Nos. 17-70810, 17-70817

United States Court of Appeals for the Ninth Circuit

NATIONAL FAMILY FARM COALITION, ET AL.,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY ET AL.,
Respondents,

DOW AGROSCIENCES LLC,
Intervenor,

NATURAL RESOURCES DEFENSE COUNCIL,
Petitioner,

v.

SCOTT PRUITT, ET AL.,
Respondents,

DOW AGROSCIENCES LLC,
Intervenor.

On Petition for Review of an Order of the Environmental Protection Agency

BRIEF OF INTERVENOR DOW AGROSCIENCES LLC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, intervenor Dow AgroSciences LLC hereby certifies that it is an indirect wholly owned subsidiary of DowDuPont, Inc. No other corporation owns 10% or more of the stock of Dow AgroSciences LLC.

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INTRODUCTION

Twenty-first century technology offers the promise of herbicides that, from both an efficacy and environmental perspective, represent marked improvements over their twentieth century predecessors. The question in this case is whether petitioners can block that promise from being fulfilled.

The product at issue here, Enlist Duo™, is an agricultural herbicide that combines two active ingredients (glyphosate and 2,4-D) that have been registered for use, and widely used, for decades. The Environmental Protection Agency (EPA), which has repeatedly registered and re-registered both ingredients, specifically concluded that their combination in Enlist Duo does not create any harmful synergies, and petitioners do not challenge that conclusion. Nor could they: Enlist Duo represents a marked improvement over the status quo. The product does not simply combine glyphosate with ordinary 2,4-D, but instead with a unique form of 2,4-D (2,4-D choline salt) and other ingredients designed to prevent the product from migrating off treated fields into the environment when applied in accordance with the stringent criteria specified in the federally approved label.

Nonetheless, petitioners challenge the Enlist Duo registration, as most recently amended in early January 2017 for a five-year term. But their grievances are primarily directed toward glyphosate and ordinary 2,4-D, not Enlist Duo. This case, however, is not about glyphosate or ordinary 2,4-D, and will not affect the legal status of either ingredient.

The simple point that Enlist Duo represents a significant improvement over glyphosate and ordinary 2,4-D—both of which will remain registered for use regardless of the outcome of this litigation—dooms petitioners' challenges to the Enlist Duo registration. As a threshold matter, it shows that petitioners lack Article III standing, because they cannot show that the Enlist Duo registration threatens any of their members with an imminent injury traceable to that registration and redressable through this action. On the merits, it shows that all of petitioners' various challenges to the registration fail, because EPA acted lawfully and reasonably, as opposed to arbitrarily and capriciously, by registering an improved herbicide. And from a remedial perspective, it shows that the proper remedy here, in the event this Court were to discern any defect in the registration process, would be a remand to the agency to cure any such defect without vacating the registration.

The irony here is palpable. Enlist Duo, a product that presents significant benefits over the status quo, is being challenged on environmental grounds notwithstanding its environmental benefits. If, as a practical matter, the regulatory and judicial process stymie the approval of such improved products, American agriculture will be forced to continue relying on existing products with a less favorable efficacy and environmental profile, and industry will lose the incentive to innovate. Accordingly, this Court should deny the petitions for review.

STATEMENT OF JURISDICTION

EPA had jurisdiction over this matter under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq*. This Court, however, lacks jurisdiction over these petitions for two separate and independent reasons. *First*, both petitions are untimely, because they were filed more than 60 days after entry of the challenged order. *See infra* Section I.A. *Second*, petitioners have failed to establish Article III standing. *See infra* Section I.B.

STATEMENT OF THE ISSUES

1. Whether the petitions for review are properly before this Court.

2. Whether the Enlist Duo registration complies with FIFRA.

3. Whether the Enlist Duo registration complies with the ESA.

4. Whether remand, rather than vacatur, is the appropriate remedy for any deficiency here.

STATEMENT OF THE CASE AND THE FACTS

A. Original Registration Decision

This case involves an herbicide, Enlist Duo, that combines two active ingredients long approved for use in the United States. 2,4-D has been approved since 1948, while glyphosate has been approved since 1974. ER147; goo.gl/eJuqX6 (last visited Aug. 27, 2018).[1] Neither the 2,4-D nor the glyphosate registration is at issue in this proceeding.

EPA first registered Enlist Duo in October 2014 for use on Enlist™ corn and soybean in six states: Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin. ER1371, 1400. In March 2015, EPA extended that registration to Enlist corn and soybean in nine additional states: Arkansas, Kansas, Louisiana, Minnesota, Missouri, Mississippi, Nebraska, Oklahoma, and North Dakota. ER1055-60.

[1] For convenience, this brief uses shortened website citations from Google URL Shortener.

B. First Round Of Proceedings

Petitioners, various environmental organizations, timely filed petitions for review of the original October 2014 registration order (and, later, the March 2015 amendment) in this Court. *See* Nos. 14-73353, 14-73359, 15-71207, 15-71213 (9th Cir. Oct. 30, 2014 & Apr. 20, 2015). They also filed motions to stay the challenged registration pending appeal, which this Court denied. *See* No. 14-73353 Dkt. 94 at 2 (9th Cir. Aug. 11, 2015) (citing *Winter v. NRDC*, 555 U.S. 7 (2008)).

While those proceedings were pending, EPA discovered that intervenor Dow AgroSciences LLC (Dow) had filed a patent application that claimed certain synergistic effects between glyphosate and 2,4-D that had not been addressed in the prior registration proceedings. ER2-3. At EPA's request, this Court remanded the matter, but declined to vacate the registration. *See* No. 14-73353, Dkt. 128 (9th Cir. Jan. 25, 2016). Thus, the existing registration remained in effect while the agency reconsidered it on remand. Dow subsequently abandoned the patent application that had precipitated the remand. *See* Dow Add.1.

C. Amended Registration Decision

With the Enlist Duo registration once again before it, EPA carefully reviewed all of the evidence relating to potential synergistic effects

between the product's two active ingredients, and reaffirmed its original finding that there was "no evidence of synergism." ER3-4. In essence, the agency concluded that the synergies identified in Dow's (abandoned) patent application were not relevant from a regulatory perspective. ER23. After conducting a "much more scientifically rigorous" quantitative analysis, and reviewing additional data submitted by Dow, EPA concluded that "the combination of 2,4-D choline ... and glyphosate in Enlist Duo does not show any increased toxicity to plants and is therefore not of concern." ER23-24.

Upon reviewing and resolving the synergy issue, EPA on January 12, 2017, issued a Final Registration Decision that contained "three new decisions for Enlist Duo":

> First, EPA is issuing a new decision on the currently registered Enlist Duo for use on GE soybean and corn in 15 states, following the remand decision .... Second, the EPA is granting the approval of Enlist Duo for use on GE soybean and corn in an additional 19 states. Third, EPA is granting a new use for Enlist Duo on GE cotton in 34 states (corresponding with the 15 states previously registered, plus the 19 additional states approved for use of Enlist Duo on GE corn and soybean).

ER2; *see generally* ER1-36. At the same time, EPA (1) issued a Notice of Registration allowing the use of Enlist Duo for five years subject to the

agency's conditions, *see* ER37-49, (2) responded to the comments received in connection with the proposed registration decision, *see* ER50-92, and (3) approved the Enlist Duo label, *see* ER93-113.

In the Registration Decision, EPA weighed Enlist Duo's benefits against its risks (as required by FIFRA), and concluded that the balance warranted the herbicide's registration subject to numerous conditions, including stringent application restrictions set forth on the label. ER28-36. In particular, the label (which carries the force of federal law) was designed to ensure proper use and prevent the product from migrating off treated fields by, among other things:

- requiring use of particular nozzles and pressure to prevent spray drift, *see* ER103-04;
- prohibiting application "at wind speeds greater than 15 mph" and during "[t]emperature inversions," ER104;
- prohibiting application without a 30 foot downwind buffer within the field (subject to a few limited exceptions), *see* ER105;
- prohibiting application "through any type of irrigation system," ER106;
- prohibiting aerial application, *see* ER103, 106-11;
- prohibiting irrigation of treated fields for at least 24 hours after application, *see* ER107;
- prohibiting application if rain is expected within 24 hours, *see id*.

In addition, as part of the registration, EPA required Dow to enter into "grower agreements" with the purchasers of any Enlist seed specifying, among other things, best management practices for use of Enlist Duo. ER45-49. When thus used as directed, EPA concluded, the herbicide warranted registration under FIFRA. ER30 ("After weighing all the risks of concern against the benefits, the EPA finds that with the required mitigation measures on the approved labeling, the risks that may remain are minimal, if they exist at all, while the benefits are potentially great.").

To comply with its additional obligations under the Endangered Species Act (ESA), 16 U.S.C. § 1531 *et seq.*, EPA also assessed Enlist Duo's potential impact on endangered species. Based on an internal EPA database and data submitted by Dow, "531 listed species were identified as inside the 'action area' (area of concern where use of [herbicide] may result in exposure to endangered species) associated with the new … corn, cotton, and soybean uses." ER24. EPA emphasized, though, that "[i]n light of the spray drift mitigation language on the label, the EPA expects that spray drift will remain confined to the 2,4-D choline treated field, and therefore the action area is limited to this field." ER25. "Consequently, 508 of the 531 species originally identified as potentially

at-risk" were given a "no effect" determination because they were "not expected to occur on corn, cotton, or soybean fields." *Id.* EPA then further analyzed whether it could categorically rule out entire taxa, which consist of numerous different species, through a "screening-level risk assessment." ER24-25, 654-78. After concluding that it could not, EPA then proceeded to analyze "species-specific information and migration habits" for the 23 remaining species and made "no effect" determinations for 19 of these species. ER25-26, 655-78.

With respect to the four remaining species, EPA made a Not Likely to Adversely Affect determination for the Eskimo curlew and consulted with the U.S. Fish & Wildlife Service (FWS) regarding that decision. ER25, 669-70. FWS concurred with EPA's determination, thereby rendering any further action unnecessary. *See id.* As for the other three species—Audubon's crested caracara (a bird), the Spring Creek bladderpod (a plant), and the Sonoran pronghorn antelope (a mammal)—EPA imposed label restrictions barring the use of Enlist Duo in these species' specific and isolated habitats. ER25-26, 664-67, 671-73, 678. These restrictions formed the predicate for EPA to make a "no effect" determination for all three species, ER26, thereby rendering consultation

with FWS unnecessary. EPA also separately assessed Enlist Duo's potential impact on habitat designated as "critical" by FWS, and concluded that the registration would not modify any such habitat. *See* ER679-81; *see also* ER978-79.

Notwithstanding its conclusion that the registration of Enlist Duo complied with both FIFRA and the ESA, EPA issued only a 5-year *conditional* registration. As the agency explained, "a 5-year registration is granted so that any unexpected weed resistance issues that may result from the uses can be addressed before granting an extension or the EPA can allow the registration to terminate if necessary." ER30. In addition, a conditional registration was appropriate "[b]ecause data have been identified in the registration review process." *Id.* EPA thus issued a conditional registration as an amendment of the existing Enlist Duo registration under 7 U.S.C. § 136a(c)(7)(B). *See id.*

Petitioners have now filed two separate petitions for review of the 2017 Enlist Duo Registration Decision in this Court. In contrast to their challenges to the previous Enlist Duo registration decision, however, petitioners did not ask this Court to stay the registration pending

resolution of those petitions. Accordingly, Enlist Duo is currently used by farmers in 34 states on Enlist corn, soybean, and cotton crops.

SUMMARY OF ARGUMENT

Petitioners' various challenges to the registration of Enlist Duo fail on multiple grounds.

As a threshold matter, the petitions are not properly before this Court for three reasons. *First*, they were not filed within 60 days of the registration order, and are thus untimely. Because that order took immediate effect for Dow, the registrant, it follows that it also took immediate effect for petitioners: the statutory and regulatory regime does not contemplate bifurcated effective dates. *Second*, petitioners lack standing, because their member declarants have failed to prove that the registration of Enlist Duo threatens them with any imminent injury that can be redressed in this proceeding. And *third*, several of the petitioners have no place of business in this Circuit, and thus no basis for filing petitions here.

On the merits, the Enlist Duo registration complies with FIFRA. The main statutory argument advanced by petitioner Natural Resources Defense Council (NRDC)—that EPA relied on the wrong FIFRA

subsection governing conditional registration—is baseless, as Enlist Duo was not a "new" herbicide in 2017, and the 2017 registration thus properly amended the existing 2014 registration. Similarly, the main statutory main statutory argument advanced by petitioners National Family Farm Coalition *et al.* (collectively NFFC)—that EPA erroneously applied the standard for an unconditional (as opposed to a conditional) registration—shows at most that EPA went above and beyond the statutory floor, as the standard for an unconditional registration is *more* demanding than the standard for a conditional registration. Finally, all of petitioners' various "substantial evidence" challenges fail, as there was ample evidence to adequately support EPA's conclusion that, for FIFRA purposes, the registration of Enlist Duo would not increase the risk of unreasonable adverse effects on the environment.

In addition, the Enlist Duo registration complies with the ESA. As the action agency, EPA had discretion to define the scope of its "action," and did by imposing conditions on the registration, including strict application restrictions on the label. Petitioners have failed to identify anything arbitrary or capricious in EPA's determination, that—given the unique properties of Enlist Duo, which is designed not to migrate off

treated fields—the herbicide would have "no effect" on any endangered species or critical habitat (with the sole exception of the Eskimo curlew, as to which EPA consulted with FWS, which in turn ratified EPA's conclusion that the registration was not likely to adversely affect that species). And because Enlist Duo is designed not to migrate beyond a treated field when used according to the label, EPA did not abuse its discretion in confining the "action area" to such fields. In particular, EPA explained why Enlist Duo would have no effect on either the whooping crane or the Indiana bat, and petitioners identify nothing arbitrary or capricious about those explanations. Far from conflating its roles under FIFRA and the ESA, EPA used conservative assumptions to derive its calculations for ESA purposes, which it then used to ensure that there would be *no* effect on a listed species or critical habitat (as opposed to merely determining, under the FIFRA standard, that there would be no *unreasonable* adverse effect). What petitioners characterize as EPA's "admission" that the Enlist Duo registration would have an effect on listed species is nothing more than EPA's recognition that it could not categorically rule *out* an effect at preliminary stages of the analysis—not that it was ruling *in* an effect. Petitioners' contention that EPA failed to

use the "best" scientific and commercial data, meanwhile, founders on their failure to identify any better data that the agency ignored.

Finally, even assuming that this Court were to identify any deficiency with the Enlist Duo registration, the proper remedy would be to remand the matter to the agency without vacating the registration. Here, the equitable balance tips decidedly against vacatur, because EPA could cure any deficiency, while vacating the Enlist Duo registration would be enormously disruptive to American agriculture and would leave farmers with no option but to use other less effective herbicides with a less favorable environmental profile.

ARGUMENT

I. THE PETITIONS FOR REVIEW ARE NOT PROPERLY BEFORE THIS COURT.

A. The Petitions For Review Are Untimely.

The statute governing judicial review of EPA herbicide registration orders could not be any clearer: a petition for review of such an order must be filed "within 60 days after the entry of such order." 7 U.S.C. § 136n(b). Here, the order was entered on January 12, 2017. ER37. However, petitioners did not file their petitions for review until March 21, 2017—68 days later. *See* No. 17-70810 Dkt. 1 (NFFC petition); No.

17-70817 Dkt. 1 (NRDC petition). Accordingly, under the statute's plain language, the petitions are untimely.

Petitioners attempt to avoid that conclusion by citing an EPA regulation specifying that *"[u]nless the Administrator otherwise explicitly provides in a particular order*, the time and date of entry of an order … shall be … on the date that is two weeks after it is signed." 40 C.F.R. § 23.6 (emphasis added). Here, according to petitioners, the relevant order was merely "signed" on January 12, 2017, but not "entered" until "fourteen days later, on January 26, 2017." NRDC Br. 5; *see also* NFFC Br. 3.

The problem with that argument, as Dow explained in its motion to dismiss for lack of jurisdiction [Dkt. 16-1], is that the Notice of Registration—the legally operative order here, akin to a license—*did* "explicitly provide[]" a different "date of entry"—January 12, 2017. 40 C.F.R. § 23.6. That date is right on the face of the Notice, in a data field entitled "Date of Issuance." ER37. The Date of Issuance is not merely the date on which the order was signed; to the contrary, there is a *separate* data field at the bottom right hand corner of the same page to record the date of signing. *See id.* Rather, the Date of Issuance is the

effective date of the registration, and entitled Dow to begin distributing or selling Enlist Duo as of that date. *See id.* ("[T]he above named [herbicide] *is hereby registered* under [FIFRA]."") (emphasis added); *see also* 40 C.F.R. § 152.130(a) ("A registrant may distribute or sell a registered product ... currently approved by the Agency."). Indeed, EPA itself has conceded that the registration order at issue here took effect for Dow on its "Date of Issuance," January 12, 2017. *See* Dkt. 24, at 3.

Petitioners attempt to dodge this point by positing that there are two different effective dates for the single Enlist Duo registration: one for Dow (January 12, 2017), and another one for them (January 26, 2017). But nothing in the text of the statute or regulation purports to bifurcate the "date of entry" in this manner. Indeed, such bifurcation would create a regulatory "black hole" where an herbicide registration is effective with respect to a registrant for two weeks (thereby allowing the herbicide's distribution, sale, and use), but not effective with respect to a challenger (thereby precluding judicial review) during that period. That position makes no sense: if a registration is ripe for the registrant to begin selling the product, it is ripe for a challenger to seek judicial review. Because the January 12, 2017 Notice of Registration by its terms took immediate

effect, petitioners' 60-day clock for seeking judicial review started on that date, and the petitions for review are untimely.[2]

B. Petitioners Lack Article III Standing.

Even assuming the petitions were timely filed, this Court still lacks subject-matter jurisdiction because petitioners lack Article III standing. "A suit brought by a plaintiff without Article III standing is not a 'case or controversy,' and an Article III federal court therefore lacks subject matter jurisdiction over the suit." *City of Oakland v. Lynch*, 798 F.3d 1159, 1163 (9th Cir. 2015) (internal citation omitted). As petitioners concede, a prerequisite for organizational standing is for "at least one identified member" to have standing to sue in his or her own right. *Summers v. Earth Island Inst.*, 555 U.S. 488, 498 (2009); *see also* NRDC

[2] This jurisdictional issue was fully briefed before a motions panel, which denied Dow's motion to dismiss for lack of subject-matter jurisdiction "*without prejudice* to renewing the arguments in the answering brief." Dkt. 43 (emphasis added). Accordingly, this merits panel has not only the power but the duty to address this jurisdictional issue. *See, e.g.*, *Hiivala v. Wood,* 195 F.3d 1098, 1104 (9th Cir. 1999). And that duty is unaffected by the fact that, in another case raising the same jurisdictional issue, the Appellate Commissioner discharged an order to show cause why the appeal should not be dismissed. *See National Family Farm Coalition v. EPA*, No. 17-70196, Dkt. 23 (9th Cir. Mar. 17, 2017). Needless to say, the Appellate Commissioner, whose role is "analogous to a magistrate judge in the district court," goo.gl/QMNXcJ (last visited Aug. 27, 2018), does not establish binding circuit law.

Br. 49; NFFC Br. 2. Thus, where, as here, an organization seeks relief to prevent an asserted future injury, it must show that at least one of its members "is under threat of suffering 'injury in fact' that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the defendant; and it must be likely that a favorable judicial decision will prevent or redress the injury." *Summers*, 555 U.S. at 493; *see also Clapper v. Amnesty Int'l, USA*, 568 U.S. 398, 409 (2013).

Here, neither NRDC nor NFFC has identified any member who meets these Article III standing requirements. Because this case comes to this Court on petitions for review of agency action, petitioners have never before been required to establish Article III standing. *See*, *e.g.*, *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002). Accordingly, they have attached to their opening briefs several declarations from their members purporting to establish standing. *See* NRDC Add.49-75; NFFC Add.92-155. In this procedural posture, "petitioners have the burden to demonstrate a 'substantial probability' of standing," *Northwest Requirements Utils. v. FERC*, 798 F.3d 796, 805 (9th Cir. 2015) (quoting *Sierra Club*, 292 F.3d at 898-99), which is "the same [burden] as that of

a plaintiff moving for summary judgment in the district court," *Sierra Club*, 292 F.3d at 899. Petitioners thus need to *prove* their standing, and mere *allegations* will not suffice. *See, e.g.*, *Gill v. Whitford*, 138 S. Ct. 1916, 1923, 1929, 1931 (2018). As explained below, petitioners' member declarations fail to establish standing.[3]

1. The NRDC Declarations

Each of NRDC's member declarations avers generally that the member was injured by the Enlist Duo registration because the member is "concerned" about (1) personal and/or family health risks as a result of potential exposure to Enlist Duo, and (2) the threat to monarch butterflies based on a decline in milkweed that the members attribute to Enlist Duo, *see* NRDC Add.50-75; *see generally* NRDC Br. 50 ("NRDC members suffer at least two injuries from the Enlist Duo registration: [1] health risks from potential exposure to Enlist Duo and [2] diminished enjoyment of their natural environment resulting from loss of monarch

[3] As a threshold matter, this Court can dismiss petitioner Family Farm Defenders for lack of standing without further ado, because *no one* affiliated with that organization—neither a leader nor a member—filed a declaration. *See, e.g.*, *New Mexico ex rel. Richardson v. BLM*, 565 F.3d 683, 696 n.13 (10th Cir. 2009) ("Because no member of the remaining organizations submitted a declaration …, they lack standing.").

butterflies."). None of these declarations satisfies the Article III standing requirements on either ground.

a. Human Health Risks

According to NRDC, its declarants "live in areas where Enlist Duo is registered for use and … *risk* exposure to the [herbicide] during their daily activities." NRDC Br. 50 (emphasis added). But the declarations show that any such "risk" is entirely attenuated and speculative. No declarant identifies any past, present, or imminent future exposure to Enlist Duo. *See*, *e.g.*, NRDC Add.51 ("I have noticed the farms nearby use a sprayer attached to a big tractor. I tried to find out which pesticides they use but couldn't get an answer."); NRDC Add.52 ("I believe that pesticides from adjacent fields—*possibly* including Enlist Duo—*could* get into our water supply.") (emphasis added); NRDC Add.59 ("My property is situated near large agricultural fields planted with soybeans and corn. I am aware that chemicals are being sprayed on these fields, even though I do not know the exact identity of those substances. I have seen machines spraying chemicals … even when winds are blowing at higher speeds."); NRDC Add.69-70 ("I have seen pesticides being sprayed on the corn and soybean fields near my home. … I have also seen crop-dusting

planes spraying pesticides on the fields two miles from my home."); *see also* NRDC Br. 50 (declarants are "reasonably concerned that exposure to Enlist Duo *may* harm them") (emphasis added).

These declarations do not come close to establishing an injury-in-fact from exposure to Enlist Duo; rather, at most the declarations establish that the declarants are concerned about *potential* exposure. But such concern is not sufficient to establish a cognizable injury-in-fact; petitioners must allege that they *have* been exposed or face an "imminent" threat of exposure. *See*, *e.g.*, *Clapper*, 568 U.S. at 409. Thus, in *Clapper*, the Supreme Court rejected the argument that plaintiffs had Article III standing to challenge a government surveillance program where they could not show that they had been surveilled or faced an imminent threat of surveillance. *See id.* at 410-22. "Although 'imminence' is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is *certainly* impending." *Id.* at 409 (emphasis in original) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 564 n.2 (1992)). Indeed, *Clapper* rejected an "objectively reasonable likelihood" of injury standard as "inconsistent

with our requirement that threatened injury must be *certainly* impending to constitute injury in fact." *Id.* at 410 (emphasis added; internal quotation omitted).

The NRDC declarants have not demonstrated any "imminent" or "*certainly* impending" exposure to Enlist Duo. In particular, they provide no factual basis for concluding that *if* any pesticide or herbicide applied in the vicinity of their homes is indeed Enlist Duo, it is being applied in a manner that will expose them or their families to imminent harm. *See*, *e.g.*, *Nuclear Info. & Res. Serv. v. NRC*, 457 F.3d 941, 954 (9th Cir. 2006) ("generalized concern" about human health risks not enough to establish injury-in-fact). The Enlist Duo label, after all, imposes stringent application restrictions designed to prevent the product from migrating beyond a treated field, *see* ER103-12, and the NRDC declarants have identified no reason (beyond speculation) to suppose that those restrictions would fail to protect them from exposure, much less exposure at a potentially harmful level.

Indeed, the potential exposure posited by the NRDC declarants would necessarily entail use of Enlist Duo in contravention of its federally approved label, and thus contrary to federal law. *See*, *e.g.*, 7 U.S.C.

§ 136j(a)(2)(G); 40 C.F.R. § 156.10(i)(2)(ii) ("It is a violation of Federal law to use this product in a manner inconsistent with its labeling."); ER100 (same). As EPA explained, "applications [of Enlist Duo] will *not* result in direct exposures to individuals, since such contact would constitute a misuse." ER59 (emphasis added). Needless to say, petitioners cannot establish standing by positing exposures predicated on violations of law by third parties, such as spraying "when winds are blowing at higher speeds," NRDC Add.59, or from "crop-dusting planes," NRDC Add.69-70; *cf.* ER104 ("Do not apply at wind speeds greater than 15 mph."); ER103 ("**Do not aerially apply this product**."). Under Article III, a court cannot "endorse standing theories that rest on speculation about the decisions of independent actors," *Clapper*, 568 U.S. at 414, much less speculation that independent actors will violate the law.

Because the NRDC declarants *at most* establish a "possib[ility]" of future exposure and injury that is "highly speculative and … not certainly impending," they have failed to establish Article III injury-in-fact with respect to their human health concerns. *Coons v. Lew*, 762 F.3d 891, 898 (9th Cir. 2014); *see also Clapper*, 568 U.S. at 416 ("[Litigants] cannot manufacture standing merely ... based on their fears of

hypothetical future harm that is not certainly impending."); *Habeas Corpus Res. Ctr. v. Department of Justice*, 816 F.3d 1241, 1251 (9th Cir. 2016) (denying standing where plaintiffs "face no 'certainly impending' harm ….").[4]

And that is not all. Even if the NRDC declarants had established the requisite injury-in-fact, they have not established that any such injury is fairly traceable to the registration of Enlist Duo or would be redressed by vacating that registration. "[T]he 'fairly traceable' and 'redressability' components for standing overlap and are two facets of a single causation requirement." *Washington Envtl. Council v. Bellon*, 732 F.3d 1131, 1141 (9th Cir. 2013) (internal quotation omitted). To satisfy these requirements, plaintiffs must show that the causal link between their alleged injury and the defendant's challenged conduct is "more than

[4] The cases on which NRDC relies, *see* NRDC Br. 51, are readily distinguishable. In *NRDC v. EPA*, 735 F.3d 873, 875, 878 (9th Cir. 2013), this Court held that the petitioners had standing to challenge a pesticide registration decision where exposure was inevitable "in light of the *expansive* scope of permissible applications" of the pesticide. *Id.* (emphasis added). Here, the NRDC declarants have not shown that exposure to Enlist Duo is similarly likely. And in *Central Delta Water Agency v. United States*, 306 F.3d 938, 948-49 (9th Cir. 2002), plaintiffs submitted extensive empirical evidence showing that harm was certainly impending. Such evidence is conspicuously absent from the NRDC declarations here.

attenuated," *id* (internal quotations omitted), so that the alleged injury could be redressed by a favorable judicial decision. Each of the declarants expresses concerns about glyphosate or ordinary 2,4-D, not any concern unique to Enlist Duo. NRDC Add.59, 60, 70. But both glyphosate and ordinary 2,4-D have long been registered for use, and the validity of those registrations is not at issue here. Accordingly, it is speculative to conclude that the registration of Enlist Duo (which, if anything, has a *more* favorable environmental profile than either glyphosate or ordinary 2,4-D individually) threatens the declarants with any injury traceable to that registration, or that could be redressed in this proceeding. *See*, *e.g.*, *Washington Envtl.*, 732 F.3d at 1141-47; *Salmon Spawning & Recovery Alliance v. Gutierrez*, 545 F.3d 1220, 1227-29 (9th Cir. 2008).

b. Harm To Monarch Butterflies

According to NRDC, its declarants "enjoy observing, studying, and interacting with monarch butterflies," and are injured because "EPA's registration of Enlist Duo is likely to exacerbate milkweed and monarch decline." NRDC Br. 51. While the NRDC declarants state that they enjoy observing the monarch butterfly (which is not an endangered species), the declarations fail to establish that the registration of Enlist Duo (as

opposed to existing uses of glyphosate and ordinary 2,4-D, or other causes) has injured the species, or that this litigation can redress any such injury. Thus, the declarants state generally that "Enlist Duo kills milkweed, the only source of food for the monarch caterpillar, and … glyphosate and 2,4-D have been linked to the decline of the monarch populations." NRDC Add.53; *see also* NRDC Add.61, 72.

As a threshold matter, the factual premise of these declarations is mistaken: there has *not* been a "nearly ninety percent" decline in the monarch population over the past twenty years, NRDC Add.61, and any such decline could not possibly be attributed to Enlist Duo, which has been registered for use for less than four years, *see* Bus Decl. ¶ 16, Dow Add.9-10. Historically, the monarch population has not remained steady from year to year; rather, it has fluctuated wildly as a result of numerous factors including the weather and deforestation in Mexico. *See id.* ¶¶ 16-17, Dow Add.9-10.[5] NRDC and its declarants arrive at the more alarmist

[5] NRDC itself acknowledges—as it must—the impact of these multiple factors on monarch butterfly population from year to year. *See* NRDC Br. 20-21. "Severe storms occur periodically," inflicting massive damage on the monarch butterfly population—including wiping out 70 and 50 percent, respectively, of the monarch population in 2004 and then in 2010—along with additional stressors such as "freezing temperatures, disease, predation, and deforestation." *Id.*

figures only by cherry-picking the data, selecting the one year in the past twenty in which the monarch population was at its zenith (1996-97), and the one year in which it was at its nadir (2013-14), and thereby suggesting a steady decline between those years. *See* NRDC Br. 17-18 ("[T]he long-term trend of decline is clear."). But even cursory review of the data shows that there has been no such steady decline. *See* ER409; Bus Decl. ¶ 16, Dow Add.9-10. To the contrary, the data show that the monarch population has zig-zagged wildly over that period, with no apparent correlation with the use of any particular pesticide or herbicide—much less Enlist Duo, which was not even registered until 2014. *See id.* ¶¶ 16-17, Dow Add.9-10. Indeed, the monarch population actually *increased* from 2014 to 2015, *after* registration of Enlist Duo, and then significantly recovered from 2015 to 2016, *see id.* ¶¶ 15-16, Dow Add.8-10—facts NRDC conveniently ignores.

And even if NRDC had established an Article III injury-in-fact based on harm to the monarchs, it has not remotely established that any such injury is traceable to the registration of Enlist Duo, and could be redressed in this proceeding. As noted above, the monarch butterfly population has *increased*, not *decreased*, since the registration of Enlist

Duo in 2014, and has been affected by myriad factors unrelated to the registration of Enlist Duo. *See* Bus Decl. ¶¶ 15-17, Dow Add.8-10. Because petitioners cannot deny this fact, they instead attribute the alleged decline in the monarch butterfly population—insofar as caused by herbicide use—to glyphosate and ordinary 2,4-D. But Enlist Duo is more than simply a combination of glyphosate and ordinary 2,4-D; rather, it a combination of glyphosate, 2,4-D choline, and other special ingredients designed to prevent migration off a treated field through spray drift and volatilization. ER28. It is telling, thus, that (as with the alleged effects on human health) NRDC and its declarants attribute the alleged harm to monarch butterflies *not* to Enlist Duo, but to glyphosate and/or ordinary 2,4-D—neither of which is at issue in this proceeding. *See* NRDC Add.53, 61, 72; *see generally* NRDC Br. 16 ("*Glyphosate* use has already decimated a substantial portion of the milkweed on which monarchs rely.") (emphasis added). NRDC's suggestion that, notwithstanding these "numerous independent sources" of its members' alleged monarch-related injury, the Enlist Duo registration will "contribute ... in some undefined way and to some undefined degree" to that injury is simply too speculative to establish standing. *Washington*

Envtl., 732 F.3d at 1143; *see also Salmon Spawning*, 545 F.3d at 1227-29.

2. The NFFC Declarations

The NFFC member declarations fall into two categories. Four of them (Buse, Crouch, Limberg, and Suckling) state that they enjoy interacting with particular species listed as endangered under the ESA, and are concerned about the impact of Enlist Duo on those species. *See*, *e.g.*, NFFC Add.104-05; *see also id.* at 154-55. And one of them (Pool) states that he operates an organic vineyard, and is concerned about the impact on his crops of Enlist Duo migrating from other fields. NFFC Add.146-47. These member declarations fail to establish Article III standing for the same reasons as the NRDC member declarations.

a. Harm To Endangered Species

Insofar as the NFFC declarants assert that they are injured because "EPA's challenged actions *threaten* to directly injure [their] members' environmental, recreational, [and] aesthetic" interests in endangered species, NFFC Br. 2 (emphasis added), their alleged injuries are too vague and speculative to give rise to an Article III injury-in-fact. None of the NFFC declarants states that any endangered species has been exposed to Enlist Duo, or that any such exposure is "imminent" or

"*certainly* impending." *Clapper*, 568 U.S. at 409 (emphasis in original). To the contrary, the declarations express generalized concerns about pesticides and herbicides that are either factually unsupported, unrelated to Enlist Duo, or both. *See* NFFC Add.97 ("Killing of non-target insects and plants by pesticides and herbicides is well-documented, and I fear that Indiana bats are being inadvertently killed and harmed by agricultural chemicals."); NFFC Add.105 ("[W]hooping cranes] also stop over in crop fields in the spring, where they have the potential to be exposed to toxic agricultural chemicals."); *id.* ("[I]t is possible that food and water sources ... could or will have very high residues of 2,4-D on them ...."); NFFC Add.136 ("Enlist Duo is more alarming than any other pesticides I have seen in the past with regard to the health hazards the pesticide poses to Indiana bat populations."); NFFC Add.152-53 ("If Enlist Duo is applied on these or new fields and reaches the rivers through direct spraying, run off or drift, the [Southwestern willow] flycatcher could be harmed, killed, or even locally extirpated."); NFFC Add.153-54 (same for yellow-billed cuckoo and Chiricahua leopard frog).

These assertions fail to establish a present or imminent injury as a result of the Enlist Duo registration—they either do not relate to Enlist Duo, or do not address EPA's conclusion that Enlist Duo will *not* migrate beyond treated fields at a level that may affect non-target organisms. ER25, 640. "[S]ubjective fear[s]" are not enough to establish standing. *Clapper*, 568 U.S. at 1153. No explanation is furnished as to why Enlist Duo is "more alarming" than other pesticides or herbicides, nor are the other pesticides or herbicides the declarant has "seen in the past" named as a point of comparison. NFFC Add.136. The fear that Enlist Duo will be sprayed "direct[ly]" into rivers, NFFC Add.152-54, meanwhile, cannot be taken seriously in light of the binding label restrictions on the herbicide's use. *See* ER94 ("This pesticide is toxic to fish and aquatic invertebrates. *Do not apply directly to water*, to areas where surface water is present, or to intertidal areas below the mean high water mark.") (emphasis added). Collectively, these asserted injuries are wholly conjectural.

Separately, by failing to provide adequate specificity in their declarations, the NFFC declarants fail to satisfy either the causation or redressability requirements. Indeed, the declarations are replete with

references to *other* pesticides, herbicides, and agricultural chemicals as alleged culprits for the plight of the various endangered species at issue. The declarations never explain why the registration of Enlist Duo would make the situation worse, as opposed to better, with respect to the baseline of currently registered pesticides. And this point is only underscored by the declarants' recognition of multiple other stressors on the endangered species at issue. *See*, *e.g.*, NFFC Add.135 ("I know that contributions to the Indiana bat's decline include disturbance from humans during winter hibernation, commercialization of caves, loss of summer habitat, pesticides and other contaminants, and the disease commonly known as white-nose syndrome."). Moreover, without knowing which other herbicides the NFFC declarants believe are less deleterious than Enlist Duo, it is impossible to deem the causation and redressability requirements satisfied, given the myriad other registered products that use glyphosate or 2,4-D in one form or another, or other pesticides or herbicides in general.

b. Harm To Crops From 2,4-D

The only remaining injury asserted by an NFFC member declarant is "drift damage from *2,4-D*" to his crops. NFFC Add.144 (emphasis

added).[6] But Enlist Duo is not 2,4-D, and the registration of 2,4-D is not at issue here. Indeed, the declarant, Eric Pool, never alleges any injury from Enlist Duo, which (unlike ordinary 2,4-D products) is designed *not* to migrate off the treated field. ER28. Pool does not even purport to explain how he faces any injury traceable to Enlist Duo, as opposed to ordinary 2,4-D products. Nor does he explain how this proceeding, which does not involve the registration of ordinary 2,4-D, could redress any such injury.

C. This Court Is Not The Proper Venue For Several Petitioners.

Finally, three of the six NFFC petitioners—National Family Farm Coalition, Family Farm Defenders, and Beyond Pesticides—have no basis for seeking review of EPA's registration decision in this Circuit, as they neither reside nor have a place of business here. *See* 7 U.S.C.

[6] Several leaders of NFFC petitioner organizations also invoke the alleged concerns of unspecified members over drift damage from 2,4-D on their crops. *See*, *e.g.*, NFFC Add.110, 117, 123 130. This Court can and must disregard such hearsay statements, which have "no more force under the summary judgment standard we apply than if [they] were alleged in a complaint." *Association of Flight Attendants-CWA, AFL-CIO v. Department of Transp.*, 564 F.3d 462, 465-66 (D.C. Cir. 2009). That is why, in this procedural posture, individual member declarations are necessary. *See id.*

§ 136n(b) (petition for review of EPA pesticide or herbicide registration decision must be filed "in the United States court of appeals for the circuit wherein [the petitioner] resides or has a place of business").

These three petitioners sought to evade that statutory limitation by "piggy-backing" on the petition filed by three other petitioners that have offices in this Circuit, and are thus entitled to file here. *See*, *e.g.*, NFFC Br. 2 n.2 (asserting that "[v]enue is proper because NFFC Petitioners *include* organizations that reside and/or have places of business within this Circuit") (emphasis added). Nothing in the statute, however, authorizes such "piggy backing." To the contrary, the statute authorizes an aggrieved person to seek review of an herbicide registration decision in a circuit where "*such* person" resides or has a place of business. 7 U.S.C. § 136n(b) (emphasis added). There is no way to interpret "such" person to refer to some "other" person, and any such interpretation would vitiate the statute's venue requirement and allow forum-shopping. And if the out-of-circuit petitioners had filed petitions in their own circuits, as required, they would have triggered a lottery to send all the petitions to a single circuit (which may or may not have been this one). *See* 28 U.S.C. § 2112(a)(3).

Accordingly, Dow filed a motion to dismiss the non-resident petitioners or, in the alternative, to transfer in part and trigger the lottery. *See* Dkt. 15-1. A motions panel denied that motion "without prejudice to renewing the arguments in the answering brief." Dkt. 43. Because the non-resident petitioners have no basis for seeking review in this Court, this panel should either dismiss those petitioners or transfer their petitions to another circuit and thereby trigger the lottery.

II. THE ENLIST DUO REGISTRATION COMPLIES WITH FIFRA.

Both petitioners' opening briefs contend that the Enlist Duo registration violates FIFRA on various grounds. *See* NRDC Br. 35-49; NFFC Br. 56-65. They are wrong on all scores.

A. EPA Was Entitled To Issue A Conditional Registration Under FIFRA Because It Amended The Existing Enlist Duo Registration.

NRDC leads with the extraordinary argument that the Enlist Duo registration must be vacated because EPA relied on the wrong subsection of FIFRA governing conditional registration. *See* NRDC Br. 35-43. That argument presents a question of law subject to *de novo* review, *see Ayala-Chavez v. INS*, 944 F.2d 638, 641 (9th Cir. 1991), although any such legal

error may be dismissed as harmless, *see*, *e.g.*, *Sagebrush Rebellion, Inc. v. Hodel*, 790 F.2d 760, 764 (9th Cir. 1986).

According to NRDC, Enlist Duo is a "new" herbicide, *see* NRDC Br. 2, 3, 6, 10, 30, 35, 36, and thus could only have been conditionally registered under subsection (c)(7)(**A**), which allows conditional registrations of new herbicides, as opposed to subsection (c)(7)(**B**), which allows amendments to existing herbicide registrations. Putting aside the fact that there is no difference between the substantive registration standards under these two subsections—both require EPA to determine that the relevant herbicide "would not significantly increase the risk of any unreasonable adverse effect on the environment," 7 U.S.C. §§ 136a(c)(7)(A),(B)—the premise of NRDC's argument is demonstrably incorrect: the 2017 registration at issue here amended the existing Enlist Duo registration.

NRDC contends that the January 2017 Registration Decision could not have been an amendment of the existing Enlist Duo registration because there was "no valid, preexisting registration of Enlist Duo," and thus "no lawful, previously approved uses of Enlist Duo." NRDC Br. 36. But that is simply not true. To the contrary, EPA first registered Enlist

Duo in October 2014, and amended that registration in March 2015. *See* ER1401 (October 15, 2014 registration); ER1019 (March 31, 2015 amendment). Petitioners challenged that registration and amendment in this Court but, while that proceeding was pending, this Court remanded *without* vacating the pending registration. *See* No. 14-73353, Dkt. 128 (9th Cir. Jan. 25, 2016); *see generally* NRDC Br. 25 (acknowledging that "the Court granted the motion for remand but denied vacatur"). Accordingly, as EPA recognized, "*the registration … remained in effect* while the agency determined whether *changes to the registration* were necessary." ER3 (emphasis added).

Because this Court remanded the matter without vacating the original registration, EPA subsequently was able to amend that registration. NRDC does not, and cannot, deny that subsection (c)(7)(B) authorizes EPA to amend an *existing* registration. *See* NRDC Br. 39. That simple point is the beginning and the end of the matter.

NRDC insists, however, that "[t]he registration challenged here is the only operative registration for Enlist Duo, because it supersedes EPA's earlier registration orders, which this Court remanded to the agency." NRDC Br. 36. That assertion is a *non sequitur*: EPA can amend

an existing registration order by replacing it with a new order. Thus, the fact that EPA chose to issue "a new decision on the currently registered Enlist Duo™" in 2017, ER2, does not mean that Enlist Duo was a new herbicide in 2017; it means only that Enlist Duo received a new registration in 2017. Accordingly, NRDC's argument that "*new* [*herbicides*] do not qualify for registration under § 136a(c)(7)(B)," NRDC Br. 36 (emphasis added), misses the point.

Given the record in this case, NRDC's insistence that "[t]here [was] no valid, preexisting registration of Enlist Duo for EPA to 'amend'" in 2017, *id.*, is inexplicable. There most certainly *was* a valid, preexisting registration of Enlist Duo for EPA to amend in 2017, and indeed Dow sold (and farmers used) Enlist Duo pursuant to that registration—acts that would have been violations of federal law in the absence of a valid registration. *See* 7 U.S.C. §§ 136j(a)(1)(A), 136j(a)(2)(G). And because Enlist Duo was *not* a new herbicide in 2017, it would have been nonsensical for EPA to conditionally register Enlist Duo as a new herbicide in 2017.

In any event, NRDC's argument about the distinction between conditional registration under subsections (c)(7)(A) and (c)(7)(B) is much

ado about nothing. NRDC does not, and cannot, contend that there is any substantive difference between the standard for conditional registration under those two subsections: both require EPA to determine, before issuing a conditional registration, that the proposed herbicide "would not significantly increase the risk of any unreasonable adverse effect on the environment." 7 U.S.C. §§ 136a(c)(7)(A),(B). As long as EPA satisfied that substantive standard, it makes no difference whether the agency invoked the wrong subsection: administrative law is not a game of "gotcha." In other words, the error alleged by NRDC is at most harmless, and a remand "'would be an idle and useless formality.'" *Li Hua Yuan v. Attorney Gen. of U.S.*, 642 F.3d 420, 427 (3d Cir. 2011) (quoting *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n.6 (1969)); *see also Sagebrush Rebellion*, 790 F.2d at 764.

B. EPA Satisfied FIFRA's Requirements For A Conditional Registration.

In passing, NFFC makes an even more startling argument: that EPA violated FIFRA by "appl[ying] the *unconditional* registration standard" to a *conditional* registration. NFFC Br. 58 (emphasis in original). This, again, is a legal argument subject to *de novo* review and harmless-error analysis. *See*, *e.g.*, *Sagebrush Rebellion*, 790 F.2d at 764.

It is certainly true, as NFFC notes, that the substantive standards for unconditional and conditional registrations differ. To issue an *unconditional* registration, EPA must determine that an herbicide would not have "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5). To issue a *conditional* registration, in contrast, the agency need only determine that an herbicide "would not significantly increase the *risk* of any unreasonable adverse effect on the environment." *Id.* § 136a(c)(7)(A), (B) (emphasis added).

Thus, while it is true that the standards for unconditional and conditional registration differ, the difference is that the unconditional registration standard is *more* demanding. *See*, *e.g.*, *Ellis v. Housenger*, 252 F. Supp. 3d 800, 822-23 (N.D. Cal. 2017). To satisfy that standard, the agency must make an actual determination about an herbicide's environmental effects. To satisfy the conditional registration standard, in contrast, the agency need only assess the *risk* of such effects. Needless to say, the agency needs more information, and more confidence in the information, to determine that an herbicide will *have* no unreasonable adverse effects than to determine only that an herbicide will not significantly increase the *risk* of unreasonable adverse effects. That is

precisely why an unconditional registration is unconditional—*i.e.*, no strings attached. A conditional registration, in contrast, is conditioned upon the submission of additional data; it is conditional precisely because the "data concerning the [herbicide] may be insufficient to support an unconditional amendment." 7 U.S.C. § 136a(c)(7)(B); *see also id.* § 136a(c)(7)(C).

It is thus perverse for NFFC to complain that "EPA applied the *unconditional* registration standard: that Enlist Duo will not 'generally cause unreasonable adverse effects.'" NFFC Br. 58 (quoting ER30; emphasis in original). Insofar as EPA applied the unconditional registration standard, it went above and beyond what it was required to do. NFFC thus get matters exactly backwards by complaining that "EPA must support with substantial evidence not only that the Enlist Duo formulation will not affirmatively and generally cause unreasonable adverse effects, but that substantial evidence supports that [Enlist Duo] will not even *increase the risk* of such unreasonable adverse effects occurring." *Id.* at 59 (emphasis in original). An affirmative determination that an herbicide will not have unreasonable adverse effects on the environment *a fortiori* encompasses a determination that

the herbicide will not significantly increase the *risk* of such unreasonable adverse effects. Accordingly, if anything, EPA held Dow to a higher standard than necessary in registering Enlist Duo in 2017, and NFFC has no grounds for complaint.

C. The Registration of Enlist Duo Is Supported By Substantial Evidence.

Both NRDC and NFFC also challenge the Enlist Duo registration as unsupported by "substantial evidence." *See* NRDC Br. 43-49; NFFC Br. 59-65; *see generally* 7 U.S.C. § 136n(b) ("The order of the Administrator shall be sustained if supported by substantial evidence when considered on the record as a whole."). The scope of judicial review in this regard is sharply limited. "Substantial evidence means more than a mere scintilla but less than a preponderance; it is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *NRDC v. EPA*, 857 F.3d 1030, 1036 (9th Cir. 2017) (internal quotation omitted). Under this deferential standard, a reviewing court must uphold an agency's decision "even if it is possible to draw two inconsistent conclusions from the evidence," as long as the agency's decision is grounded in "relevant evidence [that] a reasonable mind might accept as adequate to support a conclusion." *Id.* (internal quotation

omitted). And this deference is heightened where, as here, "the agency is making predictions, within its area of special expertise, at the frontiers of science"—a reviewing court may not substitute its "judgment for the agency's in determining which scientific data to credit, so long as the [agency's] conclusion is supported by adequate and reliable data." *Friends of Santa Clara River v. Army Corps of Eng'rs*, 887 F.3d 906, 921 (9th Cir. 2018) (internal quotation and brackets omitted); *see also North Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1075 (9th Cir. 2011) ("The court is not to act as a panel of scientists that instructs the [agency] ..., chooses among scientific studies ... and orders the agency to explain every scientific uncertainty.") (internal quotation omitted).

1. Substantial Evidence Supports EPA's Conclusion That Enlist Duo Will Not Significantly Increase The Risk Of Any Unreasonable Adverse Effect On The Monarch Butterfly.

NRDC first argues that EPA lacked "substantial evidence" to register Enlist Duo "because it ignored evidence that the [herbicide's] new uses of 2,4-D would harm the imperiled monarch population through destruction of additional milkweed habitat." NRDC Br. 43; *see also id.* at 44-47. That argument is baseless: EPA *expressly considered* the evidence regarding the impact of Enlist Duo's 2,4-D choline ingredient on non-

target terrestrial plants (which include milkweed outside a treated field), and hence on monarch butterflies. *See* ER63-64, ER644-49.

In a nutshell, EPA concluded that the choline in Enlist Duo's 2,4-D ingredient, combined with the stringent use restrictions on the Enlist Duo label, would prevent any unreasonable adverse effect on non-target terrestrial plants (including milkweed outside a treated field). *See* ER63, ER644-49. That is because, as noted above, the 2,4-D choline (accompanied by the stringent use restrictions) and the Enlist Duo formulation will prevent the product from migrating off a treated field at a level that may affect non-target organisms. *See id.* EPA also concluded that the monarchs themselves—which are *not* an endangered species—would not be harmed by exposure to Enlist Duo. *See* ER64.

NRDC complains, however, that "EPA was silent as to how Enlist Duo's effects on milkweed—a *target* plant that grows *within* treated fields—would affect the monarch population." NRDC Br. 45-46 (emphasis in original; internal citation omitted). In other words, NRDC contends that EPA ignored the impact of Enlist Duo on milkweed growing *within* designated agricultural fields on which Enlist Duo is lawfully applied. *See id.* at 46 ("[M]ilkweed decline *in agricultural fields* … could

have particularly significant repercussions for the species' survival.") (emphasis added). Indeed, NRDC goes so far as to assert that "there is evidence that monarchs have a pronounced preference for milkweed *in agricultural fields* and lay more eggs there." *Id.* (emphasis added; citing ER239, 273).

To state this argument is to refute it. The whole point of an agricultural herbicide is to kill weeds within agricultural fields. It is nonsensical for NRDC to suggest that EPA failed to consider the impact of Enlist Duo on weeds growing *inside* treated fields: Enlist Duo (like any other herbicide) is obviously meant to kill such weeds. *See* ER112 (listing milkweed as one of the "controlled weeds" targeted by Enlist Duo). Indeed, one of the benefits of Enlist Duo is that it is an effective weed killer. *See* ER556-57 (summarizing benefits of Enlist Duo). It is a matter of simple common sense that, in considering the registration of an herbicide targeted at weeds in treated agricultural fields, EPA concluded that the eradication of such weeds does not present a significant risk of an "*unreasonable* adverse effect." 7 U.S.C. § 136a(c)(7)(B) (emphasis added). That is why EPA responded to concerns about the effect of Enlist Duo on milkweed by referring to the effect of Enlist Duo on "non-target

plants," which includes milkweed *outside* the treated field. ER63-64. Nothing in the Administrative Procedure Act (APA) requires judges to check common sense at the door; to the contrary, courts must affirm agency action where, as here, "the agency's path may be reasonably discerned." *San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 994 (9th Cir. 2014) (internal quotation omitted); *see also Santa Clara River*, 887 F.3d at 925 n.17 (same); *Alaska v. Federal Subsistence Bd.*, 544 F.3d 1089, 1094 (9th Cir. 2008) (same).[7]

2. Substantial Evidence Supports EPA's Conclusion That Enlist Duo Does Not Entail A "New Use" Of Glyphosate.

NRDC next argues that EPA lacked "substantial evidence" to register Enlist Duo "because it ignored … evidence that the registration would bolster glyphosate use and the associated risks to milkweed and monarchs, and to human health." NRDC Br. 43; *see also id.* at 47-49.

[7] The studies cited by NRDC for the startling proposition that "there is evidence that monarchs have a pronounced preference for milkweed in agricultural fields," NRDC Br. 46, do not come close to proving that proposition. To the contrary, those studies are littered with disclaimers. *See* ER240, 273; *see generally* Bus Decl. ¶ 18, Dow Add.11-12. In the absence of more definitive evidence on this score, it was certainly reasonable for EPA to assume that monarchs will eat milkweed with equal gusto whether located on or off an agricultural field.

Once again, that argument is baseless. It starts from the premise that the baseline for determining whether Enlist Duo involves a "new use" of glyphosate is the hypothetical decreased use that NRDC posits would occur "but for EPA's registration of Enlist Duo." *Id.* at 47; *see also id.* at 47-48 ("Enlist Duo may perpetuate glyphosate use at higher levels, for a longer time, in comparison to a landscape without Enlist Duo.").

That argument has no basis in law or fact. Nothing in FIFRA or any relevant regulation supports the premise that the baseline for a "new use" of a pesticide is not its *current* use, but some projected *future* use. To the contrary, EPA regulations define a "new use" in relevant part as "[a]ny additional use pattern that would result in a significant *increase* in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms." 40 C.F.R. § 152.3 (emphasis added); *see also* ER3 n.2. Applying this definition, EPA determined that because "no new exposures for glyphosate are being considered with this registration action, no new assessment is needed for glyphosate." ER3; *see also* ER4 ("[T]he glyphosate in Enlist Duo would not cause unreasonable adverse effects on the environment because the use conditions authorized under the Enlist Duo registration are identical or

substantially similar to use conditions already authorized for glyphosate in other existing glyphosate registrations ...."); *id.* ("[A]ny decision on the Enlist Duo registration would likely have no effect on whether glyphosate continues to be used on corn, soybeans, and cotton—the decision would only impact *which* glyphosate product would be used.") (emphasis added).

NRDC's argument boils down to the proposition that EPA should have interpreted the word "increase" in its regulations as "the avoidance of a decrease." But that is not a "substantial evidence" argument at all; it is a legal argument about the meaning of the word "increase." And the short answer to that argument is that EPA is entitled to give the word "increase" in its own regulations its ordinary meaning: an "addition or enlargement in size, extent, quantity, number, intensity, value, substance." *Webster's Third New International Dictionary* 1145 (2002); *cf. Auer v. Robbins*, 519 U.S. 452, 461 (1997). Here, EPA recognized that glyphosate use is ubiquitous in corn, soybean, and cotton fields, *see* ER558 n.3, as NRDC itself acknowledges, *see*, *e.g.*, NRDC Br. 12, 16. Because NRDC identifies no evidence that the registration of Enlist Duo will entail the use of more glyphosate than is currently used, NRDC

identifies no evidence that the registration will result in any glyphosate "increase."

3. Substantial Evidence Supports EPA's Conclusion That Potential Volatilization Of Enlist Duo Will Not Have An Unreasonable Adverse Effect On The Environment.

NFFC, for its part, argues that the Enlist Duo registration decision is not supported by substantial evidence on two grounds. *See* NFFC Br. 59-65. First, NFFC asserts that "EPA failed to ascertain that volatilization of 2,4-D from Enlist Duo would not have unreasonable adverse effect on the environment," *id.* at 59 (capitalization modified), and thus "EPA's conclusion lacks support in substantial evidence, in violation of FIFRA," *id.* at 60; *see generally id.* at 59-63. That assertion is simply untrue.

Indeed, NFFC acknowledges that "EPA concluded … that 2,4-D volatilization from Enlist Duo would *not* unreasonably affect the environment." *Id.* at 59-60 (emphasis added; citing ER22); *see also* ER77-79. The catch, according to NFFC, is that EPA allegedly based that conclusion on "deficient" data. *Id.* at 60. Thus, NFFC states, "EPA *readily admits* that, with regard to 2,4-D vapor drift and tank mixtures, the agency lacked sufficient data to assess harm from Enlist Duo's new

uses," *id.* at 58—in other words, NFFC tries to put its argument into EPA's mouth.

But EPA never "admit[ted]" anything of the sort. NFFC seizes upon EPA's recognition of the limits of one particular Dow "vapor phase" laboratory study in the original (2013) risk assessment for Enlist Duo. *Id.* at 60-62 (citing ER2020, 2022, 2032, 2082-84, 3190-94); *see generally* ER3190 (recognizing limitations of the Dow "vapor phase" laboratory study). According to NFFC, "EPA *centered its entire assessment* of 2,4-D volatilization" on this single study. NFFC Br. 60 (emphasis added). That assertion is demonstrably incorrect.

EPA relied on a *number* of studies in assessing Enlist Duo's potential volatilization, both in its original 2013 risk assessment, *see* ER2082-84, its subsequent 2016 risk assessment, *see* ER646-47 (which NFFC completely ignores), and its 2017 registration, *see* ER58-59, 78-79. In addition to the Dow "vapor phase" *laboratory* study, EPA also considered numerous other studies, including more definitive *field* studies. *See* ER58 ("Trials were conducted at different sites (Indiana, Arkansas, and Georgia) to reflect a range of temperature and field conditions .... Results showed that 2,4-D choline salt has lower volatility

than 2,4-D esters and other salts."); ER78 ("The EPA's risk assessment considered potential effects from the volatilization of 2,4-D choline salt using several lines of evidence."); ER646 (2016), 2082 (2013) ("*In addition to the laboratory studies*, the registrant submitted several field studies that … were all considered scientifically sound and appropriate for qualitative incorporation into a risk assessment.") (emphasis added); ER647 (2016), 2083 (2013) ("Considering the results from [1] the plant-damage studies, [2] the vapor-flux study, *and* [3] the laboratory vapor-phase study, a conservative approach was taken in selecting endpoints to characterize risk from vapor-phase transport."); ER646 (2016), 2082-83 (2013) (table showing reliance on other studies); ER646-47 (2016), 2083 (2013) (relying on vapor-flux study conducted with 2,4-D choline salt). In light of EPA's reliance on these other studies (which NFFC never acknowledges, much less attempts to discredit), NFFC's reliance on *Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015), is misplaced. *See* NFFC Br. 60, 62-63. In that case, this Court found "significant flaw[s]" in "*all* of the studies" reviewed by EPA. *Pollinator Stewardship*, 806 F.3d at 529 (emphasis added); *see also id.* at 530 ("*[A]ll*

of the semi-field studies provided limited information ….") (emphasis added).

In short, NFFC fails to show that EPA relied on data that EPA itself had previously called into question. NFFC's argument is thus nothing more than a misguided attempt at a "gotcha" argument, and EPA identified more than "substantial evidence" to support its conclusion that volatilization of 2,4-D choline did not present a significant risk of unreasonable adverse effects. *See, e.g., Central Az. Water Conservation Dist. v. EPA*, 990 F.2d 1531, 1543 (9th Cir. 1993) ("The record reveals … that EPA acknowledged the limitations of the [study] ... and did not rely solely upon that report's conclusions …. We therefore reject Petitioner's argument that EPA has somehow acted arbitrarily or capriciously ….").

4. EPA Had No Need To Consider Synergistic Effects Of Mixing Enlist Duo With Glufosinate.

NFFC's second, and final, "substantial evidence" challenge asserts that "EPA failed to consider synergistic effects of mixing Enlist Duo with glufosinate." NFFC Br. 63 (capitalization modified); *see also id.* at 14 ("[I]f EPA's decision is arbitrary and capricious, it cannot be supported by substantial evidence."). That is an important issue, according to NFFC, because Dow "submitted a patent application claiming

'synergistic weed control' of pesticide combinations containing 2-4,D and glufosinate." *Id.* at 63-64 (quoting ER471-72). But that argument is based on not one, but two, material misrepresentations.

First, contrary to NFFC's representation that "the patent application asserting synergistic effects between 2,4-D and glufosinate is still active," NFFC Br. 63 n.31, Dow *abandoned* that application as of December 14, 2015. *See* Dow Add.21-23. Once a patent application is abandoned, "the application is no longer pending, and, thus, cannot mature into registration." United States Patent and Trademark Office, *Abandoned Applications*, *available at* goo.gl/u6jXaP (last visited Aug. 27, 2018). The application cannot ripen into a patent unless the applicant files a petition to revive the application and that petition is granted, *see id.*, and Dow will not revive the application.

Second, notwithstanding NFFC's representation, EPA has not "allowed mixing Enlist Duo with … glufosinate." NFFC Br. 64. To the contrary, the registration specifies that Enlist Duo may *not* be tank-mixed with any product not listed on a special website maintained by Dow (*EnlistTankMix.com*), *see* ER32, 38-39, and *no glufosinate product is on that list, see* goo.gl/nkZ8RX (last visited Aug. 27, 2018); Fordice Decl.

¶¶ 8-10, Dow Add.26-27. Because it has been, and remains, against the law to mix Enlist Duo with glufosinate, there was no reason for EPA to consider any potential synergistic effects between Enlist Duo and glufosinate.

III. THE ENLIST DUO REGISTRATION COMPLIES WITH THE ESA.

NFFC devotes the bulk of its brief to challenging EPA's determination that the conditional registration of Enlist Duo would have "no effect" on any endangered species or critical habitat, and therefore there was no need for consultation with FWS regarding any such effects. *See* NFFC Br. 16-56. According to NFFC, that determination "circumvent[s]" the ESA's "unambiguous" consultation requirements. *Id.* at 17. Because the determination whether a particular action will affect an endangered species or critical habitat is assigned to the agency that proposes to take that action (the "action agency," here EPA), the key question for this Court is whether EPA's "no effect" determinations are "arbitrary and capricious" under the APA. *See*, *e.g.*, *Defenders of Wildlife v. Flowers*, 414 F.3d 1066, 1068 (9th Cir. 2005). This "highly deferential" standard of review, *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 601 (9th Cir. 2014), is satisfied insofar as the agency has

articulated a "rational connection between facts found and conclusions made," *Santa Clara River*, 887 F.3d at 920 (internal quotation omitted); *see also Northwest Ecosystem All. v. FWS*, 475 F.3d 1136, 1140 (9th Cir. 2007). Accordingly, this Court will not vacate an agency's decision as arbitrary and capricious unless the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Santa Clara River*, 887 F.3d at 921 (internal quotation omitted). Because the agency's decision is "entitled to a presumption of regularity," this Court "may not substitute [its] judgment for that of the agency." *San Luis*, 747 F.3d at 601 (internal quotation omitted).

NFFC in essence argues that EPA has no discretion *not* to consult under the ESA regarding the registration of an herbicide insofar as that registration authorizes use in an area where an endangered species or critical habitat may be found. *See, e.g.*, NFFC Br. 38, 50-51. That argument represents a manifest distortion of the relevant statutory and regulatory scheme, which vests the *action* agency, not the *consulting*

agency, with discretion to determine whether a proposed action will have any effect on an endangered species or critical habitat. EPA's determination that consultation was not warranted in connection with the registration of Enlist Duo (with the single exception of the Eskimo curlew, about which EPA consulted FWS, which in turn concurred with EPA's "Not Likely To Adversely Affect" finding) was not remotely an abuse of such discretion or otherwise arbitrary and capricious.

A. EPA, As The Action Agency, Has Discretion To Make "No Effect" Determinations.

NFFC's ESA argument boils down to the simple, but erroneous, proposition that "every federal agency must consult the expert wildlife agencies before taking any action that *might have any effect whatsoever* on any ESA-protected species or critical habitat." NFFC Br. 18 (capitalization modified; emphasis added). That is not the law.

The starting point here, as in any statutory case, is the statutory text. The ESA provides that "[e]ach Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency ... is not likely to *jeopardize the continued existence* of any endangered species ... or result in the *destruction or adverse modification* of habitat of such species ...."

16 U.S.C. § 1536(a)(2) (emphasis added). By its plain terms, thus, the statute does not extend nearly so far as NFFC suggests: it does not mandate consultation whenever a federal agency takes "any action *that might have any effect whatsoever* on any ESA-protected species or critical habitat." NFFC Br. 18 (emphasis added).

Nor is the regulation established by the two ESA "consulting" agencies—FWS and the National Marine Fisheries Service, or NMFS (collectively the Services)—to the contrary. Under that regulation, "[e]ach Federal agency shall review its actions at the earliest possible time to determine whether any action *may affect* listed species or critical habitat. *If such a determination is made*, formal consultation is required ...." 50 C.F.R. § 402.14(a) (emphasis added). That regulation on its face recognizes that the *action agency* has the statutory responsibility to "insure" that its action is not likely to jeopardize endangered species, and that consultation is required only if the action agency determines that its proposed action "may affect" a listed species or critical habitat. *See id.*; *see also* 73 Fed. Reg. 76,272, 76,280 (Dec. 16, 2008) ("[I]f an action agency concludes that a proposed action will have no effect on a listed species, it is under no obligation to consult with the Services."); *Flowers*, 414 F.3d

at 1070 ("The determination of possible effects is the [action] agency's responsibility.") (internal quotation omitted); *id.* (action agency "has the ultimate duty to ensure that its actions are not likely to jeopardize listed species or adversely modify critical habitat," and "makes the final decision on whether consultation is required") (internal quotation omitted); *Southwest Ctr. for Biological Diversity v. Forest Serv.*, 100 F.3d 1443, 1447 (9th Cir. 1996) (action agency's "initial determination that the [action] would have no effect on" endangered species "obviates the need for formal consultation under the ESA"). Critically, "the services play no role whatsoever in that threshold determination." 73 Fed. Reg. at 76,280 (internal quotation omitted).

NFFC thus gets matters backwards when it charges EPA with "unilaterally mak[ing] determinations the law allows only FWS to make." NFFC Br. 21. As noted above, the regulation not only allows but requires the *action* agency—not the *consulting* agency—to make "effects" determinations, and that is precisely what EPA did. When an action agency determines that a proposed action will *not* affect any endangered species or critical habitat, it is not engaging in impermissible "self-consultation," *id.* at 27; rather, it is exercising its lawful discretion over

that decision. It is NFFC, not EPA, that seeks to "circumvent" the law by stripping the action agency of any such discretion.

And in exercising that discretion, it is the action agency's prerogative to define the metes and bounds of its own action. Thus, when the Postal Service proposes to build a new post office, it need only determine whether the specific project proposed—not any conceivable project—"may effect" an endangered species or critical habitat. Similarly, when EPA proposes to register a new product, it need only determine whether the use of that product, as limited by the agency through its findings and registration conditions (including the use restrictions set forth in the legally binding label), "may affect" an endangered species or critical habitat. It need not determine whether the product, used in any *conceivable* way at any *conceivable* dose, "may affect" an endangered species or critical habitat—the proposed agency "action," after all, does not *allow* the product to be used in any conceivable way at any conceivable dose.[8]

[8] Indeed, in the specific context of toxicology, as Paracelsus explained over five centuries ago, "[a]ll substances are poisonous—there is none which is not"—*any* substance, in a sufficient dose, is capable of being toxic. *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d 1345, 1351-52 (S.D. Fla. 2011); *see also In re Chantix (Varenicline) Prods. Liab.*

As the D.C. Circuit has put it, "satisfaction of the ESA mandate that no endangered life be jeopardized must be measured in view of the full contingent of … checks and balances *and all mitigating measures*." *Center for Biological Diversity v. Department of Interior*, 563 F.3d 466, 482 (D.C. Cir. 2009) (emphasis added; internal quotation omitted); *see also WildEarth Guardians v. EPA,* 759 F.3d 1196, 1208 (10th Cir. 2014) ("[T]he duty to consult is bounded by the agency action. Consultation is called for to ensure that the *action* does not jeopardize endangered or threatened species.") (emphasis in original). That is why, for example, EPA was able to conclude that the registration of Enlist Duo would have "no effect" on three particular species—Audubon's crested caracara, the Spring Creek bladderpod, and the Sonoran pronghorn antelope—by simply barring its use in these species' specific and isolated habitats. ER25-26, 664-67, 671-73, 678; *see generally* ER73 ("EPA believes that it is in the best interest of a listed species to modify a proposed action so as to avoid effects to the organism altogether, when practical."). Were the

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Litig., 889 F. Supp. 2d 1272, 1302 n.30 (N.D. Ala. 2012). This proposition is so venerable that it even has its own Latin maxim: *solo dosis facit venenum* ("the dose makes the poison"). *See, e.g.*, Laurie J. Beyranevand, *Generally Recognized As Safe?: Analyzing Flaws In The FDA's Approach To GRAS Additives*, 37 Vt. L. Rev. 887, 889 n.21 (2013).

law otherwise, the Services would be swamped with unnecessary consultation requests (diverting their focus away from species actually affected by agency action), and action agencies would effectively be paralyzed from fulfilling their statutory mandates. *Cf. Utility Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2444 (2014) ("[An] interpretation [that] would place plainly excessive demands on limited governmental resources is alone a good reason for rejecting it ….").

Thus, NFFC errs by arguing that EPA was required to consult if Enlist Duo could have any *conceivable* effect on an endangered species or critical habitat. NFFC bases that argument not on the regulation itself (much less the statute), but on a couple of sentences plucked out of context from this Court's decision in *Karuk Tribe of Calif. v. Forest Serv.*, 681 F.3d 1006 (9th Cir. 2012) (*en banc*). In particular, NFFC cites *Karuk Tribe* for the proposition that "'[a]ctions that have *any chance of affecting* listed species or critical habitat'" require consultation, and that "'*[a]ny possible effect*, whether beneficial, benign, adverse, or of an undetermined character triggers the requirement.'" NFFC Br. 19 (first emphasis added by NFFC; quoting *Karuk Tribe*, 681 F.3d at 1027); *see also id.* at 25-26, 35.

Reading that language from *Karuk Tribe* out of context, as NFFC does, sweeps away *any* limiting principle on ESA consultation, and effectively requires federal agencies to consult with respect to anything and everything they do, as anything has a "chance" of having a "possible effect" on something else. To read *Karuk Tribe* this way is to read the case to interpret the Services' regulation as plainly *ultra vires* under the statute (which is concerned only with adverse effects, not benign or beneficial effects), and to negate action agencies' discretion to make an "effects" determination in the first instance. There is a wide gulf between a statute that contemplates consultation where agency action is "likely to *jeopardize the continued existence* of any endangered species ... or result in the *destruction or adverse modification* of habitat of such species," 16 U.S.C. § 1536(a)(2) (emphasis added), and a legal rule that requires consultation where there is any chance whatsoever that agency action will have a possible effect on an endangered species or critical habitat. *Karuk Tribe*—where the action agency "d[id] not dispute" that the challenged action, if attributed to the agency as opposed to private parties, "may affect" an endangered species and critical habitat, 681 F.3d at 1027—did not purport to overrule the principle that an action agency

has discretion to make an "effects" determination in the first instance in light of the specific "action" proposed.

To the contrary, *Karuk Tribe* reaffirmed that principle. In particular, *Karuk Tribe* confirms that an "effects" determination is committed to the action agency's discretion, and that the scope of an agency "action" must be assessed by reference to the "conditions" under which the agency allows that action "to proceed." 681 F.3d at 1011. Many other cases, both before and after *Karuk Tribe*, recognize that judicial review of an action agency's "effects" determination requires consideration of the limitations that the action agency itself imposes on its proposed "action" and the agency's assessment of effects. *See*, *e.g.*, *Santa Clara River*, 887 F.3d at 924 (upholding action agency's "no effect" determinations where "water quality in the Santa Clara River would not be significantly affected by the discharges"); *Ground Zero Ctr. for Non-Violent Action v. Department of Navy*, 383 F.3d 1082, 1092-93 (9th Cir. 2004) (upholding action agency's decision not to consult upon concluding that "likelihood of jeopardy [was] too remote"); *Southwest Ctr.*, 100 F.3d at 1446, 1448 (upholding action agency's "no effect" finding based on the conclusion that the project area implicated "neither foraging nor nesting

habitat" even though spotted owls or their habitat "could be 'present'"). Indeed, in *Santa Clara River*, this Court recently upheld an action agency's "no effect" determination even where the consulting agency had predicted that the contamination levels resulting from the proposed action would have "sublethal effects" on a listed species. 887 F.3d at 924.[9]

To recognize that the ESA gives the action agency discretion to make an "effects" determination is not to say that such discretion is unbounded. To the contrary, it is bounded in the same way that most exercises of administrative discretion are bounded—by judicial review under the APA's "arbitrary and capricious" standard. *See*, *e.g.*, *Santa*

[9] The Services themselves, moreover, have recognized that an action agency is entitled to make a "no effect" determination where, as here, "the species occurs in the action area and may be present at the time of the project, but there are no plausible (*i.e.*, no credible) routes of effects (beneficial or adverse) to the species." National Marine Fisheries Service, Southeast Regional Office, *Endangered Species Act Section 7 Effects Determination Guidance* (Mar. 2014), at 1, *available at* goo.gl/dKNvnL (last visited Aug. 27, 2018); *see also* U.S. Fish & Wildlife Service, *Section 7 Consultation Technical Assistance: Step-by-Step Instructions—Step 3*, *available at* goo.gl/TqqNwx ("no effect" determination warranted where action agency determines that "the species and critical habitat *will not respond* in any manner" to the proposed agency action) (last updated Feb. 25, 2016; last visited Aug. 27, 2018; emphasis added); *see also* ER74 ("'If the best available data indicate that the species and critical habitat will not respond in any manner, conclude "no effect" and document your finding. No further consultation [is] required.'") (quoting 2016 FWS guidance).

Clara River, 887 F.3d at 924 ("Because the [action agency's] determination that the Project would not affect [a listed species] was not arbitrary or capricious, we reject [the petitioner's] ESA claim."). As explained below, NFFC has not established that EPA's "no effect" determinations are arbitrary and capricious.

B. EPA's "No Effect" Determinations Are Not Arbitrary And Capricious.

According to NFFC, "EPA violated the ESA's consultation mandates" for no fewer than six reasons. NFFC Br. 21 (capitalization modified). *First*, NFFC contends that EPA conflated the relevant analysis under FIFRA and the ESA. *See id.* at 21-31. *Second*, NFFC contends that "EPA *admitted* after initial risk assessments that the Enlist Duo registration 'may affect' hundreds of ESA-protected species." *Id.* at 31 (emphasis added); *see generally id.* at 31-32. *Third*, NFFC contends that "EPA unlawfully constricted the registration's 'action area.'" *Id.* at 32 (capitalization modified); *see generally id.* at 32-37. *Fourth*, NFFC contends that "EPA's conclusion that Enlist Duo will have 'no effect' even on protected species within sprayed fields … is unlawful" with respect to the whooping crane and the Indiana bat. *Id.* at 37 (capitalization modified); *see generally id.* at 37-47. *Fifth*, NFFC

contends that EPA violated its statutory obligation to use the "best scientific and commercial data available," 16 U.S.C. § 1536(a)(2). *See* NFFC Br. 47-48. And *sixth*, NFFC contends that "EPA violated the ESA by failing to consult the expert agencies about designated critical habitat." *Id.* at 49 (capitalization modified); *see generally id.* at 49-56. As explained below, none of these arguments has merit.

1. EPA Did Not Conflate Its Roles Under FIFRA And The ESA.

According to NFFC, "EPA's fundamental legal error was substituting FIFRA's less protective standards and processes for the ESA's." NFFC Br. 21; *see also id.* at 30-31 ("By ... conflating the 'no effect' and 'not likely to adversely affect' standards, EPA unlawfully cut FWS out of the process ...."); *id.* at 35-36 (accusing EPA of "trying to jam a FIFRA square peg into an ESA round hole"). Even cursory review of the record, however, refutes this argument: EPA carefully distinguished ESA's "no effect" standard from FIFRA's "not likely to adversely affect" standard, and applied the former standard in deciding that—with the exception of a single species (the Eskimo curlew, as to which EPA consulted with FWS, which in turn concurred in EPA's "Not Likely to

Adversely Affect" finding)—the registration of Enlist Duo did not trigger consultation with FWS. *See* ER24-26, 69-76, 649-81.

As an initial matter, the ESA does not require an action agency to use any particular methodology in making an "effects" determination. In the absence of any such requirement, the action agency—as the agency tasked with "review[ing] its actions … to determine whether any action may affect listed species or critical habitat," 50 C.F.R. § 402.14(a)—has discretion to choose the methodology it deems best-suited to make the requisite determination, and that choice is entitled to judicial deference. *See*, *e.g.*, *Bear Lake Watch, Inc. v. FERC*, 324 F.3d 1071, 1077 (9th Cir. 2003) ("'We defer to agency expertise on questions of methodology ....'") (quoting *Inland Empire Pub. Lands Council v. Schultz*, 992 F.2d 977, 981 (9th Cir. 1993)).[10]

[10] NFFC states in passing that "[t]he ESA does not allow an agency to apply its own 'interpretative policies' regarding risk, such that EPA may use its own 'risk quotients' and 'levels of concern' while the Army Corps of Engineers may use different ones it prefers, and the Department of Transportation yet others." NFFC Br. 25 (internal citation omitted). NFFC provides no authority for that statement, which is not surprising: there is none. As noted in the text, the ESA and its implementing regulations do not require action agencies to use any particular methodology in making an "effects" determination. Needless to say, courts may not impose any particular methodology on federal agencies where the relevant statute and regulations do not prescribe one.

The root of NFFC's grievance appears to be EPA's use of certain methodological tools—Levels of Concern (LOCs) and Risk Quotients (RQs)—in making ESA "effects" determinations. According to NFFC, EPA is not entitled to use those tools in the ESA context because the agency also uses them "in the FIFRA context" to determine whether a pesticide registration "has the potential to cause adverse effects." NFFC Br. 23 (emphasis omitted); *see also id.* at 24 ("These 'risk quotients' and 'levels of concern' ... were not designed to support compliance with the ESA.").

But EPA uses those methodological tools *differently* under each statute, reflecting each statute's different substantive standard. In particular, EPA applies far more conservative, and protective, LOCs and RQs in the ESA context: "[e]ndangered species acute LOCs are a fraction of the non-endangered species LOCs, or, in the case of endangered plants, RQs are derived using lower toxicity endpoints than non-endangered plants." ER2530; *see generally* ER73-74 & nn. 7, 8 (explaining that EPA "established conservative effects thresholds for plants and animals based on effects to survival, growth, and reproduction," and "[w]ith labeled mitigation measures in place, exposures … fall below the direct effects

thresholds established by the agency for *threatened and endangered species*") (emphasis added). Indeed, NFFC concedes that EPA "changes the [risk] threshold" when analyzing risk to endangered species under the ESA. NFFC Br. 24. The conservative LOCs and RQs applied in the ESA context allow EPA to conclude with confidence that a particular herbicide will have "no effect" on a species or critical habitat (the ESA standard), rather than simply concluding that it is "not likely to adversely affect" that species or habitat (the FIFRA standard).

The only question, then, is whether the particular LOCs and RQs used by EPA in making "no effect" determinations under the ESA are arbitrary and capricious. But NFFC does not actually address that question in its opening brief. Rather, NFFC simply insists that *any* degree of risk, however infinitesimal, necessarily triggers ESA consultation. *See*, *e.g.*, NFFC Br. 19-20. As noted above, that is not the law. *See*, *e.g.*, *Ground Zero*, 383 F.3d at 1092 ("[T]he calculated risk is infinitesimal. And so it was not arbitrary and capricious for the Navy to conclude that it was not required to consult ...."). Indeed, in a Joint Report to Congress during the last Administration, the Services specifically endorsed EPA's methodology and risk analysis *in this very*

case. *See* U.S. Environmental Protection Agency, U.S. Fish & Wildlife Service, National Marine Fisheries Service, and U.S. Department of Agriculture, *Interim Report to Congress on Endangered Species Act Implementation on Pesticide Evaluation Programs* (Nov. 2014), at 20, *available at* goo.gl/V4tzeE (last visited Aug. 27, 2018) ("EPA scientists used highly conservative and protective assumptions to evaluate ecological risks for the new uses of 2,4-D and Enlist Duo. The assessments confirm that these uses meet safety standards for pesticide registration, and, as approved, will be protective of non-target species, *including endangered species*.") (emphasis added).

2. EPA Made The Requisite "No Effect" Determinations.

NFFC insists, however, that "EPA *admitted* after initial risk assessments that the Enlist Duo registration 'may effect' [*sic*] hundreds of ESA-protected species and their critical habitats," but thereafter "*erased* all of these findings and converted them to 'no effect' findings to avoid consultation." NFFC Br. 31 (emphasis added). That argument displays a fundamental misunderstanding of EPA's process for making "effects" determinations under the ESA.

EPA generally makes such determinations, and made them in this case, by ruling *out* effects on listed species through application of a series of filters. *First*, EPA categorically ruled out any effects on species not located within the proposed "action area." ER24-25, 649-53, 679 (ruling out 508 species at this step). *Second*, the agency applied a "screening-level ecological risk assessment" for entire taxa of species to determine whether any effect on those taxa could be categorically ruled out. *See* ER654-55, 659, 664, 667, 674, 677, 678 (not ruling out any species at this step). And *third*, the agency then applied a species-specific analysis to determine whether any effect on remaining species could be ruled out, whether by restricting the permissible uses of the product through the label or otherwise. ER25-26, 655-78 (ruling out 22 species at this step).

The key point here is that EPA's refusal to rule *out* effects on a particular species at a preliminary stage of this iterative process does not mean that EPA thereby ruled *in* any such effects. As the result of the sequential application of the three filters here, EPA was able to rule out effects of the Enlist Duo registration on all endangered species save one—the Eskimo curlew (as to which, as noted above, EPA consulted with FWS, which in turn concurred with EPA's determination that the

registration of Enlist Duo was not likely to adversely affect that species). ER25, 75, 669-70. With respect to other listed species, EPA specifically made "no effect" determinations. ER25-26; see also ER69-76, 649-81.

That simple point refutes NFFC's argument that EPA "admitted" that the Enlist Duo registration *would* have effects on various species. Every example cited by NFFC represents nothing more than the agency's conclusion, at a *preliminary* stage of the analysis, that it could not categorically rule out any such effects. *See* NFFC Br. 31 (citing ER1062-63, 1457, 1773, 2030, 2074-75, 2079-81); *see also id.* at 28 (citing ER584). Indeed, most of NFFC's citations are *doubly* flawed, because they not only involve determinations that EPA could not rule out effects at preliminary stages of the analysis, but involve outdated risk analyses (from 2013, 2014, and 2015) superseded by the agency's 2016 risk analysis. *See* ER26 (ESA "effects" determinations in challenged 2017 Registration Decision based on 2016 risk assessment); ER568-1002 (2016 risk assessment); ER570 ("[T]his assessment … includes an *updated* species-specific Effects Determinations and Critical Habitat Modification Determinations for listed species in the 34 states to be included for Enlist Duo use.") (emphasis added).

Indeed, NFFC cites just two passages from the 2016 risk assessment at issue here. *See* NFFC Br. 31 (citing ER634-35, 642). Tellingly, however, NFFC does not cite the part of *that* risk assessment that specifically deals with risks to endangered species and critical habitats. *See* ER649-81. Rather, NFFC cites portions of the assessment that, once again, deal with "screening level" analysis at the broad taxa level. *See* ER634-35, 642. As EPA explained in the part of the risk assessment actually dealing with the ESA, this screening-level analysis uses "*generalized* risk assessment concerns within the action area," but does not "take into account the available information on the biological characteristics of each Federally-listed species in terms of important exposure variables such as food item selection and body-weight within the action area." ER654 (emphasis added). Thus, EPA proceeded to analyze potential effects on a species-specific basis before making "no effect" determinations. *See* ER654-78.

The bottom line here is that EPA never "acknowledged" that "Enlist Duo, applied at the allowed rate, may affect many protected plant and animal species, even using its own 'level of concern' standard." NFFC Br. 31. Instead, as noted above, EPA specifically determined that there

would be *no* effect on *any* listed species (with the exception of the Eskimo curlew, as to which it consulted). *See* ER24-26. Contrary to NFFC's assertion, *see* NFFC Br. 32, this case is thus a far cry from *Karuk Tribe*, where the action agency "d[id] not dispute" that the challenged action, if attributed to the agency (as opposed to private parties) "may affect" an endangered species or critical habitat. 681 F.3d at 1027.

3. EPA Properly Defined the "Action Area."

NFFC next challenges EPA's definition of the "action area" for Enlist Duo as the corn, soybean, and cotton fields to which it is applied in the 34 states where the herbicide is approved for use. *See* NFFC Br. 32-37. According to NFFC, EPA "unlawfully constrict[ed] the registration's 'action area' to just the sprayed crop fields themselves, excluding completely all surrounding areas beyond the fields' borders." *Id.* at 32-33. "This severe culling violated the ESA definition of 'action area,' as well as sound science, farming realities, and the record evidence." *Id.* at 34. Once again, NFFC is wrong, and cannot establish that EPA's definition of the "action area" here is arbitrary and capricious.

Contrary to NFFC's submission, the ESA neither uses nor defines the term "action area." Rather, that term is defined and used in the

Services' ESA regulations. *See* 50 C.F.R. §§ 402.02 (defining "action area" as "all areas to be affected directly or indirectly by the Federal action and not merely the immediate area involved in the action"); 402.12(c),(d),(g) (referring to "action area"); 402.14(g)(1)) (same). The regulations do not specify what it means for an area to be "affected directly or indirectly" by an action, and thus leaves that issue up to the action agency, subject to judicial review under the APA. *See*, *e.g.*, *Friends of the Wild Swan v. Weber*, 767 F.3d 936, 950 (9th Cir. 2014) ("[T]he choice of appropriate action areas requires application of scientific methodology and, as such, is within the [action] agency's discretion.") (internal quotation omitted); *cf. Bear Lake*, 324 F.3d at 1077 ("We defer to agency expertise on questions of methodology ....") (internal quotation omitted).

Here, EPA reasonably limited the "action area" for Enlist Duo to treated fields based on extensive findings that the unique properties of 2,4-D choline, when used as directed on the label (including the 30-foot buffer zone within the treated fields), would prevent offsite migration. ER25. That does not mean, of course, that EPA blithely assumed that not a single molecule of Enlist Duo would ever breach the treated fields' boundaries. To the contrary, the agency specifically concluded that any

such off-field migration would be so *de minimis* that it would not plausibly have any direct or indirect effect on any non-target organism. *See* ER22-23, 70-73, 638-40. Thus, "EPA used the best available information to quantitatively evaluate the extent of spray drift under the use conditions described on the Enlist Duo label. The EPA then compared those results to available effect thresholds .... This comparison indicated that non-target organism exposures would be expected to be below effects thresholds off the treated field. This logically resulted in the confinement of the area where effects could reasonably be expected to occur to the treated field itself." ER73; *see also* ER638-40 & Table 33 (concluding that, in light of the mitigation measures on the label, Enlist Duo would have no effect on non-target organisms, including endangered species, outside the treated field).

NFFC argues, however, that EPA's limitation of the "action area" to the treated fields was unlawful because EPA "knows pesticides commonly drift well beyond sprayed fields, with harmful effects," and "knew Enlist Duo specifically may travel beyond the borders of sprayed fields." NFFC Br. 33. But NFFC identifies no record evidence to support that argument. Rather, NFFC emphasizes that *ordinary* 2,4-D is prone

to migrate through spray drift and volatilization. *See*, *e.g.*, *id.* (citing ER2022 for the proposition that "*2,4-D* is known to volatilize from the field and drift off site under certain environmental conditions.") (emphasis added); *id.* (citing ER2067 for the proposition that "EPA was aware that by 2012, there had been thousands of reported incidents of terrestrial plants, aquatic plants, birds, fish, mammals, reptiles, and terrestrial insects having been killed by *2,4-D* traveling off-site") (emphasis added). But that is a *non sequitur*: as already explained, a major benefit of Enlist Duo is precisely that "the choline salt is less volatile than other forms of 2,4-D," ER28, and Enlist Duo is thus designed to prevent migration off a treated field. Needless to say, NFFC cannot establish that EPA acted unlawfully in registering Enlist Duo by complaining about the properties of ordinary 2,4-D, which is not Enlist Duo.[11]

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[11] NFFC also errs by asserting that "EPA initially *admitted* hundreds of listed species were within the registration's action area." NFFC Br. 33 (emphasis added). In support of that assertion, NFFC cites risk assessments prepared in connection with the original 2014 registration and the 2015 amendment, *see id.* (citing ER1456, 1772), both of which were superseded by an updated risk assessment in 2016, *see* ER568-1002. In any event, both the original 2014 registration and the 2015 amendment, like the 2017 Registration Decision, determined that "spray drift will remain confined to the field and that *the action area is limited*

Similarly, NFFC ignores the stringent use requirements set forth on the Enlist Duo label, which are designed to prevent the product from migrating off a treated field. *See* ER93-113 (label). NFFC cannot point to any record evidence that, when these use restrictions are obeyed, Enlist Duo will migrate off a treated field at a level sufficient to affect a listed species or critical habitat.

Finally, NFFC contends that "[e]ven if Enlist Duo were never to directly escape the crop fields' borders at all, the pesticide's application to the fields plainly has *indirect* effects on areas outside those borders." NFFC Br. 36 (emphasis added). That is so, according to NFFC, because some endangered species may consume prey, or drink water, that exited the field. *See id.* But EPA specifically "concluded the direct *and indirect* effects to any taxa would be limited to areas within the confines of treated fields." ER72 (emphasis added); *see also* ER74. NFFC cites no record evidence to challenge that conclusion; rather, its argument is based on pure speculation. And a petitioner cannot establish that agency action is arbitrary and capricious based on speculation. *See*, *e.g.*, *George v. Bay*

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to the 2,4-D choline treated field." ER1773 (emphasis added); *see also* ER1457 (same).

Area Rapid Transit, 577 F.3d 1005, 1011 (9th Cir. 2009) ("[T]he party challenging an agency's action as arbitrary and capricious bears the burden of proof …. Indeed, even assuming the agency made missteps … the burden is on petitioners to demonstrate that the agency's ultimate conclusions are unreasonable.") (internal quotation and alterations omitted).

4. EPA's Species-Specific Findings Comply With The ESA.

NFFC next challenges "EPA's conclusion that Enlist Duo will have 'no effect' even on protected species within sprayed fields." NFFC Br. 37 (capitalization modified). However, NFFC makes no effort to substantiate that challenge with respect to any listed species other than the whooping crane and the Indiana bat. *See id.* at 39-47. Accordingly, NFFC has waived any challenge to EPA's "no effect" determination for any other species. *See*, *e.g.*, *Smith v. Marsh*, 194 F.3d 1045, 1052 (9th Cir. 1999) ("[O]n appeal, arguments not raised by a party in its opening brief are deemed waived.").

a. The Whooping Crane

NFFC asserts that EPA was "required" to make a "may affect" determination for the whooping crane upon acknowledging that the

species "'may be exposed to 2,4-D choline residues in prey on crop fields'" during an annual migration from Texas to Canada. NFFC Br. 40 (quoting ER667). Whenever a risk quotient is "not zero," according to NFFC, a "may affect" determination is required "as a matter of law." *Id.*

But a determination of potential exposure is just the *beginning*, not the *end*, of the analysis. An "exposure" is not the same thing as an "effect." *See* ER72 ("In the case of Enlist Duo, the EPA conducted an analysis of exposure and effects to determine if exposures were sufficient to indicate a plausible and credible route to effects."). Here, using conservative assumptions, EPA determined that the potential exposure was so limited that it would have no effect on any whooping crane. *See* ER667-68, 2530. NFFC does not quarrel with any of EPA's scientific assumptions or conclusions; rather, NFFC's challenge to the "no effect" determination for the whooping crane is based entirely on its erroneous *legal* premise that any risk greater than "zero" requires consultation "as a matter of law." NFFC Br. 40. Because, as explained above in Section III.B.1, that is not the law, and because EPA applied an ESA-specific risk quotient and level of concern, NFFC has not shown that EPA's "no effect" determination for the whooping crane is arbitrary and capricious.

b. The Indiana Bat

NFFC's challenge to EPA's "no effect" determination for the Indiana bat is equally meritless. Once again, NFFC displays a fundamental misunderstanding of EPA's sequential approach to making "effects" determinations. According to NFFC, EPA necessarily determined that exposure to Enlist Duo "may affect" the Indiana bat when the agency concluded that it could not rule out effects in the screening-level risk assessment. *See* NFFC Br. 41-42. As explained above in Section III.B.2, that assertion is incorrect as a matter of law.

After determining that it could not rule out taxa-wide effects, *see* ER654-55, EPA proceeded to analyze whether it could rule out species-specific effects on the Indiana bat, *see* ER655-57. NFFC does not even engage with this analysis, which should be the beginning and the end of the matter. Rather, NFFC challenges EPA's *2014* risk analysis for the Indiana bat, which was superseded by the *2016* risk analysis that underlies the Registration Decision at issue here. *See* NFFC Br. 43-47 (citing ER 1775-83 (2014 analysis)). EPA did not repeat that analysis in 2016, but instead undertook an entirely new analysis. *See* ER655-57.

Because NFFC challenges the old, obsolete analysis, its challenge misses the mark.

Insofar as NFFC may try to apply its critique of the 2014 analysis to the 2016 analysis, that critique lacks merit. NFFC accuses EPA of "guess[ing]" on such questions as "how often the bats were likely to visit sprayed fields," "how much of their diet would likely come from those fields," and "how much 2,4-D residue their prey likely would carry." NFFC Br. 43. But even cursory review of the 2016 risk analysis shows that EPA did not "guess" on these questions; instead, the agency relied on scientific studies (including FWS' Indiana bat Recovery Plan), *see* ER655-57, and used conservative assumptions (such as that 100% of the bat's prey consumed per day contained 2,4-D, *see* ER657). As with the whooping crane, EPA determined, based on these conservative assumptions, that the potential exposure was so limited that it would have no effect on any Indiana bat. *See id*. And because NFFC does not quarrel with any of the scientific assumptions or conclusions in the 2016 risk analysis, it has not shown that EPA's "no effect" determination for the Indiana bat is arbitrary and capricious.

5. EPA Used The Best Scientific And Commercial Data Available.

NFFC next argues that "EPA failed to use the best scientific and commercial data available" in making its "effects" determinations under the ESA, NFFC Br. 47 (capitalization modified), in violation of the statute, *see* 16 U.S.C. § 1536(a)(2) ("In fulfilling the requirements of this paragraph each agency shall use the best scientific and commercial data available."). In particular, NFFC complains that "EPA relied on its 1993 Wildlife Exposure Factors Handbook … for critical data." NFFC Br. 47 (citing ER2886-3147). That reliance was misplaced, according to NFFC, because "EPA never intended that [the Handbook] be used for assessing effects on any endangered species." *Id.*

As a matter of law, however, NFFC cannot establish that EPA failed to use the "best" scientific and commercial data without showing what *better* data EPA ignored. Because "best" is a comparative term, NFFC must point to data "that was omitted from consideration"; it is not sufficient for a litigant simply to quarrel with the quality of an agency's data. *Kern Cnty. Farm Bureau v. Allen*, 450 F.3d 1072, 1081 (9th Cir. 2006). This NFFC has failed to do; indeed, NFFC has not identified *any* alternative data. NFFC's failure to identify any *better* data therefore

dooms its argument that EPA failed to rely on the *best* data. Indeed, as this Court recently reaffirmed, "[t]he determination of what constitutes the best scientific data available belongs to the agency's special expertise," and "warrants substantial deference" from the courts. *Santa Clara River*, 887 F.3d at 924 (internal quotation omitted).

6. EPA Did Not Act Arbitrarily And Capriciously, As The Action Agency, In Making "No Modification" Determinations With Respect To Critical Habitat.

Finally, NFFC argues that "EPA also violated the ESA by failing to consult the expert agencies about designated critical habitat." NFFC Br. 49 (capitalization modified); *see generally id.* at 49-56. In large measure, this argument rehashes the argument that EPA violated the ESA by failing to consult FWS about species. And insofar as the argument is different, it is also wrong.

The ESA defines an endangered species' "critical habitat" as "the specific areas within the geographical area occupied by the species ... on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations of protection." 16 U.S.C. § 1532(5)(A)(i). "Critical habitat" may also include "specific areas outside the

geographical area occupied by the species," but only "upon a determination by the [Services] that such areas are essential for the conservation of the species." *Id.* § 1532(5)(A)(ii)). Whether inside or outside the area occupied by the species, a "critical habitat" by definition must contain physical or biological features "essential" to the species. *Id.* In ESA jargon, "these physical and biological elements essential to the species … [are] known as 'primary constituent elements' or PCEs, [and] are at the heart of the critical habitat designation." *Alaska Oil & Gas Ass'n v. Jewell*, 815 F.3d 544, 555 (9th Cir. 2016) (citing 50 C.F.R. § 424.12(b)(5)). The PCEs for different species are highly specific, circumscribed attributes confined to particular areas.[12]

The ESA, however, neither requires nor authorizes an action agency to make a determination of critical habitat in the first instance.

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[12] *See, e.g.*, 50 C.F.R. § 17.95-a ("[T]he primary constituent element for the Canada lynx is boreal forest landscapes supporting a mosaic of differing successional forest stages and containing: (i) Presence of snowshoe hares and their preferred habitat conditions …; (ii) Winter conditions that provide and maintain deep and fluffy snow …; (iii) Sites for denning that have abundant coarse woody debris …; and (iv) Matrix habitat … that occurs between patches of boreal forest in close juxtaposition … such that lynx are likely to travel through such habitat while accessing patches of boreal forest within a home range."); *see also* ER978.

Rather, the statute "instructs the [Services] … to define the critical habitat of [endangered species]." *Lujan*, 504 U.S. at 558. Thus, the Services have designated critical habitats for endangered species as well as the PCEs within those habitats. *See* 50 C.F.R. § 17.95. An action agency's role is limited to determining whether a proposed action will modify (or affect) those designated habitats. *See* 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a). The Services have not designated a "critical habitat" for every listed species, and where they have not, an action agency by definition need not and cannot determine whether its action will modify critical habitat. *See*, *e.g.*, *Center for Biological Diversity v. BLM*, 422 F. Supp. 2d 1115, 1145 (N.D. Cal. 2006) (citing *Gifford Pinchot Task Force v. FWS*, 378 F.3d 1059, 1069-70, *amended*, 387 F.3d 968 (9th Cir. 2004)).

It should come as no surprise that EPA concluded that Enlist Duo would not modify any critical habitat. *See* ER679, 726-98. Once Enlist Duo is applied, after all, the treated corn, soybean, and cotton fields will remain corn, soybean, and cotton fields—albeit presumably with fewer weeds. NFFC, however, raises two meritless challenges to the registration in this regard.

First, NFFC contends that EPA has "created" a "rule" that there can be no "modification" of a critical habitat "unless EPA first found its action 'may affect' the listed species for which part of its designated critical habitat is a sprayed field." NFFC Br. 49-50 (emphasis omitted). This alleged "rule," according to NFFC, "conflates risks to *species* with risks to *habitat*, and attempts to restrict [EPA's] habitat consultation duties to only situations where [the agency] also finds species risks, thus making assessment of effects on critical habitat superfluous." *Id.* at 51 (emphasis added).

But EPA announced no such "rule." To the contrary, EPA explained that it would find a "modification" of a critical habitat (*i.e.*, an effect) here only if "one or more" of the following conditions exist: (1) the agency makes a "may affect" determination for a particular species and "corn, cotton, or soybean fields are habitat for the species," *or* (2) "[t]he available Services' information indicates that the species uses corn, soybean, or cotton fields and one or more effects ... would modify one or more of the designated PCEs and PBFs [physical biological features]." ER679. Note the disjunctive: far from requiring a "may affect" determination for a species as a necessary predicate for a critical habitat "modification"

determination, EPA acknowledged that a "modification" determination is appropriate if an action would modify physical and biological elements essential to a listed species' conservation, *see id.*, which is exactly what the statute requires. If anything, EPA's disjunctive test is *more* protective of "critical habitat" than the statute requires.

Second, NFFC argues that EPA erred by considering a species' "physical presence" in evaluating critical habitat. NFFC Br. 53. According to NFFC, "[a]s a matter of law, whether members of an endangered species physically occupy some part of a designated critical habitat (here, corn, cotton and soybean fields) is *completely irrelevant* to whether spraying pesticide on those fields 'may affect' the habitat, triggering consultation." *Id.* at 52-53 (emphasis added).

As noted above, however, the ESA defines a "critical habitat" primarily as the area "occupied" by a listed species, unless the Services have designated another area. *See* 16 U.S.C. § 1532(5)(A)(i), (ii). So, under the plain terms of the statute, occupancy is far from "completely irrelevant" to the critical habitat inquiry. Here, EPA considered the habitat attributes for all 531 species considered for "effects" determinations, including the 184 with designated critical habitat, and

concluded that it could rule out critical habitat modifications for the 176 species that do not use agricultural corn, soybean, or cotton fields. *See* ER679, 726-998. NFFC complains that "EPA must assess all potentially affected critical habitat, … regardless of whether members of protected species may be present in them, because the habitat nonetheless may be important for the species' survival or recovery." NFFC Br. 54 (emphasis omitted). But NFFC fails to identify critical habitat or PCEs for any of the relevant 184 species (which include such animals as the American crocodile, *see* ER982, the Green, Hawksbill, Leatherback and Loggerhead sea turtles, *see* ER984, and the North Atlantic and North Pacific Right Whale, *see* ER985) that overlap with corn, soybean, or cotton fields. *See generally* 50 C.F.R. § 17.95 (defining critical habitats). Thus, insofar as NFFC suggests that EPA erred by focusing on whether a particular species occupied the treated fields, as opposed to whether that species' PCEs were on the treated fields, any such error was harmless. *See*, *e.g.*, *Sagebrush Rebellion*, 790 F.2d at 764.

Finally, EPA correctly determined that agricultural corn, soybean, or cotton fields do not provide PCEs for any of the eight listed species that use such fields. *See* ER679, 975-98. Although NFFC asserts that such

fields provide PCEs for two of those species, the Virginia big-eared bat and the whooping crane, *see* NFFC Br. 55-56, that is simply not true. As noted above, the Services, not the action agencies, define the critical habitat (which by definition includes the PCEs), and the agricultural fields at issue here do not include critical habitats for either species. *See* 50 C.F.R. § 17.95-a (defining critical habitat for Virginia big-eared bat as five specific caves in West Virginia); 50 C.F.R. § 17.95-b (defining critical habitat for whooping crane as very specific areas in Kansas, Nebraska, Oklahoma, and Texas (mostly wildlife refuges) containing "[1] land, [2] water, *and* [3] airspace," which would rule out agricultural fields, which—unlike the areas designated by the Services—do not contain substantial bodies of water) (emphasis added). And again, because the Services, not EPA, define critical habitat and PCEs, any error by EPA in describing the critical habitat or PCEs designated by the Services was harmless. *See*, *e.g.*, *Sagebrush Rebellion,* 790 F.2d at 764.

IV. REMAND, RATHER THAN VACATUR, IS THE APPROPRIATE REMEDY FOR ANY DEFICIENCY HERE.

For all the reasons set forth above, EPA's registration of Enlist Duo fully complies with all applicable legal requirements. In the event this Court were to disagree, however, the appropriate remedy would be to

remand to the agency to address any deficiency *without* vacating the Enlist Duo registration. Under the APA, a reviewing court has discretion to remand a matter to the agency without vacating the challenged agency action (and indeed this Court did just that in the first round of this litigation). "Whether agency action should be vacated depends on how serious the agency's errors are 'and the disruptive consequences of an interim change that may itself be changed.'" *California Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (quoting *Allied-Signal, Inc. v. NRC*, 988 F.2d 146, 150-51 (D.C. Cir. 1993)). In other words, a determination that an agency made an error "is not the end of the analysis. In considering whether vacatur is warranted, [a court] must balance these errors against the consequences of such a remedy." *Id.* at 993; *see also Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995) ("When equity demands, the regulation can be left in place while the agency follows the necessary procedures.").

Here, the equitable balance tilts decidedly against vacatur. This is only a five-year conditional registration. ER37-38. As noted above, EPA on remand can readily remedy the deficiencies alleged by petitioners. *See, e.g.*, *Black Oak Energy, LLC v. FERC*, 725 F.3d 230, 244 (D.C. Cir.

2013) (refusing to vacate where "[w]e find it plausible that [the agency] can redress its failure of explanation on remand while reaching the same result"); *Allied-Signal*, 988 F.2d at 151 (refusing to vacate where "[i]t is conceivable that the [agency] may be able to explain" its action). In contrast, vacating the Enlist Duo registration—which has already been in effect for almost four years with respect to at least certain applications—would be enormously disruptive to American agriculture. *See*, *e.g.*, ER28, 556-67 (describing benefits of Enlist Duo).

As noted above, the irony here is that Enlist Duo has a *more* favorable environmental profile than other existing herbicides. Petitioners do not, and cannot, establish that if the Enlist Duo registration were vacated, farmers would simply refrain from using herbicides altogether; rather, they would go back to using herbicides with a *less* favorable environmental profile. *See* ER84 ("[A]ny decision on the Enlist Duo registration would likely have no effect on whether glyphosate continues to be used on corn, soybeans, and cotton—the decision would only impact which glyphosate product would be used."). Where, as here, vacatur "would at least temporarily defeat … the enhanced protection of the environmental values … at issue," *Center for Biological Diversity v.*

EPA, 861 F.3d 174, 188 (D.C. Cir. 2017) (internal quotation omitted), this Court and others have not hesitated to remand without vacatur. *See*, *e.g.*, *id.* at 188-89; *United States Sugar Corp. v. EPA,* 844 F.3d 268, 270 (D.C. Cir. 2016) (*per curiam*); *California Cmtys.*, 688 F.3d at 993-94; *North Carolina v. EPA*, 550 F.3d 1176, 1178 (D.C. Cir. 2008).

CONCLUSION

For the foregoing reasons, this Court should either dismiss the petitions for review for lack of jurisdiction or deny them on the merits.

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Respectfully submitted,

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STATEMENT OF RELATED CASES

Dow is not aware of any related cases pending in this Court.

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this Brief of Intervenor complies with the Appellate Commissioner's order of August 13, 2018, and is 18,996 words long, excluding the portions exempted by Fed. R. App. P. 32(f). The brief's type size and type face comply with Fed. R .App. P. 32(a)(5) and (6).

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