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

REPLY BRIEF OF PETITIONER NATURAL RESOURCES DEFENSE COUNCIL

Margaret T. Hsieh
Mitchell S. Bernard
Kaitlin Morrison
Natural Resources Defense Council
40 West 20th Street
New York, NY 10011
Telephone: (212) 727-2700

Peter J. DeMarco
Natural Resources Defense Council
1152 15th Street NW
Suite 300
Washington, DC 20005
Telephone: (202) 289-6868

Counsel for Petitioner Natural Resources Defense Council

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INTRODUCTION

Enlist Duo threatens the survival of the North American monarch butterfly population and may imperil human health. By refusing to consider existing evidence of these dangers before registering Enlist Duo, EPA has defied FIFRA and exposed the public and environment to unwarranted risk. The agency's 2017 registration order for Enlist Duo (2017 Registration) contains "three new decisions." ER 2. Decision 1 "reaffirms" EPA's 2014 and 2015 registration orders (2014/15 Registration) approving the pesticide's initial uses on corn and soy in 15 states (initial uses), Decision 2 approves additional uses on corn and soy in 19 more states, and Decision 3 approves additional uses on cotton in all 34 states (together, additional uses). *Id.* Contrary to EPA's and Dow's arguments, each of these decisions is subject to judicial review, and none of them survives scrutiny under FIFRA's substantial evidence standard. The Court should vacate the unlawful registration in its entirety.

ARGUMENT

I. The Court has jurisdiction to review EPA's registration of Enlist Duo

A. Petitioners timely challenged the 2017 Registration within 60 days of its date of entry

Without addressing any of the counterarguments already briefed by Petitioners and EPA and incorporated by reference here, ECF Nos. 24, 25-1, 26-1, Dow renews the meritless argument from its Motion to Dismiss that Petitioners

failed to challenge the 2017 Registration "within 60 days after the entry of such order," Dow Br., ECF No. 111, at 14 (quoting 7 U.S.C. § 136n(b)). In short, Dow ignores the plain language of the governing regulation, which states that unless EPA "otherwise *explicitly* provides," the "date of entry" of a pesticide registration order is "two weeks after it is signed." 40 C.F.R. § 23.6 (emphasis added). EPA signed the Notice of Registration and Final Registration Decision for Enlist Duo on January 12, 2017. ER 1, 37. Because neither document "explicitly provides" a different "date of entry," the registration order was entered two weeks later, on January 26, 2017. 40 C.F.R. § 23.6. Petitioners timely challenged that order 54 days later. *See* 7 U.S.C. § 136n(b); NRDC Br., ECF No. 63, at 5.

B. EPA cannot use voluntary remand to thwart judicial review of its registration of Enlist Duo's initial uses

The Court has jurisdiction to review the entire 2017 Registration. EPA contends that a challenge to Decision 1 (reaffirming the initial uses of Enlist Duo approved through the 2014/15 Registration) is time-barred, but does not explain why the Court lacks jurisdiction over the first of the "three new decisions," ER 2, in the agency's post-remand order, *see* EPA Br., ECF No. 83, at 64-66 (asserting NRDC may challenge only Decisions 2 and 3).

Voluntary remand cannot insulate this piece of the registration from judicial review. The Court never adjudicated NRDC's challenges to EPA's 2014/15 Registration because the agency sought and obtained a voluntary remand. But the

purpose of voluntary remand is to defer judicial review while the agency reconsiders the challenged decision. *See Cal. Cmties. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012); *accord Limnia, Inc. v. U.S. Dep't of Energy*, 857 F.3d 379, 386 (D.C. Cir. 2017). If the agency reaffirms its prior position following remand, petitioners can renew their challenge. *See, e.g.*, *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947) (reviewing a decision where, following remand, "the Commission reexamined the problem, recast its rationale and reached the same result"); *Nat'l Parks Conservation Ass'n v. EPA*, 803 F.3d 151, 157-58 (3d Cir. 2015) (same).

Voluntary remand gives agencies a chance to cure defects, not to immunize them from judicial scrutiny. *See Lutheran Church-Missouri Synod v. FCC*, 141 F.3d 344, 349 (D.C. Cir. 1998) (refusing to grant voluntary remand when the agency sought it as a "ploy" to "avoid judicial review"). Thus, when EPA "reaffirm[ed]" its approval of Enlist Duo's initial uses, ER 2, NRDC was entitled to renew its challenge to those uses—as it did by challenging Decision 1, *see, e.g.*, *Wild Fish Conservancy v. Salazar*, 628 F.3d 513, 521 (9th Cir. 2010) (reviewing a Fish and Wildlife Service Biological Opinion reissued after voluntary remand, where plaintiff contended that the new opinion still failed to adequately consider harm to a species).

Not long ago, EPA agreed. In opposing Petitioners' motion to adjudicate their challenges to the 2014/15 Registration, EPA labeled as "unfounded" Petitioners' concern that the agency would contest the timeliness of any renewed, post-remand challenge to its registration of Enlist Duo's initial uses. *Compare NRDC v. EPA*, No. 14-73353, ECF No. 129, at 8, *with NRDC v. EPA*, No. 14-73353, ECF No. 130-1, at 8. According to EPA, if the post-remand decision incorporated elements of the pre-remand decision, those elements would remain subject to review. *See NRDC v. EPA*, No. 14-73353, ECF No. 130-1, at 8 & n.1. EPA does not acknowledge, let alone explain, its change of heart.[1]

C. NRDC has standing to challenge the Enlist Duo registration

Notwithstanding EPA's and Dow's arguments, *see* EPA Br. 66-69; Dow Br. 17-29, NRDC has demonstrated that its members suffer injuries-in-fact that are fairly traceable to the 2017 Registration and that would be redressed by a favorable decision, *see Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000).

[1] Moreover, because EPA reconsidered the entire 2014/15 Registration on remand and then reaffirmed its prior position, Decision 1 is reviewable under the "reopening doctrine." *P & V Enters. v. U.S. Army Corps of Eng'rs*, 516 F.3d 1021, 1023-24 (D.C. Cir. 2008) (citing *Pub. Citizen v. Nuclear Regulatory Comm'n*, 901 F.2d 147, 150 (D.C. Cir. 1990)); *see* ER 2 (issuing a "new decision" on Enlist Duo's initial uses); *id.* at 5 (confirming that EPA "reviewed and evaluated all comments received"); *id*. at 524 (accepting comments "on all aspects of this post-remand decision").

1. The standing inquiry relates to the Enlist Duo registration as a whole, not to any isolated ingredient in the pesticide

EPA contends that "NRDC lacks standing to raise any arguments concerning glyphosate." EPA Br. 66. The agency cites no authority to support its theory that NRDC must establish standing with regard to each ingredient within Enlist Duo, as opposed to the pesticide as a whole. Nor could it, as Supreme Court precedent requires only that a party "demonstrate standing separately for each *form of relief* sought," *Friends of the Earth*, 528 U.S. at 185 (emphasis added), and not for each "*argument[]* upon which that relief might be based," *WildEarth Guardians v. U.S. Bureau of Land Mgmt.*, 870 F.3d 1222, 1231 (10th Cir. 2017) (citing *Duke Power Co. v. Carolina Envtl. Study Grp., Inc.*, 438 U.S. 59, 72-79 (1978)).

NRDC seeks vacatur of the Enlist Duo registration, relief that necessarily targets the whole pesticide. The Court may award that relief if it accepts any of NRDC's arguments regarding why the 2017 Registration is unlawful. The Court therefore has jurisdiction to hear NRDC's arguments relating to "the glyphosate component," EPA Br. 66, or any other component, of the pesticide.

2. The registration causes redressable injuries to NRDC's members who have aesthetic and recreational interests in monarch butterflies

i. Injury-in-fact

"The 'injury in fact' requirement in environmental cases is satisfied if an individual adequately shows that she has an aesthetic or recreational interest in a

particular place, animal, or plant species and that that interest is impaired by a defendant's conduct." *Ecological Rights Found. v. Pac. Lumber Co.*, 230 F.3d 1141, 1147 (9th Cir. 2000); *see Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv.*, 807 F.3d 1031, 1043-44 (9th Cir. 2015). NRDC members enjoy observing, studying, and interacting with monarch butterflies. NRDC Br. 51. It is undisputed that milkweed is necessary to sustain the monarch population, and that Enlist Duo's active ingredients kill milkweed. *Id*. at 2. Registration of Enlist Duo therefore impairs NRDC members' interests in viewing and interacting with the species.

Dow denies the imminence of this injury by challenging "the factual premise" of monarch population decline. Dow Br. 26-28. The company claims that the "population has zig-zagged wildly" over the past twenty years. *Id.* at 27. But neither expected interannual variation, nor Dow's disagreement about how best to quantify the population's changes, *see id.* at 26-27, contradicts the documented, downward trend recognized by monarch experts, *see* NRDC Br. 17-18, and captured in this figure:

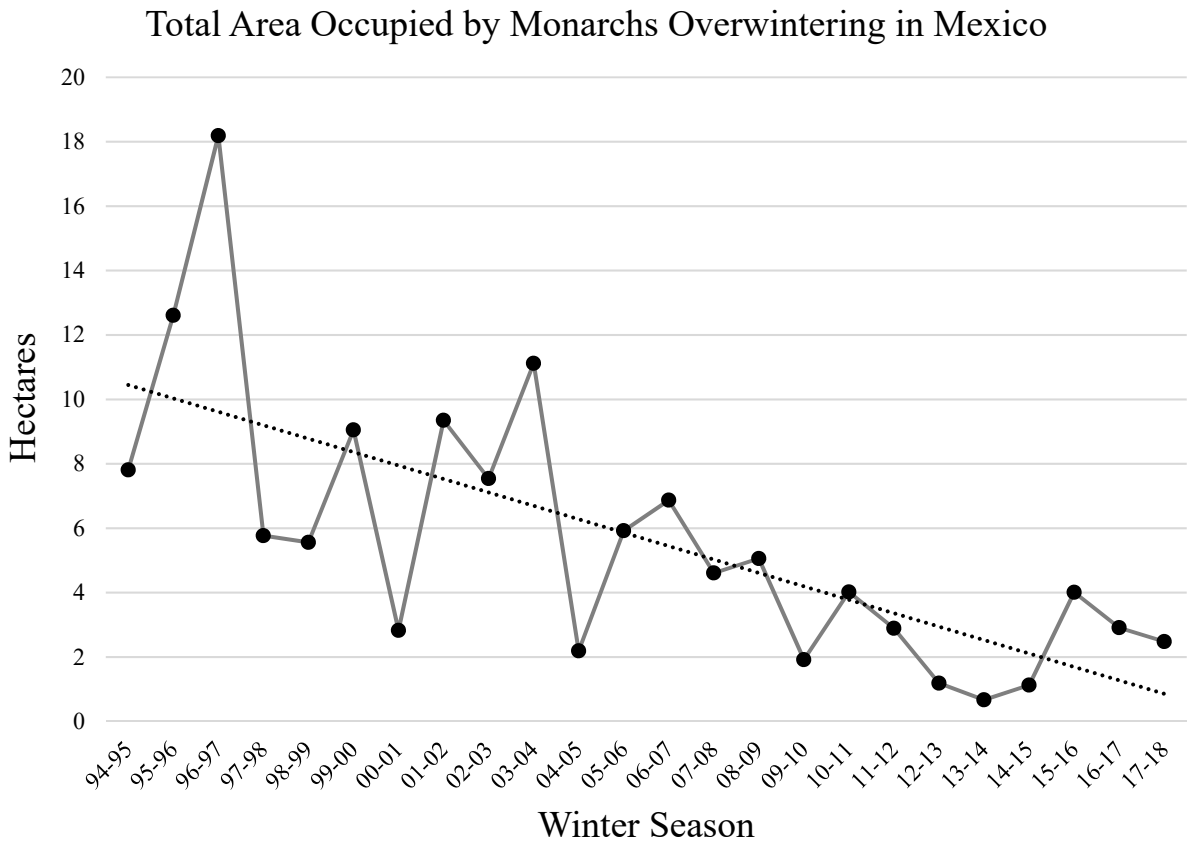

Fig. 1: Monarch Watch data displayed in an Excel chart with best fit line showing downward population trend. *See* Bus Decl., Ex. 1, ECF No. 88-2, at 20.

To support its pseudo-scientific denial of monarch population decline, Dow relies on the declaration of Dr. James Bus—a toxicologist with no apparent expertise in monarchs, ecology, or population biology. *See* Dow Br. 26-28; Bus Decl. ¶¶ 1-6, 9, ECF No. 88-2 (describing qualifications limited to the evaluation of *human health* risks posed by pesticides); *see also United States v. Wells*, 879 F.3d 900, 933-34 (9th Cir. 2018) (explaining that an expert opinion is reliable only if it has "a reliable basis in the knowledge and experience of the relevant discipline"). In contrast to Dr. Bus, actual monarch experts—including those from

federal and state agencies—recognize the trend of monarch population decline, as well as the importance of milkweed destruction from herbicide use in causing that decline. *See* NRDC Br. 18; *see*, *e.g.*, ER 263, 279-80, 297, 303-05, 405-06.

ii. Causation

Enlist Duo kills milkweed and thus causes harm to monarchs and NRDC members. *See* ER 112 (stating that Enlist Duo should be used "[f]or suppression" of milkweed); *see also* Dow Br. 45 ("Enlist Duo . . . is obviously meant to kill such weeds."). Dow makes the nonsensical assertion that "NRDC and its declarants attribute the alleged harm to monarch butterflies *not* to Enlist Duo, but to glyphosate and/or . . . 2,4-D." Dow Br. 28. But these active ingredients are precisely what allow Enlist Duo to destroy milkweed, and NRDC members are concerned about the presence of these ingredients *in Enlist Duo*. *See, e.g.*, Bristol Decl. ¶¶ 4, 10, ECF No. 63, at 115, 117; Gruber Decl. ¶¶ 5, 10, 13, ECF No. 63, at 123, 125-26; Wetzel Decl. ¶¶ 5, 10, ECF No. 63, at 134, 136.

In addition, Dow's myopic focus on the two-year uptick in monarch numbers immediately following the initial registration of Enlist Duo in 2014 (which ignores the subsequent population decrease between 2016 and 2018), *see* Dow Br. 27, does not discredit Enlist Duo's contribution to monarch population loss. It merely confirms the acknowledged existence of other factors that *also* influence population size. *See* NRDC Br. 20-21.

EPA nonetheless claims "there is no probative link" between its approvals of Enlist Duo "and the current plight of the monarch butterfly" because Enlist Duo will merely replace preexisting uses of glyphosate without increasing total use of the chemical. EPA Br. 67-68. The agency's substitution assumption is unsupported by the record. *See* NRDC Br. 11-12; *NRDC v. EPA* (*Nanosilver II*), 857 F.3d 1030, 1039-40 (9th Cir. 2017) (rejecting as "unsubstantiated" EPA's "substitution assumption" that "current users of conventional-silver pesticides will replace those pesticides with" the newly registered nanosilver pesticide); *see also WildEarth Guardians*, 870 F.3d at 1235 ("[T]his perfect substitution assumption lacks support in the record [and] is enough for us to conclude that the analysis which rests on this assumption is arbitrary and capricious.").

EPA's substitution assumption is also beside the point. To the extent growers switch from other glyphosate-based pesticides to Enlist Duo, Enlist Duo will replace those pesticides as a cause of the species' decline. This is the case, moreover, regardless of the magnitude of Enlist Duo's contribution to the decline. *See United States v. Students Challenging Regulatory Agency Procedures*, 412 U.S. 669, 689 n.14 (1973) (recognizing that even an "identifiable trifle" of harm suffices to establish injury-in-fact).

Echoing EPA's meritless argument regarding other pesticides, Dr. Bus opines that "the spraying of Enlist Duo in treated fields will have no impact on the

monarch butterfly population" because preexisting pesticides suppressed most of the milkweed in agricultural fields before EPA registered Enlist Duo. Bus Decl. ¶¶ 18, 20, ECF No. 88-2. But weeds, including milkweed, grow back unless continually suppressed. Otherwise, there would no longer be any market for Enlist Duo (or any other pesticide). Because Enlist Duo contributes to the ongoing suppression of milkweed, it is a fairly traceable cause of harm to the vulnerable monarch population and to NRDC members who value observing the species.

iii. Redressability

EPA and Dow assert that vacatur of the Enlist Duo registration would not redress NRDC members' injuries because, they speculate, the same harm would befall milkweed and monarchs through growers' use of "other pesticide products containing glyphosate" or 2,4-D. EPA Br. 68-69; *see* Dow Br. 27-28; *supra* Argument I.C.2.ii (discussing lack of record evidence for EPA's substitution assumption). Taken to its logical conclusion, this theory means that pesticide registrations (or approvals of any other harmful products) are immune from judicial review so long as equally harmful substitutes are available. Unsurprisingly, neither EPA nor Dow cites any authority to support this empty proposition.

This Court has held that "the mere existence of multiple causes of an injury does not defeat redressability." *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*. Ultimately, "[t]he relevant inquiry is . . . whether a favorable ruling could redress the *challenged* cause of the injury." *Id.* (emphasis added); *see also Massachusetts v. EPA*, 549 U.S. 497, 525 (2007) (explaining that a plaintiff "need not show that a favorable decision will relieve his every injury" to establish redressability). Here, the challenged cause of injury is EPA's registration of Enlist Duo, a pesticide that kills milkweed, which monarchs require to survive. Vacatur of the registration would redress the risk that *Enlist Duo* poses to monarchs and to NRDC members who have aesthetic and recreational interests in the species.

3. NRDC members face a credible threat of health harms from exposure to Enlist Duo

NRDC has also demonstrated injury-in-fact based on the credible threat that its members will suffer health harms from exposure to Enlist Duo. *See NRDC v. EPA* (*Nanosilver I*), 735 F.3d 873, 878 (9th Cir. 2013). Dow does not contest that Enlist Duo is toxic to human beings. Overwhelming record evidence establishes that toxicity. *See, e.g.*, ER 6, 173-74 & nn.134-35, 176-77, 462-63, 515-16. Instead, Dow complains that NRDC members are merely "concerned about *potential* exposure" to Enlist Duo. Dow Br. 21. But Dow ignores this Court's holding, issued after *Clapper v. Amnesty International USA*, 568 U.S. 398 (2013), that a "credible *threat*" of harm from potential exposure to a toxic pesticide

constitutes an "actual and imminent" injury-in-fact. *Nanosilver I*, 735 F.3d at 878 (emphasis added); *accord Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2341 (2014).

NRDC members face a credible threat that is not abstract or speculative. *Contra* Dow Br. 20. They live near agricultural fields where Enlist Duo can now be used. *See, e.g.*, Bristol Decl. ¶ 3, ECF No. 63, at 115; Gruber Decl. ¶ 4, ECF No. 63, at 123; Wetzel Decl. ¶ 3, ECF No. 63, at 133. They have no control over whether and when neighboring growers apply Enlist Duo, and thus have no ability to reduce their risk of exposure. *See Nanosilver I*, 735 F.3d at 878-79 (explaining that "lack of public information" regarding pesticide use contributed to a "credible threat" of harm because it made avoiding exposure "nearly impossible").

The record corroborates these members' fears of exposure: EPA expects that people living near fields where the pesticide is used will inhale Enlist Duo that volatilizes from crops and touch Enlist Duo that drifts onto their lawns. ER 14-15, ER 59; *see also* ER 192-95 (explaining how EPA's assessment underestimates exposures from volatilization and spray drift); NRDC Br. 22-23 (describing other pathways of exposure, such as residues on crops and contaminated drinking water). The severity of the health risks, such as kidney toxicity and birth defects, that recent studies (ignored by EPA) link to glyphosate, *see* ER 173-74 & nn.134-35, reinforces the credible threat that NRDC members will experience harmful

exposures to Enlist Duo, *see Covington v. Jefferson Cty.*, 358 F.3d 626, 652 (9th Cir. 2004) (Gould, J., concurring) (recognizing that the gravity of health harms "minimizes the required probability of their occurrence for injury in fact purposes"); *accord Baur v. Veneman*, 352 F.3d 625, 637 (2d Cir. 2003).

Dow argues that use restrictions on Enlist Duo's label will protect NRDC members from exposure to the pesticide, including "exposure at a potentially harmful level." Dow Br. 22. But courts "assume for the purposes of standing that [petitioners'] view on the merits will prevail." *Defs. of Wildlife v. Gutierrez*, 532 F.3d 913, 924 (D.C. Cir. 2008); *see also Chaudhry v. City of Los Angeles*, 751 F.3d 1096, 1109 (9th Cir. 2014) (explaining that Article III "standing in no way depends on the merits of the plaintiff's contention that particular conduct is illegal"). If NRDC is correct that EPA lacked substantial evidence to conclude that Enlist Duo will not cause (or significantly increase the risk of) unreasonable adverse human health effects, then label restrictions—crafted without regard to data critical to assessing Enlist Duo's health risks—will not eliminate the credible threat of harmful exposures to the pesticide.[2]

[2] EPA's and Dow's arguments that NRDC members' health injuries are neither traceable to EPA's approval of Enlist Duo nor redressable by vacatur mirror those made regarding members' injuries relating to monarchs, *see* EPA Br. 68; Dow Br. 24-25, and fail for the same reasons, *see supra* Argument I.C.2.ii-iii.

II. EPA's registration of Enlist Duo is unsupported by substantial evidence

EPA's answering brief offers a new interpretation of the 2017 Registration that diverges from the agency's explanation at the time of decision-making, from Dow's characterization of the registration, and, most importantly, from FIFRA's mandates.

The 2017 Notice of Registration characterized the 2017 Registration as a conditional registration that superseded the unconditional 2014/15 Registration. *Compare* ER 37, *with* ER 1401. In contrast, EPA's brief argues that only *part* of the 2017 Registration was conditional. The agency now asserts that it relied on 7 U.S.C. § 136a(c)(7)(B) to issue only Decisions 2 and 3, which conditionally amended the 2014/15 Registration to approve Enlist Duo's additional uses (on corn and soy in 19 more states, and on cotton in all 34 states); Decision 1 merely maintained the *unconditional* 2014/15 Registration of Enlist Duo's initial uses (on corn and soy in 15 states) under 7 U.S.C. § 136a(c)(5). *See* EPA Br. 11-15; *see also Chenery*, 332 U.S. at 196-97 (underscoring that the basis for administrative action "must be set forth with such clarity as to be understandable" and that "[i]t will not do for a court to be compelled to guess at the theory underlying the agency's action").

Dow, in contrast, argues that the *entire* 2017 Registration—including Decision 1—should be construed as a conditional amendment of the 2014/15

Registration. *See* Dow Br. 36-38. Neither EPA's nor Dow's explanation describes a registration that comports with FIFRA.

A. Decision 1, which reaffirms the registration of Enlist Duo's initial uses, is not supported by substantial evidence

1. Decision 1 must be reviewed under FIFRA's § 136a(c)(5) unconditional registration standard

The Court should reject Dow's suggestion to review the entire registration, including Decision 1, under the § 136a(c)(7)(B) conditional registration standard. *See* Dow Br. 38-39, 43-45. The plain language of § 136a(c)(7)(B) barred EPA from relying on that provision to issue Decision 1. Section 136a(c)(7)(B) provides that EPA may "conditionally amend the registration of a pesticide to permit additional uses of such pesticide." 7 U.S.C. § 136a(c)(7)(B). NRDC and EPA agree that § 136a(c)(7)(B) may be used to allow *additional* uses of Enlist Duo after Enlist Duo has been lawfully registered. *See* EPA Br. 42; NRDC Br. 39. Decision 1, however, did not amend the 2014/15 Registration to allow additional uses of Enlist Duo; it "reaffirm[ed]" the 2014/15 Registration to permit the pesticide's initial uses. ER 2; *see* ER 5. Consequently, EPA could not have lawfully issued Decision 1 under § 136a(c)(7)(B), either on its own or bundled with Decisions 2 and 3.

The procedural history of the registration confirms that Decision 1 must be reviewed under § 136a(c)(5). EPA issued its 2014/15 Registration of Enlist Duo's

initial uses under that provision. *See* EPA Br. 11, 13. There is no dispute that, but for EPA's voluntary remand, registration of those initial uses would have been reviewed under that standard. Because Decision 1 simply affirmed the 2014/15 Registration without any modification, *see* ER 2, 5; EPA Br. 14, it must also be reviewed under § 136a(c)(5). To conclude otherwise would allow EPA to use voluntary remand as a "ploy" to "avoid judicial review" of its initial registration decision under FIFRA's more rigorous unconditional registration standard. *Lutheran Church-Missouri Synod*, 141 F.3d at 349.

The choice of registration standard is not a technicality. Dow's suggestion that the Court construe the entire 2017 Registration as a conditional amendment of the 2014/15 Registration, *see* Dow Br. 37-38, would effectively preclude review of Decision 1. This is because § 136a(c)(7)(B) focuses on the incremental risk between an existing pesticide use and proposed additional uses of the same pesticide. *See* 7 U.S.C. § 136a(c)(7)(B); 40 C.F.R. § 152.113(a)(1). Applying that provision to the entirety of the 2017 Registration would limit the Court to examining only the differences between the 2014/15 Registration and the 2017 Registration—that is, the additional uses of Enlist Duo approved through Decisions 2 and 3. However, the Court never decided the merits of NRDC's challenge to the 2014/15 Registration, and the lawfulness of Enlist Duo's initial uses should be adjudicated, not assumed.

Dow nevertheless claims that reviewing Decision 1 under § 136a(c)(7)(B) would cause no prejudice because EPA could have registered the initial uses of Enlist Duo under another conditional registration provision, § 136a(c)(7)(A). *See* Dow Br. 38-39. But EPA did not register Enlist Duo under § 136a(c)(7)(A), and the Court should not substitute the unconditional registration standard that EPA applied with the alternative Dow suggests. *See Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 50 (1983) ("[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself."). Indeed, the agency expressly declined to register Enlist Duo under § 136a(c)(7)(A), explaining (correctly) that the product's new uses of 2,4-D precluded registration under that provision. *See* ER 4 (explaining that "EPA is not registering the product as a me-too," which refers to registration under § 136a(c)(7)(A)).

Accordingly, Decision 1 must be reviewed under the § 136a(c)(5) unconditional registration standard—the same standard that would have applied to the 2014/15 Registration but for EPA's voluntary remand.

2. EPA lacked substantial evidence to conclude that registration of Enlist Duo's initial uses would not cause "unreasonable adverse effects" under § 136a(c)(5)

EPA may unconditionally register a new pesticide, or unconditionally amend an existing registration, 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);

see 40 C.F.R. § 152.112(e); *Nw. Coal. for Alternatives to Pesticides v. EPA*, 544 F.3d 1043, 1045 (9th Cir. 2008). "Unconditional registration necessarily requires sufficient data to evaluate the environmental risks." *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 523 (9th Cir. 2015); *see* 40 C.F.R. § 158.75. Before granting an unconditional registration, 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 determination 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.

i. EPA concedes it could not have registered Enlist Duo unconditionally in 2017

EPA admits that it "was precluded from issuing an unconditional registration" for Enlist Duo's additional uses. EPA Br. 46 (internal citation and quotation marks omitted); *accord* ER 4, 30; EPA Br. 17, 27. That is because, by the time of the 2017 Registration, the agency had "identified 'outstanding data'" it needed to evaluate the effects of "all 2,4-D products." EPA Br. 46 (quoting ER 4). Without these requisite data, the agency lacked substantial evidence to conclude that Enlist Duo's additional uses would not cause unreasonable adverse effects under FIFRA's unconditional registration standard.

But the missing data were not specific to the additional uses of Enlist Duo. Rather, they pertained to "all 2,4-D products." *Id*. Consequently, the absence of these data *also* precluded the agency from reaffirming the unconditional registration of Enlist Duo's initial uses. To affirm that registration, EPA was required to find "that no additional data are necessary to make the determinations required by [§ 136a(c)(5)]." 40 C.F.R. § 152.112(c). EPA's admission that it could not make that finding for Decisions 2 and 3 means that it could not make that finding for Decision 1 either. The agency therefore lacked substantial evidence to affirm its unconditional registration of Enlist Duo's initial uses. *See Pollinator Stewardship Council*, 806 F.3d at 532. The Court need not proceed further to nullify Decision 1.

ii. EPA refused to consider evidence that Enlist Duo poses a serious risk to monarch butterflies

Independently, Decision 1 is unsupported by substantial evidence because the agency failed to consider evidence that Enlist Duo's initial uses on corn and soy in 15 states will harm monarchs by killing milkweed in agricultural fields. *See* NRDC Br. 14-21, 25-26. In its public comments, NRDC implored EPA to consider the overwhelming body of scientific evidence—that the agency had never assessed in connection with any previous pesticide registration—documenting the decline of the monarch population, the butterflies' dependence on milkweed, the significant role that milkweed destruction through herbicide use has played in diminishing the

population, and the risk that Enlist Duo poses to the species because its two active ingredients kill milkweed. *See id.* at 14-21, 26.

EPA concedes that it did not assess harm to monarchs through destruction of "milkweed in the actual crop fields on which Enlist Duo would be intended for use." EPA Br. 74. Dow objects that "[i]t is nonsensical for NRDC to suggest that EPA failed to consider the impact of Enlist Duo on weeds growing *inside* treated fields: Enlist Duo (like any other herbicide) is obviously meant to kill such weeds." Dow Br. 45; *accord* EPA Br 75. But FIFRA does not distinguish between intentional and unintentional harm. "The term 'unreasonable adverse effects on the environment' means . . . *any* unreasonable risk to man or the environment," 7 U.S.C. § 136(bb) (emphasis added), whether purposeful or not.

EPA attempts to excuse its failure to examine Enlist Duo's impacts on monarchs by speculating that "[f]armers will control milkweed on their field [sic] either through Enlist Duo's combination of 2,4-D and glyphosate, or through some other herbicide." EPA Br. 75. The Court should reject this rationale for three reasons. First, it is a post hoc rationalization with no basis in the agency's decision documents. *See State Farm*, 463 U.S. at 50; *see generally* ER 1-36, 63-64.

Second, Enlist Duo need not increase overall destruction of milkweed to cause unreasonable adverse effects. The pesticide may cause unreasonable adverse effects simply by contributing to current levels of milkweed destruction. Those

levels already place the monarch population at serious risk; experts predict that the species faces a "high probability" of population collapse within the next two decades. ER 405; *see* NRDC Br. 21. Whether other pesticides might perpetuate this risk if Enlist Duo were not registered does not excuse EPA from examining the extent to which Enlist Duo, once registered, would contribute to the risk.

Third, in concluding that previously registered pesticides containing glyphosate or 2,4-D do not cause unreasonable adverse environmental effects, EPA never considered harm to the vulnerable monarch population through milkweed destruction. Accordingly, the agency may not infer from those prior approvals that registration of Enlist Duo will not inflict unreasonable harm on the species.

Information on Enlist Duo's potential to harm monarchs is both "relevant," 40 C.F.R. § 152.112(b), and "necessary," *id.* § 152.112(c), to determining whether the pesticide's initial uses cause "unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5)(C), (D); *see* 40 C.F.R. § 158.75. Without considering evidence of how those uses would harm the butterflies by killing milkweed, EPA lacked substantial evidence to conclude that Decision 1 will not cause unreasonable adverse effects on the environment. *See* 7 U.S.C. § 136a(c)(5); *Pollinator Stewardship Council*, 806 F.3d at 532.

The Court need not find that Enlist Duo unreasonably harms monarchs to vacate Decision 1. That is a question for EPA—a question the agency ignored.

NRDC Br. 46-47; *see State Farm*, 463 U.S. at 43; *Mont. Wilderness Ass'n v. McAllister*, 666 F.3d 549, 555, 558, 561 (9th Cir. 2011).

iii. EPA failed to consider new science linking glyphosate to serious human health risks

EPA's decision to affirm the unconditional registration of Enlist Duo's initial uses is further unsupported by substantial evidence because the agency ignored current scientific research germane to evaluating the pesticide's human health risks. In public comments, NRDC urged EPA to consider recently published studies on glyphosate's health effects, including such serious harms as kidney toxicity and birth defects. NRDC Br. 2-3, 26-27.

The agency's disregard of these data violates FIFRA's prohibition on registering pesticides that pose an unreasonable health risk to people. *See* 7 U.S.C. §§ 136(bb), 136a(c)(5)(C), (D). EPA regulations require the agency to consider data "sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man," 40 C.F.R. § 158.75, and to "review[] *all* relevant data in the possession of the Agency," *id.* § 152.112(b) (emphasis added). Because EPA refused to consider significant new evidence of Enlist Duo's health risks before reaffirming the pesticide's initial uses, its conclusion that these uses would not cause "unreasonable adverse effects" is unsupported by substantial evidence. 7 U.S.C. § 136a(c)(5)(C), (D); *see Pollinator Stewardship Council*, 806 F.3d at 532. As with harm to monarch butterflies, the Court need not conclude that Enlist

Duo poses an unreasonable health risk to vacate Decision 1. *See State Farm*, 463 U.S. at 43; *Mont. Wilderness Ass'n*, 666 F.3d at 555, 558, 561. But the Court must ensure that EPA considered all relevant evidence and reached a conclusion supported by substantial evidence.

iv. EPA may not ignore evidence of risks posed by the glyphosate in Enlist Duo

Contrary to EPA's suggestion, *see* EPA Br. 69-72, Enlist Duo may cause unreasonable adverse effects even if it does not increase overall glyphosate use. The agency's fixation on the lack of any "new use" of glyphosate is irrelevant to the unconditional registration analysis, *see id.* at 44-49, 69-72; Dow Br. 46-49, because the concept of "new use" is distinct to the § 136a(c)(7)(B) conditional registration framework. *Compare* 7 U.S.C. § 136a(c)(5) (authorizing EPA to register a pesticide that will not cause "unreasonable adverse effects on the environment"), *with id.* § 136a(c)(7)(B) (authorizing EPA to conditionally amend a pesticide registration to include an "additional use" that will not "significantly increase the risk of any unreasonable adverse effect on the environment"), *and* 40 C.F.R. § 152.113(c) (interpreting § 136a(c)(7)(B) and using the term "new use" synonymously with "additional use"). That Enlist Duo does not entail a "new use" of glyphosate therefore did not relieve EPA of its duty to consider all relevant evidence of Enlist Duo's environmental and human health risks before unconditionally registering the pesticide's initial uses. *See supra* Argument II.A.2.

EPA does not deny that it has never, in reviewing any previous pesticide registration, considered the substantial body of evidence that NRDC put before the agency of glyphosate's harm to monarchs through milkweed destruction. *See* NRDC Br. 14-21, 26. Nor does it deny its failure to consider new studies on glyphosate's health risks that NRDC asked it to review. *See*, *e.g.*, *id.* at 26-27. These data are certainly "relevant," 40 C.F.R. § 152.112(b), to whether Enlist Duo will pose unreasonable risks to human health or the environment.

To justify its decision not to assess the new evidence of glyphosate's risks, EPA proffers the specious explanation that if a proposed pesticide use does not entail the "new use" of an active ingredient, then EPA treats the proposed use of that ingredient "as if it were a 'me-too'" registration under § 136a(c)(7)(A), and does not perform any new assessments for the ingredient. ER 3-4 & n.3. "Me-too" registration refers to conditional registration of a new pesticide use that is "identical or substantially similar" to an existing pesticide use, where that registration will not significantly increase the risk of any unreasonable adverse effects, compared to the existing pesticide use. 7 U.S.C. § 136a(c)(7)(A).

EPA's analogy to "me-too" registration fails because it is based on a fundamental misunderstanding of § 136a(c)(7)(A). Nothing in that provision allows EPA to ignore *existing* evidence of a pesticide's risks—regardless of whether the pesticide entails old or new uses of active ingredients. Section

136a(c)(7)(A) temporarily excuses registrants from providing, and EPA from reviewing, certain relevant evidence that "has not yet been generated" until the time that such evidence must be furnished for all similar products already on the market. *Id*. There is no additional exception for evidence that *has been generated*, but that *has not yet been reviewed*. Accordingly, EPA's analogy to § 136a(c)(7)(A) fails to justify the agency's disregard of existing evidence, properly before the agency, of glyphosate's risks to monarchs and human health.

v. Neither registration review nor non-FIFRA processes excuse EPA from evaluating Enlist Duo's risks *before* registering the pesticide

EPA also attempts to excuse its failure to consider evidence of Enlist Duo's harms to monarchs and human health by arguing that it is evaluating, or will evaluate, these harms through registration review and/or initiatives outside the FIFRA framework. *See* EPA Br. 46-49, 72, 77-78. However, the agency's arguments rely entirely on its erroneous interpretation of the congressional intent behind FIFRA's § 136a(c)(7)(B) *conditional* registration provision, *see* EPA Br. 46-49; *infra* Argument II.B.2, and are irrelevant to EPA's obligations to review all relevant evidence before granting an *unconditional* registration of Enlist Duo's initial uses under § 136a(c)(5), *see* 40 C.F.R. § 152.112(b).

Further, EPA's duty to ensure the safety of Enlist Duo *before* registration is independent from its duty to ensure the pesticide's continued safety *after*

registration. EPA has explained that "Registration Review is a lengthy process that may take many years to complete," ER 1438, and the agency need not conclude that registration review process for glyphosate or 2,4-D until October 2022, *see* 7 U.S.C. § 136a(g)(1)(A)(iii). EPA has also confirmed that, despite the progress of registration reviews, "[p]roposed new registrations are held to the most current data requirements and . . . must meet the FIFRA no unreasonable adverse effects standard to be registered." ER 1438. The agency flouted this principle when it ignored critical new evidence of harm to monarchs and human health. Allowing the agency to register first and review later is fundamentally at odds with FIFRA's core purpose "to protect against the risk of harm from pesticide products." *Sultan Chemists, Inc. v. EPA*, 281 F.3d 73, 83 (3d Cir. 2002).

Nor does EPA's participation in other "national and international efforts to protect the monarch butterfly," EPA Br. 78, relieve the agency of its duty under FIFRA to prevent, at the time of registration, any unreasonable adverse effects that Enlist Duo may pose to monarchs.

In sum, Decision 1 is unsupported by substantial evidence under FIFRA's § 136a(c)(5) unconditional registration standard. The Court should therefore vacate EPA's decision to affirm its unconditional registration of Enlist Duo's initial uses on corn and soy in fifteen states.

B. Decisions 2 and 3, which approve Enlist Duo's additional uses, are not supported by substantial evidence

Because EPA's decision to reaffirm the registration of Enlist Duo's initial uses is unlawful, any conditional amendment expanding that unlawful registration is also invalid. *See* EPA Br. 42 (noting NRDC and EPA's agreement that the agency may use § 136a(c)(7)(B) to allow additional uses of Enlist Duo "after Enlist Duo has already been *lawfully* registered" (emphasis added)). If the Court concludes that Decision 1 in the 2017 Registration violates FIFRA, it follows that Decisions 2 and 3 also violate FIFRA and must be nullified. Moreover, on their own terms, Decisions 2 and 3 are unsupported by substantial evidence.

1. EPA lacked substantial evidence to register Enlist Duo's additional uses under FIFRA's § 136a(c)(5) unconditional registration standard

EPA voluntarily "chose to apply the more stringent standard from . . . § 136a(c)(5)" in evaluating Enlist Duo's additional uses. EPA Br. 18; *see* ER 4, 28, 30 (applying the no-unreasonable-adverse-effects test from FIFRA's unconditional registration standard, 7 U.S.C. § 136a(c)(5)(C), (D)). Because "an agency's action must be upheld, if at all, on the basis articulated by the agency itself," Decisions 2 and 3 must also be reviewed under the unconditional registration standard, *State Farm*, 463 U.S. at 50.

EPA admits that it did not have adequate data to unconditionally amend the registration of Enlist Duo to encompass its additional uses. *See* ER 4

(acknowledging existence of "outstanding data"); *id.* at 30 (registering additional uses conditionally because of outstanding data "relating to 2,4-D uses and products in general"); EPA Br. 17, 27, 42, 46; *supra* Argument II.A.2. As a result, EPA lacked substantial evidence to conclude that Decisions 2 and 3 meet the § 136a(c)(5) standard. Independently, Decisions 2 and 3, like Decision 1, are also unsupported by substantial evidence under § 136a(c)(5) because of EPA's failure to consider existing evidence of harm to monarchs and human health. *See supra* Argument II.A.2.ii-v.

2. EPA lacked substantial evidence to register Enlist Duo's additional uses under FIFRA's § 136a(c)(7)(B) conditional registration standard

In the alternative, Decisions 2 and 3 are unsupported by substantial evidence under § 136a(c)(7)(B). That standard requires EPA to determine that amending a pesticide registration to include an additional use 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). The agency must analyze the "incremental risk" between an existing pesticide use and the proposed additional use of the same pesticide. 40 C.F.R. § 152.113(a)(1).

EPA never independently analyzed the incremental risk posed by Decisions 2 and 3. Instead, the agency relied on its conclusion that Decisions 2 and 3 satisfy the "more stringent" § 136a(c)(5) unconditional registration standard, EPA Br. 18,

27, 33-34, to deduce that they meet the less demanding § 136a(c)(7)(B) standard as well, *see* ER 30 (registering uses of Enlist Duo under § 136a(c)(7)(B) upon concluding that the uses "will not generally cause unreasonable adverse effects," as required under § 136a(c)(5)). Because Decisions 2 and 3 fail the § 136a(c)(5) analysis, however, *see supra* Argument II.B.1, the agency's deduction that they comport with § 136a(c)(7)(B) fails as well. Nothing more is needed for the Court to conclude that EPA lacked substantial evidence to determine that those decisions would not "significantly increase the risk of any unreasonable adverse effect" under § 136a(c)(7)(B). *See State Farm*, 463 U.S. at 50.

EPA and Dow attempt to defend Decisions 2 and 3 by arguing that the decisions will not increase overall glyphosate use. *See* EPA Br. 69-72; Dow Br. 46-49. These arguments are misplaced if one accepts EPA's new explanation for the 2017 Registration. If Decisions 2 and 3 amended the 2014/15 Registration, as EPA now contends, *see* EPA Br. 40-42, then the agency should have compared the risks posed by Enlist Duo's additional uses with the risks posed by the pesticide's initial uses. Whether Decisions 2 and 3 increase *total* glyphosate use does not answer the question whether Decisions 2 and 3 increase glyphosate use *relative to the 2014/15 Registration*. The answer is unquestionably yes, as Decisions 2 and 3 allow use of Enlist Duo in more states and on an additional crop. EPA failed to assess the risks posed by these incremental uses, as required by § 136a(c)(7)(B).

Similarly, regardless of whether the uses of Enlist Duo sanctioned by Decisions 2 and 3 increase *total* milkweed destruction, *see* EPA Br. 74-75, they unquestionably increase milkweed destruction *relative to the 2014/15 Registration*. Enlist Duo's destruction of milkweed in corn, soy, and cotton fields across 34 states will, in turn, pose greater risks to monarch butterflies when compared to the pesticide's destruction of milkweed in only 15 states' corn and soy fields. Likewise, the expanded uses contemplated by Decisions 2 and 3, compared to the uses allowed by the 2014/15 Registration, mean that more people will be exposed to the pesticide, and that people may be exposed to greater quantities of the pesticide. New evidence of glyphosate's health risks suggests that Enlist Duo may not be as safe as EPA previously concluded. The increased exposures caused by Enlist Duo's additional uses may thus pose an unreasonable incremental risk.

Without assessing the incremental harms attributable to the additional uses of Enlist Duo, EPA lacked substantial evidence to conclude that Decisions 2 and 3 would not significantly increase the risk of any unreasonable harm to humans or the environment. This violated § 136a(c)(7)(B).

EPA is correct that "NRDC's challenge concerning alleged increased glyphosate usage assumes that EPA was *required* to conduct a new glyphosate assessment under FIFRA in determining whether to issue the 2017 Registration Amendment for Enlist Duo." EPA Br. 69. That assessment was, indeed, required—

even under § 136a(c)(7)(B). *Cf. supra* Argument II.A.2.iv (explaining that § 136a(c)(5) required EPA to examine new data on glyphosate's risks). Contrary to EPA's argument, *see* EPA Br. 46-49, 76-77, § 136a(c)(7)(B) plainly prohibited the agency from deferring assessment of existing evidence of glyphosate's risks until registration review. That section provides, in pertinent part:

> An applicant seeking amended registration under this subparagraph *shall submit such data as would be required to obtain registration of a 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 [for example, at the time of registration review, *see* 7 U.S.C. § 136a(g)].

Id. § 136a(c)(7)(B) (emphases added). With a narrow exception for certain evidence that "has not yet been generated," § 136a(c)(7)(B) mandates that EPA examine all relevant data, as required for unconditional registration, *see* 40 C.F.R. § 152.112(b), before conditionally amending an existing pesticide registration to incorporate new uses. There is no additional exception for data that have been generated but not yet reviewed.

The legislative history that EPA cites corroborates this textual analysis. *See* EPA Br. 48. EPA is correct that Congress did not intend EPA to undertake a "comprehensive analysis" when conditionally amending an existing pesticide registration to allow new uses under § 136a(c)(7)(B). *Id*. Congress, however,

authorized EPA to defer evaluation of one, and only one, category of data until registration review: "data (other than data pertaining to the proposed additional use) . . . [that] has not yet been generated." 7 U.S.C. § 136a(c)(7)(B). EPA may not rewrite the "clear statutory terms" of § 136a(c)(7)(B) "to suit its own sense of how the statute should operate." *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2446 (2014).

NRDC beseeched EPA at every opportunity to review existing data regarding harms to monarchs and human health that had been submitted to the agency. Nothing in § 136a(c)(7)(B) authorized EPA to defer reviewing these crucial, existing data until registration review.

III. The Court should vacate the unlawful registration of Enlist Duo

FIFRA authorizes this Court to "affirm or set aside" the 2017 Registration Order "in whole or in part." 7 U.S.C. § 136n(b). Dow urges the Court not to vacate the order. Dow Br. 90-93. However, this Court "remand[s] without vacatur only in 'limited circumstances.'" *Pollinator Stewardship Council*, 806 F.3d at 532 (quoting *Cal. Cmties. Against Toxics*, 688 F.3d at 994) (vacating EPA's unconditional registration of a pesticide under FIFRA); *accord All. for the Wild Rockies v. U.S. Forest Serv.*, 899 F.3d 970, 986 (9th Cir. 2018) ("Although not without exception, vacatur of an unlawful agency rule normally accompanies a remand.").

An unlawful agency action is left in place "only 'when equity demands.'" *Pollinator Stewardship Council*, 806 F.3d at 532 (quoting *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)). The Court weighs "the seriousness of the agency's errors against 'the disruptive consequences'" of vacatur, as well as "possible environmental harm." *Id.* (quoting *Cal. Cmties. Against Toxics*, 688 F.3d at 992). Given the gravity of EPA's errors, Enlist Duo's risks to imperiled species and human health, and the lack of evidence of disruption to agriculture, the Court should not withhold the normal remedy of vacatur.

EPA's errors in registering Enlist Duo go to the heart of its statutory obligation to conduct thorough analyses of pesticides' health and environmental risks. EPA "reaffirm[ed]" its unconditional registration of Enlist Duo's initial uses, ER 2, despite admitting that the agency lacked the data necessary for unconditional registration, *id.* at 4, 30; *see* EPA Br. 17; *supra* Argument II.A.2.i. The agency refused to analyze key evidence concerning the pesticide's risks to monarchs and human health, despite NRDC's specific request for it to do so, and in the face of a statutory command to ensure that the pesticide will not "cause unreasonable adverse effects on the environment." *See supra* Argument II.A.2.ii-v, B.1. The no-unreasonable-adverse-effects finding is essential to pesticide registration, and EPA's failure to support that finding with substantial evidence demands vacatur. *See* 7 U.S.C. § 136a(c)(5).

"Moreover, on remand, a different result may be reached," which also counsels in favor of vacatur. *Pollinator Stewardship Council*, 806 F.3d at 532. Once EPA reviews the substantial body of evidence on harm to monarchs and the new evidence of glyphosate's toxicity, the agency may very well conclude that Enlist Duo cannot be registered without changes to the current registration terms, or that it cannot be registered at all. *See id.* at 532-33.

The potential harms from EPA's errors are significant. *See id.* at 532. NRDC offered extensive evidence of Enlist Duo's risks to monarchs and human health, *see* NRDC Br. 14-23, and explained that registration of the pesticide will likely prop up glyphosate use in the face of increasing weed resistance, *see id.* 10-14. Particularly given the precariousness of monarch populations, leaving the Enlist Duo registration in place risks more potential environmental harm than vacating it. *See Pollinator Stewardship Council*, 806 F.3d at 532; *see* ER 405 (finding that monarch populations face a "high probability" of population collapse "over the next two decades").

In light of these documented risks, EPA, Dow, and amicus American Farm Bureau's vague and speculative allegations of disruptive effects do not tip the scales against vacatur. EPA, Dow, and the Farm Bureau claim that vacating the 2017 Registration will cause "significant," "enormous[]," and "serious" disruptions to agriculture, but offer no evidence regarding the extent to which corn, soy, or

cotton growers actually use Enlist Duo. EPA Br. 111; Dow Br. 92; Farm Bureau Br., ECF No. 93-2, at 6. This information is readily accessible both to Dow, which sells the pesticide, and to the Farm Bureau, whose members might use it. Both Dow and the Farm Bureau stress that Enlist Duo has been registered since 2014, implying that growers have become reliant on the pesticide in the past four years. Dow Br. 92; Farm Bureau Br. 17-18. But "according to information submitted by [Dow], no appreciable use of Enlist Duo™ on [corn and soy] occurred in the 2015 and 2016 use seasons." ER 30. And the record is silent on the extent of Enlist Duo's use thereafter.

There are alternatives to Enlist Duo. EPA insists that "Enlist Duo simply provides *another tool* for the control of weeds." EPA Br. 75. Growers will continue to use "various methods" of weed control "even if Enlist Duo is not available." *Id.* at 75. The availability of other methods, such as non-toxic weed management practices or lawfully registered pesticides, undercuts EPA, Dow, and the Farm Bureau's hyperbolic predictions of vacatur's effects. Their abstract and unsubstantiated assertions of economic harm fall well short of the high bar this Court has set for avoiding vacatur. *See Cal. Cmties. Against Toxics*, 688 F.3d at 994 (declining to vacate an agency order in light of specific facts indicating that it would be "economically disastrous").

In a single sentence, without citation, EPA claims that vacatur would significantly disrupt "state and federal regulatory programs." EPA Br. 111. But nowhere does EPA's brief even identify a role for states in regulating Enlist Duo, let alone elaborate on how they would be affected by vacatur. Nor is it clear what potential harm to itself the agency is alleging. Vacatur leaves EPA free to decide when and how to reconsider the Enlist Duo registration. To the extent vacatur "disrupts" EPA's regulatory programs by incentivizing the agency to act more promptly on remand than it otherwise would, that disruption will advance FIFRA's goals and the interests of all parties. *See Cal. Cmties. Against Toxics*, 688 F.3d at 994 (considering whether vacatur would serve the goals of the Clean Air Act).

Finally, NRDC opposes EPA's request for further briefing on remedy. *See* EPA Br. 110-12. The Court already has the benefit of extensive briefing by Petitioners, EPA, Dow, and the Farm Bureau. Any marginal benefit from an additional round of briefs is outweighed by the harms from delay. The longer Enlist Duo remains available for use, the greater the threat it poses to monarchs and human health. NRDC respectfully requests that the Court prescribe a remedy when it decides the merits of this case, as it has done in other pesticide cases. *See, e.g.*, *Nanosilver II*, 857 F.3d at 1042 (simultaneously deciding the merits of a FIFRA petition and vacating the challenged registration); *Pollinator Stewardship Council*, 806 F.3d at 532-33 (same).

CONCLUSION

NRDC urges the Court to vacate the Enlist Duo registration in its entirety.

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Respectfully submitted,

/s/ Margaret T. Hsieh
Margaret T. Hsieh
Mitchell S. Bernard
Kaitlin Morrison
Natural Resources Defense Council
40 West 20th Street
New York, NY 10011
Telephone: (212) 727-2700
mhsieh@nrdc.org
mbernard@nrdc.org
kmorrison@nrdc.org

Peter J. DeMarco
Natural Resources Defense Council
1152 15th Street NW
Suite 300
Washington, DC 20005
Telephone: (202) 289-6868
pdemarco@nrdc.org

Counsel for Petitioner NRDC

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Cir. R. 32-1(b), as modified by Cir. R. 32-2(b) (allowing an additional 1,400 words for reply briefs that respond to multiple briefs), because it contains 8,380 words, excluding the parts of the brief exempted by Cir. R. 32-1(c) and Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using 14-point Times New Roman font.

Dated: September 17, 2018

/s/ Margaret T. Hsieh
Counsel for Petitioner NRDC

CERTIFICATE OF SERVICE

I hereby certify that on September 17, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: September 17, 2018 /s/ Margaret T. Hsieh
Counsel for Petitioner NRDC