Nos. 17-70810, 17-70817

United States Court of Appeals for the Ninth Circuit

NATIONAL FAMILY FARM COALITION, ET AL.,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY ET AL.,
Respondents,

DOW AGROSCIENCES LLC,
Intervenor,

NATURAL RESOURCES DEFENSE COUNCIL,
Petitioner,

v.

ANDREW R. WHEELER, ET AL.,
Respondents,

DOW AGROSCIENCES LLC,
Intervenor.

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

SUPPLEMENTAL BRIEF FOR INTERVENOR

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INTRODUCTION

Petitioners Natural Resources Defense Council's ("NRDC") and National Family Farm Coalition's ("NFFC") supplemental briefs fail to demonstrate any error in the Environmental Protection Agency's ("EPA") final registration of Intervenor Dow Agrosciences LLC's ("Dow") Enlist Duo herbicide. Petitioners' supplemental briefs largely rehash meritless arguments from their opening briefs and, to the extent new arguments are raised, those arguments fail.

NRDC's supplemental brief errs in suggesting that the 2017 Final Registration of Enlist Duo violates the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") because the initial, 2014 registration was an improper conditional registration rather than an unconditional registration under 7 U.S.C. § 136a(c)(5). The 2014 registration was an unconditional registration, not a conditional registration. And even if the 2014 registration had been conditional, any error in applying the unconditional registration standard would be harmless because EPA had statutory authority to issue a conditional registration in the first instance, and made the necessary findings to support such a conditional registration under 7 U.S.C. § 136a(c)(7)(A) or (c)(7)(B).

NRDC likewise fails to demonstrate any error in EPA's consideration of glyphosate-specific studies and potential risk to monarch butterflies in the context of its registration review for glyphosate. EPA has broad discretion to determine that

"no additional information" is needed to support unconditional registration, and NRDC errs in suggesting that EPA should have ignored the decades-long registration history of Enlist Duo's active ingredients. Any error on this issue would in any event be harmless because, as noted, EPA had authority to conditionally register Enlist Duo in 2014 under Section 136a(c)(7)(A), which expressly allows submission of data at the time such data are required for previously registered pesticides (here, during the registration review for glyphosate).

NFFC's supplemental brief fails to show any defect in EPA's compliance with the Endangered Species Act ("ESA). EPA properly made "no effect" determinations for listed species within the action area, which foreclosed any obligation to consult with the Fish & Wildlife Service ("FWS") or National Marine Fisheries Service ("NMFS"). NFFC's suggestion that EPA applied the wrong legal standard under the ESA is based on a non-binding, advisory report from the National Academy of Sciences and an erroneous reading of this Court's decision in *Karuk Tribe of California v. U.S. Forest Service*, 681 F.3d 1006 (9th Cir. 2012) (en banc). NFFC meanwhile ignores this Court's precedent reaffirming that EPA has broad discretion to make "no effect" determinations and to select its methodology in arriving at those determinations.

In the event this Court determines that EPA erred (it did not), the appropriate remedy is remand to the agency *without* vacatur. The enormously disruptive

consequences of vacating the registration for Enlist Duo—which has become an indispensable tool for farmers while demonstrating significant environmental benefits—far outweigh any errors alleged by Petitioners.

ARGUMENT

I. THE ENLIST DUO REGISTRATION COMPLIES WITH FIFRA

A. The 2017 Final Registration Correctly Reaffirmed The Previously Approved Uses of Enlist Duo

Contrary to NRDC's argument (Br. 2-8), EPA properly registered Enlist Duo in 2014 unconditionally under Section 136a(c)(5), not conditionally under 7 U.S.C. § 136a(c)(7)(B). Even if Enlist Duo had been registered conditionally in 2014, such a registration was statutorily permissible and would have been supported by the necessary findings under Section 136a(c)(7).[1]

1. EPA Properly Registered Enlist Duo Unconditionally In 2014

Contrary to NRDC's assertion (Br. 6), Enlist Duo was initially registered in 2014 unconditionally under Section 136a(c)(5). The Notice of Registration states that Enlist Duo "is unconditionally registered in accordance with FIFRA section 3(c)(5)," and the "Term of Issuance" is "Unconditional." ER1401. EPA has

[1] Because Enlist Duo is now a conditionally registered pesticide under 7 U.S.C. § 136a(c)(7)(B) (*see* ER1-36), the prior registration actions have no independent legal force and can no longer be amended or vacated (*see* ER37). Thus, any decision whether the prior registration actions were conditional or unconditional is arguably "advisory," *Flast v. Cohen*, 392 U.S. 83, 96 (1968).

explained (EPA Br. 12 n.3) that references to the conditional registration standard in the 2014 Final Decision resulted from a clerical error. Because NRDC's argument that registration of Enlist Duo's "inaugural uses" was invalid rests entirely on its erroneous assertion that EPA conditionally registered Enlist Duo in 2014, NRDC's argument fails.

2. EPA Had Authority To Register Enlist Duo Conditionally In 2014, Rendering Any Error Harmless

Even if EPA had registered Enlist Duo conditionally in 2014 (it did not), any error would have been harmless. *See PDK Labs. Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) ("If the agency's mistake did not affect the outcome, if it did not prejudice the petitioner, it would be senseless to vacate and remand for reconsideration."). Contrary to NRDC's suggestion (Br. 3, 6-8), EPA was not required to issue an unconditional registration in 2014 for Enlist Duo's "inaugural uses," but could have issued a conditional registration under Section 136a(c)(7)(A) or (B) as an initial matter.

Specifically, FIFRA does not require an initial unconditional registration, but instead authorizes EPA to register pesticides conditionally under Section 136a(c)(7) in the first instance where it determines that approving the registration "would not significantly increase the risk of any unreasonable adverse effect on the environment." *See* 7 U.S.C. § 136a(c)(7)(A), (B); 40 C.F.R. § 152.111 ("The Agency has discretion to review applications under either the unconditional

registration criteria of FIFRA sec. 3(c)(5) or the conditional registration criteria of FIFRA sec. 3(c)(7).”). And EPA has done so routinely. *See, e.g.*, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 434 (2005) (“Pursuant to its authority under FIFRA, the Environmental Protection Agency (EPA) *conditionally registered* Strongarm on March 8, 2000, thereby granting respondent (Dow) permission to sell this pesticide … in the United States.”) (emphasis added). Indeed, a primary purpose of the 1978 amendments to FIFRA was to permit conditional registration of pesticides, in order to alleviate the “lack of middle ground” between unconditional registration and total denial of an application that had ground the registration process “to a virtual halt.” *See* S. REP. NO. 95-334, at 3, 4 (1977); *see also id.* (“Another serious impediment in the present registration program … is EPA’s inability to issue registrations on a conditional basis.”).

a. Enlist Duo Was Eligible For Initial Conditional Registration Under Section 136(c)(7)(A)

NRDC errs in suggesting (Br. 3 n.1) that Enlist Duo was not eligible for conditional registration under subsection (c)(7)(A) because it is “not identical or substantially similar to any previously registered pesticide.” Subsection (c)(7)(A) permits conditional registration where “the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, *or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment*.” 7 U.S.C. 136a(c)(7)(A) (emphasis added); *see also* 40

C.F.R. § 152.113(a), (b). Enlist Duo is a combination of *two* previously registered pesticides—glyphosate and 2,4-D—each of which has been registered for decades (*see* EPA Br. 10), and the conclusions drawn in EPA's registration of Enlist Duo in 2014 would have satisfied this standard had it applied.

EPA's implementing regulation for Section 136a(c)(7)(A) provides that "the Agency may approve an application for registration … of a pesticide product, *each of whose active ingredients is contained in one or more registered pesticide products*," provided EPA has requisite data and "[a]pproval of the application would not significantly increase the risk of any unreasonable adverse effect on the environment." 40 C.F.R. § 152.113(a)(1), (2) (emphasis added). EPA must also determine that "the applicant's product and its proposed uses are identical or substantially similar to a currently registered pesticide and use, or that the pesticide and its proposed use differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment." 40 C.F.R. § 152.113(b).

In 2014, EPA met these standards, determining that (1) Enlist Duo's active ingredients are contained in "one or more registered pesticide products"—glyphosate and 2,4-D (ER1372); (2) the proposed use for Enlist Duo did not involve "a new use for glyphosate containing products" (ER1372); and (3) the new uses of 2,4-D would "not increase the risk of any unreasonable adverse effects on human health or the environment" (ER1394). Accordingly—to the extent Enlist Duo differs

from its long-registered active ingredients—EPA's conclusions demonstrate that those differences would not significantly increase the risk of adverse environmental effects. Registration of Enlist Duo would have thus been permissible under subsection (c)(7)(A).

NRDC attempts (Br. 3 n.1) to have it both ways in arguing that Enlist Duo did not qualify for registration under subsection (c)(7)(A) because it is "not … substantially similar to any previously registered pesticide," and that Enlist Duo did not qualify for registration under subsection (c)(7)(C) because "both of Enlist Duo's active ingredients appear … in previously registered pesticides." But NRDC is unable to identify any plausible basis to suggest that EPA was required to ignore the registration history of the two active ingredients in Enlist Duo, each of which had been registered for years—particularly where Congress has directed EPA to process FIFRA registration applications "as expeditiously as possible." 7 U.S.C. § 136a(c)(3)(A).

b. Enlist Duo Was Eligible For Initial Conditional Registration Under Section 136a(c)(7)(B)

NRDC also wrongly argues (Br. 2-3) that conditional registration of Enlist Duo under Section 136a(c)(7)(B) was unavailable in 2014 because "[t]hat provision authorizes EPA only to 'amend' the *existing* registration of a pesticide to permit '*additional*' uses of such pesticide." EPA's initial registration of Enlist Duo in 2014 functioned as an amendment of the existing registration for 2,4-D. As noted, both

of Enlist Duo's active ingredients (glyphosate and 2,4-D) are registered pesticides. For glyphosate, registration of Enlist Duo in 2014 did not involve *any* new uses. ER1372 ("All uses for [Enlist Duo] are already registered on other glyphosate products and are currently in use on … corn and soybeans for the same use pattern."). The 2,4-D component of Enlist Duo was "previously registered for over-the-top applications to corn up 8 inches tall and only pre-plant applications to soybeans," and EPA's initial registration of Enlist Duo in 2014 added over-the-top applications for corn up to 48 inches tall and soybeans. ER1372. The initial registration of Enlist Duo thus—in effect—amended the existing registration of 2,4-D to add "additional uses," 7 U.S.C. § 136a(c)(7)(B), on taller corn and soybeans.

Because the two active ingredients in Enlist Duo had been registered for decades and EPA concluded that the 2014 proposed uses of Enlist Duo "will not increase the risk of any unreasonable adverse effects on human health or the environment" (ER1394), conditional registration of Enlist Duo in 2014 would have been available under Section 136a(c)(7)(A) or (B). Any error in the initial registration of Enlist Duo under Section 136a(c)(5) (had there been one) thus would have been harmless. *See, e.g.*, *City of Portland v. EPA*, 507 F.3d 706, 713 (D.C. Cir. 2007) ("Even were EPA to redress its alleged errors, the final rule would remain unchanged, making this the epitome of harmless error.").

B. Substantial Evidence Supports The 2017 Final Registration

NRDC likewise errs in insisting (Br. 8-25) that the 2017 Final Registration is unsupported by substantial evidence.

1. The 2014 Registration Adequately Considered Effects On Monarch Butterflies and Human Health

NRDC erroneously maintains (Br. 8-21) that EPA's 2014 registration of Enlist Duo was unsupported by substantial evidence because EPA purportedly did not take into account information concerning the effect of Enlist Duo on monarch butterflies and human health. This argument is incorrect.

a. EPA Properly Concluded That Enlist Duo's 2,4-D Component Would Not Have An Unreasonable Adverse Effect On Terrestrial Plants

NRDC argues (Br. 9) that EPA disregarded the potential effect of Enlist Duo on milkweed—thus threatening monarchs—but EPA expressly considered the potential effect of Enlist Duo on terrestrial plants (ER1388-90). EPA properly determined that Enlist Duo's labeling restrictions—including a 30-foot buffer zone and a specific, low drift nozzle—would "reduc[e] the potential spray drift exposure of non-target plants to 2,4-D choline salt residues." ER1389. And EPA separately concluded that the Enlist Duo label's prohibition of application where rain or irrigation is expected within 24 hours, coupled with "2,4-D's limited uptake by roots of terrestrial plants," would likely "reduce the amount of 2,4-D choline salt that

could adversely affect plants via runoff." ER1390. NRDC fails to demonstrate any error in these determinations.

b. EPA Properly Considered Data As To Glyphosate's Effects

NRDC likewise fails to demonstrate any error in EPA's handling of glyphosate-specific studies. NRDC argues (Br. 9-10) that it "asked EPA to review studies … indicating that … Enlist Duo threatens [monarch butterflies'] … survival by destroying in-field milkweed," and suggests (Br. 11) that EPA thus failed to "consider 'all relevant data'" under the implementing regulation for unconditional registration under Section 136a(c)(5). *See* 40 C.F.R. § 152.112(b) (EPA will approve an application for unconditional registration only if it has "reviewed all relevant data in [its] possession"). But that is incorrect for several reasons.

First, EPA has interpreted FIFRA to vest *EPA* with the discretion to determine that "no additional data are necessary to make the determinations required by FIFRA sec. (3)(5)." 40 C.F.R. § 152.112(c).[2] EPA's interpretation is entitled to *Chevron* deference, *see, e.g.*, *Pronsolino v. Nastri*, 291 F.3d 1123, 1133 (9th Cir. 2002), and EPA made that determination regarding Enlist Duo in 2014 (ER1395 (""There are

[2] Section 152.112 provides that unconditional registration is proper where it "has reviewed all relevant data in [its] possession," and "*has determined* that no additional data are necessary to make the determinations required by FIFRA sec. 3(c)(5)." 40 C.F.R. § 152.112(b), (c).

no outstanding data requirements required to support the registration of [Enlist Duo].")). EPA thus satisfied any obligation to consider "all relevant data."

Second, EPA properly concluded that registration of Enlist Duo in 2014 would not involve any new use of glyphosate (*see* Dow Br. 46-49) and thus that registration of Enlist Duo would not "result in a significant increase in the level of exposure" to glyphosate. *See* 40 C.F.R. § 152.3 (defining "new use" in relevant part as "[a]ny additional use pattern that would result in a significant increase in the level of exposure"). Because registration of Enlist Duo did not involve any increase in exposure to glyphosate, EPA was entitled to piggy-back on its prior review of glyphosate for purposes of the Enlist Duo registration, while assessing any new information "*generic* to … glyphosate … in general" (ER1395)—including its impact on monarchs—in conjunction with its registration review for glyphosate. *See* ER1372; ER1436.[3] Contrary to NRDC's suggestion (Br. 11), registration review is not inferior to initial registration, but rather "is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration." 40 C.F.R. § 155.40(a).

[3] EPA appears to be doing precisely that. *See* Environmental Protection Agency, Glyphosate – Proposed Interim Registration Review Decision 11 (April 23, 2019) (confirming that "[m]onarch butterfly conservation is an important issue for the agency").

Third, NRDC's argument that milkweed studies should have been considered ignores that Enlist Duo is *intended* to kill milkweed—a target plant. EPA thus plainly considered the effect of Enlist Duo on in-field milkweed when first registering it. *See* Dow Br. 44-45. The studies cited by NRDC (Br. 9-10), moreover, involved the potential impact of Enlist Duo's active ingredients *individually*—and the studies referenced in 2014 pertained *exclusively* to glyphosate. *See* ER1623 (2014) ("The expanded use of *glyphosate* has contributed to a sharp decrease in monarch population levels through the herbicide's large-scale suppression of milkweed.") (emphasis added); NRDC SER10 (2015) (same); ER159 (2016) (similar) (emphasis added); ER173 (2016) ("Like glyphosate, *2,4-D* harms milkweed and thus monarchs.") (emphasis added). Accordingly, considering glyphosate-specific studies during registration review for glyphosate was squarely within EPA's "broad discretion" under FIFRA, *Wellford v. Ruckelshaus*, 439 F.2d 598, 601 (D.C. Cir. 1971).

c. Any Error In Considering Glyphosate-Specific Studies During Registration Review Would Be Harmless

In any event, any error in EPA's decision to consider the potential impact of glyphosate on monarchs during its registration review for glyphosate would be harmless. As shown, EPA's conclusions would have supported conditional registration for Enlist Duo in 2014, pursuant to Section 136a(c)(7)(A), which

expressly permits submission of additional data at "the time such data are required to be submitted with respect to similar pesticides [i.e., glyphosate] already registered under this subchapter." 7 U.S.C. § 136a(c)(7)(A); *see* 40 C.F.R. § 152.115(a) ("Each registration issued under [7 U.S.C. § 136a(c)(7)(A)] shall be conditioned upon the submission … of all data which are required for unconditional registration of his product under FIFRA sec. 3(c)(5) … no later than the time such data are required to be submitted for similar pesticide products already registered.").

Had EPA initially registered Enlist Duo conditionally under Section 136a(c)(7)(A)—as was within its discretion, *see* 40 C.F.R. § 152.111—then, consistent with the statute's text, additional data could have been received at the time such data were required for glyphosate. Indeed, the implementing regulation for Section 136a(c)(7)(A) does not adopt the "all relevant data" requirement on which NRDC relies (Br. 11). *See* 40 C.F.R. § 152.113(a)(3) (requiring satisfaction of "[t]he criteria of § 152.112(a), (d), and (f) through (h)," but not (b)). Accordingly, any error in EPA's 2014 consideration of data pertaining to glyphosate's potential impact on monarchs and human health (had there been one) would be harmless.[4]

[4] NRDC argues (Br. 14) that "[r]egardless … 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." But even if NRDC were correct (it is not), EPA made all necessary findings for initial registration under Section 136a(c)(7)(A). *See supra* at 5-7.

2. Substantial Evidence Supports EPA's Volatility Assessment

Separate from NRDC's arguments, NFFC wrongly maintains (Br. 24-27) that EPA's volatility assessment (*see* ER646-49; ER2082-83) was not supported by substantial evidence because it was purportedly based on flawed studies. NFFC singles out one laboratory study (SER666-694) whose limitations EPA had recognized (ER3190), while ignoring that EPA relied on several other studies in assessing Enlist Duo's potential volatization. *See* ER2082-84 (2013 risk assessment); ER646-47 (2016 risk assessment); ER58-59, ER78-79 (2017 registration); Dow Br. 49-52. Indeed, EPA explained that these additional studies used different "methodology and timing of measurements" and "were all considered scientifically sound and appropriate for qualitative incorporation into a risk assessment." ER2082 (2013 risk assessment); *see* Dow Br. 50-51. NFFC thus fails to demonstrate that EPA's volatility assessment was unsupported by substantial evidence on this ground. *See Cent. Ariz. Water Conservation Dist. v. EPA*, 990 F.2d 1531, 1543-44 (9th Cir. 1993) ("The record reveals … that EPA acknowledged the limitations of the [study] … and did not rely solely upon that report's conclusions…. We therefore reject Petitioner's argument that EPA has somehow acted arbitrarily and capriciously ….").[5]

[5] NFFC cites (Br. 27) *Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015), but that case is inapposite. That decision found that "*all* of the studies" relied on by EPA had "significant flaw[s]." *Id.* at 529. Here, by contrast, EPA relied

NFFC separately argues (Br. 26) that Dow's field volatility study did not meet EPA's standards, but fails to rebut EPA's conclusion (SER 437) that there were "no significant deviations from good scientific practices" in this study. NFFC incorrectly asserts (Br. 26-27) that Dow's air dispersion modeling assumed too small of a field (40 acres), but ignores that *EPA*'s air dispersion modeling assumed an 80-acre field. ER715, ER720. NFFC similarly ignores that, in addition to using PERFUM modeling (which supported EPA's conclusions regarding vapor drift), EPA also conducted AERSCREEN modeling (to calculate deposition of product in the environment), which provides estimates of "worst-case" concentrations. ER616-18. For Enlist Duo, the AERSCREEN modeling showed "negligible" depositions—providing a wide margin of protection. ER616-18.

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

NFFC is also incorrect to argue (Br. 27-29) that EPA's decision not to account for synergistic effects of Enlist Duo and glufosinate was arbitrary and capricious. The Enlist Duo registration expressly provides (*see* ER32, ER38-39) that Enlist Duo may not be tank-mixed with any product that is not listed on an Enlist Duo website maintained by Dow, and no glufosinate product is on that list, *see* enlist.com/en/approved-tank-mixes/enlist-duo.html. Accordingly, it is illegal to

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on several studies (and other scientific information) in assessing the volatization of 2,4-D choline, only two of which are criticized by NFFC.

tank-mix Enlist Duo with glufosinate (*see* ER38-39), and EPA had no reason to consider any potential synergistic effects. *See* Dow Br. 52-54.[6]

II. THE ENLIST DUO REGISTRATION COMPLIES WITH THE ESA

Contrary to NFFC's argument (Br. 3-20), EPA also complied with the ESA in registering Enlist Duo. Under the ESA, a federal agency must consult with FWS or NMFS regarding any "agency action" that "may affect" a listed species or critical habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14(a). Here, EPA properly made "no effect" determinations with respect to all relevant species except for one, for which it did consult with FWS. *See* ER24-26; ER726-977. EPA's "no effect" determinations and corresponding decisions not to consult—which are reviewed under the deferential "arbitrary and capricious standard," *Friends of Santa Clara River v. Army Corps of Eng'rs*, 887 F.3d 906, 920-21, 923-24 (9th Cir. 2018)—were well within EPA's discretion.

A. NFFC Is Incorrect That "May Affect" Means "Any Possible Effect"

NFFC's argument (Br. 3-20) that EPA violated the ESA in registering Enlist Duo rests entirely on the erroneous proposition (Br. 4) that "*any* potential exposure

[6] NFFC wrongly asserts (Br. 29) that "Dow's Enlist Duo business plan strategically involves … glufosinate" because Enlist Duo crops are tolerant to glufosinate in addition to 2,4-D and glyphosate. But the page from Dow's website that NFFC cites in support is not a "business plan" and does not suggest violating Enlist Duo's tank-mixing restrictions.

to [a] pesticide is a 'may affect' trigger," requiring consultation with the Services. NFFC relies (Br. 4-6) on a report by the National Academy of Sciences ("NAS"), but the NAS report merely offers "a common approach that EPA, FWS, and NMFS *could use* to conduct assessments," SBER10 (emphasis added)—it is not a binding framework for risk assessment, nor did it interpret the ESA's legal requirements. To the contrary, the NAS report expressly "does not take a position on any legal or regulatory policy issue, provide any legal or policy advice, or comment on the merit of any particular court ruling or other legal or policy decision." SBER44. Accordingly, the NAS report provides no basis to determine that EPA's ESA analysis was arbitrary and capricious. *See, e.g.*, *Gifford Pinchot Task Force v. Fish & Wildlife Serv.*, 378 F.3d 1059, 1066, *amended by* 387 F.3d 968 (9th Cir. 2004) ("An agency's scientific methodology is owed substantial deference . . . .")..

NFFC's reliance (Br. 8, 11) on *Karuk Tribe*, 681 F.3d 1006, is equally misplaced. NFFC wrongly argues that *Karuk Tribe* established that "may affect" means "*any possible effect*, whether beneficial, benign, adverse, or of undetermined character," *id.* at 1027, but takes the quoted language wholly out of context. Unlike here, the action agency in *Karuk Tribe* made no substantive "no effect" determination. 681 F.3d at 1027. To the contrary, the agency in *Karuk Tribe* "d[id] not dispute" that the challenged mining activities "may affect" listed coho salmon and critical habitat. 681 F.3d at 1027. *Karuk Tribe* thus did not address the standard

to be applied where, as here, an action agency *has already made* a "no effect" determination.[7] And NFFC completely ignores applicable cases—where substantive "no effect" determinations were actually at issue—that directly contradict its reading of *Karuk Tribe*.

For example, in *Friends of Santa Clara*, this Court determined that the Army Corps of Engineers' "determination that the [agency action] would not affect steelhead was not arbitrary and capricious." 887 F.3d at 924. It reached this conclusion despite a NMFS memorandum suggesting that copper discharges could "have 'sublethal impacts' on steelhead smolt." *Id.* And in *Defenders of Wildlife v. Flowers*, this Court upheld the Army Corps of Engineers' determination that two developments would have "no effect" on the pygmy owl or its habitat, even though

[7] NFFC also cites (Br. 9) *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472 (9th Cir. 2011), but there the Bureau of Land Management's "no effect" determination was not substantive—it was instead based on BLM's characterization of the regulations in question as "administrative changes," and, moreover, conflicted with FWS's conclusion that the regulations "*would* affect status species and their habitat." *Id.* at 495-97. In *Cal. ex. rel. Lockyer v. Dep't of Agric.*, 575 F.3d 999 (9th Cir. 2009), the agency's "no effect" determination was similarly based on its erroneous assumption that promulgation of the rule in question "simply created a new administrative procedure," even though it involved "repeal of … substantive protections afforded to inventoried roadless areas." *Id.* at 1019. And in *Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015), the Forest Service's decision to forego consultation was not based on any scientific analysis—only a mistaken determination that reinitiation under 50 C.F.R. § 402.16 had not been triggered. *Id.* at 1085-86. In contrast to these cases, EPA here made substantive (and reasoned) "no effect" determinations.

one of the development sites had previously been designated as "critical habitat for the … pygmy-owl." 414 F.3d 1066, 1070-71 (9th Cir. 2005). NFFC does not even attempt to reconcile its position with these cases, nor could it.

B. EPA Properly Exercised Its Discretion In Concluding That Registration Of Enlist Duo Would Have "No Effect" On Listed Species Or Their Habitat

NFFC also disregards that, under the relevant ESA implementing regulation, EPA was required to consult with FWS only if *EPA* determined that registration of Enlist Duo "may affect" a listed species or its habitat. 50 C.F.R. § 402.14(a) ("Each *Federal agency* shall review its actions at the earliest possible time *to determine whether* any action may affect listed species or critical habitat. *If such a determination is made*, formal consultation is required ….") (emphasis added); *see* Dow Br. 56-65. Accordingly, where an action agency makes a "no effect" determination—as EPA did here—it is exercising lawful discretion under the ESA. EPA more than satisfied its obligations under the ESA in concluding that registration of Enlist Duo would have "no effect" on any listed species but one (for which it did consult with FWS). ER24-26; Dow Br. 65-74. NFFC fails to demonstrate (Br. 10-20) that EPA's "no effect" determinations were arbitrary and capricious.

1. EPA Applied A Proper Methodology In Reaching Its "No Effect" Determinations

NFFC wrongly maintains (Br. 10-11) that EPA did not apply the proper standard because, according to NFFC, EPA "substitute[ed] FIFRA's less protective

standards and processes for the ESA's." But the ESA does not require any specific methodology in reaching a "no effect" determination, and, accordingly, the agency has discretion to apply the methodology that it deems best-suited for a particular risk assessment. *See Gifford*, 378 F.3d at 1066; Dow Br. 67-70.

While NFFC argues (Br. 10) that EPA's Levels of Concern ("LOC") are a "FIFRA risk interpretation tool," it ignores that EPA employs far more conservative LOCs and Risk Quotients ("RQ") when conducting ESA analyses. ER2530 ("Endangered species acute LOCs are a fraction of the non-endangered species LOCs, or, in the case of endangered plants, RQs are derived using lower toxicity endpoints than non-endangered plants."); ER73-74 & n.8 (EPA "established conservative effects thresholds for plants and animals based on effects to survival, growth, and reproduction," and "[w]ith labeled mitigation measures in place, exposures … fall below the direct effects thresholds established by the agency for threatened and endangered species"); *see* Dow Br. 68-70. The more conservative LOCs and RQs allow EPA to reach a "no effect" determination under the ESA, rather than a FIFRA-type determination that registration is "not likely to adversely affect" a listed species or habitat.

NFFC's argument (Br. 11-16) that EPA's "no effect" determinations were invalid because they "actually" demonstrate the "potential" to affect a listed species or critical habitat rests entirely on its mistaken interpretation of *Karuk Tribe*, and

should be rejected for this reason alone. As demonstrated (Dow Br. 79-82), moreover, far from being arbitrary and capricious, EPA's "no effect" determinations were properly based on species-specific conclusions that potential exposure to Enlist Duo was so low it would have "no effect" on each species.

2. EPA Properly Defined the "Action Area"

EPA also properly defined the "action area" as the corn, soybean, and cotton fields to which Enlist Duo is applied in the 34 states where it is approved for use. *See* ER25. "[T]he choice of appropriate action areas requires application of scientific methodology and, as such, is within the [action] agency's discretion." *Friends of the Wild Swan v. Weber*, 767 F.3d 936, 950 (9th Cir. 2014) (internal quotations omitted). EPA's choice of the appropriate action area here was reasonably based on its conclusion that Enlist Duo would not migrate off the treated field in quantities that could plausibly affect any organism when used according to the directions on the label—which is the "action" in question—due to the unique properties of 2,4-D choline. ER25; *see* Dow Br. 74-79.

NFFC argues (Br. 17) that EPA's "no effect" determinations were invalid because "some Enlist Duo will escape the fields," creating the possibility of some effect rather than no effect. Not only does this argument again turn on NFFC's erroneous interpretation of the "may affect" standard, *see supra* at 16-19, but EPA

addressed that possibility (ER73).[8] NFFC also wrongly suggests (Br. 18) that EPA's determination conflicts with an ESA regulation providing that the "action area" includes "all areas to be affected directly or indirectly by the federal action and not merely the immediate area involved in the action." 50 C.F.R. § 402.02. NFFC ignores that the regulation does not define "areas to be affected directly or indirectly"—a determination that is left to the agency and entitled to deference. *See Friends of the Wild Swan*, 767 F.3d at 950.

NFFC relies (Br. 18-19) on yet another misreading of *Karuk Tribe* in arguing that EPA should not have considered label use restrictions to arrive at its "no effect" determinations (*see* ER25-26). But in *Karuk Tribe*, this Court merely concluded that development of mitigation criteria was not a *substitute* for a "no effect" determination by the agency. *Karuk Tribe*, 681 F.3d at 1028 ("The fact that District Ranger Vandiver formulated criteria to mitigate effects of suction dredging on coho salmon habitat does not mean that the 'may affect' standard was not met."). It did not suggest that an agency conducting an ESA assessment should ignore use

[8] "EPA made no assumption that spray drift will stop at field boundaries. … EPA used the best available information to quantitatively evaluate the extent of spray drift under the use conditions described on the Enlist Duo label. The EPA then compared those results to available effect thresholds …. This comparison indicated that non-target organism exposures would be expected to be below effects thresholds off the treated field. This logically resulted in the confinement of the area where effects could reasonably be expected to occur to the treated field itself." ER73.

restrictions altogether. Nor did it remotely suggest that mitigation measures foreclose a "no effect" determination, a conclusion that would grind the registration process to a halt because mitigation measures are frequently employed.

3. EPA Properly Concluded That Enlist Duo Involved No New Uses For Glyphosate

NFFC erroneously maintains (Br. 20-21) that EPA was required to conduct a separate ESA assessment for glyphosate when it registered Enlist Duo, but this argument too fails. EPA properly determined that "Enlist Duo uses on GE corn, soybeans, and cotton *are already registered on other glyphosate products*" and accordingly, "no new assessment is needed for glyphosate." ER3. As shown (Dow Br. 46-49), EPA's conclusions that registration of Enlist Duo would not involve any "new use" of glyphosate and would not "significantly change the … volume of glyphosate used on corn, soybeans, or cotton," ER3, were supported by substantial evidence, and NFFC does not even attempt to demonstrate otherwise.

Indeed, EPA's approach was routine. Where, as here, "the use being requested for [a] combination product is currently registered for one or more of the active ingredients," EPA "does not conduct new assessments for the already registered uses." ER3. Instead, EPA reassesses an active ingredient's already registered uses during the registration review process for the active ingredient. ER 3; *see* Pesticides; Procedural Regulations for Registration Review; Final Rule, 71

Fed. Reg. 45,720, 45,726 (Aug. 9, 2006).[9] The Services have concurred in EPA's approach,[10] and Congress has encouraged it.[11] Because registration review can alter the scope of existing registrations, *see* 71 Fed. Reg. 45,720, 45,725, the glyphosate registration review proceeding—which is ongoing, *see* Registration Review; Glyphosate Docket Opened for Review and Comment, 74 Fed. Reg. 36,217, 36,219 (July 22, 2009)—is the appropriate forum for NFFC's glyphosate-related claims.

NFFC's suggestion (Br. 21) that EPA was instead required to ignore the registration history of Enlist Duo's active ingredients and conduct separate analyses even for previously registered uses, would completely paralyze the pesticide registration process. This is "alone a good reason for rejecting" NFFC's position. *Cf. Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 323–24 (2014) (strain on limited

[9] Accordingly, the Enlist Duo registration requires Dow to comply with any data requests EPA may make during registration review for glyphosate. ER 38.

[10] *See, e.g.*, EPA, NMFS, FWS & USDA, INTERIM REPORT TO CONGRESS ON ENDANGERED SPECIES ACT IMPLEMENTATION IN PESTICIDE EVALUATION PROGRAMS 2, 15 (Nov. 2014) ("INTERIM REPORT").

[11] *See, e.g.*, H.R. REP. NO. 113-333 at 532 (stating congressional expectation that EPA will generally address ESA compliance during registration review consistent with *Enhancing Stakeholder Input in the Pesticide Registration Review and ESA Consultation Processes and Development of Economically and Technologically Feasible Reasonable and Prudent Alternatives* at 2-3 (Mar. 2013)); 2018 Agriculture Improvement Act, H.R. 2, 115th Cong. § 10115 (2018) (requiring EPA, NMFS, FWS, and USDA to continue their efforts to maximize efficiencies in the consultation process, and requiring further reports).

governmental resources caused by EPA's interpretation of statute was "alone a good reason for rejecting" that interpretation).

4. EPA Employed The Best Available Science

NFFC also fails to establish (Br. 21-23) that EPA did not use the best available scientific and commercial data. NFFC argues (Br. 22) that the non-binding methodology in the NAS report was "the best available science," but Section 1536(a)(2) applies to "scientific and commercial *data*,"—i.e., facts and statistics—not methodologies. 16 U.S.C. § 1536(a)(2) (emphasis added); *see Friends of Santa Clara*, 887 F.3d at 924 ("The best available data requirement 'merely prohibits [the agency] from disregarding available scientific *evidence* that is in some way better than the *evidence* it relies on.") (emphasis added and alteration omitted). In any event, "[t]he determination of what constitutes the best scientific data available belongs to the agency's special expertise and warrants substantial deference," *id.* (quotation omitted), and EPA's approach here was well within its discretion.

NFFC asserts (Br. 22-23) that EPA previously acknowledged that the NAS report "was the best science available and followed it in the recent chlorpyrifos, malathion, and diazinon biological evaluations." But the NAS report itself recognized that transitioning to any of the various techniques it discussed would take time, and did not purport to identify the data needed for any transition. SBER58. The NAS report thus recommended that EPA "begin with simple registrations (for

example, pesticides for use on a few crops or in a small geographic area)." SBER128. Enlist Duo, by contrast, is now registered for use in 34 states (ER1-2)—not "a small geographic area." NFFC does not even attempt to show that the data necessary for departure from the RQ/LOC approach that EPA employed here was available, much less in EPA's possession.

Finally, NFFC's assertion (Br. 6 & n.4, 22-23 & n.17) that EPA "committ[ed] to follow" the proposed approach in the NAS report is incorrect. NFFC cites (Br. 6 n.4) a joint EPA, FWS, NMFS, and USDA document outlining proposed interim approaches based on the NAS report's recommendations, but that document described only a pilot program for *testing* the NAS report's recommendations.[12] And contrary to NFFC's characterization (Br. 22-23 n.17) of a 2014 interim report to Congress as including a "promise" that EPA would follow the NAS report's risk-assessment approach, that report confirmed that EPA would continue to apply its LOC/RQ approach "for all ecological assessments for all chemicals *other than chlorpyrifos, diazinon, malathion, carabryl, and methomyl*."[13] This multi-agency

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[12] EPA, FWS, NMFS & USDA, INTERIM APPROACHES FOR NATIONAL-LEVEL PESTICIDE ENDANGERED SPECIES ACT ASSESSMENTS BASED ON THE RECOMMENDATIONS OF THE NATIONAL ACADEMY OF SCIENCES APRIL 2013 REPORT 1 (Nov. 2013), epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

[13] INTERIM REPORT at 20 (emphasis added); *see* ER2529-49. NFFC points (Br. 7) to the "recent EPA biological evaluations for chlorpyrifos, malathion, and diazinon" as comparable situations where EPA "followed the [NAS report's] scientific methodology." But EPA used the NAS approach on those pesticides as part of the

report to Congress, moreover, stated that during the Enlist Duo registration process, "EPA scientists used highly conservative and protective assumptions to evaluate ecological risks for the new uses of 2,4-D in Enlist Duo," confirming that "these uses … will be protective of non-target species, including endangered species."[14]

III. REMAND *WITHOUT* VACATUR IS THE APPROPRIATE REMEDY FOR ANY ERROR

In the event this Court were to find any error in the 2017 Final Registration (it should not), the appropriate remedy would be remand to EPA *without* vacating the Enlist Duo registration. "Whether agency action should be vacated depends on how serious the agency's errors are 'and the disruptive consequences of an interim change that may itself be changed.'" *California Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (quotation omitted); *see also id.* at 993 ("In considering whether vacatur is warranted, [a court] must balance these errors against the consequences of such a remedy."). Vacating the Enlist Duo registration, which has been in effect (for some uses) for nearly five years, would be enormously disruptive

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pilot program, to test implementation of that methodology. *See* INTERIM REPORT at 9-12. As a result of the pilot program, EPA concluded that the NAS approach "did not meaningfully distinguish species that are likely to be exposed to and affected by the assessed pesticides from those that are not likely." *See* Pesticides; Draft Revised Method for National Level Endangered Species Risk Assessment Process for Biological Evaluations of Pesticides; Notice of Availability and Public Meeting, 84 Fed. Reg. 22,120 (May 16, 2019).

[14] INTERIM REPORT at 20.

to agriculture. That disruption vastly outweighs any possible error alleged by Petitioners.

As explained by amici, farmers have relied on Enlist Duo since it was first registered in 2014 and "[t]he continued availability of Enlist Duo is crucial to the production of three vital crops: corn, soybeans, and cotton." Farm Bureau Br. 5-6, 17-18. Vacatur of the Enlist Duo registration would "interrupt growers' current use of Enlist Duo," resulting in "lower per-acre yield rates for corn, soybean, and cotton crops" and disruption of the world's food supply. *Id.* at 17, 18.

Vacatur would also result in "increased expenditures for weed-management, and increased soil erosion due to increased tillage," and the development of glyphosate resistance in weeds may intensify," wreaking further havoc on the agriculture industry. *Id.* at 6, 18. Herbicide-resistant biotechnologies in general have revolutionized agriculture by allowing farmers to apply "herbicides 'over the top' during the growing season," rather than resort to "intensive tillage practices" such as hand-weeding and spot treatment. *Id.* at 13. But glyphosate-resistant weeds have, in turn, "threatened to undermine the benefits of herbicide resistant biotechnologies." *Id.* at 14. Glyphosate-resistant weeds also damage equipment and force farmers to use additional herbicides or "conventional tillage and hand-weeding,"—increasing costs—while also reducing production. *Id.* at 15-16. Because "Enlist Duo is effective to fight weeds that are resistant to glyphosate," *id.*

at 16-17, vacating the Enlist Duo registration would deprive farmers of the benefits of herbicide-resistant biotechnologies and increase farming costs while reducing revenues.

Vacatur would also have adverse environmental consequences. Enlist Duo has a favorable environmental profile—when Enlist Duo is applied consistent with its label, the potential for physical drift is minimized. *See* ER22-23; ER25-26; ER70-72; ER1043; ER1049-50. Thus, if the Enlist Duo registration were vacated, farmers would be forced to resort to herbicides with less favorable environmental characteristics, or other less environmentally-sound methods. Indeed, EPA determined that registration of Enlist Duo would not "significantly change the locations, methods, or volume of glyphosate used on corn, soybeans, or cotton." ER84; *see also* ER352 ("APHIS determined that Enlist corn and soybean varieties would not result in an increase in acres already in corn and soybean production."); ER443 (noting that "increase in 2,4-D usage [resulting from registration of Enlist Duo] would not likely displace other herbicide use and glyphosate use would be expected to stay roughly the same"). Accordingly, as EPA determined, "any decision on the Enlist Duo registration would likely have no effect on whether glyphosate continues to be used on corn, soybeans, and cotton—the decision would only impact which glyphosate product would be used." ER84; *see* Farm Bureau Br. 14.

These enormously disruptive consequences far outweigh any alleged errors here, making remand without vacatur the appropriate remedy in the event the Court grants either petition.

CONCLUSION

The petitions should be denied.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify this brief is 6,886 words long, excluding the items exempted by Fed. R. App. P. 32(f). The brief's type size and type face comply with Fed. R. App. P. 32(a)(5) and (6).

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing Supplemental Brief for Intervenor with the Clerk of 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 CM/ECF system.

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