*
19 illnesses could reduce by an average of 2,533 per year. *Id.* at 52,334.

20 **H. FOIA Requests.**

21 Plaintiff FWW sought FSIS's data for pilot plants from 2014 through 2017 through
22 Freedom of Information Act ("FOIA") requests. See AR_104331-344. FWW analyzed the data it
23 received and concluded that: (1) offline inspectors at HIMP plants were not able to perform more
24 offline inspections than those at traditional plants from 2014 to 2017; (2) federal PHVs were able
25 to evaluate fewer animals tagged as U.S. Suspect in HIMP plants than in traditional plants from
26 2012 through 2015; and (3) HIMP plants had nearly two times the regulatory violations rate of
27 traditional plants for fecal matter, digestive content, and milk contamination. FWW submitted its
28 analysis to FSIS and requested that FSIS reopen the comment period, which FSIS declined to do.

I. Present Litigation.

1 Plaintiffs filed this lawsuit challenging the Final Rule on January 13, 2020 and amended
 2 their complaint on April 6, 2020. (Dkt. Nos. 1, 26.) Plaintiffs moved for summary judgment on
 3 January 14, 2022, and Defendants filed an opposition and cross-motion for summary judgment on
 4 February 24, 2022. On April 20, 2022, the Court granted Plaintiffs' request to voluntarily dismiss
 5 the fourth and fifth claims for relief with prejudice. (Dkt. No. 85.)

6 The Court will discuss additional facts as necessary in the analysis.

ANALYSIS**A. Applicable Legal Standard.**

7
 8
 9 Under the APA, a court must “hold unlawful and set aside agency action ... found to be—
 10 arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law,” or “without
 11 observance of procedure required by law.” 5 U.S.C. § 706(2). “An agency must ‘examine the
 12 relevant data and articulate a satisfactory explanation for its action including a rational connection
 13 between the facts found and the choice made.’” *Gill v. U.S. Dep’t of Justice*, 913 F.3d 1179,
 14 1187 (9th Cir. 2019) (quoting *Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto.*
 15 *Ins. Co.*, 463 U.S. 29, 43 (1983)). Agency action is “arbitrary and capricious if the agency has
 16 relied on factors which Congress has not intended it to consider, entirely failed to consider an
 17 important aspect of the problem, offered an explanation for its decision that runs counter to the
 18 evidence before the agency, or is so implausible that it could not be ascribed to a difference in
 19 view or the product of agency expertise.” *Motor Vehicle Mfrs.*, 463 U.S. at 43; *see also Gill*, 913
 20 F.3d at 1187. The basis for the agency’s decision must come from the record. *Gill*, 913 F.3d at
 21 1187.

22 A reviewing court’s inquiry must be “thorough,” but “the standard of review is highly
 23 deferential; the agency’s decision is ‘entitled to a presumption of regularity,’ and [the court] may
 24 not substitute [its] judgment for that of the agency.” *San Luis & Delta-Mendota Water Auth. v.*
 25 *Jewell*, 747 F.3d 581, 601 (9th Cir. 2014) (quoting *Citizens to Preserve Overton Park, Inc. v.*
 26 *Volpe*, 401 U.S. 402, 416 (1971)). Although a court’s review is deferential, the court “must
 27 engage in a careful, searching review to ensure that the agency has made a rational analysis and
 28

1 decision on the record before it.” *Nat’l Wildlife Fed’n v. Nat’l Marine Fisheries Serv.*, 524 F.3d
 2 917, 927 (9th Cir. 2008); *see also Brower v. Evans*, 257 F.3d 1058, 1067 (9th Cir. 2001) (“The
 3 presumption of agency expertise can be rebutted when its decisions, while relying on scientific
 4 expertise, are not reasoned.”). A court “must not ‘rubber-stamp’ ... administrative decisions that
 5 [it] deem[s] inconsistent with a statutory mandate or that frustrate the congressional policy
 6 underlying a statute.” *Ocean Advocates v. U.S. Army Corps of Eng’rs*, 402 F.3d 846, 859 (9th Cir.
 7 2005) (first alteration in original, remaining alterations added). A court, however, may “uphold a
 8 decision of less than ideal clarity if the agency’s path may reasonably be discerned.” *Gill*, 913
 9 F.3d at 1187-88 (quoting *Motor Vehicle Mfrs.*, 463 U.S. at 43).

10 The reasoned-decisionmaking requirement the Supreme Court has often observed, includes
 11 a duty to explain any “departure from prior norms.” *Atchison, Topeka & Santa Fe Ry. Co. v.*
 12 *Wichita Bd. of Trade*, 412 U.S. 800, 808 (1973); *see also Int’l Union, UAW v. NLRB*, 802 F.2d
 13 969, 973-74 (7th Cir. 1986) (“[A]n administrative agency is not allowed to change direction
 14 without some explanation of what it is doing and why.”). “Unexplained inconsistency” between
 15 agency actions is “a reason for holding an interpretation to be an arbitrary and capricious change.”
 16 *Nat’l Cable & Telecomms. Ass’n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005).

17 A party is entitled to summary judgment if the “movant shows that there is no genuine
 18 dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R.
 19 Civ. P. 56(a). In an action reviewing the merits under the APA, however, the Court does not ask
 20 whether there is a genuine dispute as to any material fact. Rather, “the function of the district
 21 court is to determine whether or not as a matter of law the evidence in the administrative record
 22 permitted the agency to make the decision it did.” *Occidental Eng’g Co. v. I.N.S.*, 753 F.2d 766,
 23 769 (9th Cir. 1985). In an APA-review case, “summary judgment is an appropriate mechanism
 24 for deciding the legal question of whether the agency could reasonably have found the facts as it
 25 did.” *Id.* at 770.

26 **B. Article III Standing.**

27 The parties first dispute whether Plaintiffs have Article III standing to pursue their claims.
 28 At the motion to dismiss stage, the Court determined Plaintiffs adequately alleged Article III

1 standing to pursue their claims. (*See* Dkt. No. 39.) Defendants renew their challenge to Plaintiffs’
2 Article III standing in their cross-motion for summary judgment.

3 “[T]o satisfy Article III’s standing requirements, a plaintiff must show (1) it has suffered
4 an ‘injury in fact’ that is (a) concrete and particularized and (b) actual or imminent, not conjectural
5 or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3)
6 it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable
7 decision.” *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81
8 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992)).

9 The party asserting federal jurisdiction has the burden of proving the three elements of
10 standing, which are “not mere pleading requirements but rather an indispensable part of the
11 plaintiff’s case.” *Lujan*, 504 U.S. at 561. Therefore, “each element must be supported in the same
12 way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and
13 degree of evidence required at the successive stages of the litigation.” *Id.* On a motion for
14 summary judgment, “the plaintiff can no longer rest on such ‘mere allegations,’ but must ‘set
15 forth’ by affidavit or other evidence ‘specific facts,’ ...which for purposes of the summary
16 judgment motion will be taken to be true.” *Id.* (quoting Fed. R. Civ. P. 56.)

17 Plaintiffs submit numerous declarations in support of standing, including declarations from
18 two former USDA PHVs who attest that the changes to the inspection process in the Final Rule
19 are linked to increased food-safety violations, which will lead to an increased risk that consumers
20 will contract foodborne illness from pork products. (*See* Basu Decl. at ¶¶ 2, 9-20; Martin Decl. ¶
21 6-21.) Additionally, Plaintiffs cite evidence in the record linking contamination issues at plants
22 operating under NSIS with foodborne illness. The organizations’ declarant members attest that
23 they have regularly consumed pork and will suffer injury because they will be exposed to pork
24 products from NSIS plants if they continue to consume pork, or will have to spend time and
25 resources to limit their exposure to the higher-risk product.⁴ (*See* Mangini Decl. ¶¶ 9-14, Samuels
26 Decl. ¶¶ 6-19, Sperling Decl. ¶¶ 4-5, 9-17, Rubio Decl. ¶¶ 3-10; Lapp Decl. ¶¶ 5-12, Levenback

27 _____
28 ⁴ The record shows that pork from NSIS plants will account for most domestically slaughtered swine. 84 Fed. Reg. at 52,322.

1 Decl. ¶¶ 5-10.)

2 Defendants assert that Plaintiffs' declarations rest on the erroneous assertion that NSIS-
3 produced pork is "higher risk" than pork produced under the traditional inspection system.

4 According to Defendants, NSIS-produced pork is not "higher risk" than pork produced at non-
5 NSIS establishments, and thus the Final Rule does not injure Plaintiffs or their members. In
6 support of its argument, Defendants point to evidence in the record, including the Hog HIMP
7 Report and risk assessment.

8 Defendants' argument is effectively an argument on the merits, and "the Court cannot
9 consider the merits when deciding standing." *Grand Canyon Tr. v. Williams*, 98 F. Supp. 3d 1044,
10 1057 (D. Ariz. 2015). Defendants contend that the issue of whether the Final Rule exposes
11 "Plaintiffs to an increased risk of contracting foodborne illness is distinct from whether the Final
12 Rule violates the FMIA." (Defs. Reply at 3:7-8.) However, Defendants' standing arguments rely
13 on the Hog HIMP Report and risk assessment, the accuracy and validity of which are intertwined
14 with the merits of Plaintiffs' claims. For purposes of the standing inquiry, the Court must assume
15 the truth of Plaintiff's claims and that Plaintiffs will succeed on the merits. *Grand Canyon Tr.*, 98
16 F. Supp. 3d at 1057. Thus, the Court concludes that Plaintiffs have put forth sufficient evidence to
17 establish Article III standing.

18 **C. Plaintiffs' Analysis of Data.**

19 In support of their motion for summary judgment, Plaintiffs' counsel submitted analysis of
20 data relating to (1) the evaluations of animals and carcasses by PHVs from 2011 to 2019 for HIMP
21 pilot plants and comparably sized non-HIMP plants and (2) Food Safety Standard 2 ("FS-2")
22 violation rates. (*See* Dkt. No. 65-1, Declaration of Zachary B. Corrigan ¶¶ 3, 5.) Plaintiffs assert
23 that the analysis is derived from raw data in the administrative record. Plaintiffs ask the Court to
24 consider their analysis as "calculation[s] to prove the content of voluminous writings, recordings,
25 or photographs that cannot be conveniently examined in court[.]" under Federal Rule of Evidence
26 1006. Alternatively, Plaintiffs contend the analysis of the data is supplementary information that
27 can be considered under the exception in *Lands Council v. Powell*, 395 F.3d 1019 (9th Cir. 2005)
28 because the data analysis "take[s] technical and complex information from the record and

1 provide[s] it in a more understandable format to the Court.” *See Stop B2H Coal v. BLM*, 552 F.
2 Supp. 3d 1101, 1121 (D. Or. Aug. 4, 2021).

3 Rule 1006 provides that the proponent of evidence “may use a summary, chart, or
4 calculation to prove the content of voluminous writings, recordings, or photographs that cannot be
5 conveniently examined in court.” The Ninth Circuit has explained:

6 Charts and summaries as evidence are governed by Federal Rule of
7 Evidence 1006. In contrast, charts or summaries of testimony or
8 documents already admitted into evidence are merely pedagogical
9 devices, and are not evidence themselves. However, we have not
10 articulated a bright-line rule against admission of summary charts as
11 evidence. Although we do not approve of receiving summary exhibits
of material already in evidence, we have not reversed for that reason.
We have also elsewhere recognized a district court’s discretion under
Federal Rule of Evidence 611(a) to admit summary exhibits for the
purpose of assisting the jury in evaluating voluminous evidence.

12 *United States v. Anekwu*, 695 F.3d 967, 981-82 (9th Cir. 2012).

13 Here, Plaintiffs’ analysis is not a summary of voluminous evidence; it is analysis of raw
14 data that it is already in the record. Although Plaintiffs’ evidence might assist the Court in
15 understanding data, that does not make the evidence admissible as summaries of voluminous
16 evidence under Rule 1006.

17 Plaintiffs alternatively argue the Court may consider its data analysis under the *Lands*
18 *Council* exceptions, which permit a court to review extra-record material when: (1) it is necessary
19 to determine whether the agency has considered all relevant factors and explained its decision, (2)
20 the agency has relied on documents not in the record, (3) supplementing the record is necessary to
21 explain technical terms or complex subject matter, or (4) plaintiffs make a showing of bad faith.
22 *City of Las Vegas v. F.A.A.*, 570 F.3d 1109, 1116 (9th Cir. 2009) (discussing what are commonly
23 known as the “*Lands Council*” exceptions). The exceptions operate to “identify and plug holes in
24 the administrative record.” *Lands Council*, 395 F.3d at 1030. These exceptions are to be
25 “narrowly construed and applied” to ensure that they do not undermine the general rule limiting
26 review to the administrative record. *Id.* The party seeking admission of the extra-record material
27 “initially bears the burden of demonstrating that a relevant exception applies.” *San Luis & Delta*
28 *Mendota Water Auth. v. Locke*, 776 F.3d 971, 993 (9th Cir. 2014).

1 Plaintiffs assert that counsel’s data analysis can be considered under the third *Lands*
 2 *Council* exception because it takes technical and complex information from the record and
 3 provides it in a more understandable format. Plaintiffs’ counsel’s calculations of the HIMP pilot
 4 plants violation rates in 2012 and 2013 challenges FSIS’s analysis of that data; it does not provide
 5 the data in a more understandable format. (*See* Corrigan Decl. ¶ 5.) However, the Court
 6 concludes it may consider counsels’ analysis of data from after 2013 because FSIS did not analyze
 7 that data in the Final Rule; thus, the Court will consider the data for the purpose of determining
 8 whether the agency considered all relevant factors and explained its decision.

9 **D. Whether the Final Rule Violates the FMIA.**

10 **1. Section 603(a).**

11 Plaintiffs argue that the Final Rule violates 21 U.S.C. section 603(a) (“Section 603(a)”) for
 12 two reasons: (1) it prevents federal inspectors from critically appraising hogs before slaughter; and
 13 (2) it prevents the inspection and separate slaughter of swine showing symptoms of disease.

14 Section 603(a) of the FMIA provides:

15 [T]he Secretary shall cause to be made, by inspectors appointed for
 16 that purpose, an examination and inspection of all amenable species
 17 before they shall be allowed to enter into any slaughtering, packing,
 18 meat-canning, rendering, or similar establishment, in which they are
 19 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...

20 21 U.S.C. § 603(a).

21 Plaintiffs assert that “inspection” in the FMIA means that federal inspectors must “pay[]
 22 close attention to” and “critical[ly] apprais[e]” each animal prior to slaughter. *AFGE I*, 215 F.3d
 23 at 11. Plaintiffs argue the Final Rule prevents federal inspectors from critically appraising animals
 24 prior to slaughter because plant employees—not federal inspectors—conduct a pre-inspection
 25 sorting of the animals and remove animals unfit for slaughter. *See* 9 C.F.R. § 309.19(a) (requiring
 26 establishment employees to “conduct market hog sorting activities before the animals are
 27 presented for ante-mortem inspection”); *see also* 83 Fed. Reg. at 4792 (“establishment personnel
 28 would be required to sort market hogs and remove for disposal animals unfit for slaughter before

1 they are presented to FSIS PHVs for inspection and final disposition.”). Thus, Plaintiffs contend
2 that in NSIS plants, plant employees will take over jobs that are performed by trained federal
3 inspectors in traditional plants.

4 Defendants assert that the pre-inspection sorting conducted by plant employees does not
5 replace federal inspection; rather, it provides an additional step in the process before federal
6 inspection occurs. *See* 84 Fed. Reg. at 52,311 (“The new inspection system will not eliminate
7 FSIS inspection. NSIS simply requires establishments to take additional steps before FSIS
8 inspection to ensure that their products are safe and wholesome.”). Defendants contend that pre-
9 inspection sorting by plant employees is consistent with the requirements of the FMIA.

10 The Court agrees with Defendants. Under NSIS, federal inspectors still inspect each
11 animal before it is slaughtered for meat. During the pre-inspection sorting process, plant
12 employees sort animals that appear to be healthy into “Normal” pens and animals that appear to
13 have diseases or abnormal conditions into “Subject” pens. 83 Fed. Reg. at 4792. The federal
14 inspectors then inspect all animals found to be normal at rest, and five to ten percent of those
15 animals in motion. *Id.* If inspectors determine any of the “Normal” animals exhibit condemnable
16 conditions, FSIS inspectors direct establishment employees to move the animals to “U.S. Suspect”
17 pens for final disposition by the FSIS PHV. *Id.* The PHV inspects all animals in the “Subject”
18 and “U.S. Suspect” pens. *Id.*; 84 Fed. Reg. 52, 311. Thus, the pre-inspection sorting process does
19 not replace federal inspection; federal inspectors still inspect the animals “before they shall be
20 allowed to enter into any slaughtering...establishment, in which they are to be slaughtered and the
21 meat and meat food products...” 21 U.S.C. § 603(a).

22 Plaintiffs also contend that federal inspectors are unable to critically appraise animals in
23 violation of the FMIA because under NSIS, federal inspectors are required to observe only five to
24 ten percent of the “Normal” animals in motion. Plaintiffs assert that federal inspectors cannot
25 inspect the animals as required by Section 603(a) without observing them in motion.

26 Section 603(a) requires an “examination and inspection of all [swine].” 21 U.S.C. §
27 603(a). It does not require all swine to be examined at rest and in motion. Under NSIS, federal
28 inspectors do inspect all “Normal” animals at rest. This examination includes an assessment of

1 the “[t]he overall condition of each animal, including the head, with attention to the eyes, the legs,
2 and the body of the animal,” “[t]he degree of alertness, mobility, and breathing,” and “[w]hether
3 there are any unusual swellings or any other abnormalities.” AR_100705. Moreover, although it
4 is true that NSIS requires federal inspectors to observe only five to ten percent of the animals
5 sorted as “Normal” in motion, the Final Rule does not preclude federal inspectors from examining
6 a larger percentage of swine in motion if they deem necessary. *See* 84 Fed. Reg. at 52,312. The
7 Court finds the NSIS approach satisfies the requirements of Section 603(a).

8 Plaintiffs also argue that the Final Rule violates Section 603(a) because it prevents federal
9 inspectors from setting aside and ensuring that animals showing symptoms of disease are
10 slaughtered separately. Plaintiffs assert that under the NSIS system, plant employees place
11 symptomatic animals in “Subject” pens to rest and recover before a PHV evaluation. According to
12 Plaintiffs, the plant employees’ sorting precludes federal PHVs from conducting a critical
13 appraisal of the animals because the animals do not have U.S. Suspect tags and accompanying
14 paperwork detailing the symptoms that caused the animals to be put in the “Subject” pens. As a
15 result, PHVs cannot discern if animals in the “Subject” pen are recovered. Plaintiffs also argue
16 that the animals sorted into the “Subject” pens are not slaughtered separately from other animals
17 and their carcasses are not identified for further post-mortem evaluation as they would be if tagged
18 as “U.S. Suspect.”

19 The Court finds that the pre-sorting of swine by plant employees into “Subject” pens does
20 not run afoul of the FMIA’s ante-mortem inspection requirement. The animals placed in the
21 “Subject” pens by plant employees are subsequently examined by a federal PHV who may
22 condemn the animal as unfit for slaughter, deem the animal healthy and eligible for slaughter, or
23 conclude the animal is diseased and should be marked as “U.S. Suspect” and slaughtered
24 separately. Thus, under NSIS, federal inspectors examine the animals in the “Subject” pens and
25 determine if any need to be slaughtered separately as Section 603(a) requires.⁵

26
27 ⁵ The only animals that do not receive federal inspection under NSIS are the dead, moribund, or
28 otherwise unfit hogs that establishment employees remove and dispose of prior to ante-mortem
inspection. Plaintiffs argue that 9 C.F.R. section 309.1(b) requires inspection of all swine “on the
premises of the establishment,” which includes these dead, moribund, or otherwise unfit hogs.

1 Accordingly, the Court finds the Final Rule does not violate Section 603(a) of the FMIA.
 2 Although the Final Rule permits plant employees to pre-sort animals at NSIS plants, federal
 3 inspectors still inspect all hogs prior to slaughter, and the hogs that exhibit signs of disease upon
 4 that inspection are set apart and slaughtered separately as required by Section 603(a).

5 **2. Section 604.**

6 Plaintiffs argue that the Final Rule violates Section 604 of the FMIA because it prevents
 7 inspectors from critically appraising carcasses and parts after slaughter. Plaintiffs advance three
 8 reasons why the Final Rule violates Section 604: (1) the Final Rule tasks plant employees, not
 9 federal inspectors, with palpating and incising lymph nodes; (2) the Final Rule prevents federal
 10 inspectors from evaluating carcasses and parts for serious and generalized conditions because the
 11 carcasses arrive at the inspection station too late to catch these problems; and (3) the Final Rule
 12 reduces the number of federal inspectors on the slaughter lines so that each inspector has half as
 13 much time to perform their inspection.

14 Section 604 of the FMIA provides:

15 “[T]he Secretary shall cause to be made by inspectors appointed for
 16 that purpose a post mortem inspection and examination of the
 17 carcasses and parts thereof of all amenable species to be prepared at
 18 any slaughtering...establishment...which are capable of use as
 19 human food, and the carcasses and parts thereof of all such animals
 20 found to be not adulterated shall be marked...as “Inspected and
 21 condemned”; and said inspectors shall label...as “Inspected and
 22 condemned” all carcasses and parts thereof of animals found to be
 23 adulterated, and all carcasses and parts thereof thus inspected and
 24 condemned shall be destroyed for food purposes by the said
 25 establishment in the presence of an inspector...

26 21 U.S.C. § 604.

27 Under the traditional inspection process, plant employees do not conduct post-mortem
 28 carcass sorting to identify which carcasses and parts contain removable defects correctable

29 (See Opp’n 6-7 n.5.) However, that section provides that “[a]ll livestock *offered for slaughter* in
 30 an official establishment shall be examined and inspected on the day of and before slaughter” and
 31 “[s]uch ante-mortem inspection shall be made on the premises of the establishment at which the
 32 livestock are offered for slaughter before the livestock shall be allowed to enter into any
 33 department of the establishment...” 9 C.F.R. § 309.1(b) (emphasis added). Because the dead,
 34 moribund, or otherwise unfit hogs were never to be “offered for slaughter,” the FMIA does not
 35 require their federal inspection.

1 through trimming, which should be condemned because of generalized diseases or conditions, and
 2 which are eligible to bear the mark of inspection. 84 Fed. Reg. at 52,311. Rather, those tasks are
 3 conducted by federal inspectors. *Id.* Under NSIS, however, plant employees assume the role of
 4 removing contaminated carcasses and identifying defects before federal inspectors conduct a post-
 5 mortem inspection. *Id.* Federal inspectors, who are stationed on the evisceration line, then
 6 “perform inspection of the sorted head, viscera, and carcass” including “visually inspect[ing]
 7 heads and mandibular lymph nodes incised by establishment employees.” AR_100801; *see also*
 8 84 Fed. Reg. at 52,311. Moreover, federal PHVs conduct a post-mortem examination of U.S.
 9 Suspect and U.S. Retained parts and carcasses, which may include testing for chemical residues
 10 and specific diseases with implications for food safety.

11 **a. Palpation and incision of lymph nodes**

12 Plaintiffs first argue that the Final Rule violates Section 604 because it requires plant
 13 employees, not federal inspectors, to palpate and incise lymph nodes. Plaintiffs contend that
 14 federal inspectors in NSIS plants cannot conduct an adequate post-mortem inspection because they
 15 only observe the carcasses and parts and do not palpate lymph nodes, the proper incision of which
 16 is important to the detection of disease in the lymphatic system.

17 Defendants argue that the visual inspection conducted by federal inspectors complies with
 18 the FMIA’s requirement that federal inspectors conduct a “post mortem examination and
 19 inspection of the carcasses and parts” of all swine slaughtered for human food. 21 U.S.C. § 604;
 20 *see also AFGE II*, 284 F.3d at 130.

21 Thus, the issue here is whether federal inspectors are properly performing “inspections” as
 22 required by the statute if they visually inspect, but do not incise and palpate, lymph nodes.
 23 Section 604 requires a post-mortem inspection of each head, viscera, and carcass; it does not
 24 address lymph nodes or palpation, or specifically require federal inspectors to incise and palpate
 25 the lymph nodes. Finding that Section 604 includes a requirement that federal inspectors incise
 26 and palpate each animal’s lymph nodes would “add[] terms not found in the statute” and
 27 “impos[e] limits on [the] agency’s discretion that are not supported by the text” of the statute.
 28 *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 St. Ct. 2367, 2370

1 (2020) (citations omitted). Under the Final Rule, federal inspectors stationed on the evisceration
2 line visually inspect every head, viscera, and carcass. This satisfies Section 604.

3 Even if inspection is ambiguous, FSIS's interpretation of inspection as requiring a visual
4 inspection is reasonable. Plaintiffs argue Defendants' interpretation of inspection as requiring
5 only visual inspection is not entitled to deference because it contradicts Defendants' prior
6 statements. Plaintiffs are correct that the traditional inspection system requires federal inspectors
7 to conduct the palpation and incision of the lymph nodes while plant employees perform that task
8 under NSIS. However, FSIS explained its reasoning for the change, including that the change
9 frees federal inspectors to perform offline inspections which are more effective in ensuring the
10 current food safety concerns. The agency is permitted to change its position if it provides an
11 explanation for doing so, which it has done here.⁶

12 The Court also disagrees with Plaintiffs' argument that the NSIS system is akin to that
13 rejected in *AFGE I*. In *AFGE I*, the D.C. Circuit rejected FSIS verification and oversight regime,
14 under which employees would perform all tasks related to slaughter control and the federal
15 inspectors would be limited to observing establishment personnel as they processed carcasses and
16 verifying compliance by conducting random sampling of the carcasses. 215 F.3d at 10. The issue
17 with the regime rejected in *AFGE I* was that federal inspectors were evaluating people, not the
18 carcasses. See *AFGE v. Glickman*, 127 F. Supp. 2d 243, 246 (D.D.C. 2001). Here, and like the
19 regime approved of in *AFGE II*, federal inspectors visually evaluate the head, carcass, and viscera
20 of the animals.

21 **b. Evaluation of carcasses and parts for disease**

22 Plaintiffs next argue that the Final Rule violates Section 604 because plant employees'
23 sorting and trimming prevents federal inspectors from evaluating carcasses and parts for serious or
24 generalized conditions necessitating a federal PHV disposition, as well as fecal matter, digestive
25

26 ⁶ Plaintiffs also contend that *Chevron* deference does not apply because there is no definitive,
27 formal, and judicially reviewable interpretation of the FMIA that warrants deference. The Court
28 disagrees. See *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001) (“[T]he overwhelming
number of our cases applying *Chevron* deference have reviewed the fruits of notice-and-comment
rulemaking or formal adjudication.”).

1 contents, and milk contamination.

2 Defendants contend that the sorting and trimming activities performed by plant employees
3 prior to federal post-mortem inspection does not violate Section 604 because the statute does not
4 prohibit establishment employees from removing contamination from carcasses or parts before the
5 post-mortem inspection, or from identifying defects for further FSIS scrutiny. To ensure pre-
6 inspection sorting does not interfere with federal inspection, slaughter establishments must
7 “develop, implement, and maintain written procedures” regarding plant employees’ post-slaughter
8 sorting and trimming activities. *See* 9 C.F.R. § 310.26(b). Federal PHVs ensure these procedures
9 are adequate, and plant employees are only permitted to trim defects that do not affect the
10 disposition of the carcass. Moreover, the trimming occurs in the presence of federal inspectors
11 who verify that trimming and sorting is carried out correctly. *See* AR_103835; AR_100800. The
12 Court concludes that pre-inspection sorting and trimming does not prevent federal inspectors from
13 inspecting “each and every carcass and part” as required by the statute. *See AFGE II*, 284 F.3d at
14 130 (finding the FMIA does not “prohibit[] establishment employees from ... removing some
15 adulterated carcasses before they get to FSIS inspectors.”).

16 **c. Reduced number of federal inspectors on inspection line**

17 Plaintiffs also argue that the Final Rule prevents federal inspectors from critically
18 appraising “each and every carcass and part” because it significantly diminishes the time for
19 federal inspectors to perform their examination. 21 U.S.C. § 604. The Final Rule lifts line speed
20 limits and reduces the number of online inspectors by half compared to the traditional inspection
21 process. As a result, Plaintiffs contend there are fewer total federal inspectors on the lines and the
22 remaining inspectors must inspect carcasses and parts at double their prior pace. Plaintiffs assert
23 that nothing in the record indicates that inspectors can still perform the tasks required for a critical
24 appraisal of carcasses and parts at this pace.

25 However, Section 604 does not require a specific inspection speed limit. FSIS has
26 explained that based on the HIMP pilot program, federal inspectors can conduct effective online
27 inspection of the head, viscera, and carcass of each hog when operating at faster line speeds. 83
28 Fed. Reg. at 52,312; *see also AFGE II*, 284 F.3d at 130 (agreeing with agency that higher line

1 speeds were appropriate because “fewer adulterated...hog parts and carcasses [would] be
2 presented for federal inspection” because of pre-inspection sorting and trimming”). Additionally,
3 PHVs in NSIS establishments are authorized to regulate line speeds as necessary to ensure
4 adequate carcass-by-carcass inspection. 84 Fed. Reg. 52,312. The Court does not find this
5 approach runs afoul of Section 604.

6 **E. Whether the Final Rule Violates the APA.**

7 **1. Whether the Final Rule Departs from Prior Regulations and Practices.**

8 Plaintiffs first argue that the Final Rule departs from the previous regulations governing
9 the traditional inspection process. Plaintiffs contend that FSIS has not reasonably explained why
10 it has abandoned the traditional inspection process in favor of NSIS.

11 The APA requires that when an agency changes its position, “it display an awareness that
12 it *is* changing position” and “show that there are good reasons for the new policy.” *F.C.C. v. Fox*
13 *Television Stations, Inc.*, 556 U.S. 502, 515 (2009). The agency may not “depart from a prior
14 policy *sub silentio* or simply disregard rules that are still on the books.” *Id.* The agency “need not
15 demonstrate...that the reasons for the new policy are *better* than the reasons for the old one; it
16 suffices that the new policy is permissible under the statute, that there are good reasons for it, and
17 that the agency *believes* it to be better.” *Id.*

18 FSIS has met this burden. First, FSIS has displayed an awareness that it is changing its
19 position. The Final Rule explains that it establishes a new, optional inspection system and further
20 explains the key features of the new inspection process. Second, FSIS has shown that there are
21 good reasons for the policy. FSIS states that the NSIS will “improve the effectiveness of market
22 hog slaughter inspection; make better use of [FSIS’s] resources; and remove unnecessary
23 regulatory obstacles to industry innovation...” 84 Fed. Reg. at 52,300. Third, as discussed above,
24 the new inspection system is permissible under the FMIA. Finally, FSIS has provided good
25 reasons for the change—it believes the new policy will improve the effectiveness of market hog
26 slaughter inspection while “provid[ing] public health protection at least equivalent to the existing
27 inspection system.” *See id.* The Court concludes that FSIS has adequately explained its change in
28 position from the traditional inspection system to the NSIS.

1 **2. Whether the Final Rule is Arbitrary and Capricious.**

2 Plaintiffs also assert that the Final Rule is arbitrary and capricious for several reasons. “A
3 decision is arbitrary and capricious if the agency [1] has relied on factors which Congress has not
4 intended it to consider, [2] entirely failed to consider an important aspect of the problem, [3]
5 offered an explanation for its decision that runs counter to the evidence before the agency, or [4]
6 [has offered an explanation] so implausible that it could not be ascribed to a difference in view or
7 product of agency expertise.” *George v. Bay Area Rapid Transit*, 577 F.3d 1005, 1010 (9th Cir.
8 2009) (quoting *United States v. Snoring Relief Labs, Inc.* 210 F.3d 1081, 1085 (9th Cir.2000)
9 (internal quotation marks omitted, bracketed numbers added)).

10 **a. Pilot plant sample size evaluated in Hog HIMP Report**

11 Plaintiffs first challenge the adequacy of the sample size of the establishments evaluated in
12 the Hog HIMP Report, on which FSIS relied as justification for the Final Rule. Plaintiffs assert
13 the number of plants evaluated in the Hog HIMP Report is not representative of the broader
14 industry.

15 Because of the economic constraints of the program, FSIS anticipated that only large and
16 small high-volume establishments that exclusively slaughter market hogs would choose to
17 participate in NSIS. *See* 84 Fed. Reg. at 52,322. As of 2016, forty high-volume establishments
18 exclusively slaughtering market hogs existed. *Id.* These high-volume establishments account for
19 93 percent of total swine slaughter annually. *Id.* Of the forty high-volume establishments,
20 twenty-seven were large and thirteen were small. *Id.* The five HIMP pilot plants fell into the
21 large high-volume establishment category. *Id.* Those five plants produced about fifteen percent of
22 the nation’s pork supply. *Id.* No small high-volume establishments were included in the HIMP
23 pilot program. In the Final Rule, FSIS conceded that “the live market hog slaughter HIMP
24 establishments represent a small sample size of establishments.” *Id.* at 52,306. But FSIS
25 defended the adequacy of the sample size because the establishments “collectively represent
26 diversity in geography, corporate structure, management styles, product distributions patterns, and
27 other variables.” *Id.*

28 Plaintiffs criticize the fact that the Hog HIMP Report did not evaluate any of the thirteen

1 small high-volume plants and assert that significant differences exist between the large and small
2 plants. However, as Plaintiffs concede, FSIS was permitted to rely on a study with some
3 limitations to predict the outcome of the rulemaking. Moreover, although Plaintiff contends that
4 significant differences exist between the large and small high-volume establishments, their
5 citations to the record show that the plants slaughter a different number of animals, but this does
6 not establish that the large high-volume plants do not adequately represent outcomes at small
7 high-volume plants. Plaintiffs fail to show that FSIS acted arbitrarily and capriciously in relying
8 on the five HIMP pilot establishments to predict outcomes at the thirty-five other high-volume
9 establishments.

10 **b. Hog HIMP Report data**

11 Plaintiffs also challenge the adequacy of the data used in the Hog HIMP Report and assert
12 that FSIS's reliance on this data is arbitrary and capricious. Plaintiffs' critiques are twofold: (1)
13 the Hog HIMP Report analyzed only seven years of data; and (2) FSIS used performance
14 standards data collected six years after the baseline data.

15 Plaintiffs first argue that the Hog HIMP Report analyzed just seven years of data and did
16 not include data from the early years of the HIMP pilot. The modified HIMP pilot program began
17 in 2000. The Hog HIMP Report, published in 2014, used data from 2006 through 2013.⁷
18 Plaintiffs argue that FSIS acted arbitrarily and capriciously by failing to include data from the
19 early years of the HIMP pilot. However, Plaintiffs' arguments fail to show that the FSIS's
20 reliance on the HIMP Report, which used seven years of data, was arbitrary and capricious. The
21 report evaluated data for a seven-year period, which is not an insignificant period. It was not
22 unreasonable for FSIS to rely on the most recent available data in drafting the Hog HIMP Report,
23 and Plaintiffs have not shown that the absence of the data from the early years renders the Final
24 Rule arbitrary and capricious.

25 Plaintiffs further argue that FSIS's use of performance standards data collected six years
26 after the baseline data was arbitrary and capricious. At the time the HIMP pilot began in 1999,

27 _____
28 ⁷ Data from 2011 was not included in the Hog HIMP Report due to a database transition. (*See supra*, n. 2.)

1 FSIS used an independent contractor to conduct baseline sampling in volunteer plants to create a
2 “performance standard” to compare the progress of these plants operating under HIMP. The
3 performance standards addressed food safety and non-food safety conditions. *Id.* FSIS calculated
4 the 75th percentile of food-safety results achieved for each category of defects to use as a baseline.
5 The HIMP plants would need to meet those performance standards for food safety and non-food
6 safety concerns. In the Hog HIMP Report, FSIS evaluated performance standards data from April
7 2009 through 2011 and 2012 through 2013 and concluded that the HIMP plants performance
8 compared favorably to the pre-HIMP baseline. *See* AR_102018. Plaintiffs have not shown that
9 FSIS’s evaluation of four years of performance standard data was arbitrary and capricious.

10 **c. FWW’s analysis of HIMP pilot data**

11 FWW submitted a FOIA request seeking data from 2014 to 2017. In May 2019, FWW
12 sent a letter to the USDA asking them to delay finalizing the rule based on FWW’s analysis of
13 data it received from FSIS through a FOIA requests. According to FWW’s analysis of the data,
14 offline inspectors in HIMP pilot plants were not performing statistically significantly more offline
15 verifications of compliance with Public Health Regulations (“PHRs”). Violations of PHRs are
16 linked to pathogenic contamination and are an important indicator of food safety issues. 84 Fed.
17 Reg. at 52,308. FSIS declined to consider FWW’s data analysis as part of the rulemaking.

18 Plaintiffs contend that FWW’s data analysis reveals that federal inspectors performed a
19 greater number of offline verifications for PHRs in traditional inspection plants than HIMP pilot
20 plants in 2014 through 2017. Plaintiffs contend that this data contradicts FSIS’s conclusion that a
21 greater number of offline verifications of PHRs would justify reducing the number of online
22 inspectors under NSIS. Plaintiffs contend that FSIS’s failure to consider this data or explain why
23 it was inapposite is arbitrary and capricious.

24 FSIS does not dispute that it did not consider data from 2014 through 2017 in the Final
25 Rule. However, it contends that its failure to do so does not render the Final Rule arbitrary and
26 capricious because it addressed the potential staleness of the Hog HIMP Report’s data in the Final
27 Rule. 84 Fed. Reg. 52,307. In the Final Rule, FSIS defended its use of data ending in 2013
28 because no significant changes had occurred to the HIMP model or to the regulations since 2013.

1 *Id.* FSIS also stated that the findings from 2006 through 2013 were similar, which showed the
2 HIMP model was stable. Thus, although FSIS did not analyze the data from 2014 through 2017, it
3 explained why it did not do so and why its reliance on the data from the Hog HIMP Report was
4 reasonable.

5 Plaintiffs contend, however, that their submission undermined FSIS's statement that the
6 data was stable, and thus should have been considered by FSIS. Defendants first argue that they
7 did not need to consider the data presented in FWW's May 2019 submission because it was
8 received after the end of the period for public comment. However, unlike in the cases cited by
9 Defendants, Plaintiffs had raised similar claims during the original notice and comment period
10 based on the data available at that time, so FSIS was on notice of Plaintiffs' claims challenging the
11 analysis of PHRs. Thus, FSIS was not relieved of its obligation to consider the submission on this
12 basis.

13 However, the Court is not convinced that Plaintiffs' submission renders the Final Rule is
14 arbitrary and capricious. The May 2019 submission argued that federal inspectors in HIMP pilot
15 plants were unable to perform an equivalent number of PHR verifications as inspectors in non-
16 HIMP plants based on data from 2014 to 2017. A comment in the Final Rule raised a similar
17 substantive concern about the mandatory regulation verifications reported for 2012 and 2013. *See*
18 84 Fed. Reg. 52,307 (noting that the Hog HIMP Report showed an increase in total offline
19 verification tasks in HIMP establishments during 2012 and 2013, but data in the report showed
20 that the inspectors performed fewer verification tasks in HIMP establishments for more than half
21 of the PHRs). FSIS responded to the commenter's concern and explained why the 2012 and 2013
22 data did not support the commenter's argument regarding the number of offline verification tasks.
23 *Id.* The comment and FSIS's response addressed the same substantive issue that FWW raised in
24 its May 2019 submission—that FSIS did not properly analyze the compliance verification rates—
25 albeit with regard to mandatory regulations as opposed to PHRs. Thus, the FSIS's failure to
26 address FWW's submission was not arbitrary and capricious because FSIS had previously
27 considered and addressed the core issue raised by the submission challenging its data analysis and
28

1 explained its reliance on the data from 2006 through 2013.⁸

2 Finally, Plaintiffs fail to establish that any discrepancies in the PHR verification data are so
3 significant as to render arbitrary and capricious FSIS's conclusion that the NSIS system will
4 provide public health protection at least equivalent to the traditional inspection system or require
5 vacating the Final Rule.

6 **d. Food safety regulation compliance data**

7 Offline inspectors at all high-volume market hog slaughter establishments periodically
8 verify whether establishments are complying with various food-safety regulations, including FS-2
9 conditions, which include food contamination by fecal material, ingesta, and milk. If such
10 contamination is found, a noncompliance report under 9 C.F.R. section 310.18 ("Section 310.18")
11 issues. The Hog HIMP Report compared the rate of noncompliance with Section 310.18 between
12 the five HIMP establishments and the twenty-one non-HIMP establishments and concluded that in
13 2012 and 2013, the HIMP establishments had lower noncompliance rates than the non-HIMP
14 establishments in 2012 and 2013. *Id.*

15 According to Plaintiffs, however, the raw data shows HIMP pilot plants had higher
16 violation rates than comparably sized traditional plants in 2012 and 2013. Plaintiffs contend that
17 the data was in error because FSIS adjusted the rate of noncompliance with FS-2 downwards by
18 more than twofold for HIMP establishments.⁹ Plaintiffs assert that FSIS was unjustified in
19 applying the downward adjustment to the HIMP pilot plant rates, which made them appear smaller
20 than traditional plants' rates, without disclosing the assumption for doing so. Thus, FSIS's
21 reliance on an incorrect interpretation of data was arbitrary and capricious.

22 The downward adjustment FSIS applied to calculate the FS-2 noncompliance rates

23 _____
24 ⁸ Plaintiffs also contend that FWW's analysis showed that the Hog HIMP Report's evaluation of
25 pooled verification data for 2012 and 2013 likely obscured the differences between the pilot and
26 traditional plants. However, this issue was raised in the same comment and similarly addressed by
27 FSIS's response. *See* 84 Fed. Reg. 52,307.

28 ⁹ FS-2 compliance is computed as the number of non-compliances citing Section 310.18 divided
by Section 310.18 verifications performed. Section 310.18 addresses the contamination of
carcasses, organs, and other parts and requires that those parts be handled in a sanitary manner to
prevent contamination, that plants have written procedures to prevent this contamination, and that
plants must maintain records to document the monitoring of the procedures required under the
section.

1 between the HIMP and non-HIMP establishments was based on that fact HIMP establishments
2 “perform 24 food safety carcass checks versus 11 carcass food safety checks at non-HIMP market
3 hog slaughter establishments.” AR_102000. This fact is disclosed in the Hog HIMP Report.
4 Additionally, FSIS disclosed that it applied the same downward adjustment to other
5 noncompliance rates reported in the Hog HIMP Report based on this difference in the number of
6 food safety carcass checks at HIMP and non-HIMP establishments. *See* AR_102004-05, Tables 3-
7 2, 3-5. While FSIS should have included the same disclosure in Table 3-13, the Court is able to
8 discern FSIS’s path in reaching its conclusion regarding the comparison of noncompliance rates at
9 HIMP and non-HIMP establishments based on the disclosure of the assumption elsewhere in the
10 Hog HIMP Report. *See San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 1001 (9th
11 Cir. 2014). FSIS’s failure to disclose this assumption does not render the Final Rule arbitrary and
12 capricious.

13 **e. Evidence of concerns with plant employee performance**

14 Plaintiffs next argue that FSIS ignored evidence that plant employees do not adequately
15 perform the inspection tasks required of them under NSIS. In support of this argument, Plaintiffs
16 cite non-compliance reports, two of which occurred at one plant, Clemons Food Group LLC.
17 Plaintiffs argue that FSIS’s failure to address these instances of non-compliance renders the Final
18 Rule arbitrary and capricious. However, the fact that FSIS did not address these specific instances
19 of non-compliance is not a sufficient basis to find the Final Rule arbitrary and capricious. FSIS
20 addressed commenters’ concerns about the ability of plant employees to identify food safety
21 defects and cited data from the Hog HIMP Report supporting the conclusion that the NSIS system
22 would effectively protect food safety. 84 Fed. Reg. at 52,312-13. Thus, the Court cannot
23 conclude that FSIS’s failure to address these specific non-compliance reports related to plant
24 employee performance renders the Final Rule arbitrary and capricious.

25 **f. Risk assessment**

26 Plaintiffs argue that FSIS’s reliance on the risk assessment in the Final Rule was arbitrary
27 and capricious because FSIS did not adequately address peer reviewers’ comments that questioned
28 the assessment’s projected *Salmonella* reductions. Additionally, Plaintiffs assert FSIS did not

1 reveal problems with the risk assessment's use of simulated data until after the public comment
2 period closed.

3 Plaintiffs first argue that FSIS's reliance on the risk assessment was arbitrary and
4 capricious because FSIS failed to address the peer reviewers' comments that questioned whether
5 the assessment's projected *Salmonella* reductions were related to the HIMP pilot as opposed to
6 other variables. The risk assessment was peer reviewed in April 2018. In August 2018, FSIS
7 posted a summary of peer reviewer feedback and an updated risk assessment that included
8 additional analysis to respond to peer reviewer's feedback regarding the limitations of the earlier
9 risk assessment. Although Plaintiffs disagree with FSIS's response to the peer reviewer feedback
10 and the conclusions drawn in the risk assessment, the Court cannot say that FSIS failed to consider
11 the issues the peer reviewers raised and does not find FSIS's reliance on the risk assessment
12 arbitrary and capricious for this reason.

13 Plaintiffs next argue that FSIS failed to afford adequate opportunity for public comment on
14 the revisions to the risk assessment. In the original risk assessment, FSIS relied on certain
15 simulated data as the basis for its projections of avoided *Salmonella* illnesses. However, in the
16 January 2019 risk assessment that accompanied the Final Rule, FSIS did not rely on this data.
17 Without relying on this data, the Final Rule expressed greater uncertainty in the range of potential
18 benefits related to *Salmonella*-related illness reduction than was reflected in the Proposed Rule.
19 Plaintiffs assert that FSIS's failure to permit the public to respond to the revised risk assessment,
20 which reflected greater uncertainty in the benefits, was arbitrary and capricious.

21 It is not disputed that FSIS did not disclose the greater range of uncertainty regarding
22 illness estimates until the Final Rule and did not provide the public an opportunity to comment on
23 the January 2019 risk assessment. However, FSIS's failure to do so does not render the Final Rule
24 arbitrary and capricious. Although the risk assessment accompanying the Final Rule asserted a
25 larger range of potential benefits than the earlier risk assessments because it no longer relied on
26 the simulated data, FSIS continued to maintain that the estimated decrease in *Salmonella* illness
27 under the most feasible approach was expected to be 2,533 cases. This was consistent with the
28 broader conclusion it reached in the earlier risk assessments. *Compare* AR_104995 *with*

1 AR_104811. While the Final Rule acknowledged greater uncertainty surrounding illness
2 estimates, the conclusion about the likelihood of decrease in illness in the Final Rule remained
3 unchanged from the Proposed Rule. *Compare* 83 Fed. Reg. 4780-01 *with* 84 Fed. Reg. at 52,300-
4 01; *see also* 83 Fed. Reg. 4791; 84 Fed. Reg. 52,334 n. 84. Thus, FSIS's failure to allow notice
5 and comment on the revised risk assessment did not alter the conclusion in the Final Rule in a way
6 that prevented the public from providing comment on proposed illness reductions. The Court
7 cannot say this renders the Final Rule arbitrary and capricious.

8 **F. The Final Rule is Not Otherwise Contrary to Law.**

9 Plaintiffs advance two additional arguments why the Final Rule is contrary to law. First,
10 Plaintiffs contend the Final Rule is arbitrary and capricious because it undermines the FMIA's
11 purpose to protect the health and welfare of consumers by improperly handing critical inspection
12 duties to plant employees. However, as discussed above, the pre-inspection sorting tasks
13 performed by plant employees under NSIS do not violate the FMIA. Second, Plaintiffs assert the
14 Final Rule violates the APA's subdelegation bar because the FMIA requires federal inspectors, not
15 third-party plant employees, to conduct inspections. *See* 21 U.S.C. § 621. However, as discussed
16 above, the Court has concluded that federal inspectors still perform their statutorily required
17 inspection duties under the FMIA and have not impermissibly delegated those tasks to plant
18 employees.

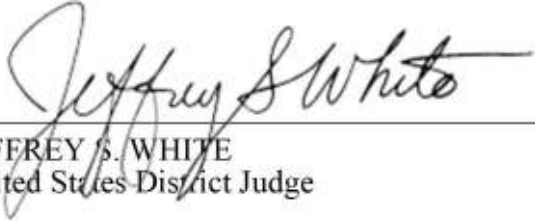
19 **CONCLUSION**

20 For the foregoing reasons, the Court DENIES Plaintiffs' motion for summary judgment
21 and GRANTS Defendants' cross-motion for summary judgment.

22 A separate judgment shall issue, and the Clerk shall close the file.

23 **IT IS SO ORDERED.**

24 Dated: September 30, 2022

25 
26 _____
27 JEFFREY S. WHITE
28 United States District Judge