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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

NATIONAL FAMILY FARM COALITION
et al.,

Plaintiffs,

v.

TOM VILSACK et al.,

Defendants.

Case No. 21-cv-05695-JD

ORDER RE SUMMARY JUDGMENT

United States District Court
Northern District of California

In 2004, the Animal and Plant Health Inspection Service (APHIS), housed within the U.S. Department of Agriculture (USDA), announced the intention to revisit regulations governing genetically engineered (GE) organisms. APHIS published a notice of proposed rulemaking in 2008 that kicked off over a decade of activity and concluded in a final rule the agency adopted in May 2020. Plaintiffs, who are non-profit and public-interest groups organized around concerns for farmers, crops, food safety, and the environment, object to the final rule. In plaintiffs' view, the final rule effectively abandoned federal government regulation of GE organisms, leaving GE crop developers and agribusinesses to their own devices without adequate safety and other oversight. Plaintiffs ask to set aside the final rule under the Administrative Procedure Act on the ground that APHIS acted arbitrarily and capriciously, and contrary to various federal statutes. *See generally* Dkt. No. 1.

Summary judgment is granted in part to plaintiffs. The rule is vacated and remanded to the agency for further consideration in a manner consistent with this order.

1 **BACKGROUND**

2 **I. STATUTORY FRAMEWORK**

3 In 1986, the Office of Science and Technology Policy promulgated a Coordinated
4 Framework for the Regulation of Biotechnology, under which regulatory jurisdiction over
5 emerging developments in genetic engineering was delegated to three agencies: (1) the USDA,
6 and specifically APHIS; (2) the Environmental Protection Agency, and (3) the Food and Drug
7 Administration. *See* Movement of Certain Genetically Engineered Organisms, 85 Fed. Reg.
8 29790, 29790 (May 18, 2020) (codified at 7 C.F.R. §§ 330, 340, & 372). At that time, three
9 federal statutes were the keystones of overseeing our national agricultural resources: the Plant
10 Quarantine Act of 1912 (PQA), Pub. L. No. 62-275, 37 Stat. 315; the Federal Plant Pest Act of
11 1957 (FPPA), Pub. L. No. 85-36, 71 Stat. 31; and the Federal Noxious Weed Act of 1974
12 (FNWA), Pub. L. No. 93-629, 88 Stat. 2148.

13 In 2000, Congress enacted the Plant Protection Act (PPA), Pub. L. No. 106-224, 114 Stat.
14 438, which consolidated the FPPA, PQA, and FNWA into a unitary statutory scheme. The PPA
15 authorizes the Secretary of Agriculture (Secretary), who has delegated her authority to APHIS, *see*
16 7 C.F.R. §§ 371.1, 371.3, to regulate plant pests and noxious weeds and requires the agency to
17 “facilitate exports, imports, and interstate commerce in agricultural products and other
18 commodities that pose a risk of harboring plant pests or noxious weeds in ways that will reduce, to
19 the extent practicable, as determined by the [agency], the risk of dissemination of plant pests or
20 noxious weeds.” 7 U.S.C. § 7701(3).

21 The statute defines a “plant pest” as an organism “that can directly or indirectly injure,
22 cause damage to, or cause disease in any plant or plant product.” *Id.* at § 7702(14). The
23 movement of “any plant pest” without a “permit” is prohibited, *id.* at § 7711(a), although the
24 agency may suspend permitting requirements for “specified plant pests . . . if the [agency] finds
25 that a permit . . . is not necessary,” *id.* at § 7711(c). The PPA defines “noxious weed” as “any
26 plant or plant product that can directly or indirectly injure or cause damage to crops (including
27 nursery stock or plant products), livestock, poultry, or other interests of agriculture, irrigation,
28 navigation, the natural resources of the United States, the public health, or the environment.” *Id.*

1 at § 7702(10). The agency is authorized to “prohibit or restrict the . . . movement in interstate
2 commerce of any . . . noxious weed” as “necessary.” *Id.* at § 7712(a). The statute contemplates
3 permitting requirements for noxious weeds and authorizes the agency to “publish, by regulation, a
4 list of noxious weeds that are prohibited or . . . subject to restrictions.” *Id.* at § 7712(c), (f).

5 **II. REGULATORY BACKDROP**

6 APHIS regulates GE plants under 7 C.F.R. § 340. The regulations date back to 1987,
7 when APHIS first imposed a pre-market authorization requirement and other measures for GE
8 plants if the plants were classified as a “plant pest” under the then-controlling FPPA. 85 Fed. Reg.
9 at 29790; *see generally* Introduction of Organisms and Products Altered or Produced Through
10 Genetic Engineering Which Are Plant Pests or Which There is Reason to Believe Are Plant Pests,
11 52 Fed. Reg. 22892 (June 16, 1987). A GE plant was classified as a “plant pest” if “it [was]
12 created using an organism that is itself a plant pest,” *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829,
13 835 (9th Cir. 2013), and so the rule covered most GE plants at the time because the predominant
14 engineering technique used plant-pest material to introduce new genetic characteristics to the
15 target plant, *see* Movement of Certain Genetically Engineered Organisms, 84 Fed. Reg. 26514,
16 26521 (June 6, 2019). Under the part 340 regulations, plant pests could not be moved interstate or
17 introduced into the environment without notification and a permit, and permitting conditions
18 included record-keeping and labeling requirements. *See, e.g.*, Importation, Interstate Movement,
19 and Release into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg.
20 60008, 600010-11 (Oct. 9, 2008). The regulatory scheme reflected a presumption of “plant pest
21 risk, until proven otherwise,” due to the means by which genetic material was introduced into the
22 target plant. Dkt. No. 60 at 6.

23 Between 1987 and the start of the rulemaking process at the heart of this lawsuit, the
24 regulations were revised several times to lessen the regulatory burden on some GE plants. *See* 84
25 Fed. Reg. at 26514. For example, one set of revisions provided that GE-plant developers could
26 introduce or move in interstate commerce certain crop species without obtaining a permit if certain
27 eligibility requirements were met and the developer went through the agency’s notification
28 procedure. *See generally* Genetically Engineered Organisms and Products; Notification

1 Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated
 2 Status, 58 Fed. Reg. 17044 (Mar. 31, 1993). Other revisions created a process through which GE-
 3 plant developers could petition for deregulation from section 340 altogether by submitting to the
 4 agency extensive data pertaining to the GE plant’s plant-pest risk. *See generally id.*

5 In all of the revisions, GE plants were treated as plant pests for regulatory purposes and so
 6 were not subject to the permitting or pre-market-authorization requirements that applied to
 7 noxious weeds. APHIS regulated, and continues to regulate, noxious weeds under 7 C.F.R. § 360
 8 and prohibits the unauthorized movement of any plant designated as a noxious weed by the
 9 Secretary of Agriculture. *See id.* § 360.300. By its own terms, part 360 regulates noxious weeds
 10 by taxon, which is defined as “[a]ny grouping within botanical nomenclature, such as family,
 11 genus, species, or cultivar.” *See* 7 C.F.R. §§ 360.100 (defining “taxon”), 360.200, 360.500-01.
 12 The result, then, is that a plant’s GE and non-GE counterparts are treated identically for noxious-
 13 weed purposes. *Cf. id.* at § 360.200 n.1. APHIS does not dispute plaintiffs’ statement that, with
 14 one minor exception, the agency does not regulate GE plants under section 360. *See* Dkt. No. 59
 15 at 23 n.39; 7 C.F.R. §360.200 (list of plant taxa designated as noxious weeds).

16 **III. THE RULEMAKING SAGA**

17 The 2020 final rule plaintiffs challenge is the culmination of nearly 15 years of attempts by
 18 APHIS to update the part 340 GE-plant regulations. These attempts entailed multiple proposals,
 19 permutations, and withdrawals of proposals. A clear map of this winding road is useful for the
 20 resolution of this lawsuit.

21 **A. CONTEMPLATING AN OVERHAUL**

22 The journey began in 2004 when APHIS published a notice of intent to open public
 23 comment and begin an environmental impact study of potential changes to section 340, including
 24 an expansion of “its regulatory scope beyond genetically engineered organisms that may pose a
 25 plant pest risk to include genetically engineered plants that may pose a noxious weed risk.”
 26 Environmental Impact Statement; Introduction of Genetically Engineered Organisms, 69 Fed.
 27 Reg. 3271, 3272 (Jan. 23, 2004).
 28

1 The USDA’s Office of Inspector General (OIG) encouraged the agency to implement
 2 changes and stated in a 2005 audit report that “APHIS has not finished updating its regulations to
 3 comply with the Plant Protection Act of 2000,” “which grant[s] new regulatory authority to the
 4 Secretary of Agriculture for controlling noxious weeds.” AR 22970.¹ The report noted that
 5 “APHIS began the process of updating its regulations” in January 2004 when it published the
 6 notice of its intent to “prepare an environmental impact statement . . . in connection with potential
 7 changes to the regulations[] regarding the movement and release of certain [GE organisms].” *Id.*
 8 APHIS responded by stating that it would soon complete its study and that “[t]he rule will include
 9 the provisions of the Plant Protection Act of 2000.” AR 22973.

10 **B. CONGRESSIONAL INTERVENTION**

11 Before any proposed updates to part 340 were published, some high-profile instances of
 12 transgenic contamination (the unintended cross-pollination of non-GE plants with the modified
 13 genetic material of GE plants) prompted APHIS to consider additional changes to section 340.
 14 *See* AR 18415, 27050. In 2007, the agency published a report entitled “Lessons Learned and
 15 Revisions under Consideration for APHIS’ Biotechnology Framework” that contained suggestions
 16 as to how APHIS could “enhance” its GE-plant rules by, *inter alia*, requiring (1) the “creation and
 17 retention of additional records” by GE-plant developers, AR 18415; (2) permit applications to
 18 prepare contingency and corrective-action plans for unauthorized releases of GE material, *see*
 19 AR 18416; and (3) “minimum distances” between GE field test sites and nearby fields to avoid
 20 inadvertent contamination events, *see* AR 18417-18.

21 In 2008, Congress passed legislation directing the agency to “take action on each issue
 22 identified” in the 2007 report. Food, Conservation, and Energy Act of 2008 (2008 Farm Bill),
 23 Pub. L. No. 110-246, 122 Stat. 1651 § 10204 (codified at 7 U.S.C. § 7701 Note). Specifically,
 24 Congress mandated that the agency “take actions that are designed to enhance,” *inter alia*, “the
 25 quality and completeness of records . . . the maintenance of identity and control in the event of an
 26 unauthorized release . . . [and] corrective actions in the event of an unauthorized release.” *Id.* at

27 _____
 28 ¹ “AR” references are to the administrative record, which consists of a dozen volumes containing thousands of pages. *See* Dkt. Nos. 66, 67, 70.

1 § 10204(b)(1), (3), & (4). Congress also directed the Secretary to “promulgate regulations to
2 improve the management and oversight of articles” regulated under the PPA “as the Secretary
3 considers appropriate.” *Id.* at § 10204(a)(2).

4 **C. RULEMAKING: 2008-2017**

5 In 2008, APHIS published a notice of proposed rulemaking (NPRM) for the part 340
6 regulations to consolidate the agency’s noxious-weed authority under the PPA and address the
7 concerns raised in the 2005 OIG audit report and the 2008 Farm Bill. *See* 73 Fed. Reg. at 60009-
8 11. The NPRM stated that, “[i]n order to best evaluate the risks associated with these GE
9 organisms and regulate them when necessary, APHIS needs to exercise its authorities regarding
10 noxious weeds . . . in addition to its authority regarding plant pests.” *Id.* at 60011. The NPRM
11 identified the risks with GE organisms it would consider under its noxious-weed authority,
12 including harms to “irrigation, navigation, the natural resources of the United States, the public
13 health, the environment and interests of agriculture.” *Id.* at 60014. APHIS received a deluge of
14 comments -- more than 88,000 comments in more than 5,500 submissions -- and ultimately
15 withdrew the proposed rule in 2015 so that it could engage in “an open and robust policy
16 dialogue” with key stakeholders. Importation, Interstate Movement, and Release into the
17 Environment of Certain Genetically Engineered Organisms, 80 Fed. Reg. 11598, 11598 (Mar. 4,
18 2015).

19 In 2015, the OIG published another audit report. The report concluded that APHIS had
20 “not implemented the agreed upon corrective actions for 3 of the 28 recommendations from [the]
21 2005 report,” specifically identifying the recommendation to “incorporat[e] additional authority to
22 control noxious weeds.” AR 23027. APHIS responded that it had attempted to revise the rule in
23 2008 but was obligated to work through the enormous number of comments. AR 23040.

24 Two years after the withdrawal, APHIS announced a new proposed rule that was again
25 said to address the concerns raised in the 2008 Farm Bill, the 2005 OIG audit, and the 2015 OIG
26 audit. *See* Importation, Interstate Movement, and Environmental Release of Certain Genetically
27 Engineered Organisms, 82 Fed. Reg. 7008, 7011-12 (Jan. 19, 2017). Like its predecessor, the
28 2017 proposed rule would evaluate GE plants for noxious-weed risk. *Id.* at 7010-11. APHIS

1 stated that the “current regulatory structure, which entails evaluating such plants solely for plant
2 pest risk, is not sufficient to properly identify all risks that these plants present to other plants and
3 plant products.” *Id.* at 7010. The agency said that part 340’s focus on plant-pest risks had been
4 workable in the past because “most GE plants to date have been agricultural crops, and most
5 agricultural crops are not biologically weeds prior to modification” and most GE plants were
6 created using plant pests and therefore already fell “under APHIS’ regulatory authority.” *Id.* The
7 agency believed that approach was no longer tenable because “[a]dvances in genetic engineering
8 have . . . made the need to evaluate GE plants for noxious weed risk more pressing.” *Id.* at 7009.
9 For the noxious-weed regulations already on the books, APHIS said that they suffered from
10 limitations that made them inadequate for GE-crop oversight. *Id.* at 7009-10.

11 Even so, the 2017 proposal was not necessarily about regulatory maximalism. APHIS
12 proposed to narrow the regulations by exempting some GE plants altogether from part 340
13 regulation. The biggest change in this respect was the proposal to move away from the prior
14 definition of “GE organism,” which the agency believed was both overinclusive and
15 underinclusive for mitigating risk. *See id.* at 7009, 7015-16. The agency proposed to exempt GE
16 plants “that could otherwise have been produced using traditional breeding techniques or chemical
17 or radiation-based mutagenesis.” *Id.* at 7015. This was because “GE plants as a class . . . pose no
18 greater plant pest or noxious weed risk than their counterparts developed through conventional
19 breeding techniques.” *Id.* at 7015-16. The agency acknowledged that the potentially exempt plants
20 are not “risk-free,” *id.* at 7017, and so proposed to exempt such plants from the blanket permitting
21 requirements of part 340 but to simultaneously amend part 330 regulations to permit some
22 oversight of those exempt GE plants that “pose a potential plant pest risk.” *Id.* at 7016.

23 In contrast to the prior tidal wave of public comment, the 2017 NPRM elicited only 203
24 comments. Even so, APHIS abruptly withdrew the 2017 NPRM in a one-page notice. *See*
25 Importation, Interstate Movement, and Environmental Release of Certain Genetically Engineered
26 Organisms, 82 Fed. Reg. 51582 (Nov. 7, 2017). APHIS represented that commentators had
27 expressed concern that the proposed rule would “hinder[] innovation” and “could result in the
28

1 creation of two parallel but inconsistent regulatory systems and thus more regulatory uncertainty.”
2 *Id.* In effect, APHIS ended 2017 back where it started in 2004.

3 **D. RULEMAKING: 2019-PRESENT**

4 The rulemaking for GE plants went silent until 2019, when APHIS promulgated a third
5 proposal that ultimately was implemented in 2020 as the final rule in question here. *See* 84 Fed.
6 Reg. 26514; 85 Fed. Reg. 29790. The final rule revised the scope of regulations under part 340 to
7 reflect the fact that APHIS changed its risk assessment of GE plants to focus on the specific trait
8 introduced in the plant and that trait’s potential to pose plant-pest risks in the modified plant. *See*
9 *generally* 7 C.F.R. § 340; 84 Fed. Reg. at 26516-17.

10 Although this revision was anticipated to some extent by the changes announced in 2017,
11 the final rule differed from its predecessors in many respects. In salient part, the final rule
12 categorically exempts GE plants created by conventional-breeding techniques. 7 C.F.R.
13 § 340.1(b). But unlike the 2017 proposal, the final rule does not regulate such plants under part
14 330. *Id.* at §§ 330.200, 340.1-3; 85 Fed. Reg. at 29823. The final rule excludes from regulation
15 under part 340 GE plants with “plant-trait-mechanism of action” combinations that the agency has
16 determined do not pose plant-pest risks. 7 C.F.R. § 340.1(c). A “mechanism of action” is the
17 “biochemical process(es) through which genetic material determines a trait.” *Id.* at § 340.3. The
18 final rule does not treat noxious weeds as a trigger for part 340 regulation, unlike the 2008 and
19 2017 proposals. 85 Fed. Reg. at 29822. APHIS said that it was not “statutorily obligated to
20 integrate noxious weed authority into a revised part 340” and that it did “not perceive a basis at
21 this time for overhauling part 360 noxious weed regulations, which we believe have functioned
22 well over the years, or establishing alternate regulations in title 7 governing noxious weeds.” *Id.*
23 APHIS also said that it would “continue [its] current practice of considering the weediness” of GE
24 plants when it considers their plant-pest risks. *Id.* Lastly, the final rule extends record retention
25 for GE-plant developers from one year to two years without requiring permit applicants to retain
26 or prepare any new types of records. 7 C.F.R. §§ 340.5, 340.6.

1 **IV. THIS LITIGATION**

2 Plaintiffs have sued to rescind the final rule under the Administrative Procedure Act
3 (APA), Pub. L. No. 404-79, 60 Stat. 237 (codified at 5 U.S.C. § 500 *et seq.*). The complaint
4 named as defendants the Secretary of Agriculture, the Administrator of APHIS, and the USDA
5 and APHIS as agencies.² Dkt. No. 1 ¶¶ 29-31. The complaint alleged that the final rule
6 contravened various federal statutes and consequently was arbitrary and capricious. Specifically,
7 plaintiffs alleged that, in promulgating the final rule, the agency failed to heed procedural
8 requirements under the Endangered Species Act of 1973 (ESA), Pub. L. No. 93-205, 87 Stat. 884
9 (codified at 16 U.S.C. § 1531 *et seq.*), and the National Environmental Policy Act (NEPA), Pub.
10 L. No. 91-190, 83 Stat. 852 (1970) (codified at 42 U.S.C. § 4321 *et seq.*). Dkt. No. 1 ¶¶ 223-47.
11 Plaintiffs also alleged that the final rule failed to implement directives set forth in the 2008 Farm
12 Bill and that the rule violated the PPA. *Id.* ¶¶ 248-76. And plaintiffs said that portions of the final
13 rule relating to the exemptions unconstitutionally delegated statutory authority to private parties
14 without Congress’s express authorization. *Id.* ¶¶ 277-86. The complaint seeks declaratory and
15 injunctive relief, most particularly a remand of the rule to the agency with vacatur. *Id.* ¶¶ 287-300.

16 Early in litigation, the Court granted permissive intervention to two agricultural-industry
17 trade associations, the American Seed Trade Association and the Biotechnology Innovation
18 Organization (intervenors). Dkt. No. 43. Plaintiffs moved for summary judgment as to four of
19 their five claims. *See* Dkt. No. 59. APHIS opposed as to all claims asserted in the complaint, *see*
20 Dkt. No. 60, and intervenors filed an opposition raising additional points against plaintiffs’
21 motion, *see* Dkt. No. 63.

22 **DISCUSSION**

23 **I. THE PROPER UNIVERSE OF EVIDENCE**

24 Before getting to the merits of the motion, some threshold issues require discussion. To
25 start, the parties disagree about the scope of the record properly before the Court. Plaintiffs’
26 opening brief featured an abundance of materials that are not part of the agency’s administrative
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² For clarity and ease of reading, the Court refers to the named defendants together as “the agency”
or “APHIS,” unless otherwise noted.

1 record. *See generally* Dkt. No. 59. The Court declines to consider most of these materials for any
 2 purpose beyond determining standing, *see Ecological Rts. Found. v. FEMA*, 384 F. Supp. 3d 1111,
 3 1119 (N.D. Cal. 2019), which is another dispute that will be discussed next. It is well established
 4 that, in a suit brought under the APA to review agency action, “the function of the district court is
 5 to determine whether or not as a matter of law the evidence in the administrative record permitted
 6 the agency to make the decision it did.” *Occidental Engineering Co. v. INS*, 753 F.2d 766, 769
 7 (9th Cir. 1985). There are limited exceptions to that rule, *see Lands Council v. Powell*, 395 F.3d
 8 1019, 1030 (9th Cir. 2005), but plaintiffs give no good reason for applying an exception.
 9 Plaintiffs also agreed in a joint status report to the Court that “there will be no need for any motion
 10 practice on the scope of the administrative record.” Dkt. No. 55 at 1. Consequently, there is no
 11 basis for the Court to consider much of the extra-record materials.

12 The only small exception to this conclusion is for judicial notice of Exhibits A and C of the
 13 Wu Declaration. *See* Dkt. Nos. 59-20, 59-22. The exhibits are simply the 2008 and 2017 NPRMs.
 14 The agency broadly objects to all documents attached to that declaration, *see* Dkt. No. 60 at 11,
 15 but the Court does not understand the agency to suggest that the prior proposed versions of the
 16 very rule under review cannot be considered. In any event, judicial notice of those exhibits is
 17 appropriate. *See* Fed. R. Ev. 201(b)(2); 44 U.S.C. § 1507 (“The contents of the Federal Register
 18 shall be judicially noticed.”).

19 **II. ARTICLE III STANDING**

20 To litigate in federal court, plaintiffs must “demonstrate standing to sue by alleging the
 21 ‘irreducible constitutional minimum’ of (1) an ‘injury in fact’ (2) that is ‘fairly traceable to the
 22 challenged conduct of the defendants’ and (3) ‘likely to be redressed by a favorable judicial
 23 decision.’” *Patel v. Facebook, Inc.*, 290 F. Supp. 3d 948, 952 (N.D. Cal. 2018) (quoting *Spokeo,*
 24 *Inc. v. Robins*, 578 U.S. 330, 338 (2016)), *aff’d by Patel v. Facebook, Inc.*, 932 F.3d 1264 (9th Cir.
 25 2019). The elements of standing “must be supported in the same way as any other matter on
 26 which the plaintiff bears the burden of proof,” *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561
 27 (1992), and so at summary judgment, “[a] plaintiff . . . must ‘set forth’ by affidavit or other
 28 evidence ‘specific facts,’ which for purposes of the summary judgment motion will be taken as

1 true,” *id.* (citation omitted), that show a “substantial probability” of standing, *Nat’l Fam. Farm*
2 *Coalition v. EPA*, 966 F.3d 893, 908 (9th Cir. 2020) (quotation omitted).

3 APHIS did not challenge plaintiffs’ standing to sue, *see* Dkt. No. 60, but intervenors say
4 that plaintiffs have not demonstrated standing, Dkt. No. 63 at 4-7. In addition, the Court “has an
5 independent duty to be vigilant about standing.” *Natural Grocers v. Vilsack*, 627 F. Supp. 3d
6 1130, 1143 (N.D. Cal. 2022) (quotation omitted).

7 The standing challenge is not well taken. In *Monsanto Co. v. Geertson Seed Farms*, the
8 Supreme Court of the United States held that farmers of non-GE alfalfa had standing to challenge
9 an agency decision to deregulate GE alfalfa where the record established that: (1) the non-GE
10 alfalfa had a “reasonable probability” of being contaminated by gene flow if GE alfalfa was
11 completely deregulated; and (2) gene flow injured those farmers by, *inter alia*, requiring them to
12 incur costs for preemptive measures to prevent or test for gene flow and ensure supply of non-GE
13 alfalfa seeds. 561 U.S. 139, 153-55 (2010).

14 So too here. Because the only relief sought is injunctive, *see* Dkt. No. 59 at 29-30, the
15 Court “need not address standing of each plaintiff” at this juncture. *Atay v. Cnty. of Maui*, 842
16 F.3d 688, 696 (9th Cir. 2016) (quoting *Nat’l Ass’n of Optometrists & Opticians LensCrafters, Inc.*
17 *v. Brown*, 567 F.3d 521, 523 (9th Cir. 2009)). The undisputed evidence establishes that:
18 (1) members of the plaintiff organizations, namely Peter Baumer, Darwin Bentlage, and Jonathan
19 Krohn, are organic or non-GE farmers; (2) if the final rule is allowed to deregulate GE plants, the
20 risk that those members’ farms will experience incidents of transgenic contamination increases
21 beyond a “reasonable probability,” *see* Dkt. No. 59-1 ¶¶ 8, 12, 14-15; Dkt. No. 59-2 at ¶¶ 7, 13,
22 16; Dkt. No. 59-12 at ¶¶ 9, 11-14; and (3) such contamination will harm their non-GE farming
23 operations, *see generally, e.g.*, Dkt. Nos. 59-1, 59-2, 59-12. Specifically, one farmer says that his
24 non-GE farm is near several GE farms, Dkt. No. 59-1 ¶ 7, which will require measures to stave off
25 contamination, *see id.* ¶ 11, and the others anticipate incurring greater costs for non-GE seeds, *see*
26 Dkt. No. 59-2 ¶¶ 7, 16; Dkt. No. 59-12 ¶ 12. Such harms were “sufficiently concrete to satisfy the
27 injury-in-fact prong” in *Monsanto*, 561 U.S. at 155, and the same goes in this lawsuit.

1 “Those harms are readily attributable to APHIS’s deregulation decision,” *id.*, because the
 2 paring back of regulatory oversight is what gives rise to the injuries, *see* Dkt. No. 59-1 ¶¶ 8, 12,
 3 14-15; Dkt. No. 59-2 at ¶¶ 7, 13, 16; Dkt. No. 59-12 at ¶¶ 9, 11-14. This is so notwithstanding
 4 some evidence that contamination has occurred in the past and may occur in the future irrespective
 5 of the regulatory scheme. *E.g.*, Dkt. No. 59-1 ¶¶ 12-13. “[A] plaintiff may sue [a] defendant” so
 6 long as that “defendant is at least partially causing the alleged injury.” *Nat’l Fam. Farm*
 7 *Coalition*, 966 F.3d at 910 (quoting *WildEarth Guardians v. U.S. Dep’t of Agric.*, 795 F.3d 1148,
 8 1157 (9th Cir. 2015)). In addition, a judicial order vacating and remanding the challenged rule
 9 would alleviate the increased risk of contamination the evidence shows to be posed by certain
 10 aspects of the rule. *See Idaho Conservation League v. Bonneville Power Admin.*, 83 F.4th 1182,
 11 1191 (9th Cir. 2023).

12 With respect to the organizations, the record establishes that the interests sought to be
 13 protected by Center for Food Safety, of which Baumer and Krohn are members, *see* Dkt. Nos. 59-
 14 1, 59-12, and National Family Farm Coalition, for which Bentlage serves as a board member, *see*
 15 Dkt. No. 59-2, are germane to the organizations’ purposes, *see* Dkt. No. 1 ¶¶ 20-23, and that
 16 nothing about the claims asserted or relief requested requires the members’ individual
 17 participation in this litigation. *See Oregon Advoc. Ctr. v. Mink*, 322 F.3d 1101, 1109 (9th Cir.
 18 2003) (quoting *Hunt v. Wash. State Apple Advert. Comm’n*, 432 U.S. 333, 343 (1977)).

19 Consequently, Article III standing to sue has been demonstrated. As a closing observation,
 20 intervenors failed to address governing precedent such as *Monsanto* and *Atay*. Dkt. No. 63. Why
 21 that happened is unknown, but it substantially diluted their argument.

22 **III. LEGAL STANDARDS**

23 In reviewing agency action other than the interpretation of a statute, the scope of review
 24 under the APA is narrow, and “agency action will be upheld unless it is found to be ‘arbitrary,
 25 capricious, an abuse of discretion, or otherwise not in accordance with law.’” *Natural Grocers*,
 26 627 F. Supp. 3d at 1142 (quoting 5 U.S.C. § 706(2)(A)). “Agency action is arbitrary and
 27 capricious when the agency ‘relie[s] on factors which Congress has not intended it to consider,
 28 entirely fail[s] to consider an important aspect of the problem, [or] offer[s] an explanation for its

1 decision that runs counter to the evidence before the agency.” *Ctr. for Biological Diversity v. U.S.*
2 *Fish and Wildlife Serv.*, 67 F.4th 1027, 1035 (9th Cir. 2023) (alterations in original) (quoting
3 *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983)).

4 “[T]he Court will not substitute its own judgment for that of the agency” but will “engage
5 in a careful, searching review to ensure that the agency has made a rational analysis and decision
6 on the record before it.” *Ecological Rts. Found.*, 384 F. Supp. 3d at 1119 (quoting *Wild Fish*
7 *Conservancy v. Salazar*, 628 F.3d 513, 521 (9th Cir. 2010)). Consequently, the Court “will not
8 ‘rubber-stamp’ agency decisions that are inconsistent with a statutory mandate or that frustrate the
9 congressional policy underlying a statute.” *Id.* (quoting *Natural Res. Def. Council, Inc. v.*
10 *Pritzker*, 828 F.3d 1125, 1139 (9th Cir. 2016)). “The Court’s deference extends to less than stellar
11 work by an agency, so long as its analytical path and reasoning can be reasonably discerned,”
12 *Natural Grocers*, 627 F. Supp. 3d at 1142 (quotation omitted), although it is still incumbent on
13 agencies to “engage in ‘reasoned decisionmaking,’” *Dep’t of Homeland Sec. v. Regents of the*
14 *Univ. of Cal.*, 591 U.S. 1, 16 (2020) (quoting *Michigan v. EPA*, 576 U.S. 743, 750 (2015)), and
15 “articulate a satisfactory explanation for its action including a ‘rational connection between the
16 facts found and the choice made,’” *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43 (quoting
17 *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

18 “Summary judgment is an appropriate procedure for deciding challenges under the APA.”
19 *Natural Grocers*, 627 F. Supp. 3d at 1142. And a grant of summary judgment is warranted where
20 there is no genuine dispute of material fact and the moving party is entitled to judgment as a
21 matter of law. *See Brickman v. Fitbit, Inc.*, No. 15-cv-02077-JD, 2017 WL 6209307, at *2 (N.D.
22 Cal. Dec. 8, 2017) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). “Because this is
23 a record review case, the summary judgment motion will be decided upon a review of the
24 administrative record as it existed at the time of the agency’s decision.” *Natural Grocers*, 627
25 F. Supp. 3d at 1142 (citing *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1017 (9th Cir.
26 2012) (en banc)).

1 **IV. NOXIOUS WEEDS**

2 The APA review starts with plaintiffs’ challenges to the rule’s assertedly unlawful failure
3 to incorporate the agency’s noxious-weed authority into the part 340 regulations. Plaintiffs first
4 contend that the failure was contrary to the PPA’s statutory mandate and so the final rule must be
5 set aside on that basis. *See* Dkt. No. 59 at 22-23.

6 The point is not well taken. “Courts must exercise their independent judgment in deciding
7 whether an agency has acted within its statutory authority.” *Loper Bright Enterp. v. Raimondo*, ---
8 U.S. ---, ---, 144 S. Ct. 2244, 2273 (2024). There is no question that the PPA expanded the
9 definition of noxious weeds, and so the scope of the agency’s regulatory authority as well,
10 *see* Pub. L. No. 106-224, 114 Stat. 438 § 403(10) (codified at 7 U.S.C. § 7702(10)), nor is there
11 any dispute the statute charges the agency with the responsibility to “facilitate . . . interstate
12 commerce in agricultural products . . . that pose a risk of harboring plant pests or noxious weeds in
13 ways that will reduce . . . the risk of dissemination of plant pests or noxious weeds,” *id.* at § 402(3)
14 (codified at 7 U.S.C. § 7701(3)).

15 But plaintiffs did not identify any statutory text that “command[s],” Dkt. No. 59 at 22, the
16 agency to discharge that responsibility in a particular way, let alone plaintiffs’ preferred way.
17 Rather, as the agency notes, *see* Dkt. No. 60 at 16, the statute is replete with language indicating
18 that the way in which that responsibility is to be discharged is within the agency’s discretion.
19 *See, e.g.*, 7 U.S.C. § 7712(a) (“The Secretary *may* prohibit or restrict the . . . movement in
20 interstate commerce of any . . . noxious weed[.]” (emphasis added)); *id.* at § 7712(c) (“The
21 Secretary *may* issue regulations to implement subsection (a)[.]” (emphasis added)). Where a
22 “statute delegates authority to an agency . . . courts must respect the delegation, while ensuring the
23 agency acts within it.” *Loper Bright Enterp.*, --- U.S. at ---, 144 S. Ct. at 2273.

24 Overall, plaintiffs did not establish that the agency exceeded its statutory authority here.
25 Plaintiffs say the agency itself previously interpreted the PPA as imposing a “statutory duty” to
26 add noxious weeds as a trigger for part 340 regulations. *See* Dkt. No. 59 at 22-23. Even if an
27 agency’s prior interpretations of a statute in rescinded NPRMs carried some persuasive value,
28 which is not at all clear, *see Loper Bright Enterp.*, --- U.S. at ---, 144 S. Ct. at 2259 (citing

1 *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)), the statements plaintiffs proffer were the agency’s
2 conclusions at the time about how to exercise its discretion, not interpretations of a statutory
3 directive, *see* 73 Fed. Reg. at 60011.

4 Plaintiffs next contend that the final rule’s failure to incorporate noxious weeds as a trigger
5 for part 340 regulations was inadequately explained. This challenge fares better.

6 The parties disagree whether the factors for assessing changes in agency policy set forth in
7 *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009), should guide the analysis here.
8 *See* Dkt. No. 59 at 23; Dkt. No. 60 at 18-19. The Court sees no reason to wade into that dispute
9 and instead takes guidance from the Ninth Circuit’s discussion in *Transportation Division of the*
10 *International Association of Sheet Metal, Air, Rail, & Transportation Workers v. Federal Railroad*
11 *Administration (Transp. Workers)*, 988 F.3d 1170 (9th Cir. 2021).

12 In that case, the Federal Railroad Administration (FRA) issued in 2016 a NPRM that
13 proposed “[a] minimum requirement of two crewmembers . . . for all railroad operations.” *Id.* at
14 1174 (emphasis omitted) (quoting 81 Fed. Reg. 13918, 13918 (Mar. 15, 2016)). After a public
15 hearing and the comments period, the FRA did not act on the NPRM until issuing an order on May
16 29, 2019. *See id.* The 2019 order withdrew the 2016 NPRM, purported to preempt any state laws
17 regulating the number of crewmembers for train operations, and “provid[ed] notice of [FRA’s]
18 affirmative decision that no regulation of train crew staffing is necessary or appropriate,” *id.* at
19 1175-77 (quoting 84 Fed. Reg. 24735, 24735 (May 29, 2019)). The Ninth Circuit understood the
20 “real and intended effect” of the 2019 order was to “authorize nationwide one-person train crews
21 and to bar any contrary state regulations.” *Id.* at 1182.

22 Reviewing the FRA 2019 order for arbitrariness and capriciousness, the court concluded
23 that the record did not support the order’s conclusions and that the agency’s contemporaneous
24 explanation was inadequate. *See id.* at 1182-84. In pertinent part, the court concluded that the
25 order did not sufficiently address the safety concerns raised by comments on the NPRM because
26 (1) the order “[did] not discuss crew fatigue at all,” despite the FRA’s own research having
27 identified crewmember fatigue as a “critical component” of safety; (2) it failed to consider
28 concerns about the technical challenges posed by passage over mountainous terrain that “FRA had

1 previously recognized”; and (3) an “assertion that [the agency] has the inherent authority to
2 implicitly preempt state law does not” explain the reason why the agency exercised its authority in
3 the manner it did. *Id.* at 1183.

4 APHIS’s 2020 final rule suffers from many of the same infirmities. It did not address
5 concerns about the adequacy of APHIS’s “current practice,” 85 Fed. Reg. at 29822, for regulating
6 GE plants and noxious weeds that the agency had “previously recognized.” *Transp. Workers*, 988
7 F.3d at 1183. The administrative record includes two OIG audit reports from 2005 and 2015
8 which, as APHIS forthrightly acknowledges, contain recommendations “that incorporating the
9 PPA’s expanded definition of noxious weed into the part 340 Rules would be preferable.” Dkt.
10 No. 60 at 19 (citing AR 22970); *see also* AR 23027, 23037, 23039; 73 Fed. Reg. at 60009. In
11 addition, APHIS discussed at great length in the 2017 NPRM the shortcomings of the current
12 regulatory regime with respect to GE plants and noxious weeds. APHIS stated that the part 360
13 regulations, “while effective, continue to have a significant restriction that limits their applicability
14 to GE organisms: They are predicated on a determination by APHIS that a taxon is a Federal
15 noxious weed.” 82 Fed. Reg. at 7010. This means that part 360 regulations would cover a GE
16 plant only if the taxon to which it belongs is deemed a noxious weed (in other words, only if both
17 a plant’s GE and non-GE counterparts are deemed to be a noxious weed). *See* 7 C.F.R.
18 §§ 360.200, 360.500-600. APHIS also said that, “in recent years, there has been an increasing
19 diversity of both agronomic and non-agronomic traits engineered in plants. . . . [and] an increased
20 use of plants in genetic engineering that, in their unmodified state, are known to possess weedy
21 traits,” which poses “a correspondingly higher risk that such a plant may be genetically engineered
22 into a noxious weed.” 82 Fed. Reg. at 7010. Finally, APHIS stated that part 340 “is not sufficient
23 to properly identify all risks that these plants present to other plants and plant products,” for
24 potentially harmful “plants may entirely escape regulation” if the GE plant is not engineered using
25 a plant-pest vector or is not itself deemed to be a plant pest. *Id.*

26 The final rule does not address a single one of these issues. The rule states that APHIS
27 “disagrees with the proposition that [it] is statutorily obligated to integrate noxious weed authority
28 into a revised part 340” and that it instead believes it has discretion to do so. 85 Fed. Reg. at

1 29822. But APHIS’s “assertion that it has the . . . authority” to make such a decision “does not
2 address why” it chose to make or not make the decision. *Transp. Workers*, 988 F.3d at 1183. In
3 the final rule, APHIS “recognize[d]” that genetic engineering could introduce traits that increase
4 the weedy aspects of a plant and stated, “[a]ccordingly, [it] would continue [its] current practice of
5 considering the weediness of the unmodified plant and whether the new trait could in any way
6 change the weediness.” 85 Fed. Reg. at 29822. The rule further provides that APHIS would
7 consider “potential effects on the weediness of other plants with which the engineered plant can
8 interbreed” and “whether the plant with the specific trait being evaluated should be considered for
9 regulation pursuant to” the separate part 360 regulations. *Id.* Statements about maintaining the
10 status quo sidestep the problems with the status quo that APHIS “had previously recognized.”
11 *Transp. Workers*, 988 F.3d at 1183. The final rule’s silence on this score indicates that APHIS
12 “failed to consider an important aspect of the problem” that the agency itself had identified. *State*
13 *Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43.

14 It bears mention that the final rule concludes APHIS does not “perceive a basis at this
15 time” for overhauling its noxious-weed regulations because it “believe[s]” those regulations “have
16 functioned well over the years.” 85 Fed. Reg. at 29822. But the agency’s perceptions and beliefs
17 are of little moment when, as here, they are asserted as fiat untethered to a clear and sound
18 analysis. The agency had in hand OIG audit reports the agency understood to suggest that
19 “incorporating the PPA’s expanded definition of noxious weeds into the part 340 Rules would be
20 preferable.” Dkt. No. 60 at 19. Yet the rule does not address the relevant recommendations in
21 those reports. *See, e.g., Rancheria v. Jewell*, 776 F.3d 706, 714 (9th Cir. 2015) (“An agency’s
22 decision is arbitrary and capricious if it ignores important considerations or relevant evidence on
23 the record.”).

24 *Transportation Workers* concluded that FRA’s failure to consider crew fatigue in
25 connection to safety in the final order after the NPRM had identified crew fatigue as a “critical
26 component” of safety was arbitrary and capricious. 988 F.3d at 1183. The same conclusion
27 applies here. APHIS’s failure to address the limitations in the part 360 regulations with respect to
28 GE plants that its prior assessments identified as justifying adding noxious weeds as a trigger to

1 part 340 regulations was arbitrary and capricious. Ignoring concerns the agency had previously
2 recognized is not “reasoned decisionmaking.” *Regents of the Univ. of Cal.*, 591 U.S. at 16
3 (quoting *Michigan*, 576 U.S. at 750).

4 APHIS tries to get around all this by saying that it was entitled to disagree, and so not
5 follow, the OIG report recommendations because “neither report discusses the noxious weed
6 authority issue in any depth” and both “merely assume, without analysis,” that incorporation is
7 preferable. Dkt. No. 60 at 19. That response might have been adequate if the agency had said it at
8 the time. It did not, and so that reason does not carry the day now. *See, e.g., State Farm Mut.*
9 *Auto. Ins. Co.*, 463 U.S. at 50 (“[A]n agency’s action must be upheld, if at all, on the basis
10 articulated by the agency itself.”). APHIS says that it was not required to “stay true to the ‘very
11 genesis of the rulemaking history’” in promulgating the final rule and that the final rule need only
12 have been a “logical outgrowth” of the NPRMs with a reasonable explanation. Dkt. No. 60 at 18-
13 20 (emphasis in original). That may be, but those comments do not excuse it from complying with
14 the APA’s basic requirement that agencies articulate the bases of their decisions. *See, e.g.,*
15 *Arrington v. Daniels*, 516 F.3d 1106, 1112-13 (9th Cir. 2008).

16 **V. EXEMPTIONS**

17 As a brief overview for the ensuing discussion, the final rule provides exemptions for: (1)
18 GE crops that can be created through conventional-breeding techniques, *see* 7 C.F.R. § 304.1(b);
19 (2) GE crops with certain “plant-trait MOAs,” *see id.* § 340.1(c); and (3) GE crops previously
20 determined to fall outside part 340’s scope under the “Am-I-Regulated” (AIR) process, *see id.*
21 § 340.1(d). Plaintiffs challenge the exemptions as arbitrary and capricious because they were not
22 based on “sound science.” Dkt. No. 59 at 20-22; Dkt. No. 65 at 7-8. Plaintiffs also say that the
23 agency’s decision to not require field test data for still-regulated GE crops was arbitrary and
24 capricious for the same reason. Dkt. No. 59 at 20.

25 APHIS suggests in a footnote that plaintiffs waived any claim that the exemptions are
26 arbitrary and capricious and may only rely on “the PPA’s ‘sound science’ standard.” Dkt. No. 60
27 at 15 n.7. This misconstrues plaintiffs’ challenge. Their theory is that the agency’s failure to
28 ground its decisions on the PPA on “sound science” renders those decisions arbitrary and

1 capricious. *See, e.g.*, Dkt. No. 1 at 82 ln. 15, ¶¶ 262-70 (alleging that the agency’s “Failure to
2 Base Decisions on Sound Science” is a reason for concluding that the agency’s “decision violated
3 the PPA and the APA as it is” arbitrary and capricious); Dkt. No. 59 at 15.

4 **A. THE CONVENTIONAL-BREEDING EXEMPTION**

5 Plaintiffs first say that “there is no scientific basis” for the conventional-breeding
6 exemption because the scientific evidence in the record bearing on this point, namely a 2002 study
7 from the National Academy of Sciences (NAS), “specifically *rejected* this rationale.” Dkt. No.
8 59 at 21 (emphasis in original) (quotation omitted). Charging plaintiffs with cherry picking,
9 APHIS says that the 2002 NAS study also concluded that “the genetic engineering process, per se,
10 presents no new categories of risk compared to conventional breeding.” Dkt. No. 60 at 23
11 (quoting AR 20484). APHIS says that, because conventional breeding poses risks that are
12 “manageable by accepted standards,” according to a 1989 report by the National Research Council
13 (NRC), the GE crops covered by the exemption “are the same in kind as, and do not pose any
14 increased plant pest risks than, the [changes] introduced through conventional breeding,” which
15 “have not led to plant pest risk concerns.” 85 Fed. Reg. at 29792, 29794; *see* Dkt. No. 60 at 23-
16 24. In the agency’s view, nothing in the record “suggests that the scientific evidence employed
17 was anything but sound.” Dkt. No. 60 at 24.

18 The flaw of this rationale is in the premise -- “the types of traits that can be introduced
19 through conventional breeding have not led to plant pest risk concerns,” 85 Fed. Reg. at 29792 --
20 and the record with respect that statement. There is no dispute that APHIS relied on the 1989
21 NRC study, which concludes that “[p]lants modified by classical genetic methods are . . .
22 ‘manageable by accepted standards.’” AR 5424. But as plaintiffs state, this was expressly
23 repudiated by other more-recent scientific evidence in the record. The 2002 NAS study
24 acknowledged that “[i]n the 1980s . . . an assumption was made that, even though conventionally
25 bred crops were not considered to be completely risk free, the risks associated with the entire class
26 of crops should be considered ‘acceptable’ to society.” AR 20519. It concluded that “the
27 assumption that all conventionally bred crops have ‘acceptable risks’ is not scientifically justified”
28

1 and therefore “[t]he risks associated with crop cultivars that have been or could be developed
2 through conventional breeding should not be assumed to be acceptable.” AR 20520-21.

3 “An agency conclusion that is in ‘direct conflict with the conclusion of its own experts’ . . .
4 is arbitrary and capricious.” *NRDC, Inc. v. Pritzker*, 828 F.3d 1125, 1139 (9th Cir. 2016) (quoting
5 *W. Watersheds Proj. v. Kraayenbrink*, 632 F.3d 472, 492 (9th Cir. 2011)). Nowhere in the final
6 rule does APHIS acknowledge the conflicting scientific evidence concerning the basis on which
7 the exemption is premised. *See* 85 Fed. Reg. at 29791-94. That is arbitrary and capricious. *See*
8 *Alaska Oil & Gas Ass’n v. Pritzker*, 840 F.3d 671, 679 (9th Cir. 2016).

9 As a closing point, APHIS says that “the whole point of Part 340 has always been to create
10 a special, heightened set of regulations to protect against the potential for *increased* plant pest
11 risks from certain GE crops -- not to eliminate that risk altogether.” Dkt. No. 60 at 21-22
12 (emphasis in original); *see* 85 Fed. Reg. at 29794. But that contention still takes the risk from
13 conventionally bred plants as the baseline on which the scope of regulatory oversight should be
14 defined, a premise the 2002 NAS study concluded is “not scientifically justified,” and to this the
15 final rule says nothing. AR 20519-22. This is not to suggest APHIS cannot take this position
16 after reasoned consideration of other evidence or its own expertise, but it must provide an
17 “adequate explanation and support for its determinations.” *Ctr. for Biological Diversity*, 900 F.3d
18 at 1069 (quoting *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 625 (9th Cir.
19 2014)).

20 **B. PLANT-TRAIT MOA EXEMPTION & FIELD TEST DATA**

21 Plaintiffs challenge the rule’s plant-trait MOA exemptions, 7 C.F.R. § 340.1(c), and the
22 portion of the rule that does not require GE-crop developers to submit field test data for regulatory
23 status review, *see id.* at § 340.4, for the same basic reason: the 2002 NAS study concluded there
24 was “no scientific basis” to forego an “initial review of the interactions between the ‘trait, [specific
25 GE] organism, and the environment” for “any GE crops.” Dkt. No. 59 at 21-22 (quoting
26 AR 20515). Plaintiffs say that is what the final rule does by not requiring field test data and
27 exempting certain plant-trait MOAs.

1 The point is not well taken. The final rule acknowledges comments suggesting that every
2 GE crop should be assessed with “case-by-case analysis and controlled field experiments,” as well
3 as the 2002 NAS study’s conclusion that “genetic engineering [*i.e.*, transformation]” is “both a
4 useful and justifiable regulatory trigger’ because ‘there is no scientific basis’” for excluding GE
5 organisms from regulation prior to some initial review. 85 Fed. Reg. at 29797. Right after, the
6 rule states that “APHIS disagrees with these points” “[b]ased on the risk assessments [the agency
7 has] performed in accordance with the petition process over 30 years.” *Id.* This experience is said
8 to have persuaded APHIS that it is “able to evaluate the plant pest risks associated with a GE
9 organism without field-test data” because “the introduced trait of the GE organism provides the
10 most reliable indicator of the organism’s potential for deleterious effects on plants and plant
11 products” -- a conclusion the rule states is consistent with a 2016 NAS study and the 1989 NRC
12 study. *Id.* The rule also notes that the 2002 NAS study also observed that “the committee expects
13 that most [GE organisms] will not produce significant actual environmental risks” and then
14 explains why the agency thinks the proposed rule strikes the proper balance in regulatory burden
15 by discriminating between risky and non-risky GE organisms per the 2002 study’s
16 recommendations. *Id.*

17 Unlike its decision-making for the conventional-breeding exemption, APHIS recognized
18 contrary scientific evidence and explained its disagreement with it based on other scientific
19 evidence, namely its own expertise from three decades’ worth of regulatory analyses. Agencies
20 need not credit every piece of scientific evidence before them, and they are permitted to credit
21 their own experts over others. *See Marsh v. Oregon Natural Resources Council*, 490 U.S. 360,
22 378 (1989). To reiterate, the Court’s task in an APA review case is to “ensure that the agency has
23 made a rational analysis and decision on the record before it,” not to “substitute its own judgment
24 for that of the agency.” *Ecological Rts. Found.*, 384 F. Supp. 3d at 1119 (quoting *Salazar*, 628
25 F.3d at 521). Deference to the agency in the exercise of delegated authority in connection with
26 technical matters such as these is appropriate where the record shows that the agency accounted
27 for the relevant evidence and offered an explanation implicating its expertise. *See, e.g., Ctr. for*
28 *Biological Diversity*, 900 F.3d at 1067; *Ctr. for Food Safety v. Regan*, 56 F.4th 648, 666-67 (9th

1 Cir. 2022). The record indicates that APHIS supported its views with scientific evidence, and
2 plaintiffs make no argument that the rule conflicts with, or is unsupported by, the evidence on
3 which the agency purported to rely or that there was other evidence undermining the conclusions
4 the agency drew from its expertise.

5 C. EXEMPTIONS GENERALLY

6 Plaintiffs make a catch-all argument that there was not a sound scientific basis in the
7 record for creating any exemptions because the 2002 NAS study concluded the mere fact of
8 genetic engineering is a logical and scientifically justifiable trigger for regulation. *See* Dkt. No. 59
9 at 20-21. For the reasons already discussed, this argument is misdirected. The agency was
10 entitled to credit its own expertise and experience over the study’s conclusions and in fact did so.
11 Plaintiffs develop no further argument challenging the AIR-process exemption under 7 C.F.R.
12 § 340.1(d).

13 VI. OTHER ISSUES

14 Plaintiffs take some shots at other aspects of the final rule. Plaintiffs say the rule is
15 arbitrary and capricious because, “[r]ather than *increasing* management and oversight, the [final
16 rule] significantly *reduces* what will be regulated,” Dkt. No. 59 at 27 (emphases in original), and
17 so contravenes the 2008 Farm Bill’s directive to APHIS to “improve the management and
18 oversight of articles regulated under the [PPA].” Pub. L. No. 110-246, 122 Stat. 1651
19 § 10204(a)(2) (codified at 7 U.S.C. § 7701 Note).

20 The argument misses the mark. The statute says that the Secretary of Agriculture “shall as
21 the Secretary *considers appropriate*, promulgate regulations to improve the management and
22 oversight of articles regulated under the [PPA].” *Id.* (emphasis added). “Increase” is not a
23 synonym for “improve,” and the plain text of the statute grants the agency the discretion to decide
24 what constitutes improvement and how to go about achieving it. Moreover, the statute does not
25 define what is an “article[] regulated under the [PPA]”; it only directs the Secretary to promulgate
26 regulations, if deemed appropriate, in connection with articles that are so regulated. *Id.* The fact
27 that the rule does not increase regulatory oversight is not itself a basis for concluding the agency
28 flouted a statutory directive.

1 Plaintiffs also say the final rule ignores Congress’s directives to the agency to “take action
2 on each issue identified in the document entitled ‘Lessons Learned and Revisions Under
3 Consideration for APHIS[.]’” 122 Stat. 1651 § 10204(a)(1) (codified at 7 U.S.C. § 7701 Note).
4 They point to subsection (b), which specifies that, “[i]n carrying out subsection (a), the Secretary
5 shall take actions that are designed to enhance,” in relevant part, “the quality and completeness of
6 records[.]” “the availability of representative samples[.]” “the maintenance of identity and control
7 in the event of an unauthorized release[.]” and “corrective actions in the event of an unauthorized
8 release[.]” *Id.* § 10204(b)(1)-(4).

9 It is true the subjects for action identified in the statute track the “list of lessons learned” in
10 the report that APHIS composed in 2007 based on its “LibertyLink investigation and from its 20
11 years of experience in the regulation of biotechnology.” AR 18415, 18419. But the statute does
12 not say that the actions to be taken are the suggestions APHIS explored in the report; the statute
13 instead appears to leave to the agency’s discretion the decision of what action to take on the
14 specified topics. *See* 122 Stat. 1651 § 10204(a), (b). Nor does it make sense to read subsection
15 (b) as directing the agency to undertake those courses of action suggested in the report given that
16 subsection (c) clearly delineates a series of more specific actions the agency “shall consider”
17 undertaking. *Id.* § 10204(c). If Congress wanted APHIS to act on the specific proposals, it knew
18 how to say so. Consequently, plaintiffs’ sole argument that the final rule contravenes the 2008
19 Farm Bill because it “utterly fails to carry out the proposed revisions” fails. Dkt. No. 59 at 28.

20 VII. REMEDY

21 Summary judgment is granted to plaintiffs on the PPA-based APA claim. *See* Dkt. No. 1
22 ¶¶ 248-270. The final rule is remanded to the agency for further proceedings consistent with this
23 order.

24 The remaining question concerns vacatur. “Ordinarily when a regulation is not
25 promulgated in compliance with the APA, the regulation is invalid,” *Idaho Farm Bureau Fed. v.*
26 *Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995), and so “[r]emand with vacatur is the typical remedy,”
27 *Natural Grocers*, 627 F. Supp. 3d at 1149 (citing *All. for the Wild Rockies v. U.S. Forest Serv.*,
28 907 F.3d 1105, 1121-22 (9th Cir. 2018)). But the Court may “leave invalid agency action in place

1 when equity demands that we do so.” *Regan*, 56 F.4th at 663 (cleaned up) (quoting *Pollinator*
2 *Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015)). The equitable inquiry requires
3 balancing “the seriousness of the agency’s errors against ‘the disruptive consequences of an
4 interim change that may itself be changed.’” *Id.* (quoting *Cal. Cmty. Against Toxics v. EPA*, 688
5 F.3d 989, 992 (9th Cir. 2012)). Weighing the seriousness of an agency’s errors entails assessing
6 “whether the agency would likely be able to offer better reasoning . . . [such that] it could adopt
7 the same rule on remand, or whether such fundamental flaws in the agency’s decision make it
8 unlikely that the same rule would be adopted on remand.” *Pollinator Stewardship Council*, 806
9 F.3d at 532.

10 APHIS’s errors are significant. For over a decade it believed it should incorporate its
11 noxious-weed authority into its part 340 regulations due to specific concerns APHIS itself
12 identified. The final rule does the opposite without so much as a mention of the concerns
13 identified in the prior NPRMs. This is not an error of a “technical nature.” *Nat’l Fam. Farm*
14 *Coalition*, 966 F.3d at 929. The error undergirding the conventional-breeding exemption is also
15 substantial, for the rule ignores scientific evidence suggesting that its premise is without scientific
16 basis. Consequently, it is unclear that APHIS would “adopt the same rule on remand.” *Pollinator*
17 *Stewardship Council*, 806 F.3d at 532.

18 APHIS says in a single sentence that the Court “should only vacate any portion of the rule
19 applicable to the error found, and not the entire Rule.” Dkt. No. 60 at 40. The point seems
20 sensible enough as it relates to the conventional-breeding exemption, but how partial vacatur
21 would work as to the noxious-weed error is unexplained by the agency. “The Court does not
22 review a party’s motion papers and offer coaching pointers for a second round of briefs. The
23 burden is on the party to make its case in the first instance, as it sees fit.” *In re Google Play Store*
24 *Antitrust Litig.*, 556 F. Supp. 3d 1106, 1108 (N.D. Cal. 2021). APHIS provided no good reason
25 for concluding that something beside the normal remedy of complete vacatur is warranted.

26 Turning to the consequences of vacatur, the record is slight. APHIS says that vacatur
27 “would jeopardize the agency’s regulatory work . . . and require a disruptive switch back to the
28 prior regulatory framework[] after years of reliance on the new one.” Dkt. No. 60 at 40. The

1 jeopardy point is inherent in vacating any regulation, and the agency does not say why that
2 consequence is somehow unusual here. For the disruption comment, APHIS did not point to
3 anything in the record indicating that the ostensible disruption outweighs the seriousness of the
4 rule’s flaws. *See Nat’l Fam. Farm Coalition*, 966 F.3d at 929-30 (observing “there is evidence of
5 potentially serious disruption if a pesticide that has been registered for over five years can no
6 longer be used”); *Ctr. for Food Safety*, 56 F.4th at 668 (noting that “vacating the sulfoxaflor
7 registration would disrupt many agricultural sectors, which could cause ‘yield quantity losses’”);
8 *see also Idaho Farm Bureau Fed.*, 58 F.3d at 1405-06 (looking to the record for possible effects of
9 leaving the rule in place).

10 Intervenor did not fill in the gap. They allege harm to farmers, consumers, GE crop
11 developers, and the agricultural sector generally if the final rule is vacated and the pre-2020
12 regime is restored. *See* Dkt. No. 63 at 7-10. But, despite being agricultural trade associations, *id.*
13 at 1 n.1, intervenors adduced no evidence to support their concerns. As the record currently
14 stands, there is no non-speculative basis for assessing the degree and gravity of disruption if the
15 challenged rule is vacated. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-251 (1986).

16 All that being true, the Court is mindful that the rule took effect in 2020 and that this area
17 of our national agricultural economy is rapidly developing. *See* Dkt. No. 80 at 4 (stating that “at
18 least 99 new GE plants have been exempted” since the rule’s adoption in 2020). With respect to
19 GE organisms that have been introduced or moved without a permit or pursuant to streamlined
20 procedures under the final rule, but that would have had to meet more stringent requirements
21 under the pre-2020 regime, “[t]he egg has been scrambled” and retroactive vacatur “seems an
22 invitation to chaos.” *Sugar Cane Growers Co-op. of Florida v. Veneman*, 289 F.3d 89, 97 (D.C.
23 Cir. 2002).

24 Consequently, the Court concludes that the remedy that best balances the law and that
25 which “equity demands,” *Pollinator Stewardship Council*, 806 F.3d at 532 (quotation omitted), is
26 vacatur of the final rule as of the date of this order. Plaintiffs themselves recognize that this form
27 of vacatur suffices to return the industry and GE-crop regulation to the *status quo ante*. *See* Dkt.
28 No. 59 at 30.

1 **CONCLUSION**

2 Summary judgment is granted to plaintiffs on the PPA-based APA claim that it was
3 arbitrary and capricious for APHIS to not incorporate its noxious-weed authority in the final rule
4 and to implement the conventional-breeding exemptions. Summary judgment is granted to the
5 agency on plaintiffs’ sub-delegation claim³ and 2008 Farm Bill-based APA claim. The final rule
6 is vacated as of the date of this order and is remanded to APHIS for reconsideration consistent
7 with this order. The parties are directed to file by January 13, 2025, a joint statement addressing
8 what effect, if any, this order will have on the rule identifying additional GE organisms qualified
9 for exemption. *See* Movement of Organisms Modified or Produced Through Genetic Engineering;
10 Notice of Additional Modifications Exempt Plants Can Contain, 89 Fed. Reg. 89569 (Nov. 13,
11 2024); Dkt. Nos. 79-80. The parties are also directed to jointly propose a status conference date
12 for the remaining procedural challenges under the ESA and NEPA.

13 **IT IS SO ORDERED.**

14 Dated: December 2, 2024

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17 _____
18 JAMES DONATO
19 United States District Judge

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³ The agency sought summary judgment on this claim, *see* Dkt. No. 60 at 39, and plaintiffs did not
oppose, *see* Dkt. No. 65.

United States District Court
Northern District of California