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 BRIEF OF PETITIONER NATURAL RESOURCES DEFENSE COUNCIL

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INTRODUCTION

EPA approved the pesticide Enlist Duo even though the Agency had "no real idea," *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015), whether the pesticide will cause unreasonable adverse effects to human health or the environment. This violated FIFRA. Without considering persuasive evidence that Enlist Duo threatens imperiled North American monarch butterflies and poses serious risks to human health, EPA could not lawfully determine whether the pesticide's harms are sufficiently outweighed by its benefits to justify the widespread uses that the Agency authorized through its 2017 Registration.

FIFRA's § 136a(c)(5) unconditional registration standard requires EPA to assess all relevant data regarding a pesticide's health and environmental risks before allowing it on the market for the first time. Evading this requirement, EPA instead registered Enlist Duo's inaugural uses under FIFRA's less demanding § 136a(c)(7)(B) conditional registration standard. EPA's use of the wrong legal standard was unlawful; it also rendered invalid the Agency's subsequent, derivative approvals of Enlist Duo's additional uses.

In addition, the 2017 Registration is not supported by substantial evidence because EPA failed to consider new evidence that Enlist Duo threatens monarch survival and human safety. Like § 136a(c)(5), § 136a(c)(7)(B) requires EPA to review all relevant data before approving proposed pesticide uses, with only one

narrow exception: the Agency may defer consideration of data that have not yet been generated. This means FIFRA required EPA to evaluate the *existing* evidence of Enlist Duo's harms to monarchs and human health under *either* registration standard. EPA's failure to do so was unlawful.

EPA's violations of FIFRA's core registration requirement have already left people and the environment exposed—for nearly five years—to a potentially dangerous pesticide, with only partially characterized risks, despite a host of available studies raising legitimate concerns about its safety. The Court should vacate the unlawful 2017 Registration.

This supplemental brief incorporates NRDC's opening brief, *see* NRDC Br., ECF No. 63, and reply brief, *see* NRDC Reply, ECF No. 121.

ARGUMENT

I. The 2017 Registration violates FIFRA because EPA used the wrong legal standard to register the inaugural uses of Enlist Duo

A. FIFRA required EPA to apply the § 136a(c)(5) unconditional registration standard in analyzing and approving Enlist Duo's inaugural uses

A pesticide must satisfy FIFRA's standard for unconditional registration unless one of three "special circumstances" for conditional registration applies. *Compare* 7 U.S.C. § 136a(c)(5), *with id.* § 136a(c)(7). Here, the single relevant exception is § 136a(c)(7)(B)—the second "special circumstance" for conditional

registration—which EPA used to approve all uses of Enlist Duo.[1] *See* ER 37. That provision authorizes EPA only to "amend" the *existing* registration of a pesticide to permit "*additional* uses of such pesticide." 7 U.S.C. § 136a(c)(7)(B) (emphasis added). This means that EPA may not conditionally register the *inaugural* uses of Enlist Duo under § 136a(c)(7)(B). *See* NRDC Br. 35-43.

B. EPA impermissibly used § 136a(c)(7)(B) to grant a conditional registration for Enlist Duo's inaugural uses

EPA agrees that it "should have used the standard from the unconditional registration provision" to assess Enlist Duo's inaugural uses.[2] EPA Br., ECF No.

[1] EPA correctly acknowledged that it could not register Enlist Duo as a "me-too" under § 136a(c)(7)(A)—the first "special circumstance" for conditional registration—because Enlist Duo is not identical or substantially similar to any previously registered pesticide. *See* ER 4; 7 U.S.C. § 136a(c)(7)(A). Nor did § 136a(c)(7)(C)—the third "special circumstance"—present a viable option. EPA may use that provision to register only pesticides containing a new active ingredient, *see* 7 U.S.C. § 136a(c)(7)(C), and both of Enlist Duo's active ingredients appear (separately) in previously registered pesticides, *see* ER 2.

[2] Because EPA finalized its reconsideration of the 2014 and 2015 Registrations for Enlist Duo's earlier uses at the same time it approved the pesticide's new uses in 2017, NRDC previously argued that these simultaneously authorized uses all constituted "inaugural uses" of the pesticide. *See* NRDC Br. 35-43. However, given the Court's Order construing the 2017 Registration to entail a sequence of approvals, *see* Order, ECF No. 166, at 4 n.1 (Suppl. Br. Order), NRDC now uses the term "inaugural uses" to include only the uses on corn and soy in six states first registered in 2014; the term "additional uses" refers to the remaining registered uses on corn and soy in twenty-eight more states, and on cotton in all thirty-four states. *See* ER 2.

83-1, at 39. Its litigation counsel insists that this "is precisely what EPA did." *Id.* The Agency's final registration documents, however, tell a different story.

Although the 2014 Notice of Registration stated that the registration of Enlist Duo's inaugural uses was *unconditional*, it made the approval contingent on future data submissions, ER 1401, which by definition made the registration *conditional*. The Notice stated that Enlist Duo was registered "provided that" Dow "[s]ubmit and/or cite all data required for registration/reregistration/registration review of [its] product under FIFRA when the Agency requires all registrants of similar products to submit such data." *Id.*; *cf.* 7 U.S.C. § 136a(c)(7)(B) (authorizing conditional registration despite certain missing data, provided that EPA "require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered"). The Notice also dictated that the registration would "automatically expire" within six years. ER 1402; *cf.* 40 C.F.R. § 152.115(c) (authorizing EPA to establish "other conditions applicable to registrations to be issued under [7 U.S.C. § 136a(c)(7)(B)]"). Furthermore, the accompanying 2014 Final Registration Decision explicitly cited § 136a(c)(7)(B)—the *conditional* registration provision—as the basis for EPA's order. ER 1394. EPA then applied the standard articulated in that section in

concluding that the "expanded uses of Enlist Duo"[3] would not "increase the risk of any unreasonable adverse effects." ER 1394; *see* 7 U.S.C. § 136a(c)(7)(B).

In expanding Enlist Duo's registration in 2015, EPA confirmed that it had previously conditionally registered the pesticide's inaugural uses. The Agency stated that its 2015 "approval does not affect any conditions that were previously imposed on this registration" and that Dow would "continue to be subject to all conditions specified on the [2014] Notice of Registration." ER 1019.

Thereafter, EPA's 2017 Notice of Registration superseded the prior registration orders and stated, without qualification, that it was registering all uses of Enlist Duo *conditionally*. ER 37. The corresponding 2017 Final Registration Decision represented that EPA was maintaining the 2014 and 2015 Registrations "with no changes." ER 5. Thus, the 2014 and 2015 Registrations must have been conditional, because otherwise the 2017 Registration would have changed them. In addition, the Agency explained that it was granting a conditional registration because it had "identified data that will be required in connection with registration review activities for 2,4-D." ER 30. EPA concedes these missing data "precluded [it] from issuing an unconditional registration." EPA Br. 46.

[3] This characterization is nonsensical, as EPA had never previously approved any use of Enlist Duo.

The record thus unequivocally shows that EPA approved Enlist Duo's inaugural uses under FIFRA's § 136a(c)(7)(B) conditional registration standard, instead of the § 136a(c)(5) unconditional standard, as required. Because "the proper legal standard[] w[as] not applied in weighing the evidence and making the decision," *Benitez v. Califano*, 573 F.2d 653, 655 (9th Cir. 1978), EPA's registration of Enlist Duo's inaugural uses was unlawful.

EPA's litigation counsel attempts to dismiss the 2014 Final Registration Decision's explicit reliance on § 136a(c)(7)(B) as a "clerical error." EPA Br. 12 n.3. The Court should reject this characterization not only because it is "post hoc rationalization by counsel," *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983), but also because it is contradicted by the record. Except for the contrary language in the 2014 Notice of Registration, *see* ER 1401, the final registration documents all indicate that EPA improperly relied on the § 136a(c)(7)(B) conditional registration standard to approve Enlist Duo's inaugural uses. To the extent EPA suggests that the Court should credit the lone contrary words in the 2014 Notice of Registration because that document "is the actual 'order' granting the registration," EPA Br. 12 n.3, EPA "breached the requirement of reasoned decisionmaking" by "applying a different standard" than the "standard formally announced" in its order, *Turlock Irrigation Dist. v. Fed. Energy Regulatory Comm'n*, 903 F.3d 862, 873 (9th Cir. 2018).

EPA's failure to apply the proper legal standard has potentially serious consequences; this is not a mere technical mistake. By circumventing the more demanding standard for unconditional registration, the Agency avoided making the required finding—based on a review of adequate data—that Enlist Duo's harms are sufficiently outweighed by its benefits to justify the expansive human and environmental exposures EPA authorized. *See* 7 U.S.C. § 136a(c)(5); *Pollinator Stewardship Council*, 806 F.3d at 532-33. The public cannot have confidence in the pesticide's safety when EPA's approval was based on incomplete information.

In the alternative, if the significant unexplained inconsistencies in EPA's registration documents prevent the Court from reasonably discerning what standard the Agency applied in registering Enlist Duo's inaugural uses, that itself is a reason for holding the registration unlawful. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196-97 (1947) ("If the administrative action is to be tested by the basis upon which it purports to rest, that basis must be set forth with such clarity as to be understandable. It will not do for a court to be compelled to guess at the theory underlying the agency's action . . . ."); *see also Nat'l Parks Conservation Ass'n v. EPA*, 788 F.3d 1134, 1141 (9th Cir. 2015) ("EPA's actions must also be consistent; an internally inconsistent analysis is arbitrary and capricious.").

C. EPA's unlawful registration of Enlist Duo's inaugural uses means the entire 2017 Registration violates FIFRA

EPA's 2017 Registration "incorporates all registered uses of Enlist Duo for [genetically engineered] corn, soybean, and cotton in 34 states." Suppl. Br. Order 7. The linchpin to this registration is EPA's approval of Enlist Duo's inaugural uses, because a registrant must obtain and maintain a valid unconditional registration for a pesticide before amending that registration to incorporate additional uses. *Compare* 7 U.S.C. § 136a(c)(5), *with id.* § 136a(c)(7)(B). If the underlying primary license is invalid, then any derivative additional licenses are invalid too. Because EPA may not expand a registration that itself violates FIFRA, the Agency's unlawful registration of Enlist Duo's inaugural uses renders the entire registration unlawful. *See* NRDC Reply 27. The Court need not proceed further to invalidate the 2017 Registration.

II. The 2017 Registration is not supported by substantial evidence

A. EPA failed to support its registration of Enlist Duo's inaugural uses with substantial evidence under the § 136a(c)(5) unconditional registration standard

In the alternative, assuming the Court credits EPA's litigation counsel's assertion that the Agency complied with FIFRA's requirement to register Enlist Duo's inaugural uses under § 136a(c)(5), that approval is still unlawful because EPA did not support the required determinations with substantial evidence.

Under § 136a(c)(5), EPA may unconditionally register a new pesticide only if it determines that the pesticide will not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C), (D). "Unconditional registration necessarily requires sufficient data to evaluate the environmental risks." *Pollinator Stewardship Council*, 806 F.3d at 523; *see* 40 C.F.R. § 158.75. EPA must review "all relevant data in the possession of the Agency," 40 C.F.R. § 152.112(b), and conclude "that no additional data are necessary to make the determinations required by [that standard]," *id.* § 152.112(c)—including the determinations that use of the pesticide will not cause unreasonable adverse effects, *see* 7 U.S.C. § 136a(c)(5)(C), (D); *Pollinator Stewardship Council*, 806 F.3d at 528.

1. EPA ignored relevant evidence of Enlist Duo's risks to monarch butterflies and human health

The 2017 Registration is subject to review "on the combined records of the 2014, 2015, and 2017 orders, all of which is incorporated into the 2017 order's record." Suppl. Br. Order 7. As this record shows, NRDC timely commented on each of EPA's three proposed orders. *See* ER 1614-64; NRDC-SER 1-36; ER 144-211. Each time, NRDC asked EPA to review studies—that the Agency had never previously considered—indicating that monarchs face a high probability of population collapse and that Enlist Duo threatens the species' precarious survival by destroying in-field milkweed. *See* ER 1614-16, 1619-27; NRDC-SER 2-3, 6-19; ER 146-48, 151, 155-73, 198-202; NRDC Br. 14-21. Noting that over two decades

had elapsed since EPA's last comprehensive review of glyphosate's human health risks, NRDC also asked EPA to evaluate updated scientific literature linking the chemical to serious harms such as birth defects and kidney toxicity. *See* ER 1631-32; NRDC-SER 4, 19-20; ER 148-49, 151, 173-74, 178, 202-03; NRDC Br. 22.

EPA did not reject these studies as invalid. Nor did it conclude that, although they documented real risks, those risks were acceptable when weighed against the pesticide's benefits. Instead, the Agency simply refused to consider the new data, *see* ER 1372, 1436 (2014 Registration); ER 1041-42 (2015 Registration); ER 3-4, 63-64 (2017 Registration)—notwithstanding their unquestionable relevance to whether Enlist Duo poses "any unreasonable risk to man or the environment," 7 U.S.C. § 136(bb); *see id.* § 136a(c)(5). Without reviewing these pertinent studies, EPA lacked substantial evidence to conclude that reapproving Enlist Duo's initial uses would not cause unreasonable adverse effects. *See Pollinator Stewardship Council*, 806 F.3d at 532.

i. EPA must review relevant evidence of Enlist Duo's risks before granting an unconditional approval

FIFRA required EPA to review the evidence of Enlist Duo's risks to monarchs and humans before unconditionally approving the pesticide. *See* NRDC Reply 25-26. The Agency is mistaken in contending that it could postpone review of this evidence until years after the approval, during the separate registration review processes for the pesticide's active ingredients. *See, e.g.*, ER 1436

(asserting that EPA would consider "glyphosate's direct and indirect effects on monarch butterflies" during registration review for glyphosate—which the Agency need not complete until October 2022, *see* 7 U.S.C. § 136a(g)(1)(A)(iii)); *see also* ER 1438 (acknowledging that "Registration Review is a lengthy process that may take many years to complete").

As EPA previously acknowledged, "Registration of new pesticides or new uses of pesticides under [FIFRA, as amended by the Pesticide Registration Improvement Act (PRIA),[4]] is a separate program from registration review." 71 Fed. Reg. 45,720, 45,726 (Aug. 9, 2006). The requirement that EPA consider "all relevant data in the possession of the Agency," 40 C.F.R. § 152.112(b), at the time of *initial* registration is crucial to preventing unreasonably harmful pesticides from ever reaching the market, *see* 7 U.S.C. § 136a(a), (c)(5). Allowing EPA to ignore relevant evidence in the administrative record when considering a new pesticide application would defeat this purpose. *Cf. id.* § 136n(b) (providing that "[t]he court shall consider all evidence of record" in deciding whether to sustain a pesticide registration). It makes no sense to approve a new pesticide while deferring evaluation of its potential dangers until years later.

[4] PRIA simply authorized EPA to collect fees for pesticide registration applications and established deadlines for reviewing those applications. Pesticide Registration Improvement Act of 2003, Pub. Law 108-199, div. G, tit. V, sec. 501, 118 Stat. 3, 419 (2004). It did not alter the substantive standards for registration under § 136a.

In contrast, the purpose of registration review is to ensure that a pesticide "*continues* to meet the FIFRA standard for registration in light of new knowledge." 71 Fed. Reg. at 45,726 (emphasis added); *accord* 40 C.F.R. § 155.40(a). During registration review, EPA "will assess any *changes that may have occurred since the Agency's last registration decision* in order to determine . . . whether the pesticide *still* satisfies the FIFRA standard for registration." 40 C.F.R. § 155.53(a) (emphases added). Registration review thus ensures that EPA reevaluates *previously approved* pesticides in light of subsequently generated data (or previously existing data that EPA "missed or overlooked," 71 Fed. Reg. at 45,726); it does not allow EPA intentionally to ignore current data in deciding whether to register *new* pesticides. EPA's refusal to consider up-to-date science before registering Enlist Duo contravenes its established policy that "the Agency must continue to respond to emerging risk concerns and not defer action until a pesticide's regularly scheduled registration review." 70 Fed. Reg. 40,251, 40,270 (proposed July 13, 2005); *accord* 71 Fed. Reg. at 45,722; ER 1438 (stating that "[p]roposed new registrations" arising between registration reviews "are held to the most current data requirements and up-to-date risk assessment practices and must meet the FIFRA no unreasonable adverse effects standard to be registered").

Other FIFRA provisions confirm that Congress intended EPA to review all available evidence of a pesticide's risks at the time of registration. Under

§ 136d(a)(2), "[i]f at any time *after the registration* of a pesticide the registrant has *additional* factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator." 7 U.S.C. § 136d(a)(2) (emphases added); *accord* 40 C.F.R. § 152.125. The clear implication is that EPA should have already reviewed all evidence available at the time of initial registration.

While § 136d(a)(2) requires registrants to submit "additional" information about a pesticide's adverse effects after a pesticide has already been registered, EPA's regulations impose a "parallel requirement" on applicants *before* pesticides are first registered. 48 Fed. Reg. 34,000, 34,002 (July 26, 1983). Specifically, "[a]n applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under [7 U.S.C. § 136d(a)(2)] if the product were registered." 40 C.F.R. § 152.50(f)(3). As EPA previously stated, "The Agency wants *all available information about the adverse effects* of an applicant's product, so that EPA can determine whether it should be registered." 48 Fed. Reg. at 34,002 (emphasis added).

FIFRA requires EPA to balance a pesticide's environmental costs and benefits before making a registration decision. 7 U.S.C. § 136a(c)(5)(C), (D); *id.* § 136(bb). This balancing effectuates the statute's core purpose of safeguarding

people and the environment from unreasonable harm. *See United States v. Neal*, 776 F.3d 645, 652 (9th Cir. 2015) (instructing that statutory provisions must be interpreted "in light of the overall purpose and structure of the whole statutory scheme" (internal quotation marks omitted)); NRDC Br. 40, 42-43. But EPA cannot properly weigh a pesticide's costs against its benefits unless it understands what the costs are. EPA's decision here to delay reviewing evidence of Enlist Duo's threats to monarchs and people until years after the Agency registers the pesticide defies FIFRA's language, structure, and purpose, and cannot be reconciled with the Agency's regulations or prior statements of policy.

ii. EPA may not avoid assessing evidence of Enlist Duo's risks by examining each of the pesticide's active ingredients in isolation

FIFRA's registration requirement applies to "pesticide[s]" as a whole, not the individual active and inert ingredients that comprise them. *See* 7 U.S.C. §§ 136a(a), 136(a), (m), (u); 40 C.F.R. §§ 152.3, 152.15, 152.42. Regardless of whether EPA awarded Enlist Duo a § 136a(c)(5) or § 136a(c)(7)(B) registration, it did not analyze the entire pesticide under that single standard.

Rather, the Agency used different registration standards to assess Enlist Duo's two active ingredients, as though it were registering each of those ingredients in isolation. *See* EPA Br. 43-45. Specifically, EPA used § 136a(c)(7)(B) to approve the 2,4-D component of Enlist Duo. *See* ER 4

(representing that "the application in front of EPA is for a new use for 2,4-D choline salt," which "is being conditionally registered under FIFRA section 3(c)(7[])(B)"); ER 1372, 1394. In contrast, EPA analyzed glyphosate "as if" it were considering an application under the § 136a(c)(7)(A) conditional registration standard, ER 3, which is limited to pesticides that are "identical or substantially similar to any currently registered pesticide," 7 U.S.C. § 136a(c)(7)(A)—hence the Agency's repeated assertion that Enlist Duo did not entail any new use patterns for glyphosate, *see* ER 3-4, 1372.

There is no legal basis for EPA's piecemeal approach. A pesticide approval can satisfy FIFRA's registration standard only when the pesticide *as a whole* meets that standard. *See* 7 U.S.C. § 136a(c)(5), (7) (each providing for registration of a "pesticide," rather than an "active ingredient"); *see also id.* § 136(a) (defining "active ingredient"); *id.* § 136(u) (defining "pesticide"). Enlist Duo is a "pesticide" under FIFRA because it is a "mixture" of two active ingredients and various inert ingredients. *See id.* § 136(u). EPA must analyze the risks associated with this entire mixture. The statute does not sanction EPA's approach of dividing a pesticide into various component parts and analyzing or registering different ingredients under different safety standards. *See* NRDC Br. 38-40.

iii. EPA must consider all existing evidence of Enlist Duo's risks, regardless of whether it is approving a "new use" of any active ingredient

Continuing its myopic focus on Enlist Duo's individual active ingredients in isolation, EPA maintains that it did not have to assess the new evidence of Enlist Duo's risks to monarchs or human health because that evidence is not specific to any "new use" of glyphosate or 2,4-D. *See* ER 3-4, 83-84, 1372; EPA Br. 16; *id*. at 76-77.

The Agency's "new use" argument is a red herring. Whether there is a "*new use*" of any active ingredient is irrelevant to the data EPA must consider before approving a new pesticide; what matters is whether there is any *new evidence* of risks that EPA has not reviewed before. *See* NRDC Reply 23-25. There is no statutory or regulatory basis for EPA's contention otherwise.

Tellingly, § 136a(c)(5) does not even mention the term "new use," much less use it to exclude new evidence from the universe of data EPA must consider in determining whether a pesticide will cause unreasonable adverse effects. *See* 7 U.S.C. § 136a(c)(5). On the contrary, such an exclusion would defy common sense. EPA's own regulations instruct the Agency to review "*all* relevant data in the possession of the Agency" before registering a pesticide, 40 C.F.R. § 152.112(b) (emphasis added), and those data necessarily encompass both old studies EPA previously reviewed *and* new studies it has since received.

The studies that EPA previously reviewed might be "sufficient . . . to evaluate the environmental risks," *Pollinator Stewardship Council*, 806 F.3d at 523, only if no relevant new studies have since been published. But science changes over time. For example, in the more than quarter century since EPA's last comprehensive review for glyphosate, *see* NRDC-SER 53-72, use of glyphosate has skyrocketed; and, as NRDC commented, the studies documenting glyphosate's risks to monarchs postdate that review, while research on the chemical's risks to human health has grown significantly since that time. *See* ER 147-49, 162-74, 178, 198-200; *see also* NRDC-SER 37-52 (summarizing EPA's last comprehensive review for 2,4-D, which also did not address harm to monarchs from milkweed destruction). While EPA may certainly build off its past assessments for glyphosate and 2,4-D in evaluating Enlist Duo's risks, *see* 7 U.S.C. § 136a(c)(1)(F); 40 C.F.R. § 152.90(b)(3), (5), the Agency may not disregard new data that *also* inform the inquiry into whether Enlist Duo will cause unreasonable adverse effects. *See* NRDC Br. 42.

In addition, EPA's "new use" argument fails for another reason with respect to the glyphosate in Enlist Duo. The Agency lacked substantial evidence to conclude that Enlist Duo would not entail any "new use" of glyphosate, *see* ER 3-4, 83-84, 1372, because it simply asserted, without supporting data or analysis, that

registration of Enlist Duo would not increase total glyphosate use. *See* NRDC Br. 11-12, 48; NRDC Reply 9; *see also* 40 C.F.R. § 152.3 (defining "new use").

iv. EPA must evaluate Enlist Duo's indirect effects on monarchs from destruction of in-field milkweed

FIFRA requires EPA to evaluate "*any* unreasonable risk to man or the environment," whether direct or indirect. 7 U.S.C. § 136(bb) (emphasis added); *see id*. § 136a(c)(5)(C), (D). EPA concedes that it did not assess the indirect effects on monarchs from the destruction of "milkweed in the actual crop fields on which Enlist Duo would be intended for use." EPA Br. 74. Dow argues, however, that no such assessment was needed, because Enlist Duo "is obviously meant to kill" the milkweed in agricultural fields. Dow Br., ECF No. 111, at 45.

The issue is not whether Enlist Duo poses unreasonable harm to *milkweed*. Acknowledging that Enlist Duo destroys milkweed does not address how this destruction will, in turn, impact *monarchs*. By way of analogy, recognizing that a timber harvest will "obviously" destroy trees does not address how this destruction will impact species that live in the affected forest. How significant is the habitat destruction given the species' population size and the availability of alternative habitat? Are the impacts to the species justified by the action's benefits? Should the proposed action be modified to mitigate harm to the species? It is impossible to answer such questions here, because EPA did not consider the relevant data—notwithstanding record evidence highlighting the importance of agricultural

milkweed to monarchs, *see* ER 166, 273. Indeed, EPA's registration documents reflect no awareness of the severity of monarch population decline or the precariousness of the species' continued survival. *Compare* ER 63-64, *with* NRDC Br. 20-21. The Agency's complete failure to consider Enlist Duo's indirect harm to monarchs in balancing the pesticide's costs and benefits violated FIFRA. *See* 7 U.S.C. § 136a(c)(5)(C), (D); *id*. § 136(bb).

v. EPA must consider new evidence of Enlist Duo's harms even if market substitutes pose commensurate risks

EPA's litigation counsel suggests that the Agency need not consider Enlist Duo's harms so long as other, registered pesticides pose equivalent risks. *See* EPA Br. 75-76. In other words, Enlist Duo's adverse effects are necessarily reasonable if they are not *worse* than the harms caused by other pesticides; and EPA need only assess the increment of harm that Enlist Duo poses beyond the status quo. *See id.* The Court should reject this specious argument, not only because it is post hoc rationalization by counsel, *see State Farm*, 463 U.S. at 50, but also because it would excuse EPA from examining new evidence of a pesticide's harms whenever the Agency previously approved equally harmful chemicals without the benefit of the new science.

Such an approach flies in the face of FIFRA's prohibition on pesticides that cause unreasonable adverse effects. *See* 7 U.S.C. § 136a(c)(5). EPA's prior

determinations that pesticides containing glyphosate or 2,4-D satisfy § 136a(c)(5) provide no assurance "the same pesticide[s] will meet the standard at all times in the future." 71 Fed. Reg. at 45,725. Nor, then, do those prior approvals guarantee that Enlist Duo—a new and different pesticide that combines glyphosate and 2,4-D for the first time—also meets that standard. FIFRA therefore required EPA to consider the current evidence of Enlist Duo's harms, weigh those harms against the pesticide's benefits, and then determine whether the harms would, on balance, be unreasonable. *See* 7 U.S.C. § 136a(c)(5).

The possibility that previously registered pesticides present the same dangers as Enlist Duo does not justify avoiding this analysis. Rather, a revelation that those pesticides are more dangerous than EPA previously thought should timely prompt a separate inquiry into whether to maintain those preexisting registrations. *See* 70 Fed. Reg. at 40,270 (stating that "the Agency must continue to respond to emerging risk concerns" regardless of the regular registration review schedule); *accord* 71 Fed. Reg. at 45,722; *see, e.g.*, 7 U.S.C. § 136d(b) (authorizing EPA to cancel or restrict registered pesticide uses to avoid unreasonable adverse effects).

Accordingly, even if growers used other pesticides to destroy the same amount of in-field milkweed prior to Enlist Duo's registration, *see* EPA Br. 75-76, EPA is not excused from evaluating new evidence—that the Agency has never considered in connection with any previous pesticide registration—that Enlist Duo

threatens monarch survival by destroying in-field milkweed. Rather, EPA must determine whether Enlist Duo's destruction of in-field milkweed is outweighed by the pesticide's countervailing benefits; and if not, whether restrictions (such as expanded buffer strips or reduced application rates) are warranted. If the Agency concludes that restrictions on Enlist Duo are needed to prevent unreasonable harm, this should trigger a separate assessment of whether other pesticides containing glyphosate or 2,4-D *also* require similar restrictions. Thus, if EPA were to perform the analyses FIFRA required, it would not be a foregone conclusion "that farmers will control the same amount of milkweed on their crop fields through the use of herbicides or other means with or without Enlist Duo," EPA Br. 76.

Moreover, nothing in the administrative record supports such a conclusion, advanced for the first time in EPA's brief. *Compare* ER 63-64, 1436, *with* EPA Br. 76. If anything, the record suggests that Enlist Duo is *more* destructive to milkweed compared to other pesticides because it can be applied later in the growing season, during milkweed's most vulnerable flowering stage. *See* NRDC Br. 44. Ultimately, however, EPA's failure to examine all relevant evidence of Enlist Duo's harms makes it impossible to conduct a meaningful comparison between Enlist Duo and its alternatives and to determine whether the pesticide's risks are, on balance, reasonable.

EPA's registration of Enlist Duo's inaugural uses is therefore unsupported by substantial evidence under § 136a(c)(5).

2. EPA concedes that missing data on 2,4-D's risks precluded unconditional registration of Enlist Duo in 2017

Independently, EPA lacked substantial evidence to reaffirm its approval of Enlist Duo's inaugural uses under § 136a(c)(5), because the Agency admitted that newly identified "data gaps" relating to 2,4-D's risks "precluded . . . issuing an unconditional registration" in 2017. EPA Br. 46; *see id.* at 17; ER 30; NRDC Reply 18-19; *see also* 40 C.F.R. § 152.82 ("Data gap means the absence of any valid study or studies in the Agency's files which would satisfy a specific data requirement for a particular pesticide product."). Despite concluding that there were sufficient data to support a *conditional* registration, EPA acknowledged that outstanding data "applicable to 2,4-D uses . . . in general" prevented an *unconditional* registration. ER 30; *cf.* 7 U.S.C. § 136a(c)(7)(B) (authorizing EPA, under certain circumstances, to register conditionally additional uses of a pesticide "notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment"). These missing data included, for example, tests on 2,4-D's acute and chronic toxicity to honeybees. *See* ER 682.

Once it determined in 2017 that the data were lacking, *see* ER 30, EPA was barred from reissuing its earlier approvals for Enlist Duo under § 136a(c)(5)—even if the Agency had previously concluded that the 2014 and 2015 records supported

unconditional registration.[5] *See* 7 U.S.C. § 136n(b) (providing that EPA's order must be "considered on the record as a whole"); Suppl. Br. Order 6-7 (holding that the record for the 2017 Registration includes the "combined records of the 2014, 2015 and 2017 orders").

B. EPA failed to support its registration of Enlist Duo's additional uses with substantial evidence under the § 136a(c)(7)(B) conditional registration standard

Because EPA's registration of Enlist Duo's inaugural uses is unsupported by substantial evidence, the entire 2017 Registration violates FIFRA, and the Court's analysis can end here. *See supra* Argument I.C. That said, EPA lacked substantial evidence to conclude that Enlist Duo's additional uses would not "significantly increase the risk of any unreasonable adverse effect on the environment" or human health, 7 U.S.C. § 136a(c)(7)(B); *see id.* § 136(bb), because the Agency failed to consider the new evidence of Enlist Duo's harms to monarchs and people.

Contrary to EPA's argument, *see* EPA Br. 47-49, 76-77, § 136a(c)(7)(B) plainly prohibits the Agency from deferring assessment of *existing* evidence of Enlist Duo's risks until registration review. Section 136a(c)(7)(B) provides:

> An applicant seeking amended registration under this subparagraph shall submit *such data as would be required to obtain registration of a*

[5] It does not appear that EPA ever made this requisite finding, *see* 40 C.F.R. § 152.112, insofar as the 2014 Final Registration Decision concluded only that "[t]here are no outstanding data requirements required to support the registration of *this action*," ER 1395 (emphasis added), and "this action" meant a § 136a(c)(7)(B) conditional registration, *see supra* Argument I.B.

> *similar pesticide under [§ 136a(c)(5)]*. If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) *because it has not yet been generated*, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter.

7 U.S.C. § 136a(c)(7)(B) (emphases added); *see* 40 C.F.R. § 152.115(a). Thus, with a narrow exception for certain evidence that "has not yet been generated," § 136a(c)(7)(B) mandates that EPA consider all relevant data, as required for unconditional registration, *see* 40 C.F.R. § 152.112(b), before conditionally amending an existing pesticide registration to add more uses. EPA may not "rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 328 (2014).

Notably, EPA agreed with these clear statutory terms when it promulgated its regulations implementing § 136a(c)(7)(B). In discussing "Data Requirements for Conditional Registration," the Agency stated that "an applicant must provide data showing that his product is acceptable for registration, including . . . any . . . available factual information concerning the adverse effects of the pesticide on humans or the environment *which has not previously been submitted to the Agency*." 48 Fed. Reg. at 34,001 (emphasis added). As EPA explained, "The Agency wants all available information about the adverse effects of an applicant's product, so that EPA can determine whether it should be registered." *Id*. at 34,002.

Because EPA failed to consider existing evidence of Enlist Duo's risks to monarchs and people, its decisions to conditionally register additional uses of the pesticide under § 136a(c)(7)(B) are unsupported by substantial evidence.

III. The Enlist Duo registration should be vacated

An unlawful agency action is left in place only "when equity demands," and this Court remands without vacatur only in "limited circumstances." *Pollinator Stewardship Council*, 806 F.3d at 532. Here, the gravity of EPA's errors in registering Enlist Duo, the lack of disruption to the agricultural industry if the pesticide is taken off the market, and the risks this pesticide poses to health and the environment all favor the normal remedy of vacatur. *See id.* at 532-33.

EPA's legal errors cut to the core of the Agency's statutory responsibilities under FIFRA. A finding that a pesticide will not cause, or significantly increase the risk of, unreasonable adverse effects is an essential prerequisite to registration. *See* 7 U.S.C. §§ 136a(c)(5)(C), (D), 136a(c)(7)(B). To make this finding, EPA was required to evaluate Enlist Duo's health and environmental effects before authorizing it for use. *See supra* Argument II.A.1.i. Yet, EPA ignored studies from the past two decades indicating that glyphosate poses serious human health risks, and refused to consider overwhelming evidence that Enlist Duo's suppression of agricultural milkweed threatens the beleaguered monarch population. By registering Enlist Duo despite these significant gaps in its risk assessments, EPA

"failed to follow Congress's clear mandate," and "the appropriate remedy is to vacate that action," *Cal. Wilderness Coal. v. U.S. Dep't of Energy*, 631 F.3d 1072, 1095 (9th Cir. 2011).

This Court has vacated unlawful pesticide registrations based on similarly deficient risk analyses. *See NRDC v. EPA*, 857 F.3d 1030, 1042 (9th Cir. 2017); *Pollinator Stewardship Council*, 806 F.3d at 532-33; *NRDC v. EPA*, 735 F.3d 873, 884 (9th Cir. 2013); *see also NRDC v. EPA*, 676 F. Supp. 2d 307, 308-09, 317 (S.D.N.Y. 2009) (vacating a pesticide registration issued without notice and comment). Vacatur is the presumptive remedy given such flawed risk assessments, because a pesticide with inadequately understood dangers should never have been allowed on the market. The Court should order the same remedy here.

Vacatur will not cause undue disruption to the agricultural industry. *Cf. Cal. Cmties. Against Toxics*, 688 F.3d 989, 994 (9th Cir. 2012) (per curiam) (declining to vacate an agency order given specific facts demonstrating the outcome would be "economically disastrous"). EPA concedes that Enlist Duo is just one of many weed management tools available to growers of corn, soy, and cotton. EPA Br. 75. For example, the U.S. Department of Agriculture noted that growers can control glyphosate-resistant weeds with "non-glyphosate herbicides and adjustments to crop rotation and tillage." ER 354; *see also* Am. Farm Bureau Amicus, ECF No. 93-2, at 15-16 (conceding that other herbicides and tillage provide alternatives to

Enlist Duo for controlling glyphosate-resistant weeds). To the extent that vacatur would cause any disruption, EPA could expedite remand proceedings by prioritizing its reassessment of Enlist Duo. In the unlikely event of an emergency where Enlist Duo is needed to avoid significant economic or environmental harm, EPA may issue a special exemption to authorize its use. *See* 7 U.S.C. § 136p; 40 C.F.R. § 166.2(a)(1).

In addition, vacatur will protect public health and the environment by preventing Dow from continuing to market a pesticide with significant unassessed risks. Enlist Duo's registration is projected to spur a dramatic increase in 2,4-D use. ER 353, 442-43. It will also prop up and potentially expand glyphosate use, which would otherwise decline as glyphosate-resistant weeds continue to spread. *See* NRDC Br. 12-14. FIFRA demands a full accounting of Enlist Duo's risks before this expansion is allowed to proceed—a precautionary approach that is particularly appropriate here given the precarious status of monarch butterflies, *see Pollinator Stewardship Council*, 806 F.3d at 532 (weighing the "precariousness of bee populations" when deciding to vacate a pesticide registration), and the seriousness of the human health harms, such as birth defects and kidney toxicity, that exposure to Enlist Duo may cause. Vacatur is appropriate where, based on all relevant evidence, EPA may decide to deny the registration or issue a modified registration with restrictions to mitigate Enlist Duo's risks to people and/or

monarchs. *See id.* (vacating unlawful pesticide registration where, "on remand, a different result may be reached").

Dow's claim that vacatur will, on balance, harm the environment is unsupported. *See* Dow Br. 92. Even if older, non-choline forms of 2,4-D are more volatile and prone to drift, as Dow and EPA insist,[6] growers could not simply substitute non-choline 2,4-D for Enlist Duo in the event of vacatur; compared to Enlist Duo, pesticides containing non-choline 2,4-D are registered for a narrower range of uses on corn, soy, and cotton. ER 28, 1445-46. Furthermore, volatility is only a single, narrow metric by which to assess how vacatur would change overall exposures to 2,4-D. Looking at the bigger picture, vacatur may very well *reduce* overall human and environmental exposures by preventing a steep increase in total 2,4-D use. *See* ER 353, 442-43 (describing estimates by the U.S. Department of Agriculture that authorization of Enlist crops and Enlist Duo would increase annual use of 2,4-D from 26.7 million pounds to between 84 and 185.3 million pounds).

To the extent Dow asserts that growers will start using other, unspecified herbicides or increased tillage in lieu of Enlist Duo, *see* Dow Br. 92, the record contains no evidence as to how the environmental risks of these alternatives compare to those of Enlist Duo. A full comparison is currently impossible because

[6] NFFC Petitioners explain why EPA's analysis of 2,4-D choline salt's volatility is unsupported by substantial evidence. NFFC Br., ECF No. 64-1, at 59-63; NFFC Reply, ECF No. 118, at 36-40.

EPA has yet to evaluate significant evidence of Enlist Duo's risks to people and monarchs. There is no basis for concluding that Enlist Duo is environmentally superior to its potential alternatives when EPA failed to look at important ways in which the pesticide may cause more severe environmental harm.

In sum, EPA and Dow have not met their burden to show that the unlawful registration of Enlist Duo presents one of the "rare circumstances" meriting departure from the normal remedy of vacatur. *See Humane Soc'y of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010). Notably, EPA itself previously moved to vacate the 2014 and 2015 Registrations after admitting that newly discovered evidence of synergism withheld by Dow undermined the Agency's conclusion that Enlist Duo met FIFRA's registration standard.[7] *See* EPA's Mot. for Voluntary Vacatur and Remand, *NRDC v. EPA*, No. 14-73353, ECF No. 121-1, at 2, 9-10.

Because the 2017 Registration's defects are not confined to particular crops or states, vacatur of the entire registration is merited. *See* 7 U.S.C. § 136n(b). If the

[7] In opposing vacatur then, Dow twice represented to this Court that "Dow will agree to stop sales of Enlist Duo [during remand proceedings], and to work out an appropriate agreement to that effect with the agency." Dow's Response to Resp'ts' Mot. for Voluntary Vacatur and Remand, *NRDC v. EPA*, No. 13-73353, ECF No. 122, at 2, 10-11. Thereafter, the Court remanded without vacatur. *See* Order, *NRDC v. EPA*, No. 14-73353, ECF No. 128. Within two days, Dow reneged on its commitment; a company spokesman stated, "It was never agreed to. . . . It was something we offered. That time has passed." Pet'rs' Mot. to Adjudicate Pending Claims, *NRDC v. EPA*, No. 13-73353, ECF No. 129, at 4. Dow continued to sell Enlist Duo during remand.

Court holds that EPA's reapproval of Enlist Duo's inaugural uses violates FIFRA and should be vacated, then the Agency's approval of the pesticide's additional uses should be vacated, too. *See supra* Argument I.C.

EPA repackages its flawed standing argument to assert that the Court should carve out glyphosate from any vacatur order. *See* EPA Br. 110-11. There is no practical way to tailor vacatur to just one of Enlist Duo's active ingredients. EPA issued a single registration for a single pesticide product. The entire registration violates FIFRA, and it fails as a whole.

CONCLUSION

For the foregoing reasons, as well as the reasons set forth in NRDC's earlier briefs, NRDC urges the Court to vacate the Enlist Duo registration in its entirety.

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Respectfully submitted,

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