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,
Petitioner,
v.
ANDREW R. WHEELER, ET AL.,
Respondents,
DOW AGROSCIENCES LLC,
Respondent-Intervenor.

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

SUPPLEMENTAL REPLY BRIEF OF PETITIONER NATURAL RESOURCES DEFENSE COUNCIL

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INTRODUCTION

The 2017 Registration violates FIFRA because EPA used the wrong legal standard to register Enlist Duo's inaugural uses and the error was not harmless.[1] FIFRA authorized EPA to evaluate these initial uses under only the more rigorous § 136a(c)(5) unconditional registration standard, but the Agency granted a § 136a(c)(7)(B) conditional registration instead. EPA insists any error was harmless because its analysis would have supported an unconditional approval. But EPA lacked substantial evidence to conclude that Enlist Duo's initial uses would not cause unreasonable adverse effects—as required for unconditional registration—because the Agency ignored evidence of serious risks to monarch butterflies and human health. EPA's failure to ensure that Enlist Duo meets FIFRA's safety standard requires vacatur of the 2017 Registration.

ARGUMENT

I. EPA applied the wrong legal test to register Enlist Duo's inaugural uses

A. FIFRA prohibited EPA from conditionally registering Enlist Duo's initial uses

FIFRA sets a lower bar for conditional registration under § 136a(c)(7) than for unconditional registration under § 136a(c)(5), *see* EPA Suppl. 17, but

[1] This brief focuses on Enlist Duo's inaugural uses (on corn and soy in six states, first approved in 2014) because, if EPA unlawfully registered those uses, its approval of the pesticide's additional uses necessarily violates FIFRA too. *See* NRDC Suppl. 8.

conditional registration is available only in limited circumstances. Here, the statute barred EPA from approving Enlist Duo's initial uses under § 136a(c)(7). *See* NRDC Suppl. 2-3. Dow disagrees, quoting 40 C.F.R. § 152.111 for the proposition that "[t]he Agency has discretion to review applications under either [standard]." Dow Suppl. 4-5.

But FIFRA restricts conditional registration to three sets of "special circumstances," 7 U.S.C. § 136a(c)(7), and EPA may not rely on § 152.111 of its regulations to grant a conditional registration when none of those statutorily enumerated circumstances are present. Rather, § 152.111 affords EPA discretion to choose between unconditional and conditional registration only when the statute has made both options available.

None of the "special circumstances" justifying conditional registration applied here. *See* NRDC Suppl. 2-3 & n.1. *Contra* Dow Suppl. 4-8, 12-13. First, § 136a(c)(7)(B) authorizes EPA only to "*amend* the registration of *a pesticide* to permit *additional uses* of such pesticide." 7 U.S.C. § 136a(c)(7)(B) (emphases added). Consequently, EPA could not register Enlist Duo's *first* uses under that provision; § 136a(c)(7)(B) is available only for registering additional uses of an already registered pesticide. Second, EPA declined to apply § 136a(c)(7)(A) given the pesticide's "new use[s]" of 2,4-D, ER 4, and the registration cannot be upheld on legal theories disavowed by the Agency, *see Motor Vehicle Mfrs. Ass'n of U.S.*,

Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 50 (1983). Tellingly, Dow did not even seek approval for Enlist Duo's initial uses under § 136a(c)(7)(A).[2] Third, nobody argues that § 136a(c)(7)(C) could apply, and it is plainly unavailable here. *See* NRDC Suppl. 3 n.1.

Ultimately, Dow's musings on what it thinks EPA could have done only underscore what the Agency did not do: register Enlist Duo's initial uses under § 136a(c)(5), as FIFRA required.

B. EPA granted an unlawful conditional registration for Enlist Duo's initial uses

Through the 2017 Registration, EPA unlawfully relied on § 136a(c)(7)(B) to "reissue[]" its 2014 approval of Enlist Duo's inaugural uses.[3] ECF No. 166 at 5;

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[2] *Compare* NRDC SER vol.II at 1 (leaving unchecked the box for "'Me Too' [i.e., § 136a(c)(7)(A)] Application" and not identifying any previously registered pesticide product that was "similar or identical" to Enlist Duo), *with* 7 U.S.C. § 136a(c)(7)(A) (requiring EPA to compare the proposed pesticide with a "currently registered pesticide"), *and* EPA, Pesticide Registration Manual: Chapter 2 – Registering a Pesticide Product, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-2-registering-pesticide-product#meetoo (last visited Nov. 14, 2019) (requiring § 136a(c)(7)(A) applicants to "identify an already registered product that is substantially similar to the proposed product").

[3] In 2014, EPA proposed registering Enlist Duo's initial uses under § 136a(c)(5). *See* EPA Suppl. 13; RSBER 27. After NRDC commented that EPA must analyze new science on Enlist Duo's risks before granting an unconditional registration, *see* ER 1619-20, 1627-47, EPA switched to using the less demanding § 136a(c)(7)(B) standard instead, *see* ER 1394. *Contra* EPA Suppl. 13-16, 18-19, 21. EPA's change of registration standard—the cornerstone of its order—thus appears to have been a deliberate choice and not a mere "typographical error,"

see ER 30, 37. *Contra* EPA Suppl. 20. To justify its order, the Agency undertook a piecemeal analysis applying different conditional registration standards to each of Enlist Duo's active ingredients. Specifically, EPA analyzed glyphosate under § 136a(c)(7)(A) and assessed 2,4-D under § 136a(c)(7)(B). *See* NRDC Suppl. 14-15; ER 3, 4, 1372, 1394. Defying FIFRA, the Agency then reapproved Enlist Duo's initial uses under § 136a(c)(7)(B). *See* ER 30, 37.

II. EPA's unlawful conditional registration of Enlist Duo's inaugural uses was not harmless error

An agency's legal error is harmless only if it "had no bearing on the procedure used or the substance of [the] decision reached." *Cal. Wilderness Coal. v. U.S. Dep't of Energy*, 631 F.3d 1072, 1092 (9th Cir. 2011) (internal quotation marks omitted). EPA insists that any error was harmless because, even if the Agency had conditionally registered Enlist Duo's initial uses, it nonetheless used FIFRA's "more stringent" § 136a(c)(5) unconditional registration standard "to determine whether Enlist Duo would cause any 'unreasonable adverse effects.'" EPA Suppl. 21; *see id.* at 17-18. However, to the extent EPA made such a determination, it is unsupported by substantial evidence.

"Unconditional registration necessarily requires sufficient data to evaluate the environmental risks." *Pollinator Stewardship Council v. EPA*, 806 F.3d 520,

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EPA Suppl. 13, 15. In any event, the 2014 Registration no longer has independent legal force, because the 2017 Registration superseded it. *See* ER 37.

523 (9th Cir. 2015). The Agency's improper reliance on § 136a(c)(7) led it to narrow its risk analysis, excluding relevant evidence of Enlist Duo's risks to human health and monarchs from consideration. Had EPA considered this "relevant data in the possession of the Agency" as required for unconditional registration, 40 C.F.R. § 152.112(b), it might have found that Enlist Duo presented unreasonable risks warranting either restrictions on the pesticide's use or denial of the registration. *See Pollinator Stewardship Council*, 806 F.3d at 532-33 (concluding that EPA's consideration of data on a pesticide's effects on bees might lead to a different outcome on remand); *see also Or. Nat. Desert Ass'n v. Jewell*, 840 F.3d 562, 569-71 (9th Cir. 2016) (holding that it was not harmless error for an agency to use inaccurate evidence when evaluating potential harm to a bird species from a proposed energy project).

In addition, had EPA complied with § 136a(c)(5), it could not have reapproved Enlist Duo's initial uses in 2017 without first gathering additional data, such as studies on toxicity to honeybees, about 2,4-D's risks. *See* NRDC Suppl. 22-23. The 2017 Final Registration Decision, which is part of the combined record for the 2017 Registration, *see* ECF No. 166 at 6-7, confirmed that outstanding data were needed to characterize the risks of *all* pesticides containing 2,4-D. *See* ER 30; EPA Suppl. 20. These data gaps thus precluded unconditional registration of Enlist Duo's initial uses.

The Agency nonetheless makes a half-hearted plea for deference to its weighing of evidence on a pesticide's risks and benefits. *See* EPA Supp. 21; *see also id.* at 6 (citing 40 C.F.R. § 158.1(b)(3), inaccurately, to say that EPA "is not restricted in" how it evaluates registration data). However, EPA did not assess the new data before it concerning risks to monarchs and human health. And the Agency ignored the data gaps that it had itself identified regarding 2,4-D-based pesticides. Each of these failures means that EPA did not have substantial evidence to register Enlist Duo's initial uses unconditionally. The Agency receives no deference where it refuses to apply its technical expertise. *See Pollinator Stewardship Council*, 806 F.3d at 538 (Smith, J., concurring); *California v. F.C.C.*, 905 F.2d 1217, 1230 (9th Cir. 1990) ("[A]n agency's discretion is not boundless, and we must satisfy ourselves that the agency examined the relevant data . . . .").

A. EPA failed to review "all relevant data" before the Agency on Enlist Duo's risks

EPA agrees that, to withstand scrutiny under § 136a(c)(5), a registration must be based on a review of "all relevant data in the possession of the Agency." 40 C.F.R. § 152.112(b); *see* EPA Suppl. 27. However, EPA is mistaken that "all relevant data" include only data specific to the "new uses"[4] of any individual

[4] *See* 40 C.F.R. § 152.3 (defining "new use" to include (1) any proposed use pattern that would require establishing or increasing the exemption from a "tolerance or food additive regulation"; (2) any terrestrial use pattern, "if no product containing the active ingredient is currently registered for that use pattern";

active ingredient in a pesticide. *See* EPA Suppl. 5-7, 12, 22-23, 26-29. EPA's approach defies the statutory and regulatory framework for unconditional registration and is no less unlawful just because it is "longstanding." *Contra* EPA Suppl. at 7, 23.

1. "All relevant data" mean all data that bear on whether Enlist Duo, as a whole, meets the § 136a(c)(5) standard

The phrase "all relevant data" must be interpreted "in light of the overall statutory and regulatory scheme." *Campesinos Unidos, Inc. v. U.S. Dep't of Labor*, 803 F.2d 1063, 1069 (9th Cir. 1986). Section 152.112 concerns "[a]pproval of registration under [§ 136a(c)(5)]." 40 C.F.R. § 152.112. Section 136a(c)(5), in turn, concerns the unconditional registration of "a pesticide" 7 U.S.C. § 136a(c)(5). "Relevant" data under § 152.112(b) thus mean data pertaining to whether "a pesticide" meets § 136a(c)(5)'s requirements: including the requirements that the pesticide not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C), (D); *accord* 40 C.F.R. § 152.112(e).

The "pesticide" at issue is Enlist Duo. *See* 7 U.S.C. § 136(u) (defining "pesticide" to include a "mixture of substances" intended to control pests). Thus, any data concerning whether Enlist Duo causes unreasonable adverse effects fit squarely within the universe of "all relevant data" that EPA had to consider under

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or (3) any use pattern that would significantly increase the exposure, or change the route of exposure, "to the active ingredient of man or other organisms").

§ 136a(c)(5). New evidence that both the glyphosate and 2,4-D in Enlist Duo harm imperiled monarchs by destroying in-field milkweed, and that glyphosate poses serious human health risks such as birth defects and kidney toxicity, are certainly "relevant" to whether the "pesticide" Enlist Duo causes unreasonable harm.[5]

It is EPA, not NRDC, who "ignores the statutory definition of 'pesticide,'" EPA Suppl. 24, in arguing that "all relevant data" under § 152.112(b) exclude data not specific to the "new use" of individual active ingredients. *See* EPA Suppl. 5-7, 22-23, 26-29. The Agency insists that it could simply evaluate evidence of Enlist Duo's "new uses" of 2,4-D and ignore all new evidence of glyphosate's risks absent "new uses" of glyphosate.[6] *See id.* at 23, 26-29. But the "pesticide" Enlist

[5] NRDC has consistently argued that EPA must assess all evidence pertaining to the risks posed by Enlist Duo as a whole, which includes both active ingredients. *See, e.g.*, NRDC Suppl. 15-16. *Contra* EPA Suppl. 27, 28-29. In addition, the record contains evidence that milkweed destruction harms monarchs, and that both chemicals destroy milkweed. *See* NRDC Br. 18-21. *Contra* Dow Suppl. 12.

[6] EPA's conclusion that Enlist Duo does not involve any "new use" of glyphosate is unsupported by substantial evidence. *See* NRDC Br. 11-12, 48; NRDC Reply 9; NRDC Suppl. 17-18. *Contra* EPA Suppl. 26, 24; Dow Suppl. 11. Notably, EPA has authorized Enlist Duo to be tank-mixed with other herbicides containing glyphosate, which indicates these pesticides may be used additively, and not just alternatively, thereby increasing total glyphosate use. *See* ER 32 (referring to EnlistTankmix.com); EnlistTankmix.com, https://www.enlist.com/en/approved-tank-mixes/enlist-duo.html (last visited Nov. 14, 2019) (listing glyphosate-based pesticides such as Praxis Plus and Showdown); Praxis Plus Label 1, https://www.fbn.com/chemical-labels/12348/Praxis-Plus.801f5d89842ce0bc5db7a4b670b6718d4e09d571537c9a6e7d0a96e71b60fb61.pdf (last visited Nov. 15, 2019); Showdown Label 1, https://s3-us-west-

Duo is the entire "mixture of substances" that compose it, 7 U.S.C. § 136(u), not just the "new uses" of 2,4-D within it. "All relevant data" do not mean "some relevant data."[7]

Under EPA's theory, moreover, the Agency could ignore even compelling evidence of harmful synergies from the novel combination of two active ingredients for which there are no "new uses." *See* EPA Suppl. 6. This absurd result demonstrates the incoherence of EPA's "new use" theory. Evidence of synergistic effects are "relevant," 40 C.F.R. § 152.112(b), to the risks posed by a "pesticide," 7 U.S.C. § 136(u), and must be considered before EPA grants an unconditional registration.

2. EPA's "new use" argument defies the statutory and regulatory framework for unconditional registration

Further analysis of the unconditional registration framework confirms that EPA erred in its myopic focus on the "new uses" of 2,4-D.

1.amazonaws.com/agrian-cg-fs1-production/pdfs/Showdown_Label3.pdf (last visited Nov. 17, 2019).

[7] EPA suggests it could have avoided assessing glyphosate's risks by simply registering a pesticide containing the new uses of 2,4-D and then allowing that pesticide to be tank-mixed with glyphosate. EPA Suppl. 25. This is wrong as a matter of law. EPA must ensure that a pesticide is safe when used as intended, which includes looking at harm from approved tank-mixing with other pesticides. *See* NFFC Suppl. 27-28. In addition, EPA does not assert that tank mixing these ingredients would result in an equivalent product; other, unspecified ingredients—including a new inert ingredient that required approval, *see* NRDC SER vol.II at 1—make up about 53% of Enlist Duo. ER 93.

First, EPA's "new use" theory has no basis in the statutory or regulatory provisions governing *unconditional* registration. *See* 7 U.S.C. § 136a(c)(5); 40 C.F.R. § 152.112. None of those provisions even mentions the "new use" of active ingredients, much less limits the data that EPA must review to evidence specific to the "new use" of active ingredients in isolation. *See id.*; *see also* NRDC Suppl. 16. Rather, the "new use" of active ingredients is relevant only in the context of *conditional* registration under § 136a(c)(7)(B). *See* 40 C.F.R. § 152.113(c); EPA Suppl. 12. But EPA could not grant a lawful conditional registration for Enlist Duo's initial uses under § 136a(c)(7)(B), and the Agency itself disclaims having done so. *Supra* Argument I.

Second, EPA's "new use" argument contravenes the Agency's regulations at § 152.107, which describe how EPA complies with its duty to review "all relevant data" under § 152.112(b) when evaluating a pesticide for unconditional registration. *See* 40 C.F.R. §§ 152.107, 152.112(b). Section 152.107 provides that EPA will normally review only new "data submitted with an application that have not previously been submitted to the Agency" except in limited circumstances not present here, in which case the Agency will also reexamine previously submitted data. *See id*. § 152.107(a)-(b). Yet, EPA refused to consider the NRDC-provided evidence on Enlist Duo's risks to monarchs and human health that had "not previously been submitted to the Agency," *id.* § 152.107(a).

EPA insists that "§ 152.112(b) does not require EPA to review emerging scientific data about an active ingredient in a pesticide product when the application does not seek a new use of that active ingredient." EPA Suppl. 27; *see also id.* at 22. But §§ 152.107 and 152.112(b) together require EPA to review new data on a pesticide's risks regardless of whether there is a "new use" of an active ingredient. EPA may not rewrite its regulations to suit its litigation position. *See NRDC v. EPA*, 735 F.3d 873, 884 (9th Cir. 2013) (explaining that, "[h]aving established a rule of decision," "EPA cannot unmake it" simply because the Agency dislikes the outcome that the rule compels in a particular case, and that the Court cannot "alter [EPA's] rule of decision" either).

EPA argues that it would be unfair to require the Agency to review new evidence regarding the preexisting uses of an active ingredient in a combination pesticide but not in a single-active-ingredient pesticide. *See* EPA Suppl. 23. However, all pesticides that EPA reviews for unconditional registration are subject to the same requirements, regardless of how many active ingredients they contain. *See* 7 U.S.C. § 136a(c)(5); 40 C.F.R. §§ 152.107, 152.112(b). In effectively trying to exempt combination pesticides from § 152.107(a), it is EPA that seeks to create an "uneven playing field," EPA Suppl. 23, by lowering the bar for the unconditional registration of combination pesticides.

Third, EPA is incorrect that "there would be no point" to the separate and later process of registration review if, during unconditional registration of a new pesticide, the Agency analyzed new evidence concerning any preexisting uses of the active ingredient(s) in the pesticide. EPA Suppl. 24; *see id.* at 22-23. Registration review ensures that EPA evaluates the current science on registered pesticides *at least* once every 15 years. *See* 7 U.S.C. § 136a(g)(1)(A)(iii), (iv); 40 C.F.R. § 155.40(a). It does not displace EPA's other risk review responsibilities, including those triggered by an application for unconditional registration. *See* 7 U.S.C. § 136a(g)(1)(C); 40 C.F.R. § 155.40(c)(1).

Indeed, EPA's "policy is to continue to make registration determinations for new actions" during the "lengthy process" of registration review. ER 1438. Through these registrations, "the Agency will receive new data and conduct new risk assessments for many pesticides." 70 Fed. Reg. 40,251, 40,261 (July 13, 2005). EPA acknowledged that these "new risk assessments" might leave "very little additional work" to be done when a recently registered pesticide comes up for registration review. *Id.* This is intentional, to ensure that EPA fulfills FIFRA's mandate to assess pesticides' risks *before* authorizing their use. *See id.* at 40,270 ("[T]he Agency must continue to respond to emerging risk concerns and not defer action until a pesticide's regularly scheduled registration review."). *Contra* EPA Suppl. 24.

Fourth, EPA's regulations at § 152.111 do not support the Agency's attempt to narrow the meaning of "all relevant data" under § 152.112(b). *Contra* EPA Suppl. 27-29 (claiming that these two provisions required EPA simply to "confirm" that the uses of glyphosate in Enlist Duo "were already registered"—and not to "consider additional data concerning glyphosate because there was no new use being sought"). EPA could not exercise the discretion described in § 152.111 to apply § 136a(c)(7)'s relaxed data requirements to Enlist Duo's initial uses, because FIFRA prohibited registration of those uses under § 136a(c)(7). *See supra* Argument I.A. *Contra* EPA Suppl. 9-10. This prohibition also means that the legislative history and regulatory preamble concerning conditional registration offer no support for EPA's position. *Contra* EPA Suppl. 24; Dow Suppl. 5.

Furthermore, while § 152.111 provides guidance on *when* EPA will choose to review a pesticide application under the criteria for § 136a(c)(5), it does not purport to limit *what* the applicable criteria are. *See* 40 C.F.R. § 152.111. Thus, even if the Court credits EPA's argument that it chose § 136a(c)(5) when registering Enlist Duo's initial uses, EPA would still have been bound by § 152.112(b)'s requirement to consider "all relevant data."

Fifth, § 152.112(c) did not authorize EPA to ignore data already in the Agency's possession regarding risks to monarchs or human health from the previously registered uses of glyphosate in Enlist Duo. *Contra* Dow Suppl. 10-11.

Read alongside § 152.112(b), subsection (c) simply provides that EPA must determine that no additional data, beyond that already in its possession, are necessary to evaluate a pesticide's risks. *See* 40 C.F.R. § 152.112(b), (c).

3. EPA exaggerates the burden of reviewing "all relevant data" on a pesticide's risks

EPA complains that it would be "impracticable" to "review all new scientific information" for the "hundreds" of applications it receives each year for pesticide products containing already registered active ingredients. EPA Suppl. 22-23. But if EPA frequently reviews pesticide applications involving the same active ingredients, then it is unlikely that relevant new studies will proliferate during the short intervals between applications. Conversely, if EPA rarely reviews pesticide applications involving the same active ingredients, then EPA will seldom have to review new science on those ingredients.

Furthermore, EPA's duty to review "all relevant data," 40 C.F.R. § 152.112(b), does not mean that the Agency must re-examine all previously reviewed data. EPA need not conduct a "new full-blown risk assessment," EPA Suppl. 26, or "ignore the registration history" of active ingredients, Dow Suppl. 7, when reviewing a pesticide for unconditional registration, *see* 40 C.F.R. § 152.107. The Agency may build on previous risk assessments for the pesticide's active ingredients, updating those assessments only as needed based on new science. *See* 7 U.S.C. § 136a(c)(1)(F); 40 C.F.R. § 152.90(b)(3), (5). Requiring EPA to at least

consider new, relevant information is not the same as making the Agency redo everything.

EPA has not shown that complying with FIFRA when registering new combination pesticides would impose an undue burden. And not even a substantiated claim of administrative burden would justify departure from a statutory mandate. *See EPA v. EME Homer City Generation, L.P.*, 572 U.S. 489, 509 (2014).

B. EPA may not ignore Enlist Duo's risks to monarch butterflies

NRDC's argument that § 136a(c)(5) required EPA to consider Enlist Duo's risks to monarchs from the destruction of agricultural milkweed applies to the entire pesticide, including both the 2,4-D and glyphosate active ingredients (both of which kill milkweed and therefore harm monarchs). *See supra* n.5. *Contra* EPA Suppl. 28-29. EPA responds that "FIFRA does not require that EPA consider whether the pesticide product's efficacy in controlling the target pest will have indirect effects." EPA Suppl. 31. The Agency is simply wrong.

FIFRA compels EPA to determine whether a pesticide presents "*any* unreasonable risk to man or the environment." 7 U.S.C. §§ 136(bb) (emphasis added), 136a(c)(5). There is no exemption for indirect risks to a non-target species (monarchs) caused by killing a "target pest" (milkweed). *See* NRDC Suppl. 18-19. Killing an intended target may have unintended consequences; FIFRA requires

EPA to acknowledge the possible impacts and balance the costs and benefits. *See* 7 U.S.C. §§ 136(bb), 136a(c)(5)(C), (D).

EPA's current litigation position is inconsistent with its past practice. For example, the Agency has previously found that pesticides pose unreasonable risks to the environment when non-target species are poisoned by eating target pests exposed to the pesticide. *See* 78 Fed. Reg. 8123, 8126 (Feb. 5, 2013) (providing notice of intent to cancel registrations of warfarin, brodifacoum, and difethialone); 48 Fed. Reg. 48522, 48524 (Oct. 19, 1983) (cancelling registration of strychnine). EPA offers no explanation for why it now believes such "indirect" harm lies beyond FIFRA's ken.

EPA is also wrong that "the record shows that growers would continue to control on-field milkweed even without Enlist Duo." EPA Suppl. 33. As support, EPA cites its main opposition brief, which in turn cites nothing. *See* EPA Opp'n 75-76. The proposition that growers would suppress all milkweed absent Enlist Duo is thus post hoc argument by counsel. In contrast, the record indicates that some milkweed remained in agricultural fields before Enlist Duo's registration, suggesting that, without Enlist Duo, farmers might not fully suppress milkweed. ER 266-75. In any event, even if growers would use equally risky market substitutes to suppress all agricultural milkweed absent Enlist Duo, this would not

exempt EPA from assessing, and mitigating if necessary, Enlist Duo's risks to monarchs. *See* NRDC Suppl. 19-21.

Because EPA refused to consider the matter, it does not know how Enlist Duo will affect monarchs through destruction of agricultural milkweed, how risks to monarchs weigh against the pesticide's benefits, or whether those risks must be mitigated by restrictions on Enlist Duo's use.

* * *

Without considering relevant evidence of Enlist Duo's risks to monarchs and human health—evidence EPA had never previously reviewed—as well as the outstanding data on 2,4-D's risks, the Agency had "no real idea" whether Enlist Duo will cause unreasonable harm to the environment. *See Pollinator Stewardship Council*, 806 F.3d at 532.

C. NRDC has not waived its argument that EPA's conditional registration of Enlist Duo's initial uses violates § 136a(c)(5)

EPA contends that NRDC "waived any argument that EPA issued a conditional registration in 2014." EPA Suppl. 16. But the legality of the 2014 Registration is not at issue in this proceeding. NRDC challenges only the 2017 Registration, which reissued and superseded the 2014 Registration. *See* ECF No. 166 at 5.

Although EPA does not argue otherwise, NRDC preserved its argument that the Agency issued an unlawful conditional registration of Enlist Duo's initial uses

in 2017. After EPA proposed to issue the 2017 Registration conditionally, *see* ER 549, NRDC commented that EPA must evaluate Enlist Duo's inaugural uses based on all relevant data under § 136a(c)(5) and could not register those uses conditionally under § 136a(c)(7). *See* ER 151, 198-99, 202-11. In the Final Registration Decision, EPA attempted to explain its choice of registration standard and resulting decision not to analyze the new data submitted by NRDC. *See* ER 2-5, 30. Thus, NRDC did not waive its argument that EPA could not conditionally register Enlist Duo's inaugural uses. *See Nat'l Parks & Conservation Ass'n v. Bureau of Land Mgmt.*, 606 F.3d 1058, 1065 (9th Cir. 2010).

Nor did NRDC have to preserve its claims against the 2017 Registration by raising them in litigation over the 2014 and 2015 Registrations. *Contra* EPA Suppl. 17. The Court remanded those registration decisions without ruling on the merits, so issue preclusion and res judicata do not apply. *See Oyeniran v. Holder*, 672 F.3d 800, 806 (9th Cir. 2012); *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 322 F.3d 1064, 1077 (9th Cir. 2003).

Finally, in supporting EPA's motion to vacate and remand the prior Registrations, NRDC did not concede that EPA had applied the proper registration standard. *Contra* EPA Suppl. 17. NRDC argued then, as it does now, that the registration of Enlist Duo's inaugural uses failed to satisfy FIFRA's unconditional registration standard. *See NRDC v. EPA*, No. 14-73353, ECF No. 125 at 2-5.

III. EPA lacked substantial evidence to register the additional uses of Enlist Duo in 2017

EPA offers no response to NRDC's argument that the registration of Enlist Duo's additional uses (on corn and soy in 28 states, and on cotton in 34 states) independently violates the *text* of § 136a(c)(7)(B). *Compare* NRDC Suppl. 23-25, *with* EPA Suppl. 35-37. Section 136a(c)(7)(B) requires EPA to review all data necessary for unconditional registration except data that "ha[ve] not yet been generated." 7 U.S.C. § 136a(c)(7)(B). Because EPA ignored the *existing* data that NRDC submitted regarding Enlist Duo's risks to monarchs and human health, the Agency lacked substantial evidence to conclude that the pesticide's additional uses satisfied § 136a(c)(7)(B).

IV. The Enlist Duo registration should be vacated

Respondents fail to show that this case fits within the "limited circumstances" in which "equity demands" that the Court withhold the normal remedy of vacatur. *Pollinator Stewardship Council*, 806 F.3d at 532.

EPA's refusal to consider relevant evidence is a "fundamental flaw[]" in the registration decision. *See id.* That evidence documented Enlist Duo's serious risks to both human health (birth defects and kidney toxicity) and monarchs (population collapse from loss of milkweed habitat). NRDC Suppl. 9-10. Because EPA ignored these data, there was no possibility that it could understand the gravity of these risks or craft restrictions to mitigate them. *See* NRDC Suppl. 21, 27-28. EPA also

denied the public an opportunity to comment on the risk assessment that the Agency would have performed had it complied with FIFRA.

EPA's assertion that it "would likely re-issue the Enlist Duo registration" following any remand of the 2017 Registration, EPA Suppl. 59, speaks only to the Agency's closed mind, not its legal obligations or expert judgment. EPA does not know how data it ignored will affect the risk-benefit balancing mandated by FIFRA. Although EPA attempts to distinguish *Pollinator Stewardship Council*, EPA Suppl. 58-59, this case is remarkably similar: EPA has yet to review critical evidence of a pesticide's risks—including risks to a species whose survival is "precarious[]"—and might reach a different registration decision on remand once it does. *See* 806 F.3d at 532-33. Thus, the seriousness of EPA's errors favors vacatur.

Dow warns that vacatur will wreak havoc on the agriculture industry and disrupt "the world's food supply." Dow Suppl. 28. But Dow does not disclose the basic facts needed to evaluate this dramatic claim: How many growers use Enlist Duo on how many acres of crops? How much would it cost to switch from Enlist Duo to any of the myriad chemical and mechanical weed control alternatives available? Why would vacatur of a relatively new pesticide approval in the United States cause global disruption? *See* NRDC Suppl. 26-27. Dow relies solely on the

unsubstantiated hyperbole in the American Farm Bureau's amicus brief.[8] By contrast, the record suggests that the impact from vacatur would be slight: "according to information submitted by [Dow], no appreciable use of Enlist Duo™ on [corn and soybean] crops occurred in the 2015 and 2016 use seasons," ER 30, even though EPA had registered the pesticide for use in 16 Midwestern states on millions of acres of cropland. Absent actual evidence, Dow's self-serving predictions of calamity fail to tip the scales away from the normal remedy of vacatur.[9]

EPA speculates that vacatur would leave growers who purchased Enlist seed and pesticide with stranded inventory. EPA Suppl. 57-58. There is no evidence that growers could not obtain a refund from Dow for products that they can no longer legally use.

Vacating the 2017 Registration would effectuate FIFRA's mandate that EPA fully evaluate the risks of pesticides before unconditionally approving them for sale and use.

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[8] In *Pollinator Stewardship Council*, Dow made similarly conclusory assertions that vacatur would cause extreme disruption, none of which were borne out. *See* Br. for Resp.-Int., *Pollinator Stewardship Council v. EPA*, No. 13-72346, ECF No. 34-1 at 39 (claiming vacatur could result in "near total crop loss" and "catastrophic loss" for growers).

[9] NRDC previously rebutted the claimed environmental harm from vacatur. *See* NRDC Suppl. 28-29. Dow and EPA offer no new arguments on this issue in their supplemental briefs.

CONCLUSION

For the foregoing reasons, the Court should vacate EPA's 2017 Registration of Enlist Duo.

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Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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