

Case 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,
Respondent-Intervenor.

NATURAL RESOURCES DEFENSE COUNCIL, INC.,
Petitioners,

v.

SCOTT PRUITT, et al.,
Respondents,
DOW AGROSCIENCES LLC,
Respondent-Intervenor.

On Petition for Review from the
United States Environmental Protection Agency

PETITIONERS' PETITION FOR REHEARING AND REHEARING EN BANC

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioners National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Center for Biological Diversity, Center for Food Safety, and Pesticide Action Network North America certify that they have no parent corporations and that no publicly held corporation owns more than ten percent of the Petitioners.

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GLOSSARY OF ACRONYMS AND TERMS

Academy	National Academy of Sciences
APA	Administrative Procedure Act
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide Fungicide and Rodenticide Act
FWS	Fish and Wildlife Service
LOC	Level of Concern
LOC/RQ	Level of Concern/Risk Quotient
NMFS	National Marine Fisheries Service
NOAEL	No Observed Adverse Effect Level
NOEL	No Observed Effect Level
RQ	Risk Quotient

RULE 35 STATEMENT

Rehearing of *National Family Farm Coalition (NFFC) v. EPA*, 966 F.3d 893 (9th Cir. 2020) is warranted because:

(A) The panel majority’s decision raises questions of exceptional importance. The decision allows over 500 endangered species spanning nearly 200 million acres to be exposed to a toxic pesticide without any Endangered Species Act (ESA) consultation. No court, in any jurisdiction, has ever held an agency approval of this type and magnitude could have absolutely no effect on any of hundreds of endangered species. Nor has any court previously permitted an agency in its ESA decision to rely on modeling and data that the National Academy of Sciences deemed “not scientifically defensible.”

(B) The majority’s decision conflicts with the *en banc* decision of *Karuk Tribe of California v. U.S. Forest Service*, 681 F.3d 1006, 1027 (9th Cir. 2012), as well as *Center for Biological Diversity v. Bureau of Land Management*, 698 F.3d 1101, 1022 (9th Cir. 2012), *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2011), *California ex rel. Lockyer v. U.S. Dep’t of Agriculture*, 575 F.3d 999, 1018-19 (9th Cir. 2009), *Washington Toxics Coalition v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005), and *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988). Rehearing is vital to secure and maintain uniformity.

PROCEDURAL HISTORY

This case challenges EPA’s registration of Dow’s pesticide product “Enlist Duo,” comprised of two active ingredients: 2,4-D and glyphosate. ER1-36. It is a novel “new use” registration allowing direct spraying over-the-top of crops engineered to resist both pesticides. ER28. The registration covers soy, corn, and cotton grown across 34 states, totaling over 185 million acres.¹ Federal regulators conservatively estimated the registration would increase 2,4-D use by 200 to 600 percent. ER353, ER443.

EPA recognized 2,4-D is toxic to plants, birds, and mammals. ER572, ER2063-67. EPA found 531 ESA-protected species and 184 critical habitats “inside the action area.” ER543, ER726-952. These included endangered mammals, birds, and plants, such as the whooping crane, Mexican wolf, and California condor. *Id.*

Nonetheless, EPA concluded that its approval—to spray this toxic combination pesticide on millions of acres, in new ways, at new seasonal times, and dramatically increasing 2,4-D—could have absolutely no effects on any endangered species in or near sprayed fields. ER24-25. EPA disclaimed any obligation to undertake ESA consultation with the expert wildlife agencies.

¹ Nat’l Agric. Statistics Serv., *Crop Acreage* (June 30, 2017), <https://downloads.usda.library.cornell.edu/usda-egmis/files/j098zb09z/9306t159c/mg74qp76z/Acre-06-30-2017.pdf>.

The panel majority affirmed. Judge Watford dissented and would have held that EPA violated the ESA and vacated the registration.

STATUTORY FRAMEWORK

In the ESA, Congress spoke “in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities, thereby adopting a policy which it described as ‘institutionalized caution.’” *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 194 (1978).

Section 7, the ESA’s “heart,” *Lockyer*, 575 F.3d at 1018, mandates federal agencies “insure” their actions (here, EPA’s registration of Enlist Duo) are not likely to jeopardize any endangered species or adversely modify their critical habitat. 16 U.S.C. § 1536(a)(2).

In complying with Section 7 agencies must use the “best scientific and commercial data available,” *id.*, and must “give the benefit of the doubt to the species,” *Conner*, 848 F.2d at 1454 & n.31 (quoting ESA’s legislative history).

Section 7(a)(2) and its regulations establish a process requiring EPA to evaluate the registration’s effects “in consultation and with the assistance of” the agencies that—unlike EPA—Congress designated as having special expertise in endangered species, Fish and Wildlife Service (FWS) and National Marine Fisheries Service. 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b).

I. The “No Effect/May Affect” Standard

At issue here is only the critical first consultation step: the Step 1 “No Effect/May Affect” threshold. If Enlist Duo “may affect” any endangered species or critical habitat, then EPA *must* consult. 50 C.F.R. §§ 402.14(a), 402.01(b). This Court, *en banc* in *Karuk Tribe*, defined the low threshold:

[A]ctions that have *any chance of affecting* listed species or critical habitat—even if it is later determined that the actions are ‘not likely’ to do so—*require* at least some consultation under the ESA.

681 F.3d at 1027 (emphases added). Further:

Any possible effect, whether beneficial, benign, adverse or of an undetermined character triggers the requirement [for consultation].

Id. (quoting *Lockyer*, 575 F.3d at 1018-19) (emphasis in *Lockyer*). *Karuk Tribe* enshrined *en banc* what the Court previously held, *e.g.*, *Kraayenbrink*, 632 F.3d at 496; *Lockyer*, 575 F.3d at 1018-19, and how the expert agencies define the threshold. 51 Fed. Reg. 19,926, 19,949 (June 3, 1986).² The intentional hair trigger to involve the expert agencies reflects the ESA’s “institutionalized caution” mandate. *Cottonwood Env’tl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1091 (9th Cir. 2015); *Lockyer*, 575 F.3d at 1018.

² FWS, *Endangered Species Consultation Handbook: Procedures for Conducting Consultation* (1998) at xvi, at https://www.fws.gov/endangered/esa-library/pdf/esa_section7_handbook.pdf.

Consultation takes two forms, formal (Step 3) and informal (Step 2). In formal consultation, FWS issues a Biological Opinion analyzing if the action is likely to jeopardize the existence of species or adversely modify critical habitat. 50 C.F.R. § 402.14(h). FWS provides “reasonable and prudent alternatives” to avoid jeopardy, or “reasonable and prudent measures” to minimize the impact of incidental take (no jeopardy). *Id.* § 402.14(g)-(h).

Formal consultation is not required if, during informal consultation (Step 2), FWS concurs in writing that, while the agency action “may affect” a species or habitat, the action is “not likely to adversely affect” it. *Id.* § 402.13. “The burden imposed by the consultation requirement need not be great.” *Karuk Tribe*, 681 F.3d at 1029 (explaining “informal consultation need be nothing more than discussions and correspondence with the appropriate wildlife agency”).

II. FIFRA and EPA’s “Risk Quotient” and “Levels of Concern” Modeling

Here, EPA used a Federal Insecticide Fungicide and Rodenticide Act (FIFRA) risk interpretation tool, its “Levels of Concern” (LOC), imported into the ESA context. ER18-19; ER2529. By its own terms, the LOC “interpretative policy” does not look for “no effect.” Rather, it is used to “indicate whether a pesticide, when used as directed, has the potential to cause *adverse effects* to non-target organisms.” ER18 (emphasis added), ER2529. EPA concluded “No Effect” whenever its Risk

Quotient (RQ), which is the measure of harm or mortality when a species is exposed to a certain pesticide amount, did not exceed its own LOC, which represents a level of adverse effect or mortality acceptable to EPA. ER18, ER2529; *NFFC*, 966 F.3d at 923.

EPA's model makes sense only under FIFRA's cost-benefit standard, where EPA need determine only if adverse effects are "unreasonable." 7 U.S.C. § 136(bb). The ESA, designed to insure agencies do not push imperiled species to extinction, emphatically prohibits such cost-benefit balancing. *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 929 (9th Cir. 2008).

III. The 2013 National Academy of Sciences Report

To address continuing disagreements, EPA and the expert agencies requested the National Academy of Sciences (Academy) evaluate the best scientific data for assessing pesticides' effects on endangered species. The 2013 Academy report has two relevant core conclusions. SBER001-195.³

First, in reviewing EPA's approach, the Academy resoundingly rejected the "Level of Concern/Risk Quotient" (LOC/RQ) process EPA applied here, concluding that it is "*not scientifically defensible* for assessing the risks to listed species

³ Also available at <https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides>.

posed by pesticides” SBER034 (emphasis added); SBER168-69 (criticizing EPA’s approach as making assumptions that are “not reliable;” with “unpredictable performance outcomes;” and as “not appropriate for assessments for listed species”). Instead, at Steps 2/3 of consultation, the Academy recommended EPA apply a “probabilistic approach that requires integration of the uncertainties.” SBER034.

Second, regarding Step 1, the Academy concluded that *any potential exposure* triggers “May Affect.” Because of pesticides’ inherent toxicity and the species expertise required for broad and unique ESA analyses, EPA should proceed to Step 2 and at least informally consult if there is geographic overlap between the pesticide’s potential use and species’ habitats. SBER028 (“If area overlaps are identified in Step 1, EPA would confer with the Services”); SBER072 (same); SBER048 (consequently some consultation “almost always” triggered for outdoor pesticides).⁴

⁴ EPA subsequently agreed to overlap as the “May Affect” trigger. EPA, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences*, at 2 (Figure 1), 4 at <https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf>.

REASONS FOR GRANTING REHEARING EN BANC

EPA violated the ESA in two core, interrelated ways. EPA vitiated the ESA's best science mandate and made arbitrary and capricious "No Effect" findings, because its model and resulting data were not reliable, appropriate, or even defensible for ESA assessments. That approach also meant EPA substituted an unlawful legal standard for the ESA's very low "May Affect" Step 1 consultation threshold. These errors allowed EPA to make its unprecedented "No Effect" conclusion and warrant rehearing.

I. EPA's Approach Violated the ESA.

EPA's LOC/RQ model is geared for "adverse effects," not no effects; that is the wrong Step 1 threshold. ER18; ER2529; *Karuk Tribe*, 681 F.3d at 1027. "Not Likely to Adversely Affect" is Step 2 of the process, requiring informal consultation and FWS concurrence. *Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1054 n.8 (9th Cir. 1994).⁵ The majority erred in letting EPA substitute FIFRA's less protective standards for the ESA's. *Washington Toxics Coal. v. U.S. Dep't of Interior*, 457 F. Supp. 2d 1158, 1179-80, 1184 (W.D. Wash. 2006) (rejecting earlier rulemaking effort to

⁵ Of 531 species, EPA informally consulted on one (eskimo curlew). FWS concurred because the bird is presumed already extinct, not because Enlist Duo exposures would be innocuous. SER432-434. For 3 geographically limited species, EPA prohibited use in their counties to avoid effects. ER544-45.

circumvent consultation similarly, explaining “[t]he risk framework of FIFRA (no unreasonable adverse effects) does not equate to the survival and recovery framework of the ESA”).

The majority acknowledged EPA applied FIFRA’s “unreasonable adverse effects” LOC/RQ model, but claimed EPA used “much more conservative assumptions” for ESA species. *NFFC*, 966 F.3d at 923. This is inaccurate.

First and fundamentally, EPA’s assumptions cannot be deemed “conservative” because, as the Academy explained, they are fundamentally flawed, “not [even] scientifically defensible.” SBER034. The EPA model is not properly probabilistic, does not account for the full range of pesticide harms, and does not incorporate uncertainties, rendering it “not appropriate” and “not reliable.” SBER168-69; *NFFC*, 966 F.3d at 933 (“No matter how conservative its thresholds, EPA will be interpreting an unreliable metric of risk.”) (Watford, J., dissenting). Furthermore, the levels (LOCs) set to trigger consultation are not calculated scientific measurements; they are EPA’s self-described “interpretative policy” for determining whether certain adverse effects are unreasonable (“of concern”) or not. ER2529; *NFFC*, 966 F.3d at 934 (LOC/RQ “does not qualify as ‘scientific data’ in the first place”) (Watford, J., dissenting).

EPA's approach is also too narrow because RQs hinge on acute and chronic harm levels; they do not account for some sub-lethal pesticidal harms, like behavioral effects. SBER111-12 ("Pesticides can have sub-lethal effects at multiple levels"); SBER113 & 116 (examples, e.g., a bird's ability to attract a mate, or a fish's ability to escape predators). "By relying on a scientifically indefensible method that generated speculative and unreliable estimates, EPA failed to meet its burden." *NFFC*, 966 F.3d at 934 (Watford, J., dissenting).

Second, even applying EPA's flawed and improperly cabined rubric, what EPA did still was not "conservative." *NFFC*, 966 F.3d at 923. While EPA used a lower *acute* toxicity LOC for listed animals, it applied the *same* LOC of 1 for *chronic* effects to all ESA-listed and non-listed animals, and for all listed *and* non-listed plants. ER2529-30, ER2105-06. That means, for example, EPA used the *same threshold* of chronic harm for the ubiquitous pigeon and the whooping crane, among the world's most endangered animals.⁶

Overall, the EPA system was so flawed that what it delivered was not actually a meaningful "risk estimate" even for "adverse effects," SBER168, SBER033, let alone a conservative one looking for "any chance" of "any possible effect." *Karuk Tribe*, 681

⁶ Even for acute animal harm, a *lowered* harm and mortality threshold is still not a legitimate "No Effect" finding. *Karuk Tribe*, 681 F.3d at 1027.

F.3d at 1027. EPA relied on a scientifically *indefensible* model to avoid any expert consultation, SBER034, the antithesis of the best science, 16 U.S.C. § 1536(a)(2), and giving endangered species the benefit of the doubt, *Conner*, 848 F.2d at 1454 & n.31. These errors rendered its “No Effect” conclusions arbitrary and capricious, and violated both the ESA’s “May Affect” standard, *Karuk Tribe*, 681 F.3d at 1027, and its Best Science mandate, *League of Wilderness Defs. v. Connaughton*, 752 F.3d 755, 763-64 (9th Cir. 2014) (to pass muster under ESA’s “best science” mandate, agencies “must support their conclusions with accurate and reliable data” and “consider[] all relevant data”).

II. EPA’s “May Affect” Admissions Triggered Consultation.

The majority admitted that EPA concluded endangered species would be “exposed to potentially harmful chemicals,” but said “exposure is not a recognition” of “may affect.” *NFFC*, 966 F.3d at 924. Maybe elsewhere, but that makes no sense here: Enlist Duo is a substance intended to kill, sprayed over millions of acres, known to be toxic to plants, mammals, and birds. That is precisely why the Academy (and EPA elsewhere) explained that pesticide/habitat overlaps *do* trigger consultation. *See supra* p.7-8 & n.4.

Moreover, contrary to the majority’s framing, EPA was *not* just measuring and acknowledging “exposure.” EPA inexpertly guessed what happens when there is

exposure to a certain amount. ER18 (“[RQs] are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic (RQ=Exposure/Toxicity).” EPA’s calculation does not measure for *no* toxic effect, just one that does not rise to EPA’s self-determined, overly narrow, and policy-based *level* of concern. That is not EPA’s decision to make unilaterally under the ESA.

For example, the chronic effect RQ’s for ESA-protected mammals were based on a toxicity threshold (the No Observed *Adverse* Effect Level, NOAEL) of 55 mg/kg/day from a rat reproduction study. ER626. The NOAEL use again proves that EPA’s entire approach was improperly tied to *adverse* effects. Moreover, the rats were *affected* (decreased body weight) at a far lower dose, under EPA’s more stringent No Observed Effect Level (NOEL) of just 5 mg/kg/day. ER625. Had EPA correctly used the NOEL instead of the NOAEL, it would have found risks even above its own “Level of Concern” for a host of ESA-protected mammals. ER657-664 (using NOAEL in “No Effect” determinations for endangered species in cropfields). “Any effect” requires consultation, not just those EPA deems toxic enough. *Karuk Tribe*, 681 F.3d at 1027.

Elsewhere, the majority acknowledged EPA’s admissions were not just of “exposure,” but that “Enlist Duo may affect hundreds of protected species.” *NFFC*, 966 F.3d at 924. *See* ECF 64-1 at 31-32 (listing record admissions). No matter how

EPA couched these admissions, just as in *Karuk Tribe*, given their “ordinary meaning” they should have triggered consultation “as a textual matter.” 681 F.3d at 1027 (mining that “might cause disturbance of surface resources” crossed the “May Affect” threshold).

III. EPA’s “No Effect” Determinations Were Arbitrary and Capricious.

Even just using EPA’s flawed approach, EPA *still* did not actually find “No Effect,” contrary to the majority’s statement. *NFFC*, 966 F.3d at 924. Rather in *every one* of the mere 23 species-specific assessments,⁷ EPA actually found a measurable risk of harm from acute and/or chronic toxicity. *See* ER654-78; *e.g.*, ER657 (Indiana Bat: “chronic RQ of 0.31 does not exceed the chronic LOC of 1.0 for listed species”); ER668 (Attwater’s prairie-chicken: “acute RQ of 0.09 does not exceed the acute LOC of 0.1”).

An acute RQ of 0.09 means EPA estimated endangered prairie-chickens could be exposed to 9% of the 2,4-D dose that would kill 50% of the exposed animals (LD50). ER2509 (defining Lethal Dose (LD) 50). A chronic RQ of 0.31 means that

⁷ For over 500 endangered species near sprayed cropfields, EPA categorically made “No Effect” findings with *no* individual species-specific assessments, despite those species initially being “within the action area.” ER649; ER543; ER25. *NFFC*, 966 F.3d at 924. Instead, EPA shrank the action area to just the sprayed fields, because it concluded the pesticide use instructions would reduce—but not eliminate—off-field drift and runoff. *See infra* pp.15-16.

endangered bats could be exposed to 31% of the highest exposure level found to not cause *adverse* effects (the NOAEL) on reproduction and growth. ER2045, ER657.

The majority did not grapple with any of this evidence.

While the “reasonableness” of these toxic effects might be debatable, it is undebatable that they *are* cognizable effects. *Karuk Tribe*, 681 F.3d at 1027 (“any chance” of “any possible effect”). EPA may believe they are insignificant or discountable, but as a matter of law such effects are the definition of “*Not Likely To Adversely Affect*,”⁸ which requires informal consultation and concurrence. 50 C.F.R. §§ 402.13(a), 402.14(b)(1). By redefining possible effects below its own “Level of Concern” to “No Effect” EPA unlawfully cut FWS out of the process.

IV. The Decision is Contrary to *Karuk Tribe*.

The majority quoted *Karuk Tribe*’s “No Effect/May Affect” definition, but as shown above it simply defied that which should have bound it. 681 F.3d at 1027. The majority’s own language reveals it sanctioned an improper standard. *NFFC*, 966 F.3d at 905 (claiming EPA properly found “no risk of *harm*,” not no effect); *id.* at 924 (EPA made “No Effect” findings for species that were not “at *risk*”).

⁸ FWS, *supra* n.2, at xv-xvi (defining “not likely to adversely affect” as “discountable, insignificant, or completely beneficial” effects).

It also created illusory distinctions. *NFFC*, 966 F.3d at 924-25. For example, the majority noted that *Karuk Tribe* held “mitigation measures that merely ‘reduce’ but cannot scientifically ‘eliminate’ an ‘effect’ probably compel a ‘may affect’ finding.” *Id.* at 924-25; *Karuk Tribe*, 681 F.3d at 1028. Yet that is *precisely* what EPA admitted, for 500+ endangered species: the pesticide *will* leave the fields via drift and runoff and affect species, just not in amounts EPA believed—using its scientifically indefensible model—were “of concern.” ER1043 (For ESA-listed species off-field, EPA “makes no claim that drift and runoff do not occur” but found only that, with mitigation, “exposures high enough to cause acute or chronic effects are not reasonably expected to occur”); *supra* n.7; ECF 64-1 at 34-35 (more record citations).

Thus, EPA did not “rule out,” *NFFC*, 966 F.3d at 925, any possible effects. ER19, ER20 (“reduce exposures off-site” thereby “limiting any potential risk of concern to the treatment site”) (emphasis added); ECF 170 at 16-17 (citations therein). Hundreds of nearby endangered birds, plants, and mammals will be exposed and may be affected. The majority let EPA use an unlawful (and fundamentally flawed) lens: the standard is not just what EPA inexpertly thinks is “adverse” but “any possible effect” on or off the fields. *Karuk Tribe*, 681 F.3d at 1027.

The majority instead cited *Friends of Santa Clara River v. Army Corps of Engineers*, 887 F.3d 906 (9th Cir. 2018), which had a “no effect” determination where a project discharged dissolved copper into a river; however it was undisputed the discharged copper was *well-below* background levels already in the river and would not increase fish exposure. *Id.* at 923-24; *Ctr. for Biological Diversity v. Army Corps of Eng’rs*, 2015 WL 12659937, at *14-16 (C.D. Cal. 2015) (explaining discharges actually *lower* risk by diluting copper concentration). Enlist Duo will massively *increase* 2,4-D use up to 600 percent. ER353. Nor does *Santa Clara* authorize an agency to find “no effect” using thresholds designed to measure adverse effects. This case is much more like *Kraayenbrink*, where the “sheer number of acres affected” by an agency decision—there, 160 million, here 185 million—can “alone suggest” and “handily meet” the consultation trigger. 632 F.3d at 496.

V. The Majority Created a Dangerous New Loophole.

The majority “ground” its best science holding on its conclusion that enforcing the ESA’s mandate required new data, and it applies only when that data is already “readily available.” *NFFC*, 966 F.3d at 926. As Judge Watford explained, the majority created a “new rule with serious implications.” *Id.* at 933.

First, EPA erred in using a model and resulting data that the Academy declared “not scientifically defensible” for endangered species’ risk assessment, for

multiple reasons. *See supra* p.7, 9-10; SBER034. That inappropriate reliance caused EPA to violate the ESA’s best science requirements and the APA’s baseline requirement that agencies “examine the relevant data” and make a “rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The majority focused on why EPA allegedly could not be expected to do *better*, but failed to address the fundamental problems with what EPA *did*. *See supra* pp.7-10. ESA claims are reviewed under the APA’s standard of review, *Karuk Tribe*, 681 F.3d at 1017, and EPA failed it.⁹

Second, EPA did *not* need to create new data because the answer was “readily available.” EPA needed simply to apply its geographic use/species habitat overlap data. ER24, ER649. According to the Academy—and EPA elsewhere—overlap *by itself* warrants a “May Affect” finding, triggering consultation. *See supra* n.4 (EPA: “The ‘No Effect/May Affect’ determination (NAS’ Step 1) will largely be based on the overlap ... any species or critical habitat that overlaps with the action area will be

⁹ The *data* EPA used was arbitrary and capricious, *see supra*, but more fundamentally, the model/data distinction the majority posits, *NFFC*, 966 F.3d at 926 n.12, is illusory. *Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1050 (9th Cir. 2008) (reliable data relies on the “reliability of its models”); *see also* 84 Fed. Reg. 44,976, 45,000 (2019) (models part of best available science).

considered a ‘May Affect’”). In short, co-occurrence is the best science available in the pesticide context to determine what is at issue in this case, Step 1.

Even for Step 2/3, the agencies would not have to create something new to apply the Academy’s probabilistic approach. SBER034 (Academy in 2013 pointing to then-existing “probabilistic methods that have already been successfully applied to pesticide risk assessments”); *see also* SBER56-57, SBER170. They simply had to compile existing information and consider it using the correct scientific and legal lens. *Conner*, 848 F.2d at 1454 (agency required to “develop projections of oil and gas activities which may indicate potential conflicts between development and [protected species]”).

Finally, the majority claimed EPA could not apply the Academy’s approach immediately, but the actual timing shows EPA acted arbitrarily and capriciously. EPA registered Enlist Duo in 2014, but during litigation requested remand. *NFFC*, 966 F.3d at 906. When EPA re-registered Enlist Duo in 2017—now four years after the Academy’s 2013 report—EPA *still* failed to apply it, despite having the perfect opportunity. EPA’s continued use of an older, discredited scientific model was

arbitrary and capricious. *Sierra Club v. EPA*, 671 F.3d 955, 966-68 (9th Cir. 2012) (EPA action arbitrary and capricious for not utilizing more recent model).¹⁰

At the same time as the 2017 re-approval, EPA applied the Academy's model for other pesticides (chlorpyrifos, malathion, and diazinon),¹¹ with dramatic differences for hundreds of species. For example, for chlorpyrifos on cotton, soybeans, and other crops, EPA made a "may affect" determination for 99% (1819 of 1835) and a "likely to adversely affect" determination for 97% (1778 of 1835) of listed species.¹² For malathion, the call was "may affect" for 99% (1819 of 1835) and 97% "likely to adversely affect" (1778 of 1835).¹³

¹⁰ The majority erroneously claimed FWS agreed with EPA's approach, but the cited report says only that "EPA intends" to use its LOC/RQ approach to assess Enlist Duo, without mention of FWS. EPA *et al.*, *Interim Report to Congress*, 20, 22 (Nov. 2014), at <https://www.epa.gov/sites/production/files/2015-07/documents/esareporttocongress.pdf>. EPA is the action agency responsible for using the best available science and even if FWS *had* agreed, that could not "absolve" EPA of its ESA duties, as the majority admits. *NFFC*, 966 F.3d at 926.

¹¹ EPA, *EPA Releases Final Biological Evaluations of Three Chemicals' Impacts on Endangered Species* (Jan. 18, 2017), at <https://www.epa.gov/pesticides/epa-releases-final-biological-evaluations-three-chemicals-impacts-endangered-species>.

¹² EPA, *Chlorpyrifos Executive Summary* i, iv (Tables 1 & 2), at <https://www3.epa.gov/pesticides/nas/final/chlorpyrifos/executivesummary.docx>.

¹³ EPA, *Malathion Executive Summary* i, iv (Tables 1 & 2), at <https://www3.epa.gov/pesticides/nas/final/malathion/executive-summary.docx>.

However, EPA has not stopped using the scientifically indefensible LOC/RQ model, *used earlier this year* to register another pesticide,¹⁴ contrary to the majority's erroneous assurances that they "do not expect [this situation] to reoccur." *NFFC*, 966 F.3d at 926.

CONCLUSION

The majority's decision cut a gaping hole in the ESA's heart. It creates perverse agency incentives to use models and data they know are scientifically unsound, and to determine endangered species' toxicity levels or mortality risks they believe appropriate, rather than consult the expert agencies for "any possible effect," as required. And it will leave 500+ endangered species indisputably exposed to massive new use of toxic pesticides without any expert analysis of the true risk to them.

Accordingly, Petitioners respectfully request the Court vote to grant this petition.

¹⁴ EPA, *Isoxaflutole Registration* (Mar. 25, 2020) at 9, at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2019-0398-0071> (applying same LOC/RQ model, finding "No Effect" on any of 158 listed species across 25 states).

DATED: September 15, 2020.

Respectfully submitted,

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for Food Safety, and Pesticide Action Network
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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rule 35(b)(2)(a), this brief is proportionately spaced, has typeface of 14 points or more and contains 4,198 words excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

DATED: September 15, 2020.

s/ George A. Kimbrell
George A. Kimbrell

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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ADDENDUM

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM
COALITION; FAMILY FARM
DEFENDERS; BEYOND PESTICIDES;
CENTER FOR BIOLOGICAL DIVERSITY;
CENTER FOR FOOD SAFETY;
PESTICIDE ACTION NETWORK NORTH
AMERICA,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION
AGENCY; ANDREW R. WHEELER, in
his official capacity as
Administrator,

Respondents,

DOW AGROSCIENCES LLC,

Respondent-Intervenor.

No. 17-70810

EPA No.
EPA-HQ-OPP-
2016-0594

2 NAT'L FAMILY FARM COALITION V. USEPA

NATURAL RESOURCES DEFENSE
COUNCIL,

Petitioner,

v.

ANDREW R. WHEELER, in his official
capacity as Administrator of the
United States Environmental
Protection Agency; U.S.
ENVIRONMENTAL PROTECTION
AGENCY,

Respondents,

DOW AGROSCIENCES LLC,

Respondent-Intervenor.

No. 17-70817

EPA No.
EPA-HQ-OPP-
2016-0594

OPINION

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

Argued and Submitted May 16, 2019
Submission Withdrawn May 30, 2019
Resubmitted July 22, 2020
Portland, Oregon

Filed July 22, 2020

Before: N. Randy Smith, Paul J. Watford, and
Ryan D. Nelson, Circuit Judges.

Opinion by Judge R. Nelson;
Concurrence by Judge R. Nelson;
Dissent by Judge Watford

SUMMARY*

Environmental Protection Agency

The panel granted one petition for review, denied another petition for review, and remanded without vacatur to the Environmental Protection Agency (“EPA”) in actions challenging the EPA’s decisions to register Enlist Duo – a pesticide designed to kill weeds on corn, soybean, and cotton fields – in 2014, 2015, and 2017.

Enlist Duo combines two chemicals – 2,4-dichlorophenoxyacetic acid (“2,4-D”) choline salt and glyphosate.

The panel held that the petitions for review were timely. A petition for review challenging a pesticide registration order in a court of appeal must be filed within 60 days after entry of such order. Here, the 2017 Notice of Registration was signed on January 12, 2017. The panel held that because the “date of entry” was not “explicitly” provided in the Notice of Registration, the “date of entry” was “two weeks after ... [the Notice of Registration was] signed” – January 26, 2017. 40 C.F.R. § 23.6. The petitions filed 54 days later were therefore timely. 7 U.S.C. § 136n(b).

The panel next addressed petitioners’ Article III standing. First, concerning the claims under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), alleging that EPA misapplied FIFRA’s procedural

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

requirements and lacked substantial evidence in support of its decision that Enlist Duo's registration complied with those requirements, the panel held that petitioners National Resource Defense Council ("NRDC") and Center for Food Safety ("CFS"), based on their members' standing, both had associational standing to bring FIFRA claims. Because one petitioner from each petition had associational standing, the panel did not need to decide whether the other National Family Farm Coalition ("NFFC") petitioners had associational standing. Second, concerning the claims under the Endangered Species Act ("ESA"), alleging that EPA violated the ESA's consultation procedures in registering Enlist Duo, the panel held that because one of CFS's members had Article III standing, the organization also had associational standing to bring the ESA claims. In addition, the Article III standing of one NFFC petitioner made the ESA claims asserted by NFFC petitioners justiciable.

Turning to the merits, the panel considered petitioners' FIFRA claims. FIFRA is a regulatory scheme aimed at controlling the use, sale, and labeling of pesticides; and the mechanism used to further this aim is a process called "registration." Registration can be unconditional or conditional, and both types often involve "pesticide products."

The panel rejected NRDC's claim that the EPA incorrectly applied what NRDC believed to be the more lenient "conditional" registration standard rather than the more stringent "unconditional" standard when it registered Enlist Duo in 2014. First, the panel held that NRDC waived the argument. Second, even absent waiver, the panel held that NRDC's argument was not persuasive. The registration

documents supported the conclusion that EPA was applying the unconditional standard.

NFFC petitioners argued that EPA incorrectly applied FIFRA's "cause any unreasonable adverse effects" unconditional registration standard in its 2017 registration decision. EPA conceded that it cited the wrong standard, but the panel held that any error was harmless because the standard for unconditional registration was higher, not lower, than the standard for conditional registration. The panel held that the error did not show that EPA lacked substantial evidence to support its conclusions.

Petitioners argued that EPA lacked substantial evidence for its 2014, 2015, and 2017 registration decisions for four reasons. First, the panel agreed with petitioners that EPA failed to properly assess harm to monarch butterflies from increased 2,4-D use on milkweed in target fields. The panel held that given the record evidence suggesting monarch butterflies may be adversely affected by 2,4-D on target fields, EPA was required, under FIFRA, to determine whether any effect was "adverse" before determining whether any effect on the environment was, on the whole, "unreasonable." The panel concluded that EPA's failure to do so meant that its decision was lacking in substantial evidence on the issue. Second, the panel rejected the argument that EPA failed to consider that Enlist Duo would increase the use of glyphosate over time. The panel held that substantial evidence supported EPA's conclusion that neither the initial 2014 registration of Enlist Duo – nor the subsequent approvals for new use – will increase the overall use of glyphosate. Third, the panel rejected petitioners' contention that EPA failed to properly consider 2,4-D's volatility – i.e., its tendency to evaporate into a gas and drift to non-target plants. The panel held that EPA reasonably

relied on studies to support its conclusion that the volatility of 2,4-D choline salt will not cause on unreasonable adverse effects on the environment. Accordingly, substantial evidence supported EPA's findings. Fourth, the panel rejected NFFS petitioners' contention that EPA should have accounted for the potential synergistic effect of mixing Enlist Duo with a different chemical called glufosinate. The panel held that this concern was speculative. In conclusion, as to FIFRA, the panel granted NRDC's petition for review in part, and denied it in part.

The panel next addressed, and rejected, the petitioners' ESA claims. The ESA and its implementing regulations delineate a process – known as Section 7 consultation – for determining the biological impacts of a proposed action. The process starts with a determination whether the proposed action will have “no effect” or if it “may effect” listed species or critical habitat. If an action will have no effect, no consultation with the expert agencies is needed.

First, the panel rejected NFFC petitioners' challenge to EPA's “no effect” findings for plants and animals. The panel held that the EPA did what the ESA required it to do: assess risks to determine whether the exposure of protected species and critical habitat to potentially harmful chemicals would have any possible effect. The panel concluded that EPA's ultimate “no effect” findings, and adoption of mitigation measures, were not arbitrary, capricious, or contrary to law. Second, the panel rejected NFFC petitioners' argument that EPA's rationale for limiting the “action area” to the treated field was not sound. The panel accorded deference to the EPA in the way it chose to define the action area. Third, the panel rejected NFFC petitioners' argument that EPA violated its duty to insure no “adverse modification” of “critical habitat” by relying on its 2016 risk assessment.

Finally, the panel addressed the remedy for EPA's error in its registration decisions under FIFRA. The panel held that remand without vacatur was warranted. EPA's error in failing to consider harm to monarch butterflies caused by killing target milkweed was not "serious." The panel remanded so that EPA can address the evidence concerning harm to monarch butterflies and whether the registration of Enlist Duo will lead to an unreasonable adverse effect on the environment.

Concurring, Judge R. Nelson wrote separately to address how the interplay of FIFRA's venue provision and standing could make a difference in a future case. In this case, the interplay between FIFRA's venue provisions and Article III standing did not make a difference because, for each petition, one petitioner over which venue was proper also demonstrated standing.

Dissenting, Judge Watford agreed with the majority that there was jurisdiction to review the petitioners' challenges and that the EPA violated FIFRA by failing to assess the impact that Enlist Duo's use will have on the monarch butterfly. However, in his view, EPA also violated the ESA by failing to use the best scientific data to assess whether Enlist Duo will adversely affect threatened or endangered species. Accordingly, he would vacate the 2014 and 2017 registrations under review.

COUNSEL

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OPINION

R. NELSON, Circuit Judge:

Petitioners challenge EPA's decisions to register Enlist Duo—a pesticide designed to kill weeds on corn, soybean, and cotton fields—in 2014, 2015, and 2017. According to Petitioners, EPA's decisions violate FIFRA and the ESA. We grant one petition in part as to FIFRA, deny the other petition as to both the ESA and FIFRA, and remand to the agency without vacatur.

I

Corn, soybeans, and cotton are three of the most important agricultural commodities in the United States. Corn is the primary feed grain in the United States and worldwide, soybeans are the world's largest source of protein feed for animals and the second largest source of vegetable oil, and cotton is one of the most important textile fibers in the world.

These crops provide vital value to the United States and the world. Domestically, these three crops together have a gross production value of approximately \$103 billion per year. Internationally, the United States is the world's leading corn and soybean producer and exporter. The United States also provides, together with China and India, two-thirds of the world's cotton.

This important industry, however, is not immune from a plight that threatens every gardener: weeds. Since the 1970s, glyphosate dimethylammonium salt ("glyphosate") has been used on corn, soybeans, and cotton crops to reduce weeds. Over time, however, certain noxious weeds have grown resistant to glyphosate. That resistance in turn decreases crop yield, with severe economic consequences.

To help solve this problem, Dow Agrosiences LLC ("Dow") invented Enlist Duo. Enlist Duo combines two chemicals—2,4-dichlorophenoxyacetic acid ("2,4-D") choline salt and glyphosate. Both 2,4-D and glyphosate have been registered for certain uses as pesticides for decades. When combined, however, they represent a significant improvement over glyphosate and 2,4-D, used separately. Combining the two chemicals delays the development of the weeds' resistance and allows pesticide use later in the growing season, thereby improving yields.

EPA issued a final order registering Enlist Duo under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") in October 2014. In that registration decision, EPA did not perform a risk assessment for Enlist Duo's glyphosate component. Instead, it found that a new assessment was not needed because glyphosate was already being used in the same way in other pesticides to treat weeds. But the same was not true for 2,4-D. That component was being approved for use later into the growing season and on

taller-growing crops for the first time. So EPA performed a full risk assessment for 2,4-D. That analysis assessed human health risks; ecological risks; and risks to endangered species, plants, and critical habitats posed by 2,4-D. It also considered whether 2,4-D would volatilize—that is, evaporate into a gas—and drift to non-target plants and animals.

EPA found, based on multiple studies, that the type of 2,4-D in Enlist Duo—a choline salt variety—is less volatile than other forms of 2,4-D. That meant there was no risk of harm off the treated field, so long as the label requirements—including the use of nozzles, buffers, and avoiding application aerially—were followed to avoid the risk of spray drift. This finding led EPA to limit the “action area” to treated fields, thereby reducing the number of species subject to an ESA analysis. EPA then concluded, based on its FIFRA risk assessments and conservative ESA analysis, that Enlist Duo’s registration would “not generally cause unreasonable adverse effects on the environment” under FIFRA and would comply with the ESA, subject to certain use restrictions.

Based on this conclusion, EPA issued a registration of Enlist Duo under FIFRA, which allowed Enlist Duo to be used on corn and soybean crops in six states. EPA’s decision, however, was ambiguous as to which FIFRA registration standard it was applying. The pesticide license approved an “unconditional” registration. So did the Proposed Decision Document. But the final registration document articulating EPA’s reasoning cited FIFRA’s “conditional” registration provision instead. EPA also referenced additional data requirements in the registration, even though outstanding data requirements are typically referenced in conditional registrations.

Petitioners National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Center for Biological Diversity (“CBD”), Center for Food Safety (“CFS”), and Pesticide Action Network North America (“PANNA”) (collectively, the “NFFC Petitioners”) and Petitioner National Resource Defense Council (“NRDC”) challenged EPA’s 2014 registration decision in this Court. *NRDC v. EPA*, No. 14-73353 (9th Cir. Oct. 30, 2014); *Ctr. for Food Safety v. EPA*, No. 14-73359 (9th Cir. Oct. 30, 2014). While that litigation was pending, EPA issued a final order amending the 2014 registration to allow the use of Enlist Duo on corn and soybean crops in an additional nine states. That 2015 registration decision was supported by an ecological risk assessment for the protected species in the new states. The decision also relied on critical habitat modification determinations for the new uses of 2,4-D.

Petitioners challenged the 2015 registration decision as well, *NRDC v. EPA*, No. 15-71213 (9th Cir. Apr. 20, 2015); *Ctr. for Food Safety v. EPA*, No. 15-71207 (9th Cir. Apr. 20, 2015), and the challenges to the 2014 and 2015 registration decisions were consolidated in one proceeding. But briefing was never completed. Instead, EPA moved to remand and vacate the 2014 and 2015 registrations. EPA did so after discovering that Dow had filed a patent application with the U.S. Patent and Trademark office claiming “synergism”—that is, two chemicals working together to produce a greater combined effect than they would separately—between glyphosate and 2,4-D. This Court granted the request to remand the case, but denied the request for vacatur, leaving the 2014 and 2015 registration decisions in place.

Shortly thereafter, on January 12, 2017, EPA issued another registration decision regarding Enlist Duo. In that decision, EPA relied on new data on synergy to conclude

that no concern lay with synergy between the glyphosate and 2,4-D in Enlist Duo. EPA did not, however, address evidence that destruction of milkweed on target fields would harm the monarch butterfly population. The decision also contained three main conclusions. First, it reaffirmed EPA's 2014 and 2015 registration decisions. Second, it authorized the use of Enlist Duo on corn and soybean crops in 19 additional states, bringing the total number of permitted-use states to 34. Third, it authorized a new use of Enlist Duo on cotton crops in all 34 states.

To support these decisions, EPA relied in part on its prior analysis of glyphosate and 2,4-D. But EPA did perform some new analysis. For example, EPA relied on an updated ecological risk assessment for 531 ESA-listed species in the 34 states where Enlist Duo was approved. The updated risk assessment, like the prior ones, used an iterative approach, through which species were ruled out and given "no effect" findings if their exposure to 2,4-D did not exceed a set "level of concern" after screening-level and, in some cases, species-specific assessments. Using this methodology, EPA made "no effect" findings as to all plants and animals off the treated field, after imposing similar mitigation measures as it had in 2014. This same methodology supported EPA's "no effect" findings for 19 of 23 species on the treated field. EPA therefore did not contact the consultation agencies as to these species. As to the remaining four species, EPA imposed location-based label restrictions to avoid harm to three of them. EPA then consulted the Fish and Wildlife Service ("FWS") as to the Eskimo curlew—after which FWS concurred with EPA's conclusion that the Eskimo curlew would not be adversely affected by Enlist Duo. The 2017 decision, relying on new critical habitat analysis, also concluded that no critical habitats would be affected because the eight species that occurred on corn, cotton, and soybean

fields did not have physical or biological features essential to the species in agricultural fields.

Despite this new data and analysis, there were, for the first time, data gaps relating to 2,4-D that were not present during the prior registrations. These gaps—which related to 2,4-D generally—meant that EPA could not register Enlist Duo unconditionally. Instead, EPA registered the entire Enlist Duo product on a “conditional” basis under FIFRA. In doing so, however, EPA cited FIFRA’s unconditional “cause unreasonable adverse effects” standard rather than FIFRA’s conditional “significantly increase the risk of unreasonable adverse effects” standard.

Petitioners challenged EPA’s 2017 decision on March 21, 2017. In the resulting briefing, the parties disagreed about whether EPA’s 2014 and 2015 registration decisions could also be reviewed. We held, after oral argument, that all three decisions were subject to review. We then ordered the parties to submit supplemental briefing addressing any challenges to the 2014 and 2015 registrations.

II

We first address whether this case is properly before us. EPA does not raise any overarching challenge to jurisdiction.¹ Dow, by contrast, argues that (1) the petitions

¹ EPA does argue that NRDC lacks Article III standing to raise arguments about glyphosate. According to EPA, any favorable decision about glyphosate would not redress NRDC’s alleged injuries because glyphosate will continue to be used in the same quantities. We address—and reject—that argument below. *See infra* Section II.B.2.

for review were untimely; and (2) Petitioners lack associational standing.²

A

We begin with Dow's argument that the petitions for review were untimely. A petition for review challenging a pesticide registration order in a court of appeals must be filed "within 60 days after the entry of such order." 7 U.S.C. § 136n(b).³ The "date of entry of an order" is governed by regulation. 40 C.F.R. § 23.6. "Unless . . . [EPA's] Administrator otherwise explicitly provides in a particular order, the time and date of entry of an order issued by the Administrator" is "two weeks after it is signed." *Id.*

Here, the 2017 Notice of Registration was signed on January 12, 2017. In addition, the "Date of Issuance" on the Notice of Registration is January 12, 2017. But Petitioners did not file their petitions until March 21, 2017—68 days

² Dow also argues that venue is improper as to three of the six NFFC Petitioners (National Family Farm Coalition, Family Farm Defenders, and Beyond Pesticides) because none of them "reside[]" or "ha[ve] a place of business" in the Ninth Circuit. 7 U.S.C. § 136n(b). But we need not address that argument. Venue is proper as to the other three NFFC Petitioners (CFS, CBD, and PANNA) because they do "reside" or "have a place of business" in the Ninth Circuit. So regardless whether venue is improper as to three of the six NFFC Petitioners, we can address the merits of the NFFC petition.

³ FIFRA also allows for judicial review of EPA's decisions in federal district courts when EPA refuses to "cancel or suspend a registration or to change a classification" or for "other final actions of the Administrator not committed to the discretion of the Administrator by law." 7 U.S.C. § 136n(a).

after the Notice of Registration was issued. According to Dow, this means the petitions were eight days too late.

Dow's argument rests on the date of issuance—January 12—being the “date of entry” of the order under 7 U.S.C. § 136n(b) and 40 C.F.R. § 23.6. But for this argument to work, the date of issuance must say that it is the “date of entry” “explicitly,” 40 C.F.R. § 23.6—that is, “without ambiguity or vagueness,” *Explicit*, Black's Law Dictionary (10th ed. 2014). And here, considerable ambiguity exists. The Notice of Registration does not “explicitly” include a “date of entry.” Nor does “issue” mean the same thing as “entry.” *Compare Issue*, Black's Law Dictionary (10th ed. 2014) (“to send out or distribute officially”), *with Entry*, Black's Law Dictionary (10th ed. 2014) (“the placement of something before the court or on the record”). Thus, the date of issuance of the 2017 registration does not “explicitly” indicate the “date of entry.”

Because the “date of entry” was not “explicitly” provided in the Notice of Registration, the “date of entry” was “two weeks after . . . [the Notice of Registration was] signed”—January 26, 2017. 40 C.F.R. § 23.6. The petitions, filed 54 days later, were therefore timely. 7 U.S.C. § 136n(b); 40 C.F.R. § 23.6.⁴

B

Dow also argues Petitioners lack standing to bring their petitions for review. To have associational standing, each organization must show that “(a) its members would otherwise have standing to sue in their own right; (b) the

⁴ This comports with EPA's interpretation of the relevant statute and regulation in this and other cases.

interests it seeks to protect are germane to the organization's purposes; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Am. Diabetes Ass'n v. U.S. Dep't of the Army*, 938 F.3d 1147, 1155 (9th Cir. 2019) (citation omitted). Here, there is no dispute that at least one Petitioner from each petition for review has satisfied the second and third requirements. We therefore decide whether at least one Petitioner from each petition has shown that at least one of its members would have Article III standing to sue in his or her own right. *Mont. Shooting Sports Ass'n v. Holder*, 727 F.3d 975, 981 (9th Cir. 2013) ("the presence in a suit of even one party with standing suffices to make a claim justiciable" (quoting *Brown v. City of Los Angeles*, 521 F.3d 1238, 1240 n.1 (9th Cir. 2008))).

Article III of the United States Constitution confines federal courts to hearing only "[c]ases" and "[c]ontroversies." U.S. Const. art. III, § 2, cl. 1. "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) (citation omitted). To establish standing, a plaintiff must demonstrate "(1) a concrete and particularized injury that is 'actual or imminent, not conjectural or hypothetical'; (2) a causal connection between the injury and the defendant's challenged conduct; and (3) a likelihood that a favorable decision will redress that injury." *Pyramid Lake Paiute Tribe of Indians v. Nev., Dep't of Wildlife*, 724 F.3d 1181, 1187 (9th Cir. 2013) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992)).

To meet this standard, Petitioners must show a "substantial probability" of standing, *Nw. Requirements*

Utils. v. FERC, 798 F.3d 796, 805 (9th Cir. 2015) (citation omitted), which is the same burden “as that of a plaintiff moving for summary judgment in the district court,” *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002). Because a “plaintiff must demonstrate standing for each claim he seeks to press and for each form of relief that is sought,” we analyze Petitioners’ Article III standing for the ESA and FIFRA claims separately. *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017) (quoting *Davis v. FEC*, 554 U.S. 724, 734 (2008)).

1

First, the FIFRA claims. NFFC Petitioners and NRDC both assert that EPA misapplied FIFRA’s procedural requirements and lacked substantial evidence in support of its decisions that Enlist Duo’s registration complied with those requirements. These are procedural injuries. Indeed, the registration standards at issue are the safeguards put in place by Congress to ensure that approved pesticides do not cause adverse effects on the environment. 7 U.S.C. § 136a. And EPA’s alleged failure to follow those standards is what leads to the alleged “substantive harm to the environment” in this case. *Citizens for Better Forestry v. U.S. Dep’t of Agric.*, 341 F.3d 961, 971 (9th Cir. 2003) (internal quotation marks and citation omitted). We therefore apply the rules of Article III standing that apply to procedural injuries in determining Petitioners’ standing to assert their FIFRA claims. *See Nat. Res. Def. Council v. Jewell*, 749 F.3d 776, 783 (9th Cir. 2014). NRDC and one of NFFC Petitioners, CFS, meet that standard here based on their assertion of procedural violations of FIFRA.

Injury in Fact for NRDC. In the context of procedural violations, the injury-in-fact requirement is met if “the procedures in question are designed to protect some

threatened concrete interest of [the petitioner] that is the ultimate basis of his standing.” *Salmon Spawning & Recovery All. v. Gutierrez*, 545 F.3d 1220, 1225 (9th Cir. 2008) (internal quotation marks and citation omitted). NRDC meets that standard here. Members of NRDC have submitted declarations stating that they enjoy watching the monarch butterfly migration where they live, that Enlist Duo is approved for use in their states, and that they are concerned they will no longer be able to enjoy observing monarch butterflies because of Enlist Duo’s effects on milkweed.

These declarations show a concrete interest for two reasons. First, a concrete interest can be “an aesthetic or recreational interest in a particular place, or animal, or plant species.” *Ecological Rights Found. v. Pac. Lumber Co.*, 230 F.3d 1141, 1147 (9th Cir. 2000). And second, there is a “geographic nexus between the individual[s] asserting the claim and the location suffering [the] environmental impact.” *Ashley Creek Phosphate Co. v. Norton*, 420 F.3d 934, 938 (9th Cir. 2005) (internal quotation marks and citation omitted); *see id.* (“[P]laintiffs who use the area threatened by a proposed action or who own land near the site of a proposed action have little difficulty establishing a concrete interest.”).

Moreover, the registration provisions at issue are designed to protect the environment. *Salmon Spawning*, 545 F.3d at 1226. Both the conditional and unconditional registration provisions in FIFRA require EPA to consider “unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(C), (c)(7). These effects would include any effect on monarch butterflies, which is what NRDC’s members are concerned about.

Dow argues that NRDC cannot satisfy the injury-in-fact requirement because it cannot prove that Enlist Duo has caused a decline in the monarch butterfly population. But “a credible threat of harm is sufficient to constitute actual injury for standing purposes.” *Cent. Delta Water Agency v. United States*, 306 F.3d 938, 950 (9th Cir. 2002). Thus, NRDC need only show that the exercise of a procedural right “could protect [its] concrete interests.” *Cottonwood Env'tl Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1082 (9th Cir. 2015). It has done so here.

Causation and Redressability for NRDC. We now turn to the second and third requirements for Article III standing, which are relaxed for NRDC because it has established injury in fact. *See Salmon Spawning*, 545 F.3d at 1226. The causation requirement is satisfied by showing a “reasonable probability of the challenged action’s threat to [NRDC’s] concrete interest.” *Hall v. Norton*, 266 F.3d 969, 977 (9th Cir. 2001) (internal quotation marks and citation omitted). To satisfy the redressability requirement, by contrast, NRDC need only show “that the relief requested—that the agency follow the correct procedures—*may* influence the agency’s ultimate decision of whether to take or refrain from taking a certain action.” *Salmon Spawning*, 545 F.3d at 1226–27 (emphasis added).

Here, the causation element is satisfied because there is a “reasonable probability” that EPA may have further minimized any alleged harm to monarch butterflies had it adopted NRDC’s arguments. *Hall*, 266 F.3d at 977. Moreover, adopting NRDC’s arguments “*may* influence the agency’s ultimate decision of whether to take or refrain from taking a certain action,” which satisfies the redressability requirement. *Salmon Spawning*, 545 F.3d at 1226–27 (emphasis added).

Both EPA and Dow argue that this conclusion cannot be right. EPA contends, for example, that NRDC lacks standing to raise any arguments about glyphosate. According to EPA, vacatur of the registration of Enlist Duo would not redress any alleged glyphosate-based harms because, even if Enlist Duo was not registered, other pesticides containing glyphosate would continue to be used such that overall glyphosate use would not decrease. Dow, for its part, advances a very similar argument, contending that because the registration does not alter any existing uses of glyphosate and 2,4-D, NRDC cannot show that a favorable decision here would redress its supposed injuries.

These arguments misunderstand the redressability inquiry for procedural injuries. “[T]he mere existence of multiple causes of an injury does not defeat redressability, particularly for a procedural injury.” *WildEarth Guardians v. U.S. Dep’t of Agric.*, 795 F.3d 1148, 1157 (9th Cir. 2015). “So long as a defendant is at least partially causing the alleged injury, a plaintiff may sue that defendant, even if the defendant is just one of multiple causes of the plaintiff’s injury.” *Id.* That is the case here.

Moreover, the redressability arguments Dow and EPA advance ask the Court to perform its Article III standing analysis on an argument-by-argument basis. But standing is assessed based on the claims asserted, *Town of Chester*, 137 S. Ct. at 1650, and the type of injury alleged, *Citizens for Better Forestry*, 341 F.3d at 971, not argument-by-argument. NRDC therefore has Article III standing to seek vacatur of the registration decisions under FIFRA.

Standing for NFFC Petitioners. CFS has likewise shown “that the procedures in question are designed to protect some threatened concrete interest . . . that is the ultimate basis of [its] standing” for purposes of standing for NFFC

Petitioners. *Salmon Spawning*, 545 F.3d at 1225 (citation omitted). Eric Pool, a member of CFS, submitted a declaration stating that Enlist Duo is approved for use in his home state of Illinois and that his crops are affected by the use of the components of Enlist Duo on nearby fields. These effects, according to his declaration, have caused economic damage, including harming his grapevines and forcing him to decrease the amount of acreage he plants on.

Mr. Pool's declaration establishes a concrete interest that is geographically linked to his home. *Ecological Rights Found.*, 230 F.3d at 1147; *Ashley Creek*, 420 F.3d at 938. And FIFRA is designed to protect these interests. Indeed, the statute requires EPA to determine whether any given action will cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C), (c)(7). This effects-based test considers not only "environmental costs," but also "economic" ones, which are the interests Mr. Pool claims. 7 U.S.C. § 136(bb).

The Pool declaration also meets the relaxed threshold for showing causation and redressability for procedural injuries. The causation element is satisfied because there is a "reasonable probability" that EPA would have assessed the threat to farmers differently had it adopted CFS's arguments. *Hall*, 266 F.3d at 977. Moreover, vacating the registration so that EPA reanalyzes the issues CFS raises "*may* influence the agency's ultimate decision of whether to take or refrain from taking a certain action," which satisfies the redressability prong. *Salmon Spawning*, 545 F.3d at 1226–27 (emphasis added).

In sum, NRDC and CFS, based on their members' standing, both have associational standing to bring FIFRA claims. *Am. Diabetes*, 938 F.3d at 1155. Because one petitioner from each petition has associational standing, we

need not decide whether the other NFFC Petitioners have associational standing. *Mont. Shooting Sports*, 727 F.3d at 981.⁵

2

Next, the ESA claims. NFFC Petitioners allege that EPA violated the ESA's consultation procedures in registering Enlist Duo. These alleged violations are procedural in nature, so the standing rules applicable to such violations apply here, too. *Jewell*, 749 F.3d at 783.

Injury in Fact. CFS has shown injury in fact for NFFC Petitioners. One of its members, Leslie Limberg, submitted a declaration stating that she lives in a state where Enlist Duo is approved for use and that she enjoys observing endangered species where she lives, including the Indiana bat. This declaration shows an aesthetic and recreational interest that is geographically linked to the individual asserting the claim, thereby satisfying the injury-in-fact requirement. *Ecological Rights Found.*, 230 F.3d at 1147; *Ashley Creek*, 420 F.3d at 938.

⁵ Neither Dow nor EPA argue that any Petitioner lacks statutory standing under the APA to challenge the EPA's action under FIFRA. But we conclude those requirements—that (1) “there has been final agency action adversely affecting the plaintiff”; and (2) the plaintiff “suffers legal wrong or that its injury falls within the zone of interests of the statutory provision the plaintiff claims was violated,” *Citizens for Better Forestry*, 341 F.3d at 976 (citation omitted)—are met as well. These requirements are not relevant to the ESA claim because the ESA provides for a private right of action outside of the APA. *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1034 (9th Cir. 2005) (citation omitted), *abrogated on other grounds as recognized in Cottonwood*, 789 F.3d at 089.

Moreover, the ESA's consultation procedures that CFS claims have been violated—for example, the requirement that EPA consult when a proposed action “may affect” any listed species—are designed to protect these concrete interests. *Salmon Spawning*, 545 F.3d at 1229; *see id.* at 1225–26. “These procedures are designed to advance the ESA's overall goal of species preservation, and thus the groups' specific goals” as well as “ensur[e] agency compliance with the ESA's substantive provisions.” *Id.* at 1226 (citing *Bennett v. Spear*, 520 U.S. 154, 176 (1997)).

Dow contends CFS cannot establish injury in fact as to the ESA claims because its members' concerns are speculative and far from imminent. But CFS need only provide evidence of “an increased risk [of harm] based on a violation of a statute.” *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 860 (9th Cir. 2005) (alteration adopted and citation omitted). That standard is met here because a reconsideration of ESA's consultation standards could lead to a different result—that is, it “*could* protect [Petitioners' members'] concrete interests.” *Cottonwood*, 789 F.3d at 1082.

Causation and Redressability. We now turn to the second and third requirements for Article III standing. Redressability is satisfied here because the consultation CFS argues is required under the ESA may have modified EPA's decision. *See Hall*, 266 F.3d at 977 (holding redressability prong met where relevant decision “could be influenced” by environmental studies plaintiff requested).

Dow argues that causation is not met because CFS acknowledges that other factors besides Enlist Duo may endanger the species at issue and because other similar pesticides may cause the same harms even if Enlist Duo is never used. For purposes of standing, however, “the causal

connection . . . need not be so airtight . . . to demonstrate that the plaintiffs would succeed on the merits.” *Ecological Rights Found.*, 230 F.3d at 1152. Instead, the standing inquiry focuses on whether the petitioner’s injury is “fairly traceable to the challenged conduct,” *WildEarth*, 795 F.3d at 1154—that is, whether the claim of injury relies merely on “the behavior of other parties” or “an attenuated chain of conjecture” as to what could happen in the future, *Hall*, 266 F.3d at 977 (citation omitted). And here, CFS’s ESA claim does not rely on other parties to take action or an attenuated chain of conjecture. As a result, a “reasonable probability” exists that EPA’s failure to consult threatens CFS’s concrete interests and the causation prong is satisfied. *Hall*, 266 F.3d at 977 (citation omitted).

Because one of CFS’s members has Article III standing, the organization also has associational standing to bring its ESA claims. *Am. Diabetes*, 938 F.3d at 1155. The Article III standing of one NFFC Petitioner makes the ESA claims asserted by NFFC Petitioners justiciable. *Mont. Shooting Sports*, 727 F.3d at 981.

III

FIFRA “is a comprehensive regulatory scheme aimed at controlling the use, sale, and labeling of pesticides.” *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002). Under the statute, the mechanism used to further this aim is a process called “registration.” 7 U.S.C. § 136a(a). Before any pesticide can be sold or used in the United States, EPA must register the pesticide—that is, provide a license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used within the United States. *Id.* § 136a(c). The terms and conditions on the license include exactly what product can be sold, the specific packaging it must be sold in, and labeling that

contains instructions on proper use. *Id.* § 136(p); 40 C.F.R. §§ 152.115, 156.10.

Registration occurs in a variety of ways. The principal type of registration is called unconditional registration. 7 U.S.C. § 136a(c)(5). For unconditional registration, EPA must “review[] all relevant data in [its] possession” and “determine[] that no additional data are necessary” to its decision. 40 C.F.R. § 152.112(b), (c). EPA can unconditionally register the pesticide only if it will “not generally cause unreasonable adverse effects on the environment” “when used in accordance with widespread and commonly recognized practice.” *Id.* § 152.112(e). “[U]nreasonable adverse effects on the environment” is defined, in relevant part, as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” 7 U.S.C. § 136(bb).

FIFRA also allows EPA to “*conditionally* register or amend the registration” of a pesticide for use in certain “special circumstances.” 7 U.S.C. § 136a(c)(7) (emphasis added). Conditional registration allows for an existing registration to be amended with less data than is required for an unconditional registration. *See id.* § 136a(c)(7)(B). But it still imposes a burden on EPA. *Id.* To conditionally register a pesticide or amend a pesticide registration, EPA must determine that “the applicant has submitted satisfactory data pertaining to the proposed additional use”; and that “amending the registration in the manner proposed . . . would not significantly increase the risk of any unreasonable adverse effect on the environment.” *Id.*

Both types of registration often involve “pesticide product[s].” 40 C.F.R. § 152.15. A “pesticide product” is a “pesticide in the particular form (including composition,

packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold.” *Id.* § 152.3. As such, a “pesticide product” may include one or more active or inert chemical ingredients. *See id.* (“Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant . . .”). “Active ingredient[s]” are those ingredients in the pesticide product that do the work to “prevent, destroy, repel or mitigate any pest.” *Id.* Enlist Duo, for example, is a “pesticide product” composed of two “active ingredients” that do the work: glyphosate and 2,4-D. *See* 7 U.S.C. § 136a(c)(7)(C) (contemplating a “pesticide” containing more than one “active ingredient” and some “active ingredient[s]” being registered previously).

Under FIFRA’s implementing regulations, EPA takes a specific approach in cases involving “active ingredient[s]” that have already been registered as part of other “pesticide product[s].” 40 C.F.R. § 152.111. In such cases, “the Agency will not commence a complete review of the existing data base on a given chemical in response to receipt of an application for registration.” *Id.* “Instead, the Agency will review the application using the criteria for conditional registration” under 7 U.S.C. § 136a(c)(7)(A) and (B). *Id.* Under those provisions, EPA may “conditionally register or amend the registration of a pesticide” if “the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ” only slightly and the registration would not “significantly increase the risk of any unreasonable adverse effect on the environment.” 7 U.S.C. § 136a(c)(7)(A); *see also* 40 C.F.R. § 152.113 (allowing conditional registration for pesticide products “that do not contain a new active ingredient”). These registrations are often called “me-too” registrations.

FIFRA also allows EPA to cancel or change the classification of a registration if it determines that the pesticide “generally causes unreasonable adverse effects on the environment.” 7 U.S.C. § 136d(b). FIFRA also contains a provision requiring that “[t]he registrations of pesticides”—including “active ingredients”—“be periodically reviewed,” a process called “registration review” that takes place every 15 years. 7 U.S.C. § 136a(g)(1)(A)(i), (iii). During registration review, EPA “evaluate[s] elements of FIFRA 3(c)(5) including the composition, labeling and other required material (including studies and other data), risks and benefits of a pesticide, and incident data or other information relating to its use.” Pesticides; Procedural Regulations for Registration Review, 65 Fed. Reg. 24,586, 24,587 (Apr. 26, 2000). Based on its evaluation, which includes public input, 7 U.S.C. § 136a(g)(2); 40 C.F.R. §§ 155.25, 155.30, 155.42, EPA can cancel an existing registration, 7 U.S.C. § 136a(g)(1)(A)(v).

We review EPA’s compliance with these requirements for “substantial evidence when considered on the record as a whole.” 7 U.S.C. § 136n(b); *Nat. Res. Def. Council v. EPA (Nanosilver II)*, 857 F.3d 1030, 1035 (9th Cir. 2017). For there to be substantial evidence, the administrative record must show “such relevant evidence as a reasonable mind might accept as adequate to support a conclusion even if it is possible to draw two inconsistent conclusions from the evidence.” *Nanosilver II*, 857 F.3d at 1036 (internal quotation marks and citation omitted). This review is “relatively deferential to the agency factfinder,” but must still be “searching and careful, subjecting the agency’s decision to close judicial scrutiny.” *Containerfreight Corp. v. United States*, 752 F.2d 419, 422 (9th Cir. 1985) (internal quotation marks and citation omitted).

A

NRDC first claims EPA incorrectly applied what NRDC believes is the more lenient “conditional” registration standard rather than the more stringent “unconditional” standard when it registered Enlist Duo in 2014. We disagree.

As a preliminary matter, NRDC waived any argument that EPA applied the incorrect standard when it registered Enlist Duo in 2014. NRDC did not raise this argument during the administrative process, or during its first challenge to the 2014 registration. In fact, NRDC affirmatively acknowledged that EPA’s 2014 registration of Enlist Duo was an unconditional registration. NRDC has therefore waived this particular challenge to the 2014 registration. *See N. Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1081 (9th Cir. 2011) (“Parties must alert an agency to their position and contentions.”).

Even absent waiver, however, NRDC’s argument that EPA applied the wrong standard is not persuasive. NRDC’s primary support for this argument is one line in the 2014 Final Registration Decision citing FIFRA’s conditional registration provision. But this stray line appears to be a typographical error. The EPA’s 2014 registration was plainly unconditional—not conditional. The Notice of Registration—which is the actual license—states that Enlist Duo “is unconditionally registered in accordance with FIFRA section 3(c)(5)” and the “Term of Issuance” is “Unconditional.” Similarly, the Proposed Decision Document cites subsection 3(c)(5) and “concludes that . . . approving this application as set forth below will not cause any unreasonable adverse effect on the environment,” language tracking the unconditional registration standard.

Moreover, the analysis in the registration documents does not suggest EPA was applying the more limited “significantly increase the risk of unreasonable adverse effect[s]” standard. To the contrary, the documents indicate EPA applied the broader “cause any unreasonable adverse effects” standard for unconditional registrations. For example, EPA did not just analyze how the use of 2,4-D in Enlist Duo differed from how 2,4-D was being used in previous pesticides and then address the risks associated with those new uses. Instead, it analyzed the human and ecological risks of using 2,4-D. This context supports that EPA was applying the unconditional registration standard, a conclusion NFFC Petitioners agreed with in their briefing.

That EPA mentioned outstanding data Dow should provide to the agency in unconditionally approving the product does not change that conclusion. True, it is FIFRA’s conditional registration provision that allows EPA to approve a product without all relevant data. 7 U.S.C. § 136a(c)(7)(A). But that does not mean EPA cannot request additional data when unconditionally approving a product. EPA can. When it does so, however, any such data must not be “necessary to make the determinations” under subsection (c)(5), 40 C.F.R. § 152.112(c)—that is, not needed to determine whether the product will “generally cause unreasonable adverse effects on the environment,” 7 U.S.C. § 136a(c)(5)(D). EPA’s decision to unconditionally register Enlist Duo therefore did not prevent it from requesting additional data; it merely prevented it from requesting additional data relevant to whether the unconditional registration standard was met. Here, NRDC does not argue that the additional data EPA requested was necessary to that inquiry.

Even assuming the requested data were necessary to assessing the risks associated with Enlist Duo, however, EPA's unconditional registration would not be transformed into a conditional one. As discussed above, EPA's analysis and the relevant registration documents make clear that EPA was applying the broader unconditional registration standard. Thus, to the extent EPA was requesting data relevant to assessing risk under FIFRA, any such request only suggests EPA erred in applying the unconditional registration standard. And no Petitioner argues there was any such error here.⁶

B

NFFC Petitioners argue that EPA incorrectly applied FIFRA's "cause any unreasonable adverse effects" unconditional registration standard in its 2017 registration decision rather than the "significantly increase the risk of any unreasonable adverse effect" conditional registration standard. EPA concedes that it cited the wrong standard but argues any error is harmless because the standard for unconditional registration is higher, not lower, than the standard for conditional registration.

⁶ We reach a similar conclusion as to NRDC's argument that EPA unlawfully imposed "conditions" on its 2014 registration decision. We are not persuaded that EPA was imposing "conditions" on registration merely because it used the phrase "provided that" before listing a few additional requirements for Dow. Nor do we decide whether EPA can impose "conditions" on unconditional registrations under FIFRA. *Cf.* 40 C.F.R. § 152.115(c) (authorizing EPA to establish "other conditions applicable to registration[]" for conditional registrations). Even if EPA were imposing "conditions" on its unconditional registration, that would only suggest error in applying that standard—not transform EPA's unconditional registration into a conditional one.

We agree with EPA. At first blush, the conditional registration standard appears to impose a higher standard than the unconditional one. After all, “cause,” as used in the unconditional registration standard, entails the pesticide “produc[ing]” harm, *Cause*, Black’s Law Dictionary (10th ed. 2014), while “risk,” as used in the conditional standard, connotes the “possibility of harm,” *Risk*, Black’s Law Dictionary (10th ed. 2014). But those words are not the only clues as to what this statute means. We must also look to the statute as a whole to find meaningful context. *See Exxon Mobil Corp. v. EPA*, 217 F.3d 1246, 1249 (9th Cir. 2000).

That context provides significant guidance here. The conditional registration standard, with its “risk” language, only applies when a registrant is proposing to use an already-registered pesticide or active ingredient in a new way. 7 U.S.C. § 136a(c)(7)(A), (B). That means conditional registration is an option only when a pesticide or active ingredient has already been registered using the unconditional registration, causation-based standard. The conditional registration standard is therefore best understood as limiting the scope of new evidence EPA must consider in making its registration decision, a conclusion Petitioner NRDC agreed with in its briefing. EPA need only consider evidence that bears on whether the new or additional use changes EPA’s original conclusion that the pesticide or active ingredient will “not generally cause unreasonable adverse effects.” *Id.* § 136a(c)(7). Any error by EPA in citing the more burdensome unconditional registration standard therefore does not show that EPA lacked substantial evidence to support its conclusions.

C

Petitioners argue that EPA lacked substantial evidence for its 2014, 2015, and 2017 registration decisions because

EPA failed to: (1) properly assess harm to monarch butterflies from increased 2,4-D use on milkweed in target fields; (2) consider that Enlist Duo would increase the use of glyphosate over time; (3) correctly consider the volatility of Enlist Duo's 2,4-D component; and (4) consider the synergistic effects of mixing Enlist Duo with glufosinate. We address each argument in turn.

1

With the approval of Enlist Duo, the use of Enlist Duo's 2,4-D ingredient will increase. NRDC argues that EPA failed to consider the harm of expanded 2,4-D use to certain monarch butterfly habitats and human health.

We decline to address NRDC's challenge to EPA's analysis of human health risks because NRDC failed to address that argument in its opening brief and therefore waived it. NRDC's opening brief states that "Enlist Duo may pose serious risks to human health" and discusses those risks in the Statement of the Case but does not meaningfully address them in any of its briefing. We have regularly held that "an issue referred to in the appellant's statement of the case but not discussed in the body of the opening brief is deemed waived." *Martinez-Serrano v. INS*, 94 F.3d 1256, 1259 (9th Cir. 1996). This case is no exception.

As to the impact on the monarch butterfly population, EPA did assess some of these risks as part of its registration decisions. Before the 2017 decision, for example, EPA performed a risk assessment that considered the "toxic effects to non-target plants (a grouping that includes plants important to monarchs)." EPA found "no concerns for terrestrial invertebrates (including monarchs)" because Enlist Duo would only affect treated fields—not non-target plants—as long as it was used under the "conditions

prescribed by the label.” These conditions include requiring a “30 foot downwind buffer (in the direction in which the wind is blowing)” and a specific, low drift nozzle. These mitigation measures, among others, will avoid spray drift of 2,4-D to non-target fields, thereby ensuring that no non-target milkweed is affected. EPA reached similar conclusions, using similar reasoning, in its 2014 registration decision.

So far, so good. But NRDC also argues EPA should have considered how the destruction of milkweed on *target fields* would affect monarch butterflies. This argument carries some force because EPA acknowledged in its briefing that it did not assess those risks. According to EPA, it was not required to do so because “farmers will control the same amount of milkweed on their crop fields through the use of herbicides or other means and at the same crop growth stages, with or without Enlist Duo.”

Despite the intuitive appeal of EPA’s argument, we must reject it. EPA did not assert this rationale as a reason for declining to assess the destruction of milkweed on target fields, so neither can we. *See Motor Vehicle Mfrs. Ass’n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (“We may not supply a reasoned basis for the agency’s action that the agency itself has not given.” (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947))). After all, “judicial review of agency action is limited to ‘the grounds that the agency invoked when it took the action.’” *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)). Moreover, even had EPA asserted such a rationale, it would likely be premised on legal error. That milkweed would likely be targeted in the same ways even absent Enlist Duo’s registration suggests

that registering Enlist Duo may not be “unreasonable” under FIFRA. 7 U.S.C. § 136a(c)(5), (c)(7). But it says nothing about whether an effect would be “adverse.” *Id.* Given the record evidence suggesting monarch butterflies may be adversely affected by 2,4-D on target fields, EPA was required, under FIFRA, to determine whether any effect was “adverse” before determining whether any effect on the environment was, on the whole, “unreasonable.” EPA’s failure to do so means that its decision was lacking in substantial evidence on this issue.

2

NRDC also challenges EPA’s conclusion that Enlist Duo’s glyphosate ingredient “would not cause unreasonable adverse effects on the environment” because glyphosate was already being used in the same locations and doses and on the same crops. According to EPA, Enlist Duo’s registration “would only impact which glyphosate product was used”—not how much glyphosate was used.

NRDC contends that FIFRA does not allow EPA to take this ingredient-by-ingredient approach. But as discussed above, FIFRA allows an ingredient-by-ingredient approach. 40 C.F.R. § 152.111. For cases involving “active ingredient[s]” that have already been registered—like glyphosate—EPA need not perform a complete review of the data. *Id.* “Instead, the Agency will review the application using the criteria for conditional registration” under 7 U.S.C. § 136a(c)(7)(A) and (B), *id.*, to determine whether the proposed use is “identical or substantially similar” to a prior use and whether the proposed use will “significantly increase the risk of any unreasonable adverse effect on the environment,” 7 U.S.C. § 136a(c)(7)(A).

Here, there is no such increase in the risk of unreasonable adverse effects because substantial evidence supports EPA's conclusion that neither the initial 2014 registration of Enlist Duo—nor the subsequent approvals for new uses—will increase the overall use of glyphosate. That is because corn, cotton, and soybean crops have long been genetically engineered to be glyphosate resistant, meaning that the use of glyphosate on these crops was nearly ubiquitous *before* Enlist Duo was registered in 2014. Indeed, “during the 2010 to 2014 period,” 80 to 85 percent of corn was “treated one or more times with glyphosate.” The same is true of soybean and cotton. During the same period, “approximately 95 percent” of soybean was treated one or more times and between “75 and 90 percent” of cotton was sprayed with glyphosate at least once. Even absent Enlist Duo's registration, therefore, farmers would continue to use glyphosate on these same crops. Thus, there was no increased risk of unreasonable adverse effects caused by glyphosate in approving Enlist Duo.⁷

This does not mean, of course, that new data about glyphosate will go unconsidered. If a proposed new use in a future registration will, unlike in this case, “significantly increase the risk of any unreasonable adverse effect on the environment,” EPA must consider those risks. 7 U.S.C. § 136a(c)(7)(A). Or, in the alternative, EPA can cancel a registration if it determines the pesticide “generally causes unreasonable adverse effects on the environment.” 7 U.S.C.

⁷ NRDC argues that, at a minimum, the 2015 and 2017 amendments to the 2014 registration increase the overall use of glyphosate because they allow for use in new states and on new crops. But this argument fails for the same reason discussed above. The 2015 and 2017 amendments may increase the overall use of Enlist Duo relative to the 2014 registration. But that does not mean these amendments will increase the overall use of glyphosate.

§ 136d(b). And if it does not do so, the “registration review” process serves as a backstop to ensure that pesticides do not remain registered once new data has shown them to be harmful to humans or the environment. 7 U.S.C. § 136a(g).⁸

3

Third, NFFC Petitioners contend that EPA failed to properly consider 2,4-D’s volatility—that is, its tendency to evaporate into a gas and drift to non-target plants. Here, too, we disagree.

In its 2014 and 2017 registration decisions, EPA concluded that the 2,4-D in Enlist Duo—a choline salt variety distinct from the 2,4-D used in many other pesticide products—exhibited lower volatility and off-site vapor drift than other registered forms of 2,4-D. EPA began with the “Ouse” laboratory study. The Ouse study was designed to examine the degree of visual damage or injury—like cupping of leaves or twisting of foliage—caused by exposure to vapors of 2,4-D. Soybean, tomato, grape, and cotton plants were exposed to varying doses of 2,4-D vapors for various lengths of time. Researchers then observed the level of visible injury each plant exhibited based on the dose administered. Using the data gathered from these

⁸ NRDC also argues that EPA’s decision is unsupported by substantial evidence because once EPA determined in 2017 that there was “outstanding data” about 2,4-D that would preclude an unconditional registration, it was “barred from reissuing its earlier [unconditional] approvals for Enlist Duo.” But the 2017 license—which is the operative license approving Enlist Duo for use—approves Enlist Duo “conditionally” because of the “outstanding data.” So although EPA’s 2017 registration decision reissued its 2014 and 2015 decisions, it did not reissue an unconditional *license* for the uses of Enlist Duo approved in 2014 and 2015.

observations, the study concluded that grapes were the most sensitive to 2,4-D vapor, followed by cotton, tomatoes, and soybeans. Further, a “dose-response curve” indicated the level of visual plant injury that would occur at a particular dose.

Recognizing that this study did not meet the regulatory measure for assessing plant damage—plant growth or survival—EPA relied on six publicly available studies that assessed the relationship between visual damage to plants and effects on plant growth and survival. According to these studies, for example, 20% visual damage to grape plants resulted in decreases in plant growth in grapes. Cotton and soybean had a much higher threshold. For those plants, visual damage between 35 and 66% resulted in decreases in plant growth and yield.

EPA also relied on another vapor flux study called the “Havens” study. Plants were placed directly on fields and also 5 and 15 meters away from treated fields. Those fields were treated with a higher dose of 2,4-D than the label would allow, and researchers measured outward signs of damage to the plants. Only plants on treated fields showed growth or survival damage; even plants located within 5 meters of the treated fields did not.

EPA used the most conservative estimates from this data to perform computer modeling. Specifically, EPA used the data’s finding that growth or survival occurred at statistically significant levels when there was a minimum of 20% visual plant damage and the dose-response curve from the Ouse study to find the dose level of 2,4-D that would produce 20% visual plant damage. That dose level was 1.9 ug/m³/hour—which measures the mass of pesticide in a cubic meter of air space to which an organism is exposed over a one-hour time period.

EPA then used this dose level to predict the air concentration of 2,4-D that would be expected at the edge of a field and various distances beyond. The results showed that the air concentrations of 2,4-D at the edge of a treated field were below 1.9 ug/m³/hour, the threshold for what might cause 20% of visual plant damage thereby affecting plant growth or survival. The model therefore predicted no adverse damages to plants off-field.

EPA also relied on two additional data points. First, EPA performed AERSCREEN modeling, which assesses drift of wet and dry depositions of the pesticide. That modeling showed negligible risk. EPA also relied on atmospheric monitoring data showing that negligible amounts of 2,4-D were detected in rainwater samples and air samples. These data points provided further evidence to support EPA's conclusion that the choline salt form of 2,4-D in Enlist Duo is less prone to volatilization than other forms of 2,4-D.

NFFC Petitioners claim that EPA's conclusion is based on the flawed underlying Ouse study, which EPA conceded was limited due to its methodology and "was not well-aligned with the 850.4150 protocol." But using a limited study does not make EPA's actions lacking in substantial evidence as long as EPA "acknowledge[s] the limitations" and does not "rely solely upon [the study's] conclusions." *Cent. Ariz. Water Conservation Dist. v. EPA*, 990 F.2d 1531, 1543 (9th Cir. 1993) (holding that EPA's reliance on a "seriously flawed study" did not undermine EPA's overall conclusions); *see also Ctr. for Biological Diversity v. Esper*, 958 F.3d 895, 910–11 (9th Cir. 2020) (finding substantial evidence in support of a Department of Defense conclusion relying on studies the Department itself "criticized" as not "rigorous," "extremely poorly-done," and "not withstanding scientific scrutiny").

NFFC Petitioners also argue that EPA requested a new study to replace the Ouse study but failed to wait for that new study before rendering its decision. Neither premise is correct. EPA did not request a “replacement” study. It recommended an additional study—that is, a “vapor-phase study with vegetative vigor endpoints” that would “*further* characterize the risk to plants from” exposure to 2,4-D vapor. EPA then relied on that study—the Havens study—in arriving at its conclusion about 2,4-D.⁹

NFFC Petitioners also criticize the studies EPA relied on in several other ways. We address each criticism in turn.

First, NFFC Petitioners claim that the Ouse study is too different from the other six studies because the grape plants used in the six studies were of a different age and species than those used in the Ouse study. This difference matters, according to NFFC Petitioners, because the threshold level of harm for a plant is dependent on its species and growth stage. But Petitioners have not pointed to any record evidence showing that the species and age of the grape plants affected the validity of the six studies. Without such evidence, we cannot conclude that EPA lacked substantial evidence to support its conclusion.

Second, NFFC Petitioners argue that EPA’s conclusion about a 20% visual damage threshold was contradicted by EPA scientists, who concluded that the damage threshold was actually 5%. But EPA did not contradict itself. EPA summarized the Ouse study’s conclusion that the harm

⁹ NFFC Petitioners claim the Havens study, which was a non-Guideline 850.4150-compliant field study, was not the study EPA requested. But EPA never requested that the recommended study comply with particular test guidelines or be performed in a laboratory. The Havens study was the requested study.

threshold was 5%. But then EPA analyzed additional data and determined that growth or survival occurred at statistically significant levels when 20% visual damage could be observed.

Third, NFFC Petitioners posit that the six studies relied on by EPA do not satisfy the regulatory guidelines in the vegetative vigor test—which look to survival, height, and biomass—because the studies examine yield and growth, which are not endpoints listed in the guidelines. But EPA is not required to follow the regulatory guideline NFFC Petitioners cite. *See* OCSPP 850.4150, at i (Jan. 2012), (“[T]hese guidelines are not binding on either EPA or any outside parties, and the EPA may depart from the guidelines . . .”). Moreover, the studies closely tracked the specific endpoints in the guidelines. Examining visual growth and yield directly addresses whether plants are growing (height and biomass) and flourishing (survival). EPA’s decision to rely on studies that do not precisely track a regulatory guideline therefore does not undermine its decision. EPA “may apply [its] expertise to draw conclusions from . . . probative preliminary data not yet certifiable as fact.” *Cent. Ariz. Water*, 990 F.2d at 1543 (internal quotation marks and citation omitted).

Fourth, NFFC Petitioners argue EPA’s computer modeling considered field sizes much smaller than the average corn, cotton, or soybean field even though vapor drift increases with the size of a sprayed field. But Petitioners provide no reason why EPA could not extrapolate from its modeling. “The Administrator may apply his expertise to draw conclusions from . . . theoretical projections from imperfect data.” *Cent. Ariz. Water*, 990 F.2d at 1543 (internal quotation marks and citation omitted). Moreover, NFFC Petitioners’ argument ignores

the AERSCREEN modeling EPA performed, which provides further evidence supporting EPA's volatilization conclusions.

Ultimately, EPA's evaluation of 2,4-D volatility probably could have been better. But it is not our role to second-guess EPA's conclusion. Moreover, there is no evidence in the record that its conclusion was wrong. Petitioners do not suggest that, in the five-plus years since Enlist Duo was originally approved, their fears surrounding 2,4-D volatility have materialized in the real world.¹⁰ We therefore hold that a "reasonable mind might accept" the studies on which EPA relied "as adequate to support a conclusion" that the volatility of 2,4-D choline salt will not cause unreasonable adverse effects on the environment. *Nanosilver II*, 857 F.3d at 1036 (citation omitted). Accordingly, substantial evidence supports EPA's findings.

4

Finally, NFFC Petitioners contend EPA should have accounted for the potential synergistic effect of mixing Enlist Duo with a different chemical called glufosinate. According to them, Dow intends to mix glufosinate with Enlist Duo.

NFFC Petitioners' concern about mixing Enlist Duo with glufosinate is speculative. Nothing in the record suggest that

¹⁰ NFFC Petitioners point to generic data on 2,4-D drift from the 1970s through early 2000s. This data mainly addresses spray drift—not drift from volatilization—and does not address 2,4-D choline salt. Even assuming the data is relevant to volatility here, EPA was aware of the general risk of 2,4-D volatility. EPA nonetheless concluded, relying on the above studies, that the choline salt variety of 2,4-D was less prone to volatilization than other forms of 2,4-D.

such mixing has occurred in the five-plus years since Enlist Duo was first registered. Indeed, EPA has stated that Enlist Duo cannot be tank-mixed with any product that has not been tested, approved, and listed on the website EnlistTankMix.com. And no product containing glufosinate is listed on that website. It is therefore currently unlawful to mix Enlist Duo with glufosinate.

NFFC Petitioners point to Dow's now-abandoned patent application, which claims synergism between 2,4-D and glufosinate, and notes that crops genetically engineered to withstand Enlist Duo are also designed to withstand glufosinate. But FIFRA only requires EPA to consider the uses of the pesticide contemplated by the label. *See* 7 U.S.C. § 136a(c)(5). That includes currently planned tank mixing. It does not include theoretical tank mixing—that is, tank mixing that might occur at a future date. NFFC Petitioners may separately challenge any future EPA final action approving this potential tank mixing.

NFFC Petitioners argue that the current registration is its only opportunity to challenge the potential mixing of Enlist Duo and glufosinate as having an unreasonable adverse effect on the environment because the Enlist Duo label allows tank mixing to be approved as long as mixing is shown “not to adversely affect” “spray drift properties” and does not require testing on synergy. EPA's decision not to require testing for potential synergy may appear to provide a loophole for ingredients to be mixed long after initial review. But this decision reflects EPA's broader stance on synergy. Following the recommendation of the National Research Council, EPA “views synergism to be a rare event” and assumes that the components of pesticide products will not have “synergistic effects.” EPA's assumption is not undermined by the limited evidence NFFC Petitioners cite

supposedly showing synergism between glufosinate and Enlist Duo. And nothing prevents a Petitioner from approaching the EPA with concerns about synergy in the future.

Moreover, FIFRA does not prohibit EPA from undertaking review of a pesticide product whenever it becomes necessary. 7 U.S.C. § 136a(g). According to EPA, this “means that the Agency must continue to respond to emerging risk concerns and not defer action until a pesticide’s regularly scheduled registration review.” Pesticides; Procedural Regulations for Registration Review, 70 Fed. Reg. 40,251-01, 40,270 (July 13, 2005). What’s more, EPA can cancel a registration, change a classification, or amend a label at any time if it determines that the registration, as constituted, “generally causes unreasonable adverse effects on the environment.” 7 U.S.C. § 136d(b). Finally, there are opportunities for NFFC Petitioners to provide input during the registration review process, 40 C.F.R. §§ 155.25, 155.30, 155.42, which is currently ongoing for both 2,4-D and glyphosate. Petitioners’ claim that they have no remedy for potential future violations of FIFRA involving glufosinate therefore rings hollow.

* * *

Almost all of EPA’s registration decisions are supported by substantial evidence because the record evidence was of the type that “a reasonable mind might accept as adequate to support a conclusion even if it is possible to draw two inconsistent conclusions from the evidence.” *Nanosilver II*, 857 F.3d at 1036 (internal quotation marks and citation omitted). However, as discussed above, EPA failed to consider risks to monarch butterflies caused by the treatment of milkweed on target fields. As to FIFRA, therefore, we

grant NRDC's petition for review in part and deny it in part. We discuss the remedy for this partial grant below.

IV

To protect endangered or threatened species, the ESA sets forth legal requirements with which federal agencies must comply. *See* 16 U.S.C. § 1531. “Each 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).

The ESA and its implementing regulations delineate a process—known as Section 7 consultation—for determining the biological impacts of a proposed action. 16 U.S.C. § 1536. The process starts with two possible roads, which turn on whether the proposed action will have “no effect” or if it “may affect” listed species or critical habitat. If a listed species is outside the proposed “[a]ction area”—that is, it will not be “affected directly or indirectly by the Federal action,” 50 C.F.R. § 402.02—it will, by definition, not be affected by the proposed action and consultation is not required. Similarly, if the action agency finds “that its action will have no effect on listed species or critical habitat” even within the “action area,” it need not consult with the expert agencies, FWS or the National Marine Fisheries Service (“NMFS”). *California ex rel. Lockyer v. U.S. Dep’t of Agric.*, 575 F.3d 999, 1019 (9th Cir. 2009). If, however, the action agency’s proposed action “may affect”—that is, might have “[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character,” *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (internal quotation marks and citation omitted)—

on a “listed species or critical habitat,” consultation is required, 50 C.F.R. § 402.14(a). In determining whether to consult, the action agency must use “the best scientific and commercial data available.” 16 U.S.C. § 1536(a)(2).

Consultation also arises in the context of “critical habitat” determinations. Under the ESA, “critical habitat” is “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 or protection.” *Id.* § 1532(5)(A)(i). “[C]ritical 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). In either case, the critical habitat must contain physical or biological features “essential” to the species, *id.* § 1532(5)(A)(i)–(ii)—features known as “primary constituent elements or PCEs,” *Alaska Oil & Gas Ass’n v. Jewell*, 815 F.3d 544, 555 (9th Cir. 2016) (internal quotation marks omitted) (citing 50 C.F.R. § 424.12(b)(5)). The consultation agencies define, by regulation, critical habitat and the corresponding PCEs for endangered species. 16 U.S.C. § 1533(a)(3)(A); 50 C.F.R. § 17.95. The action agency’s role is to determine whether a proposed action modifies or affects these critical habitats. 16 U.S.C. § 1536(a)(2).

Mitigation measures are frequently adopted as part of ESA compliance. *E.g.*, *Defs. of Wildlife v. Zinke*, 856 F.3d 1248, 1258 (9th Cir. 2017). Such mitigation measures are permissible as long as they are the result of “specific and binding plans.” *Id.* (citation omitted). Mitigation measures must also be “reasonably certain to occur.” *Nat’l Wildlife*

Fed'n v. Nat'l Marine Fisheries Serv., 524 F.3d 917, 936 n.17 (9th Cir. 2008); *see also Sierra Club v. Marsh*, 816 F.2d 1376, 1388 (9th Cir. 1987) (consultation should occur if “mitigation efforts” “have been delayed,” “may not take place at all,” or are otherwise ineffective), *abrogated on other grounds as recognized in Cottonwood*, 789 F.3d at 1088–91.

Because the ESA does not specify a standard of review, we review EPA’s compliance under the APA and uphold agency action unless it is arbitrary, capricious, an abuse of discretion, or contrary to law. *Or. Nat. Res. Council v. Allen*, 476 F.3d 1031, 1036 (9th Cir. 2007); 5 U.S.C. § 706(2)(A). An agency decision is arbitrary or capricious “only if the agency relied on factors Congress did not intend it to consider, entirely failed to consider an important aspect of the problem, or offered an explanation 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.” *Lands Council v. McNair*, 629 F.3d 1070, 1074 (9th Cir. 2010) (internal quotation marks and citation omitted). Here, EPA’s “no effect” findings, decision about the scope of the “action area,” and “critical habitat” determinations survive this deferential review.

A

NFFC Petitioners primarily challenge EPA’s “no effect” findings for plants and animals as legally erroneous. We disagree.

In making its “no effect” findings, EPA used “risk quotients” and interpretative “levels of concern” developed as part of compliance with FIFRA, but applied much more conservative assumptions. The “risk quotients” are calculated by estimating the amount of exposure to the

pesticide. That estimate is then divided by established acute and chronic ecotoxicity levels for specific classes of plants and animals—for example, aquatic animals and terrestrial mammals and birds. The calculated risk quotient is then compared to EPA’s “levels of concern.” If the risk quotient does not exceed the “levels of concern,” EPA determines there will be “no effect” on the listed species. If, however, the risk quotient exceeds the “level of concern” for acute or chronic exposure, EPA conducts a refined, species-specific assessment before making a “no effect” finding.

This methodology applies the correct legal standard. The “may affect” standard is only met—triggering consultation—if there is “[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character.” *Karuk Tribe*, 681 F.3d at 1027 (quoting *Lockyer*, 575 F.3d at 1018 (quoting Interagency Cooperation—Endangered Species Act of 1973, as Amended; Final Rule, 51 Fed. Reg. 19,926, 19,949 (June 3, 1986))). And EPA’s risk quotient/level of concern methodology found that there would be no such effects. True, EPA concluded that protected species and critical habitats would be *exposed* to potentially harmful chemicals. But it concluded that any such exposure would have “no effect” on listed species and habitats. EPA’s recognition of exposure is not a recognition that Enlist Duo “may affect” protected species and critical habitats. It is a recognition that EPA did what the ESA requires it to do: assess risks to determine whether the exposure would have “any possible effect.” *Id.*

Our decision in *Friends of Santa Clara River v. United States Army Corps of Engineers* supports this conclusion. 887 F.3d 906, 915, 925–26 (9th Cir. 2018). In that case, steelhead salmon would be exposed to copper concentrations as a result of the discharge of dredged or fill material in the

Santa Clara River. *Id.* at 910, 914–15. But that did not mean the relevant agency was required to consult with NMFS. *Id.* at 915, 924–26. Instead, the agency could reach its own “no effect” conclusion—that the amount of copper to which the salmon would be exposed was within a normal range—without consultation. *Id.* at 925–26. EPA’s conclusions here—which recognize potential exposure but nonetheless conclude there will be “no effect”—are no different.

This conclusion is not altered by the fact that EPA’s preliminary risk assessments—which relied on conservative assumptions—found a chance that Enlist Duo “may affect” hundreds of protected species. Those assessments were just that—preliminary. EPA did a more refined, species-specific assessment for the species initially believed to be at risk. After that assessment, EPA concluded that none of the species believed to be at risk after the initial assessment were in fact at risk. EPA therefore made “no effect” findings for those species. Nothing about this iterative process suggests EPA’s ultimate “no effect” findings were arbitrary, capricious, or contrary to law.

Nor did EPA’s adoption of mitigation measures, including a 30-foot downwind buffer and certain label restrictions, to reach a “no effect” finding as to plants and animals off the treated field render EPA’s conclusions arbitrary, capricious, or contrary to law. Mitigation measures are frequently adopted to avoid effects on listed species or habitats. *See Ctr. for Biological Diversity v. U.S. Dep’t of Interior*, 563 F.3d 466, 482 (D.C. Cir. 2009) (noting that “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 adopted in pursuance thereof” (internal quotation marks and citation omitted)).

To be sure, mitigation measures that merely “reduce,” but cannot scientifically “eliminate” an “effect” probably compel a “may affect” finding. *Karuk Tribe*, 681 F.3d at 1028. In *Karuk Tribe*, gold miners argued that mitigation measures taken by the action agency showed that there would be “no effect” on threatened species although the agency never made a “no effect” finding. *Id.* We held that the mitigation measures “cut[] against” a “no effect” finding because they merely “reduce[d]” but could “not eliminate” the impact to threatened species. *Id.*

Here, by contrast, EPA was able to *rule out* any effect on plants and species off the treated field in partial reliance on mitigation measures. EPA applied the correct legal standard and supported its conclusions, as discussed in greater detail below. Under these circumstances, EPA’s use of mitigation measures is not evidence of a required “may affect” finding as in *Karuk Tribe*. Instead, the mitigation measures are reasonable under the ESA when they are, like the label restrictions here, “specific and binding plans.” *E.g., Defs. of Wildlife*, 856 F.3d at 1258; *see also Selkirk Conservation All. v. Forsgren*, 336 F.3d 944, 954–56 (9th Cir. 2003).

Nor did EPA’s use of the risk quotient/level of concern methodology for its ESA analysis violate its statutory duty to “use the best scientific and commercial data available.” 16 U.S.C. § 1536(a)(2). The purpose of this requirement “is to ensure that the ESA not be implemented haphazardly, on the basis of speculation or surmise.” *Bennett*, 520 U.S. at 176. Under this standard, the agency must not “disregard available scientific evidence that is in some way better than the evidence it relies on.” *San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 995 (9th Cir. 2014) (alterations adopted and citation omitted). “On the other hand, where the information is not readily available, we cannot insist on

perfection.” *San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 602 (9th Cir. 2014). As a result, the standard does not “require an agency to conduct new tests or make decisions on data that does not yet exist.” *Locke*, 776 F.3d at 995. Nor does it allow us to second guess the agency’s decisions using our own judgment. Because “what constitutes the best scientific and commercial data available is itself a scientific determination,” *id.*, it “belongs to the agency’s special expertise and warrants substantial deference,” *Santa Clara River*, 887 F.3d at 924 (internal quotation marks and citation omitted). A court should therefore “be especially wary of overturning such a determination on review.” *Locke*, 776 F.3d at 995 (citation omitted).

We cannot overturn EPA’s scientific determination here. True, a 2013 National Academy of Sciences (“NAS”) report called the risk quotient/levels of concern methodology relied on by EPA “not scientifically defensible” if the goal “is to base a decision on the probabilities of various possible outcomes.” NAS also recommended that EPA adopt a “probabilistic approach” to assessing risk to endangered species. But that same report recognized that the data needed to adopt the recommended approach was not readily available. Instead, EPA would be required to generate new data, a process that would require the “integration of the uncertainties (from sampling, natural variability, lack of knowledge, and measurement and model error) into the exposure and effects analyses by using probability distributions.” Those distributions would then be “integrated mathematically to calculate the risk as a probability.” In short, this new process and generation of data would require a “transition” that could use some available scholarship as a model, but would nonetheless involve significant changes to EPA’s risk quotient/level of

concern approach and the data on which EPA relied. That is why NAS expressly recognized that EPA would not be able to begin implementation of the new approach on many pesticide registrations immediately.

EPA therefore did not reject better data that was “readily available” in registering Enlist Duo using the risk quotient/level of concern approach. *Jewell*, 747 F.3d at 602. Instead, it elected to continue applying that approach while it put a system in place to use NAS’s proposed approach, as set forth in the Interim Report to Congress EPA and the consultation agencies sent to Congress in November 2014.¹¹ In that Report, EPA and the consultation agencies agreed that they would implement NAS’s proposed approach in stages. EPA and the consultation agencies agreed that NAS’s proposal would not be applied to all pesticide registration decisions, including specifically the registration of Enlist Duo. Instead, the agencies elected to focus application of NAS’s new methodology on pesticides that were at the time subject to nationwide litigation. The agencies also highlighted their efforts to implement the new approach up until the Report was submitted.

EPA and the consultation agencies therefore specifically agreed that the risk quotient/levels of concern approach could be used for the registration process for Enlist Duo while EPA began implementing NAS’s new approach. EPA and the consultation agencies noted that the risk quotient/level of concern approach was “highly

¹¹ Although the Interim Report is not in the administrative record, we can consider it “for the limited purpose[] of reviewing [Petitioners’] ESA claim.” *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 497 (9th Cir. 2011).

conservative” and “will be protective of non-target species, including endangered species.”

This interagency agreement does not absolve EPA of its duty to “use the best scientific and commercial data available.” 16 U.S.C. § 1536(a)(2). But it does show that EPA’s actions in implementing NAS’s proposed approach have been reasonable and protective of endangered species. After all, the consultation agencies EPA would have been required to consult had there been a “may affect” finding have recognized as much. Ultimately, however, we ground our decision in the fact that the best-scientific-data-available requirement “does not require the agency to conduct new tests or make decisions on data that does not yet exist.” *Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 807 F.3d 1031, 1047 (9th Cir. 2015) (internal quotation marks and citation omitted). EPA’s determination that this well-established rule applied here is ultimately a scientific judgment that we will not overturn. *See Locke*, 776 F.3d at 995.¹² It is also one we do not expect to reoccur given EPA’s commitment to gather the data necessary to implement NAS’s new methodology going forward.

Finally, we are not persuaded that EPA’s “no effect” conclusions are rendered arbitrary, capricious, or contrary to law because EPA relied in part on the 1993 Wildlife Exposure Factors Handbook. EPA relied on the 1993 Handbook for its ESA level assessment to measure how 2,4-

¹² NFFC Petitioners and the dissent focus in large part on the NAS approach being a superior methodology. But the statutory requirement EPA must comply with is about using the “best scientific and commercial *data* available.” 16 U.S.C. § 1536(a)(2) (emphasis added). That is why we have focused on whether the data EPA needed was available—not whether the NAS methodology is superior to the one EPA used.

D within Enlist Duo might affect protected species' food and water consumption within the action area. According to NFFC Petitioners, that 1993 Handbook is not the "best scientific and commercial data available," 16 U.S.C. § 1536(a)(2), because it was intended only for screening assessments—not ESA level risk assessments—and never mentions several of the protected species at issue.

But again, "[t]he determination of what constitutes the best scientific data available belongs to the agency's special expertise and warrants substantial deference." *Santa Clara River*, 887 F.3d at 924 (internal quotation marks and citation omitted). Such deference is warranted for two reasons. First, the Handbook appears to contemplate EPA's approach. To be sure, some portions of the Handbook suggest it is intended for "screening-level risk assessments." But other portions acknowledge it should be used in support of "assessments for species of concern in a risk assessment," like the one here, for "endangered and threatened species." Second, although the Handbook does not include consumption rates for some of the species at issue, it allows for the use of equations to calculate the consumption rates of species for which no measurement exists. And EPA used these equations here. EPA therefore did not act arbitrarily in partially relying on the 1993 Handbook to make "no effect" findings.¹³

¹³ NFFC Petitioners argue for the first time in their supplemental briefs that EPA was required to perform an ESA-level analysis and make "no effect" findings for glyphosate as well. We decline to address this argument because it was not raised in Petitioners' initial opening brief even though it was directly relevant to the 2017 registration decision. See *Martinez-Serrano*, 94 F.3d at 1259–60.

B

NFFC Petitioners also argue that EPA's rationale for limiting the "action area" to the treated field was not sound. We accord deference to EPA in the way it chose to define the action area. *See Friends of the Wild Swan v. Weber*, 767 F.3d 936, 950 (9th Cir. 2014) ("The choice of appropriate action areas requires application of scientific methodology and, as such, is within the agency's discretion." (internal quotation marks and citation omitted)).

NFFC Petitioners first argue that because 2,4-D is known to drift beyond treated fields, the "action area"—that is, the area "to be affected directly or indirectly by the Federal action," 50 C.F.R. § 402.02—cannot be limited to the treated fields. But EPA accounted for this risk as to spray drift by including the mitigation measure of a 30-foot buffer zone and other label restrictions, including a prohibition on aerial application and specific nozzle, temperature, and wind speed requirements. And its decision to impose these measures was not based on a mere "assumption that spray drift will stop at field boundaries" as long as those measures were in place. EPA performed its own evaluation of the risk of spray drift using "empirical data" that measured spray drift deposition rates when Enlist Duo was used according to its label restrictions. EPA then compared this data to its effect thresholds for plants and animals off the treated field and concluded that any exposure to Enlist Duo off the treated field would "be below effects thresholds."¹⁴

¹⁴ To the extent NFFC Petitioners argue that EPA only made "no adverse damage"—not "no effect"—findings with respect to volatility, they are wrong. EPA specifically found, based on "spray drift mitigation label requirements and analyses of volatility and runoff loadings" that

EPA did not violate the “no effect” standard in performing this analysis. As discussed above, a recognition of “exposure” is not the same as a recognition of an “effect.” Nor is the use of mitigation measures like label restrictions legally erroneous, as long as the measures themselves are not arbitrary or capricious. *See Marsh*, 816 F.2d at 1388 (consultation should occur if “mitigation efforts” “have been delayed,” “may not take place at all,” or are otherwise ineffective). No such error is evident here. EPA had good—and science-based—reasons for limiting the action area to the treated field. And NFFC Petitioners have not pointed to any record evidence—such as data undermining EPA’s scientific conclusion or showing that mitigation measures are not working—suggesting that the mitigation measures EPA selected are not “specific and binding” and “reasonably certain to occur.” *Nat’l Wildlife Fed’n*, 524 F.3d at 936 n.17; *see also Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1244 (9th Cir. 2013) (placing the burden on the party challenging agency action to show that the action was arbitrary, capricious, an abuse of discretion, or contrary to law).¹⁵ We therefore cannot conclude there is not “a rational connection between the facts [EPA] found and the choices

“any risks of *effects* to non-target organisms will be confined to the treated field.”

¹⁵ Petitioners’ argument that EPA failed to consider whether ESA-protected plants and animals off the treated field would be indirectly affected by the on-field treatment is not persuasive for a similar reason. EPA considered indirect effects and Petitioners have not cited any evidence contradicting EPA’s conclusions.

[it] made.” *Arrington v. Daniels*, 516 F.3d 1106, 1112 (9th Cir. 2008) (internal quotation marks and citation omitted).¹⁶

C

Finally, NFFC Petitioners argue EPA violated its duty to insure no “adverse modification” of “critical habitat” by relying on its 2016 risk assessment. EPA used an iterative approach to make this determination. First, EPA determined that critical habitats had been designated for 184 of the 531 species in the states proposed for Enlist Duo registration. EPA then determined that because 176 of those species were not found on corn, cotton, or soybean fields, Enlist Duo’s registration would not modify their critical habitats or any PCEs. That left eight species with critical habitat designations that did use corn, cotton, or soybean fields. EPA then considered whether Enlist Duo “may affect” those eight species or their PCEs. Because none of those eight species’ critical habitats contained PCEs “related to agriculture,” EPA concluded that there would be no “modification” to their critical habitats.

This methodology did not misapply the “may affect” standard as to critical habitats. EPA explicitly considered whether there would be any effect on “one or more of the

¹⁶ Petitioners’ claims of error as to the whooping crane and Indiana bat—which rely on outdated species-specific analysis and selective quotation of the record—are based largely on arguments we have already rejected. EPA’s recognition that the whooping crane and Indiana bat would be exposed to Enlist Duo did not necessitate a “may affect” finding because exposure is not the same thing as effect. And EPA’s statements about the whooping crane and Indiana bat in its preliminary assessment are irrelevant because EPA subsequently performed a species-specific assessment to make its “no effect” finding. EPA’s analysis about these two species was technically sound. It was neither arbitrary, capricious, nor contrary to law.

designated PCEs,” as required by the statute. 16 U.S.C. § 1532(5)(A). True, EPA at times used the word “modify” instead of “effect,” but EPA was using “modify” as a synonym for “effect” because EPA used both words interchangeably in its analysis.

We likewise reject NFFC Petitioner’s argument that EPA erred by only considering species who use corn, cotton, or soybean fields. As discussed above, EPA reasonably concluded there would be no effect outside of the treated field and limited the action area accordingly. By extension, it was not unreasonable for EPA to consider only species who use corn, cotton, or soybean in assessing effect on critical habitat. 16 U.S.C. § 1532(5)(A)(i), (ii) (“critical habitat” includes the “geographical area occupied by the species” unless additional areas are designated by the consultation agencies).

Nor are we persuaded that EPA’s PCE conclusions are contradicted by the record as to the Virginia big-eared bat and the whooping crane. According to NFFC Petitioners, EPA’s conclusion that there were no PCEs “related to agriculture” for those two species cannot be right because EPA explicitly recognized that there are PCEs “related to agriculture” in a table attached to its 2016 risk assessment. But regardless of EPA’s notations, no PCEs have been designated by the consultation agencies for the Virginia big-eared bat or the whooping crane. 50 C.F.R. § 17.95-a-Mammals (listing critical habitat and PCEs for protected species without including any PCEs for the Virginia big-eared bat); 50 C.F.R. § 17.95-b-Birds-Part 1 (same for the whooping crane). Any contradiction by EPA as to whether these species have PCEs related to agriculture is thus legally irrelevant.

* * *

In its ESA analysis, EPA did not “rel[y] on factors Congress did not intend it to consider, entirely fail[] to consider an important aspect of the problem, or offer[] an explanation 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.” *League of Wilderness Defs. Blue Mountains Biodiversity Project v. Allen*, 615 F.3d 1122, 1130 (9th Cir. 2010) (internal quotation marks and citation omitted). EPA therefore did not violate the ESA in registering Enlist Duo.

V

Having found error in EPA’s registration decisions under FIFRA, we now analyze the remedy. “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.” *Cal. Cmty. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (internal quotation marks and citation omitted). We also look to “whether the agency would likely be able to offer better reasoning or whether by complying with procedural rules, it could adopt the same rule on remand, or whether such fundamental flaws in the agency’s decision make it unlikely that the same rule would be adopted on remand.” *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015). Finally, we “consider whether vacating a faulty rule could result in possible environmental harm.” *Id.*

Here, remand without vacatur is warranted. EPA’s error—failing to consider harm to monarch butterflies caused by killing target milkweed—is not “serious,” *Cal. Cmty.*, 688 F.3d at 992, especially in light of EPA’s full compliance with the ESA and substantial compliance with FIFRA. Moreover, given the technical nature of EPA’s error, EPA will “likely be able to offer better reasoning” and

“adopt the same rule on remand.” *Pollinator*, 806 F.3d at 532. Thus, regardless of how “disruptive” the consequences of vacatur would be, *Cal. Cmty.*, 688 F.3d at 992 (citation omitted)—and there is evidence of potentially serious disruption if a pesticide that has been registered for over five years can no longer be used—vacatur would not be warranted. We therefore remand without vacatur so EPA can address the evidence that monarch butterflies may be harmed by the destruction of milkweed on target fields in determining whether the registration of Enlist Duo will lead to any “unreasonable adverse effect” on the environment. We “expect and urge EPA to move promptly on remand.” *EME Homer City Generation, L.P. v. EPA*, 795 F.3d 118, 132 (D.C. Cir. 2015); *cf. In re Core Commc’ns, Inc.*, 531 F.3d 849, 862 (D.C. Cir. 2008) (Griffith, J., concurring) (“Remand without vacatur is common . . . [b]ut experience suggests that this remedy sometimes invites agency indifference.” (citation omitted)).

VI

NFFC Petitioners’ petition for review is **DENIED**. Petitioner NRDC’s petition for review is **GRANTED in part and DENIED in part**. The case is **REMANDED WITHOUT VACATUR**.

R. NELSON, Circuit Judge, concurring:

We have addressed venue and standing to ensure that we have jurisdiction over one petitioner for each petition. Here, the interplay between FIFRA’s venue provision and Article III standing does not make a difference because, for each petition, one petitioner over which venue is proper has also demonstrated standing. I write separately, however, to

address how the interplay of FIFRA's venue provision and standing could make a difference in a future case.

Under FIFRA's venue provision, "any person who will be adversely affected by [a pesticide registration] order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business." 7 U.S.C. § 136n(b). "Person," as used in FIFRA, "means any individual, partnership, association, corporation, or any organized group of persons whether incorporated or not." *Id.* § 136(s).¹ Here, three of the NFFC Petitioners (National Family Farm Coalition, Family Farm Defenders, and Beyond Pesticides) do not "reside" or "have a place of business" in the Ninth Circuit and three do (Center for Food Safety ("CFS"), Center for Biological Diversity ("CBD"), and Pesticide Action Network North America ("PANNA")).

As I read the statute, this means venue is not proper as to the first three petitioners. Nothing in FIFRA's venue provisions suggests Congress intended venue to be analyzed petition-by-petition. To the contrary, the provision's use of the singular noun "person" and definition of that word in a way that requires individual analysis suggests venue should be analyzed on a petitioner-by-petitioner basis. I therefore read the statute as requiring us to analyze venue on an individual basis, even if multiple petitioners join one petition. *Id.* §§ 136n(b), (s).

¹ Venue should be addressed before standing because venue is, like *forum non conveniens*, a nonmerits issue that "den[ies] audience to a case on the merits" without assuming "substantive law-declaring power." See *Sinochem Int'l Co. v. Malay. Int'l Shipping Corp.*, 549 U.S. 422, 432–33 (2007) (internal quotation marks omitted).

This reading of the statute is consistent with 28 U.S.C. § 2112(a)(1)–(5), cited in 7 U.S.C. § 136n, which recognizes that petitions for review may be filed in multiple courts of appeal. *Id.* If that happens, one of two things occurs. If petitions for review are filed in “at least two courts of appeals” “within ten days after issuance of the” relevant order, a lottery before the judicial panel on multidistrict litigation is triggered, through which one court of appeals is designated to adjudicate all of the petitions. *Id.* § 2112(a)(1), (a)(3). If, however, a petition for review is filed in only one court of appeals within ten days, or, if multiple petitions for review are filed more than ten days after the order, the administrative record is filed in the court where the first petition for review was filed. *Id.* § 2112(a)(1). Any subsequent petitions “shall [be] transfer[red] . . . to the court in which the record [was] filed.” *Id.* § 2112(a)(5). The court of appeals where the administrative record is filed then becomes the court with “exclusive jurisdiction to affirm or set aside the order complained of in whole or in part.” 7 U.S.C. § 136n(b); *see also Remington Lodging & Hosp., LLC v. NLRB*, 747 F.3d 903, 904 (D.C. Cir. 2014) (describing the lottery provision).

This process would be circumvented if all petitioners could join a single petition in the same circuit, regardless of whether each petitioner had proper venue. The Tenth Circuit reached the same conclusion in a case involving a similar venue statute under the Natural Gas Act. *See Amerada Petroleum Corp. v. Fed. Power Comm’n*, 338 F.2d 808, 810 (10th Cir. 1964). In that case, six corporations and four individuals filed a “joint petition” for review of a Federal Power Commission order in the Tenth Circuit even though only one of those petitioners did business or resided in the Tenth Circuit. *Id.* at 809. Relying on 28 U.S.C. § 2112, the Tenth Circuit held that the proper procedural step was for

each petitioner to file in the proper venue, so that proceedings could be consolidated in one circuit. *Id.* at 810; *see also Fed. Power Comm'n v. Texaco, Inc.*, 377 U.S. 33, 39 (1964) (dismissing one of two petitions for review because one petitioner did not have its principal place of business within the circuit where the petition was filed); *Dalton Trucking, Inc. v. EPA*, 808 F.3d 875, 878–82 (D.C. Cir. 2015) (dismissing petition for review filed in D.C. Circuit for failure to satisfy Clean Air Act's venue provision).

Whether FIFRA requires an individualized venue analysis becomes important when there are joint petitioners, only some of whom can show proper venue and Article III standing. In this case, one NFFC Petitioner—CFS—“resides or has a place of business” in the Ninth Circuit, 7 U.S.C. § 136n(b), and submitted sufficient proof to satisfy the requirements of Article III, as discussed in the majority opinion, Majority Op. at 15, 16–17. But that will not always happen. By way of example, one of the other two NFFC Petitioners with proper venue here—CBD—would not have satisfied Article III standing with respect to NFFC Petitioners' FIFRA claims. That is so because the interests asserted by CBD's members relate exclusively to the ESA—not FIFRA. So CBD did not show that FIFRA is the statute “designed to protect” the “threatened concrete interest[s]” that CBD asserts. *Salmon Spawning & Recovery All. v. Gutierrez*, 545 F.3d 1220, 1225 (9th Cir. 2008) (internal quotation marks omitted).

And PANNA would not have satisfied Article III's standing requirements with respect to either claim advanced in the NFFC Petition. PANNA's lone declaration does not include any statements “establishing that at least one identified member ha[s] suffered or would suffer harm.”

Summers v. Earth Island Inst., 555 U.S. 488, 498 (2009). Instead, it generally asserts that PANNA's members will be adversely affected by the registration of Enlist Duo. This generalized harm is not enough to establish injury in fact for purposes of associational standing. *Associated Gen. Contractors of Am., Inc. v. Cal. Dep't of Transp.*, 713 F.3d 1187, 1194–95 (9th Cir. 2013) (dismissing appeal for lack of standing because plaintiff did not “submit[] declarations by any of its members attesting to harm they have suffered or will suffer” under the challenged program).

What happens, then, if venue is proper as to some petitioners, but only a petitioner without proper venue satisfies the requirements for Article III standing? In my view, the petition for review should be dismissed. I therefore believe that future panels should closely scrutinize both venue and Article III standing in FIFRA cases to ensure that both requirements are met.

WATFORD, Circuit Judge, dissenting:

I agree with my colleagues that we have jurisdiction to review the petitioners' challenges and that the Environmental Protection Agency (EPA) violated the Federal Insecticide, Fungicide, and Rodenticide Act by failing to assess the impact that Enlist Duo's use will have on monarch butterflies. But in my view, EPA also violated the Endangered Species Act by failing to use the best scientific data available to assess whether Enlist Duo will adversely affect threatened or endangered species. For that reason, I would vacate the 2014 and 2017 registrations under review.

The Endangered Species Act and its implementing regulations require EPA to determine whether registering a pesticide for use “may affect” any species listed as threatened or endangered. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a). If registering the pesticide for use may affect one or more listed species, EPA must then consult with expert wildlife agencies to ensure that its action is not likely to jeopardize the continued existence of any such species. 16 U.S.C. § 1536(a)(2). In making its threshold “may affect” determination, EPA must, in the words of the statute, “use the best scientific and commercial data available.” *Id.* EPA did not comply with that statutory mandate here because the method it used to assess Enlist Duo’s effects on listed species is scientifically unsound.

To evaluate the risks that Enlist Duo poses to listed species, EPA applied the “risk quotient” method, an approach that integrates exposure and toxicity data using single-point estimates. When EPA calculates risk quotients, it divides a single-point estimate of the maximum amount of a pesticide to which a species might be exposed by a single-point estimate of the minimum amount of that pesticide expected to adversely affect the species. In theory, the higher the resulting number, the higher the purported risk.

But as the National Academy of Sciences explained in a 2013 report—issued in response to EPA’s own request for advice on the subject—the risk quotient method does not “estimate risk” at all. National Research Council of the National Academies, *Assessing Risks to Endangered and Threatened Species From Pesticides* 149 (2013).¹ It

¹ The report is available at: <https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides> [<https://perma.cc/M7V3-AYEL>].

“provides no information about the probability of an adverse effect” because single-point estimates do not account for the full range of possible exposure scenarios. *Id.* at 149–50. What’s more, risk quotients may not even reflect the worst-case scenario, despite EPA’s attempt to maximize the numerator and minimize the denominator in the equation. That is because the underlying data on which EPA relies to calculate the numerator and denominator includes single-point estimates of uncertainties. *Id.* If EPA gets those single-point estimates wrong, the ultimate risk quotient could underestimate risk and EPA would never know it. *Id.* Thus, even if EPA uses conservative thresholds to assess whether a particular risk quotient is high enough to warrant consulting with the expert wildlife agencies, that precautionary measure will not offset the method’s fundamental flaws. No matter how conservative its thresholds, EPA will still be interpreting an unreliable metric of risk. *See id.*

In light of these observations, the Academy concluded that risk quotients “are not scientifically defensible for assessing the risks to listed species posed by pesticides or indeed for any application in which the desire is to base a decision on the probabilities of various possible outcomes.” *Id.* at 15. The Academy further concluded that adoption of an alternative methodology entirely—one that actually measures probabilities—is the only way to achieve “realistic, objective estimates of risk.” *Id.* And though the Academy recognized that EPA would not be able to implement probabilistic methods overnight, it reiterated that EPA’s current approach to risk assessments is “not appropriate.” *Id.* at 150, 152.

EPA does not dispute the Academy’s scientific conclusions. Nor has EPA made any attempt to justify, on a

scientific basis, its continued reliance on the risk quotient method. Instead, EPA simply highlights its use of conservative assumptions—without addressing the Academy’s criticisms of such assumptions—and points to practical reasons for adhering to its risk quotient approach. Specifically, EPA emphasizes the administrative burdens of applying the probabilistic method to all pesticide registration decisions, and explains that it will use risk quotients to assess Enlist Duo’s effects until it allocates the necessary resources to switch methodologies. That approach is permissible, EPA contends, because the wildlife consultation agencies have agreed that EPA can implement the Academy’s recommendations in stages. But it should go without saying that neither pragmatic concerns nor an interagency agreement can absolve EPA of its statutory obligation to use the best scientific data available. Rather, EPA must apply its scientific expertise to identify and use data that meets the statutory standard. *See Conservation Congress v. Finley*, 774 F.3d 611, 620 (9th Cir. 2014). EPA failed to do so here.

The majority nonetheless upholds EPA’s use of the risk quotient method for making “may affect” determinations. In the majority’s view, an agency does not violate its statutory obligation to use the best scientific data available unless it rejects better *existing* data. Because probabilistic data for Enlist Duo was not available at the time EPA conducted its analysis, the majority concludes that EPA fulfilled its statutory duty by using the data it already possessed, however unreliable that data may have been.

In reaching this outcome, the majority has created a new rule with serious implications. Following today’s decision, an agency may rely on data produced by a scientifically indefensible methodology so long as better data, produced by a methodology that *is* scientifically defensible, has not yet

been generated. Because courts in our circuit must now accept that fundamentally flawed data as the “best” scientific data available, the agency will have no incentive to implement the scientific methods necessary to obtain reliable data. That is not what Congress intended when it required EPA and other federal agencies to use the best scientific data available, and it is certainly not the outcome that our cases demand.

The purpose of the “best scientific data available” requirement is to “ensure that the [Endangered Species Act] not be implemented haphazardly, on the basis of speculation or surmise.” *Bennett v. Spear*, 520 U.S. 154, 176 (1997). This standard does not require agencies to use “the best scientific data possible,” *San Luis & Delta-Mendota Water Authority v. Jewell*, 747 F.3d 581, 602 (9th Cir. 2014) (emphasis added), but it does require them to “support their conclusions with accurate and reliable data,” *Conservation Congress*, 774 F.3d at 620. Accordingly, while we have permitted agencies to rely on “imperfect” or “weak” data, we have never suggested that agencies may rest their decisions on data that is scientifically unsound. *See id.* Yet that is precisely what the majority has allowed EPA to do here.

Of course, the statutory standard does not compel agencies to “conduct new tests,” and we cannot direct EPA to obtain better data using the probabilistic approach recommended by the National Academy of Sciences. *See San Luis & Delta-Mendota Water Authority v. Locke*, 776 F.3d 971, 995 (9th Cir. 2014). But we can—and indeed, must—ensure that EPA uses the best scientific data available to assess Enlist Duo’s effects on listed species. By relying on a scientifically indefensible method that generated speculative and unreliable estimates, EPA failed to meet its burden. While the unavailability of better data can excuse

an agency's reliance on flawed or weak data, that rule has no application when, as here, an agency's data does not qualify as "scientific data" in the first place.

EPA's use of the risk quotient method violated the Endangered Species Act, and the 2014 and 2017 registrations of Enlist Duo should be vacated as a result.