IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Nos. 17-70810, 17-70817

NATIONAL FAMILY FARM COALITION, *ET AL.*
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY, *ET AL.*
Respondents,

and

DOW AGROSCIENCES LLC,
Intervenor-Respondent.

NATURAL RESOURCES DEFENSE COUNCIL,
Petitioner,

v.

ANDREW R. WHEELER, *ET AL.*,
Respondents,

and

DOW AGROSCIENCES LLC,
Intervenor-Respondent.

On Petition For Review of Agency Action
of the United States Environmental Protection Agency

BRIEF OF U.S. ENVIRONMENTAL PROTECTION AGENCY, ET AL.

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Academy	National Academy of Sciences
APA	Administrative Procedure Act
EPA	Environmental Protection Agency
ER	Petitioners' Excerpts of Record
ESA	Endangered Species Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FWS	Fish and Wildlife Service
LOAEC	Lowest Observed Adverse Effect Concentration
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
SER	Respondents' Supplemental Excerpts of Record
USDA	United States Department of Agriculture

INTRODUCTION

In these consolidated petitions for review, Petitioners National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Center for Biological Diversity, Center for Food Safety, Pesticide Action Network North America, Beyond Pesticides, Environmental Working Group, and Center for Biological Diversity ("National Family Farm Coalition" or "Coalition") and Petitioner Natural Resources Defense Council ("NRDC") (collectively, "Petitioners") challenge the United States Environmental Protection Agency's ("EPA")[1] action under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136a(c)(7)(B), amending a registration for the herbicide Enlist Duo. Intervenor-Respondent Dow Agrosciences LLC ("Dow") developed Enlist Duo so that farmers could better control weeds on genetically engineered corn, soybean, and cotton crops by being able to apply Enlist Duo to those crops after they have already begun to grow, *i.e.*, post-emergence. Enlist Duo is a combination of two active ingredients - "2,4-D" and "glyphosate" – and the corn, soybean, and cotton crops to which Enlist Duo will be applied have been genetically engineered to be resistant to those two active ingredients. ER2; ER93.

[1] Andrew R. Wheeler, Acting Administrator of the United States Environmental Protection Agency, is substituted for Scott Pruitt pursuant to Federal Rule of Appellate Procedure 43(c)(2).

In earlier litigation before this Court challenging a pre-existing Enlist Duo registration (issued in 2014 and amended in 2015), EPA sought and was granted a remand of that original registration to allow the Agency to further evaluate possible synergistic effects between the two active ingredients in Enlist Duo. During that remand, the original Enlist Duo registration (as amended) remained in effect and was never vacated. As will be explained herein, following the remand, EPA conducted further analysis to confirm that Enlist Duo, when used in conjunction with labeling conditions, meets all applicable health and environmental standards set forth in FIFRA and the Endangered Species Act ("ESA"). Thus, on January 12, 2017, EPA issued the registration amendment for Enlist Duo ("2017 Registration Amendment") that Petitioners challenge here.

JURISDICTIONAL STATEMENT

Petitioners bring their petitions for review under FIFRA Section 16(b), 7 U.S.C. § 136n(b), which provides for judicial review in the appropriate federal court of appeals of final EPA orders issued under FIFRA following a hearing. A petition for review of such orders must be filed within 60 days after entry of EPA's order. *Id.*; *see* 40 C.F.R. § 23.6. Under that judicial review provision, this Court has jurisdiction over EPA's January 12, 2017 order that amended the Enlist Duo registration under FIFRA Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B). *See United Farm Workers of Am., AFL-CIO v. EPA*, 592 F.3d 1080 (9th Cir. 2010). For the

reasons discussed below, however, NRDC does not have standing to substantively challenge EPA's FIFRA review of the glyphosate active ingredient in Enlist Duo and, to the extent NRDC seeks relief as to the 2014 registration of Enlist Duo, as amended in 2015, such request is time-barred under FIFRA Section 16(b), 7 U.S.C. § 136n(b).

ISSUES PRESENTED

1. Does substantial evidence support EPA's determination that the proposed new uses of Enlist Duo under the terms and conditions of the conditional registration would not generally cause unreasonable adverse effects under FIFRA Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B), where the determination was consistent with the statute and based on a rigorous scientific review that balanced foreseeable costs and benefits of the proposed new use?

2. Does NRDC have standing to challenge EPA's consideration of the glyphosate component of Enlist Duo where any alleged injuries are linked to other previously-registered pesticide products containing glyphosate for use on genetically engineered crops, and no decision by the Court on the 2017 Registration Amendment for Enlist Duo can redress those alleged injuries?

3. Did EPA reasonably determine that the 2017 Enlist Duo Amendment would have "no effect" on certain species and their critical habitat and thus that the

Agency did not need to initiate consultation with the Fish and Wildlife Service or National Marine Fisheries Service under Section 7, 16 U.S.C. § 1536, of the ESA?

STATEMENT OF THE CASE

I. STATUTORY AND REGULATORY BACKGROUND

A. FIFRA

FIFRA establishes a federal registration scheme that generally precludes the distribution or sale of any pesticide in the United States unless it is "registered" by EPA. 7 U.S.C. § 136a(a). A "pesticide" is "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest . . . ." *Id.* § 136(u). The form in which a pesticide is distributed or sold is a "pesticide product." 40 C.F.R. § 152.3. A "pesticide product" may contain one or more "active ingredients" (in addition to other ingredients). *See* 7 U.S.C. § 136(a) (definition of "active ingredient"); 40 C.F.R. § 152.3 (same). A FIFRA registration is a license that establishes the terms and conditions under which a pesticide product may be lawfully sold, distributed, and used in the United States. 7 U.S.C. § 136a(c); *see also Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002). These terms and conditions include the specific formulation that may be sold, the specific packaging it may be sold in, and labeling that contains, among other things, instructions on proper (and lawful) use. *See* 7 U.S.C. § 136(p); 40 C.F.R. §§ 152.115, 156.10.

FIFRA gives EPA authority to issue different types of registrations and amendments to registrations. For example, EPA shall issue an *unconditional* registration for a pesticide product under FIFRA Section 3(c)(5) if EPA finds that the pesticide will, among other requirements, perform its intended function without causing "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C). "Unreasonable adverse effects on the environment" is defined as:

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21.

Id. § 136(bb).

In certain special circumstances, EPA has discretion to *conditionally* register or amend a pesticide product. As relevant here, FIFRA Section 3(c)(7)(B), *id.* § 136a(c)(7)(B), authorizes EPA to amend a registration to permit a "new use" for currently-registered active ingredients in the pesticide product, "notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment," if EPA determines that "(i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment." A "new use" "means . . . [a]ny additional use pattern that would result in a significant increase in the level

of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms." 40 C.F.R. § 152.3.

EPA's evaluation of whether a proposed new use meets the registration requirements must take into account all registration terms and conditions relevant to that use. These may be stated in the registration as well as included on packaging and labeling requirements providing directions for and restrictions on use of the pesticide. *See* 7 U.S.C. § 136(p); 40 C.F.R. § 156.10. It is unlawful to use a pesticide "in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G). A registration's terms, conditions, and labeling statements therefore are integral to EPA's registration decision.

After EPA registers a pesticide product, the Agency is obligated to periodically review the associated active ingredients to ensure they continue to meet the current standard for registration. *See id.* § 136a(g) (registration review process). Specifically, under this registration review program, EPA is required to conduct registration review for currently-registered pesticide products by the later of October 1, 2022, or 15 years after the date on which the first pesticide containing a new active ingredient was registered, and at 15-year intervals thereafter. *Id.* § 136a(g)(1)(A)(iii), (iv). Both of the active ingredients in the Enlist Duo pesticide product are currently in the registration review process. *See* https://www.regulations.gov/docket?D=EPA-HQ-OPP-2009-0361 (current

registration review for all glyphosate products);

https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0330 (current registration review for all 2,4-D products).

B. ESA

Congress enacted the ESA in 1973 to, among other things, conserve species deemed to be endangered or threatened. *See* 16 U.S.C. §§ 1531(b), 1532(6), 1532(20), 1533. The ESA requires a list of all endangered or threatened species to be maintained. *Id.* § 1533(c). The ESA imposes certain legal requirements protecting "listed species." As pertinent here, ESA Section 7(a)(2) requires federal agencies to "insure that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification" of designated critical habitat. *Id.* § 1536(a)(2).

To help ensure compliance with this requirement, Section 7 and its implementing regulations delineate a process for determining the biological impacts of a proposed action known as Section 7 consultation. 16 U.S.C. § 1536; 50 C.F.R. pt. 402. Through this process, an agency proposing an action ("the action agency") must determine whether its action "may affect" a listed species or the designated critical habitat for a listed species. 50 C.F.R. § 402.14. If the action agency determines that its proposed action will have "no effect" on a listed species

or its designated critical habitat, Section 7 consultation is not triggered. *Id.* § 402.12.

Where the action agency determines that its action "may affect" listed species or designated critical habitat, it must consult with either the Fish and Wildlife Service ("FWS") or National Marine Fisheries Service ("NMFS"), depending on the species involved. *Id*. §§ 402.13, 402.14. There are two types of consultation: informal and formal. Informal consultation is an optional process that includes all discussions, correspondence, etc., between the action agency and consulting agencies undertaken to assist in determining whether formal consultation is required. *Id.* § 402.13(a). If during informal consultation the consulting agency concurs with the action agency's determination that the action is not likely to adversely affect listed species or critical habitat, the consultation process is terminated, and no further action is necessary. *Id*.

Section 4(b)(2) of the ESA requires FWS and NMFS to designate critical habitat for threatened and endangered species, to the maximum extent prudent and determinable. A listed species' "critical habitat" includes areas occupied by the species that are "essential to the conservation of the species" and whose "physical or biological features may require special management considerations or protection." 16 U.S.C. § 1532(5)(A)(i). Once FWS or NMFS designate critical habitat, Section 7 of the ESA requires Federal agencies to ensure they do not fund,

authorize, or carry out any actions that will destroy or adversely modify that designated habitat.

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Background on Enlist Duo

Dow developed the Enlist Duo herbicide for use on corn, soybean, and cotton crops that had been genetically engineered to be resistant to the active ingredients in Enlist Duo: 2,4-Dichlorophenoxyacetic acid, choline salt ("2,4-D") and glyphosate (which consists of N-(phosphonomethyl) glycine and dimethylammonium salt). ER2, 30. Corn, soybean, and cotton crops are important agricultural commodities in the United States, where soybeans are grown on approximately 85 million acres, corn on approximately 94 million acres, and cotton on approximately 9 million acres. ER29. The United States Department of Agriculture ("USDA") describes corn as one of the world's major feed grains and the primary feed grain in the United States; soybean as the world's largest source of animal protein feed and the second largest source of vegetable oil; and cotton as one of the most important textile fibers in the world. ER29-30. USDA estimates the annual United States gross production value of corn, soybean, and cotton at approximately 49, 48, and 6 billion dollars, respectively. *Id.*

Growers of these crops in the United States, however, have experienced yield and economic losses due to the spread of herbicide-resistant weeds. ER26,

28. "The need for additional tools to manage resistant weeds has become important as resistance to glyphosate and other herbicides has become a significant economic and pest management issue to growers." ER28. For genetically engineered corn, soybean, and cotton, the use of Enlist Duo "is expected to become an important part of a resistance management strategy for these crops." ER29.

Because Enlist Duo contains two active ingredients, it is referred to as a "combination product." ER3. By combining 2,4-D and glyphosate, each with overlapping weed control spectrums, Enlist Duo presents growers with an additional tool to effectively control broadleaf weeds in herbicide-resistant corn, soybean, and cotton. ER29-30. 2,4-D and glyphosate are both well-studied chemicals that have been registered for use in the United States since the mid-1940s and 1970's, respectively. *See* https://www.epa.gov/ingredients-used-pesticide-products/24-d; https://www.epa.gov/ingredients-used-pesticide-products/glyphosate; *see also* ER2, ER147, ER160. 2,4-D is already registered for a variety of food and feed uses, including use in the early growth stages of corn and in pre-plant applications of soybeans. ER28. Although 2,4-D has been a commonly-used broadleaf herbicide, the 2017 Registration Amendment for Enlist Duo will allow 2,4-D to be used on "post-emergence," *i.e.*, late-stage growth, corn, soybean, and cotton crops that have been genetically engineered to be resistant to

Enlist Duo. ER28. This post-emergence use of 2,4-D was a "new use" beyond the previously-registered uses for 2,4-D.

Conversely, the glyphosate component in Enlist Duo did not present a "new use" for this active ingredient. ER3. Glyphosate has been registered in pesticide products since the mid-1970's, ER2, ER147, ER160, and has been registered specifically for the same post-emergence use on glyphosate-resistant corn, soybean, and cotton crops since the 1990's as Dow requested in the Enlist Duo registration application. ER2. Given these pre-existing registrations for the same uses of glyphosate, EPA had already conducted various risk assessments on glyphosate. ER3-4.

B. EPA's FIFRA Registration History For Enlist Duo

On October 15, 2014, EPA issued a final order registering Enlist Duo under FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), for use on genetically engineered corn and soybean crops in six states ("2014 Registration").[2] ER1371-72, 1934, 1400; ER1401-1413. The 2014 Registration action was issued under FIFRA Section 3(c)(5) because at that time (1) EPA had satisfactory data concerning the proposed uses of Enlist Duo on genetically engineered corn and soybean crops, (2) there were no unfulfilled data requirements, and (3) approving the registration with

[2] The six states were Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin. ER2; ER1400.

the terms and conditions set forth therein would not cause any unreasonable adverse effect on the environment.[3] NRDC and National Family Farm Coalition challenged that 2014 Registration action. *See NRDC v. EPA*, No. 14-73353 (9th Cir. Oct. 30, 2014); *Center for Food Safety v. EPA*, No. 14-73359 (9th Cir. Oct. 30, 2014).

During the pendency of that litigation, EPA issued a final order amending the 2014 Registration to allow the use of Enlist Duo on genetically engineered corn and soybean crops in an additional nine states ("2015 Registration Amendment").[4] ER1055-56; ER1019-1040. NRDC and the National Family Farm Coalition also challenged the 2015 Registration Amendment. *See NRDC v. EPA*, No. 15-71213 (9th Cir. Apr 20, 2015); *Center for Food Safety v. EPA*, No. 15-71207 (9th Cir.

[3] The 2014 Final Decision Document contained a clerical error stating that the registration was being issued as a "conditional" registration under FIFRA Section 3(c)(7)(B). ER1394-1395. The Proposed Decision Document, however, correctly stated that the registration was proposed to be issued as an "unconditional" registration under FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), and the analyses and conclusions described in both the Proposed and Final Decision Documents were clearly contemplated to be – and were – in satisfaction of the "unconditional" registration standard under FIFRA Section 3(c)(5). The 2014 Notice of Registration, which is the actual "order" granting the registration, correctly identified the registration as "unconditional" under FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5). ER1401.

[4] The nine additional states were Arkansas, Kansas, Louisiana, Minnesota, Mississippi, Missouri, Nebraska, North Dakota, and Oklahoma. ER2; ER1019-1040; ER 1055-1060.

Apr. 20, 2015). (The cases challenging the 2014 Registration and 2015 Registration Amendment are hereinafter referred to as "*Enlist Duo I*"). The action in the 2015 Registration Amendment did not change the registration's status under FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5).

Before briefing could proceed for *Enlist Duo I*, EPA discovered that Dow had filed a patent application with the U.S. Patent and Trademark Office, claiming "synergism" between the two active ingredients in Enlist Duo. ER2-3.[5] Dow had not included data regarding such synergy in the information it provided to EPA in support of its application for the 2014 Registration and 2015 Registration Amendment. ER3. EPA therefore moved this Court for remand and vacatur of those two orders so the Agency could consider this information to determine whether it affected EPA's conclusions concerning the 2014 Registration and 2015 Registration Amendment. *Id*. On January 25, 2016, the Court granted the remand but denied EPA's request for vacatur, thereby leaving the 2014 Registration and its 2015 Registration Amendment in full effect. ER3; *see Enlist Duo I*, Case No. 15-71213, ECF No. 94. The Court also denied the petitioners' request to delay the

[5] In its patent application, Dow used the following definition of synergy: "an interaction of two or more factors such that the effect when combined is greater than the predicted effect based on the response of each factor applied separately." *See* ER473 (Non-provisional patent application at 0020). Dow also stated that "the herbicidal active ingredients are more effective in combination than when applied individually." *See id.*

mandate, which the Court issued on March 28, 2016, and denied petitioners' request to adjudicate the pending claims. *See Enlist Duo I*, ECF No. 132 (Case No. 14-73353). The Court further stated that "[t]he motion for voluntary vacatur of the registration of Enlist Duo is denied without prejudice to the rights of either party to litigate that question before the agency." *Id.* ECF #128. The *Enlist Duo I* Court did not retain any jurisdiction and closed the case.[6] The 2014 Registration as amended in 2015 therefore remained valid and in effect during the *Enlist Duo I* remand, and Enlist Duo has continued to be distributed, sold, and used during that time.

Following the remand, EPA directed Dow to provide the Agency with certain information concerning the potential "synergy" issue. ER4. Dow provided the requested data, which EPA used to address any uncertainty in its previous assessments. *Id.* After reviewing that additional data, EPA determined that the data supported the Agency's Enlist Duo decisions in 2014 and 2015. *Id.* Thus, EPA maintained the preexisting 2014 Registration, as amended in 2015, without any modification. ER5.

[6] Following the *Enlist Duo I* remand, NRDC submitted to EPA an administrative Petition to Cancel the Registrations for Enlist Duo Herbicide, dated May 17, 2016. EPA is evaluating, but has not yet acted on, that administrative Petition and there is no statutory or regulatory deadline for doing so.

On January 12, 2017, EPA granted an additional amendment to the Enlist Duo registration under the *conditional* amendment provision in FIFRA Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B) ("2017 Registration Amendment").[7] ER37-49. The 2017 Registration Amendment authorizes the use of Enlist Duo "post-emergence" or "over-the-top" on genetically engineered corn and soybean crops in an additional 19 states (for a total of 34 states), and added a new use for Enlist Duo on genetically engineered cotton crops in all 34 states.[8] ER37-49; ER1-36. "Post-emergence" or "over-the-top" application will allow users to apply Enlist Duo to control weeds after the crops have already started to grow while not damaging the crops. This provides farmers a much-needed additional tool for combatting the spread of weeds resistant to the commonly used herbicide glyphosate.

This resistance to glyphosate (the current market leader herbicide used on these crops) is having severe economic consequences, which weed control experts expect to increase without effective alternatives for weed control. ER29-30. Use of Enlist Duo on genetically engineered corn, soybean, and cotton is expected to give growers an alternative tool in their resistance management strategy for these

[7] The 2017 Registration Amendment expires in five years (on January 12, 2022), unless EPA extends it as part of a future Agency process. ER30; ER38.

[8] The additional 19 states were: Alabama, Arizona, Colorado, Delaware, Florida, Georgia, Kentucky, Maryland, Michigan, North Carolina, New Jersey, New Mexico, New York, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and West Virginia. ER2; ER89.

crops, which are extremely important agricultural commodities in the United States and the world. *Id*. Thus, Enlist Duo has been (for the last several years) and will continue to be an effective tool to treat glyphosate-resistant weeds, help reduce the spread of glyphosate-resistant weeds, aid significantly in crop production, and reduce economic losses to growers of these important crops. *Id*.

Because Enlist Duo is a combination pesticide product, EPA looked at each of the active ingredients to determine whether the uses being requested for 2,4-D or glyphosate were "new uses" or were uses that had been previously registered in other pesticide products. ER3; ER82-83. Only 2,4-D – not glyphosate – presented a "new use" in Enlist Duo because that active ingredient had not already been registered for post-emergence use on corn, soybean, or cotton crops. ER2-4. Conversely, pesticide products containing glyphosate have been registered since the 1990's for post-emergence use on genetically engineered crops (including the relevant corn, soybean, and cotton crops) and, thus, the requested uses for glyphosate in Enlist Duo did not present any new use pattern or new exposure. *Id.* EPA therefore was not required to conduct, nor did it conduct, any new assessments for glyphosate in considering whether to grant the 2017 Registration Amendment (or, for that matter, the 2014 Registration and 2015 Registration Amendment) for Enlist Duo. *Id*. Instead, because the application methods, use sites, use rates, and timing of application to these same crops that were being

requested for Enlist Duo were the same as those presented by previously-registered pesticide products containing glyphosate, EPA appropriately relied on its prior risk assessments and analyses conducted for previous glyphosate pesticide product registrations. ER4. Thus, none of EPA's decisions on Enlist Duo represent any "new use" authorization for glyphosate. For the "new use" of 2,4-D component of Enlist Duo, however, EPA conducted a full FIFRA analysis. ER3.

As explained above, EPA's 2014 Registration and the 2015 Registration Amendment were granted under FIFRA section 3(c)(5), 7 U.S.C. § 136a(c)(5), whereas the 2017 Registration Amendment was granted as a *conditional* registration under FIFRA Section 3(c)(7), *id.* § 136a(c)(7). When EPA granted the 2014 Registration and 2015 Registration Amendment for Enlist Duo, there were no outstanding data gaps identified for the active ingredient 2,4-D, generally. By 2017, however, EPA identified some data gaps during the ongoing FIFRA registration review process for 2,4-D generally. ER30. Because of that outstanding data in the registration review process, EPA was precluded from relying on FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), to grant the new post-emergence use on genetically engineered cotton. Instead, the proper statutory provision for registering the new use on cotton was Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B), the conditional amendment provision.

Although EPA merely granted the 2017 Registration Amendment as "conditional" under FIFRA Section 3(c)(7)(B), *id.*, the Agency continued to apply the more stringent standard for review of registrations under Section 3(c)(5), *id.* § 136a(c)(5). ER28-30; ER83-84. Thus, in issuing the 2017 Registration Amendment, EPA continued to apply the same standard that had been used in 2014 and 2015 to determine that the active ingredients in Enlist Duo would not generally "cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5); ER28-30. Logically, if a pesticide does not cause unreasonable adverse effects on the environment in the first instance, it necessarily cannot "significantly increase," 7 U.S.C. § 136a(c)(7)(B), the risk of unreasonable adverse effects, which is the statutory standard for conditional registrations. Thus, although the 2017 Registration Amendment for Enlist Duo was granted under Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B), EPA chose to apply the more stringent standard from Section 3(c)(5), *id.* § 136a(c)(5), in assessing Enlist Duo.

Finally, EPA granted its 2017 registration action as an "amendment" because, as explained above, the original 2014 Registration (as amended in 2015) had remained in full effect since its issuance and during the remand without vacatur in the *Enlist Duo I* litigation. Consequently, EPA's Decision Document supporting the 2017 Registration Amendment not only explained the rationale supporting the expanded use of Enlist Duo on genetically engineered corn and

soybean in 19 additional states and the new use of the product on genetically engineered cotton in all 34 states, but also reaffirmed the rationale underlying the still-existent registration for use on genetically engineered corn and soybean in 15 states. ER2-3. The Enlist Duo registration now includes all the registration actions taken in 2014, 2015, and 2017. Due, however, to the outcome of the *Enlist Duo I* litigation, the earlier registration actions in 2014 and 2015 (which remained valid during the remand) are not, and cannot be, challenged here.

C. EPA's Risk Assessment Process for Endangered Species

EPA undertakes a careful and extensive scientific analysis in all its ESA-related pesticide effects analyses. SER6-7; ER2511-2557. EPA follows a specific process based on sound science when assessing risks to listed species for pesticide products like Enlist Duo that are registered for use on genetically engineered herbicide-tolerant plants. ER70-71; ER2511-2557. EPA begins with a screening level assessment–which allows EPA to efficiently use its scarce resources by identifying those species for which it need not conduct a more refined analysis–that includes a basic ecological risk assessment based on its 2004 Overview of the Ecological Risk Assessment Process document. ER70; ER2511-2529. That assessment uses conservative default assumptions to establish estimated environmental concentrations of particular pesticides. ER70-71; ER2511-2529. If the screening level assessment results in a determination that no levels of concern

are exceeded, EPA concludes its analysis. ER71; ER 2520, 2547. On the other hand, where the screening level assessment (like the one done for 2,4-D) does not rule out potential effects (exceedances of the level of concern) based on the conservative default assumptions, EPA then uses increasingly specific methods and exposure models to refine its estimated environmental exposures. ER71; ER 2547-2557; SER16-17, 35-36, 139-140.

EPA determines that there is "no effect" on listed species if, at any step in the screening level assessment, no levels of concern are exceeded. ER 71, 2549, 2544. If, after performing all the steps in the screening level assessment, a pesticide still exceeds the Agency's levels of concern for listed species, EPA then conducts a species-specific refined assessment to make effects determinations for individual listed species. ER71, ER2547-2557. The determination that additional analysis is required does not amount to a "may affect" determination within the meaning of the ESA. ER72-73. The refined assessment takes account of species' habitats and behaviors to determine whether any listed species may be affected by use of the pesticide. ER72-73, 2547-2557. The screening level ecological risk assessment generates a series of taxonomic (e.g., mammals, birds, fish, etc.) risk quotients, which are the ratio of estimated exposures to acute and chronic effects endpoints. ER72-73, 2547-2557. These risk quotients are then compared to EPA-

established levels of concern to determine if risks to any taxonomic group are of concern. ER72-73, 2547-2557.

The levels of concern address risks for both acute and chronic effects. ER 71, 2529-2530. Acute effects levels of concern range from 0.05 for aquatic animals that are federally listed threatened or endangered species (listed species) to 0.5 for aquatic non-listed animal species and 0.1 to 0.5 for terrestrial animals for listed and non-listed species. ER71-73, 2529-2530, 2575 (discussing safety factor for listed species). The level of concern for chronic effects for all animal taxa (listed and non-listed) is 1. ER71-73, 2529. Plant risks are handled in a similar manner, but with different toxicity threshold used in risk quotient calculation for listed and non-listed species and a level of concern of 1 used to interpret the risk quotients. ER71-73, 2529-2530. When a given taxonomic risk quotient exceeds either the acute or chronic level of concern, a concern for direct toxic effects is identified for that particular taxon. ER71-73, 2529-2530. If risk quotients fall below the level of concern, a "no effect" determination is identified for the corresponding taxon. ER71-73, 2529-2530. EPA conducts a separate analysis as to specific areas designated as critical habitat. SER112-114; ER2534. It bases its critical habitat modification analysis on an assessment of how (1) 2,4-D would affect certain primary constituent elements ("PCEs") or principle biological

features ("PBFs") of habitat designated as "critical" by FWS or NMFS,[9] and (2) direct species effects outcomes would impact critical habitat's present and future ability to promote the conservation of the species. SER112. For 2,4-D, EPA concluded "modification" of designated critical habitat if the range of designated critical habitat co-occurs with a state for which 2,4-D is authorized *and* one or more of the following conditions existed:

1. FWS's or NMFS's information indicates that corn, cotton, or soybean fields are habitat for the species and there is a "may affect" determination for the species associated with 2,4-D use, as labeled.

2. FWS's or NMFS's information indicates that the species uses corn, soybean, or cotton fields and one or more effects on taxonomic groups predicted for 2,4-D on corn, cotton, and soybean fields would modify one or more of the designated PCEs and Primary Biological Features.

SER112. If the range of designated critical habitat does not co-occur with a state for which 2,4-D is authorized, EPA concludes "no modification." SER112; ER2534. Additionally, if the critical habitat co-occurs with an authorized state, but neither of these two conditions listed above is met, EPA also concludes "no modification." SER112. If either of the above conditions exists, EPA would

[9] In 2016, FWS removed the term "primary constituent elements" from its critical habitat regulation and replaced it with "physical and biological features." FWS, *Implementing Changes to the Regulations for Designating Critical Habitat*, 81 Fed. Reg. 7414, 7431 (Feb. 11, 2016) ("Having defined "physical or biological features," we are also removing the term "primary constituent element" and all references to it from the regulations in § 424.12."); *see also id.* at 7426, 7432.

conclude that 2,4-D may affect FWS or NMFS-designated critical habitat. SER112; ER2534.

D. ESA "No Effect" Determinations.

After conducting a number of ecological risk assessments, EPA observed that it would need to assess potential direct and indirect effects to ESA-listed species because the levels of concern for certain species were exceeded at the preliminary stage. SER1-2, 16-18. EPA stated that at the screening level it was not making effects determinations for taxa where the level of concern for listed species has been exceeded, but rather that EPA would conduct further evaluations for listed species in subsequent addenda to its assessment. SER17; ER538 ("potential" risk to birds); 539 ("potential" risks to mammals), 584 (more toxicologically, biologically, and geographically-relevant information on specific species is used for subsequent effects determinations).

EPA conducted multiple screenings and, later, species-specific ESA analyses as to 2,4-D. In 2013, as part of the 2014 Registration, EPA completed a FIFRA Section 3 registration screening level risk assessment for use of 2,4-D choline on corn and soybean that had been genetically engineered to be resistant to 2,4-D choline. SER1. On February 14, 2014, also as part of the 2014 Registration, using that 2013 risk assessment and published sources of species-specific biological information, EPA completed its first effects determination concerning multiple

species listed as threatened or endangered. SER1-2; ER1771-1818. On September 26, 2014, in connection with the 2015 Registration Amendment, EPA completed a second effects determination concerning listed species in ten additional states in response to a request to amend the Enlist Duo registration to include those states. SER2; ER1455-1533. On January 29, 2015, also in connection with the 2015 Registration Amendment, EPA finalized critical habitat modification determinations concerning uses of 2,4-D on genetically modified corn and soybean crops in sixteen states. SER2; ER1079-87.

In 2015, after obtaining a remand to consider possible synergistic effects between glyphosate and 2,4-D, EPA obtained and assessed additional information from the registrant. SER2. These data included testing of Enlist Duo for plant vegetative vigor and seedling emergence toxicity. *Id.* EPA used these data to address any uncertainty in its prior 2013-2015 assessments. SER2-3. After EPA reviewed the new information, because of the time that had lapsed since its earlier review, the agency decided to update its risk assessment for Enlist Duo. SER3. EPA further concluded that it would also need to assess the then-pending proposed use of Enlist Duo on herbicide resistant cotton. *Id.*

On October 19, 2016, EPA issued its new ESA analysis. SER2. The 2016 Ecological/ESA Assessment included a new screening level risk assessment addressing the ecological risks to non-target organisms from the use of 2,4-D.

SER3, 5, 16. It also included a new, updated effects determination for 531 ESA-listed species in the 34 states in which Enlist Duo was proposed for use on corn, cotton, and soybeans. SER3, 82-114. The 2016 Ecological/ESA Assessment differed in some material respects from the previous screening risk assessment and species-specific analyses. SER3-4. The 2016 Ecological/ESA Assessment first identified the number of species whose habitat overlapped with one or more of the authorized states. SER86.[10] For those species for which the screening level analysis did not preclude the possibility of potential effects, EPA next reviewed recovery plans and other FWS or NMFS documents for all listed species occurring in the 34 states in which Enlist Duo would be registered, to determine whether listed species in those states would be expected to occur within treated fields. SER6-8, 18-20, 82-124, 139-140, 159-431. EPA also reviewed FWS and NMFS

[10] EPA made five "likely to adversely affect" or "not likely to adversely affect" determinations concerning the Spring Creek bladderpod, the Audubon's Crested Caracara (one "likely to adversely affect" for corn and one "not likely to adversely effect" determination for cotton applications), the Eskimo curlew, and the Sonoran pronghorn antelope. SER6-7. As to those species for which EPA made "may affect, likely to adversely affect" or "may affect, not likely to adversely affect" findings, EPA either consulted with FWS or modified the label to exclude those counties where the species were found, resulting in no overlap between the expected use of Enlist Duo and those species' habitats. SER7-8, 19-20, 104, 106, 113-114, 120-121, 176, 409, 412 (Audubon's crested caracara); SER6-7, 19, 20, 86, 100, 113-114, 120, 306, 410, 414 (Sonoran pronghorn); SER6-7, 19, 87, 102-103, 113-114, 121, 174, 409, 412, 432-435 (Eskimo curlew); SER7-8, 19-20, 87, 111, 113, 120, 176, 410, 414 (Spring Creek bladderpod)). Petitioners do not challenge any aspect of EPA's analyses for these species.

recovery plans regarding habitat, dietary habits, and body weight. SER82-111, 119-121. EPA's 2016 Ecological/ESA Assessment took into account required mitigation restrictions related to nozzle use, speed and ground boom height maximums, wind speed and direction, humidity, restrictions on use during temperature inversions, and application when the wind is blowing towards adjacent commercially grown sensitive crops. SER2, 6, 14-15, 17-18, 22 26-27, 31, 63, 79, 81) ("Analysis of volatilization information for the 2,4-D choline products indicates that volatilization from the treatment site to off-site areas is not of concern."), 82 ("risks for non-target plants will not extend to off-treatment site areas"), 83-86, 111, 116. EPA separately conducted critical habitat analyses as to 184 potentially affected critical habitat designations in 2015, which it updated in the 2016 Ecological/ESA Assessment. SER112-114; *see also* SER18, 20, 70, 103 (Eskimo Curlew), 159-431; ER1079-87. After conducting all of these assessments, EPA determined that the ingredients would have no effect on a number of listed species and designated critical habitat. SER8 ("The Agency has considered the potential for modification of critical habitat for 531 listed species identified in the states of proposed product use. Critical habitats have been designated for 184 of the 531 species and the Agency reached a No modification determination for each."); SER18-20, 82-114.

SUMMARY OF ARGUMENT

EPA properly issued the 2017 Registration Amendment under FIFRA Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B), using an appropriate and more stringent legal standard than what that Section requires. EPA determined that the new use of 2,4-D for Enlist Duo on post-emergence genetically engineered cotton crops in 34 states, and the expanded use of Enlist Duo on genetically engineered corn and soybean crops in an additional 19 states, would not generally cause unreasonable adverse effects. That determination was more than sufficient to meet FIFRA's conditional registration standard in Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B). The 2017 Registration Amendment also had to be issued under Section 3(c)(7)(B), *id.* § 136a(c)(7)(B), (as opposed to Section 3(c)(5), *id.* § 136a(c)(5)) due to outstanding data for 2,4-D that EPA identified through the FIFRA registration review process for all 2,4-D uses. Further, EPA properly granted an amendment (rather than a new registration) to the Enlist Duo registration because the previous 2014 Registration and its 2015 Registration Amendment had remained valid and in effect following the *Enlist Duo I* remand.

In addition, EPA's scientific determinations are well-reasoned and support the Agency's 2017 Registration Amendment. The Coalition's scientific arguments lack evidence and are based on a misunderstanding of the registration process. Contrary to the Coalition's assertion, EPA relied on several lines of evidence

(which the Coalition does not address) to assess the volatility of 2,4-D. The Coalition simply is incorrect that EPA relied on only one study during its assessment, or that EPA's conclusions about volatility are flawed. Further, rather than challenge EPA's conclusions about the purported synergism of glyphosate and 2,4-D following the remand in *Enlist Duo I*, the Coalition raises a hypothetical concern about synergism with another chemical – glufosinate. The Coalition's argument that EPA had to consider a theoretical synergism (which is irrelevant to and entirely different from the synergism issue that prompted the remand in *Enlist Duo I*) finds no support in the statute and, furthermore, there is no evidence in the record of any potential synergistic effects between glufosinate and Enlist Duo. The Coalition entirely ignores that EPA properly imposed prohibitions (through Enlist Duo's label) against the tank mixing of Enlist Duo with any other pesticide product, unless certain scientific requirements are met and EPA approves the tank mix.

NRDC's scientific arguments fare no better. The record demonstrates that EPA assessed the risks to both monarch butterflies and to off-field milkweed (as opposed to milkweed in the actual crop fields on which Enlist Duo would be intended for use). That analysis, which NRDC does not seriously dispute, found no effects from Enlist Duo. The real gravamen of NRDC's argument seems to be, however, more of a general concern about the use of 2,4-D across all uses (not just

those authorized by the Enlist Duo registration), and the use of 2,4-D to do what it is intended to do – control milkweed in the crops where it is being applied. NRDC has the opportunity to bring forward those broad active ingredient concerns about 2,4-D in other fora, such as during the FIFRA registration review for all 2,4-D products.

As to the glyphosate component of Enlist Duo, NRDC does not have standing to challenge the 2017 Registration Amendment as it relates to glyphosate. Given the use of glyphosate in other registered pesticide products on these same crops at the same growth stages, NRDC has failed to show it has any injuries that are caused by the glyphosate in the 2017 Registration Amendment for Enlist Duo (as opposed to other registered pesticide products containing glyphosate), or that any such injuries could be redressed by a decision in its favor. Even if NRDC has standing to challenge the glyphosate component of Enlist Duo, however, its arguments as to that active ingredient lack merit. EPA was not required to conduct a new, independent analysis of glyphosate in issuing the 2017 Registration Amendment given that glyphosate has already been registered for these same uses and EPA appropriately relied on previous analyses for those registrations. Again, NRDC's concerns can be brought forward and addressed during the FIFRA registration review of glyphosate where all uses of glyphosate are being assessed.

EPA's decision to grant the 2017 Amended Registration also complies with the requirements of the ESA. EPA correctly applied its levels of concern approach to analyzing potential effects to listed species and their critical habitat. FWS and NMFS have espoused the levels of concern approach in a report to Congress. EPA assessed all possible impacts based on the best available information and, after making its effects determinations, completing informal consultation and addressing issues through precluding application in some counties (known as "off-labeling"), EPA concluded that there would be "no effects" to listed species. SER6-8. EPA also appropriately defined the action area as the fields where Enlist Duo may be applied based on the best available scientific data. Finally, EPA comprehensively considered potential impacts to critical habitat. Petitioners do not identify any aspect of EPA's level of concern approach, any risk quotient with which they disagree, or any primary constituent element of a species' critical habitat that EPA did not consider. As stated in *Karuk Tribe of Cal. v. U.S. Forest Serv.* 681 F.3d 1006, 1027 (9th Cir. 2012), Petitioners do not identify "any possible effect . . . of an undetermined character," occurring below EPA's levels of concern, that they believe EPA did not consider. EPA cannot prove the absence of an unidentified "effect." The Court should defer to EPA's expertise in assessing potential risk and benefits under FIFRA as well as the agency's effects determinations made under

the ESA and uphold these findings as reasonable and scientifically sound decisions underlying the 2017 Amended Registration of Enlist Duo.

ARGUMENT

I. STANDARD OF REVIEW

Under FIFRA, EPA's order granting the conditional 2017 Registration Amendment "shall be sustained if it is supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b); *see Nat. Res. Def. Council ("NRDC") v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013). This deferential standard requires courts to "affirm the Administrator's finding where there is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion even if it is possible to draw two inconsistent conclusions from the evidence." *Id*. (internal quotation marks and citations omitted); *see also Nw. Food Processors Ass'n v. Reilly*, 886 F.2d 1075, 1080 (9th Cir. 1989).

Further, when, as here, "the agency is making predictions, within its area of special expertise, at the frontiers of science[,] a reviewing court must generally be at its most deferential." *NRDC*, 735 F.3d at 877 (internal ellipses, quotation marks, and citations omitted); *United States v. Alpine Land & Reservoir Co.*, 887 F.2d 207, 213 (9th Cir. 1989) ("Deference to an agency's technical expertise and experience is particularly warranted with respect to questions involving . . . scientific matters."). An agency "is not required to support its finding with

anything approaching scientific certainty." *ASARCO, Inc. v. Occupational Safety & Health Admin.*, 746 F.2d 483, 490 (9th Cir. 1984) (internal ellipses, quotation marks, and citation omitted).

The Administrative Procedure Act ("APA"), Pub. L. No. 79–404, 60 Stat. 237 (1946), provides the standard of review as to the Coalition's ESA claims. Under the APA, a reviewing court may only set aside an agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *see, e.g.*, *Earth Island Inst. v. Carlton*, 626 F.3d 462, 468 (9th Cir. 2010) (internal quotation marks and citation omitted). "A decision is arbitrary and capricious only if the agency relied on factors Congress did not intend it to consider, entirely failed to consider an important aspect of the problem, or offered an explanation that runs counter to the evidence before the agency or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Lands Council v. McNair*, 629 F.3d 1070, 1074 (9th Cir. 2010) (internal quotation marks and citation omitted).

Review of all Petitioners' claims under the ESA and FIFRA is limited to the record before the Agency at the time of its decision. *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 743–44 (1985); *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005). The Court must therefore review EPA's 2017 Registration Amendment based on the record in existence at the time of that decision.

II. EPA'S 2017 REGISTRATION AMENDMENT SATISFIES FIFRA'S REQUIREMENTS.

A. EPA Properly Granted The 2017 Registration Amendment Under FIFRA Section 3(c)(7)(B) After Finding It Would Not Generally Cause Unreasonable Adverse Effects.

1. National Family Farm Coalition's arguments

EPA granted the 2017 Registration Amendment conditionally under FIFRA section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B), because (1) the 2017 amendment to the 2014 Registration (as amended in 2015) added a new use for post-emergence application to genetically engineered cotton, and (2) the Agency identified outstanding data during the separate registration review process for 2,4-D currently underway pursuant to FIFRA Section 3(g), *id.* § 136a(g); ER4; ER30. Nonetheless, in granting the 2017 Registration Amendment, EPA used the more stringent standard from FIFRA Section 3(c)(5) to determine that the registration would "not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5). In applying this standard, EPA went beyond what was required under the conditional registration provision in Section 3(c)(7)(B), which is to determine that the registration "would not significantly increase the risk of any unreasonable adverse effect on the environment." *Id.* § 136a(c)(7)(B). Indeed, EPA weighed the risks against the benefits and found that the new post-emergence use of Enlist Duo on cotton crops genetically engineered to be resistant to Enlist Duo, and the expansion of Enlist Duo to an additional 19 states on genetically

engineered corn and soybean crops, would not generally cause unreasonable adverse effects on the environment.[11]

National Family Farm Coalition mounts a meritless statutory challenge to EPA's use of the more stringent standard (claiming the standard actually is less stringent), arguing that EPA used "the wrong legal standard" and therefore "never made the statutorily-mandated findings, for a conditional approval of a pesticide new use." Coalition Br. 56-59. That argument is illogical and belied by the plain purpose of the conditional registration provision.

FIFRA provides that to grant a registration under Section 3(c)(5), EPA must determine that the pesticide "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C). In the case of a proposed new use for an active ingredient in a previously-registered pesticide, however, the Agency may lack data necessary to grant an unconditional registration. When there are missing data associated with the active ingredient, generally, but not data specific to the use being reviewed, EPA can only consider a *conditional* registration or amendment for the new use under Section 3(c)(7)(B) so long as the new use "would not significantly increase the risk of any unreasonable adverse effect on the environment." *Id*. § 136a(c)(7)(B). The purpose behind this conditional registration and amendment provision in Section 3(c)(7)(B) is to provide EPA

[11] *See*, *e.g.*, ER28-30 (showing EPA's consideration of the benefits of Enlist Duo).

flexibility in making registration decisions. Indeed, in 1978 when Congress added the conditional registration provisions in Section 3(c)(7), it expressed its belief that "[t]he single largest problem [with FIFRA] [wa]s the fact that the registration and reregistration process ha[d] ground to a virtual halt," harming the "availability of pesticides." S. Rep. No. 95-334 at 3. In particular, EPA's "inability to issue registrations on a conditional basis" was a "serious impediment in the present registration program." *Id.* at 4. Through these amendments to FIFRA, Congress sought to rectify the slow pace of registrations by providing EPA the "flexibility" to grant conditional registrations in certain circumstances. *Id.*

One bit of flexibility offered by the 1978 amendments was allowing EPA to amend a currently-registered pesticide to add a new use. "In this situation, the Administrator could grant a conditional registration after an applicant has provided all the necessary test data to show the safety of the pesticide in the new use even though some data gaps exist for the current registration." S. Rep. No. 95-334 at 10; *see* 48 Fed. Reg. 34,000, 34,001 (July 26, 1983) (citing S. Rep. No. 95-334 at 20-21; H.R. Rep. No. 95-663 at 28) ("FIFRA section 3(c)(7) is intended to allow the issuance of conditional registrations without having all the data necessary to support unconditional registration, and . . . a comprehensive analysis of the risks and benefits of a pesticide need not be performed until it is accomplished for all similar products already on the market."). Thus, when presented with a new use

for an already-registered pesticide product, EPA may conditionally amend the registration to permit those additional uses, even if the data concerning the relevant active ingredient may be insufficient to support an unconditional registration or amendment under Section 3(c)(5), 7 U.S.C. § 136a(c)(5). In doing so, EPA must determine that (1) the applicant has submitted satisfactory data pertaining to the proposed additional use that is necessary to make the registration determination, and (2) amending the registration in the manner proposed by the application would not significantly increase the risk of any unreasonable adverse effect on the environment. *Id.* § 136a(c)(7)(B). If EPA makes those determinations, it may issue a conditional registration or amendment, thereby making the pesticide product available to meet pest-control needs. *See* S. Rep. No. 95-334 at 3.[12]

This determination under Section 3(c)(7)(B) that a new use will "not significantly increase the risk of any unreasonable adverse effect[s]" is a lower bar than the determination in Section 3(c)(5) that the pesticide will not cause "unreasonable adverse effects." *Compare* 7 U.S.C. § 136a(c)(5) *with id.* § 136a(c)(7)(B). In other words, if there is a determination that there generally are no unreasonable adverse effects to begin with, there cannot be any increased risk

[12] The entirety of FIFRA Section 3(c)(7) supports that Congress intended to allow conditional registrations to make registration decisions easier than registrations under FIFRA Section 3(c)(5). *See* 7 U.S.C. § 136a(c)(7)(A), (B).

of unreasonable adverse effects. Such a determination is more than sufficient to meet the FIFRA conditional registration standard in Section 3(c)(7)(B).

Here, EPA used the more stringent standard and concluded that amending the Enlist Duo registration to allow the new uses of 2,4-D would "not cause unreasonable adverse effects on man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide." ER28. Although that finding would have been sufficient to grant a registration under Section 3(c)(5), EPA determined that the Enlist Duo registration could *only* be conditionally amended under Section 3(c)(7)(B) because, as described earlier, additional data were found to be necessary for all 2,4-D products (unrelated to the new uses presented with Enlist Duo) during the ongoing FIFRA registration review. ER30. The Coalition nonetheless insists that EPA should have applied the less stringent standard from Section 3(c)(7)(B). Coalition Br. 56-59. Based on the plain statutory language, however, if a new use has been determined to *not cause* unreasonable adverse effects in the first place, it necessarily will not significantly *increase* the risks of such effects.

Here, EPA determined there were no unreasonable adverse effects from either the new use of 2,4-D on genetically engineered cotton in 34 states, or the expansion of Enlist Duo to an additional 19 states (for a total of 34 states) for use on genetically engineered corn and soybean crops:

> [a]fter weighing all the risks of concern against the benefits of the new uses, the EPA finds that with the required mitigation measures on the approved labeling, the risks that may remain *are minimal*, if they exist at all, while the benefits are potentially great. Therefore the benefits outweigh the risks and registering these uses will not generally cause unreasonably adverse effects on human health or the environment during the 5-year time limited registration. . . .

ER30 (emphasis added). A "minimal" risk (to the extent it exists at all) is plainly less than any "significant increase" in risk. That EPA did not use the Coalition's preferred parlance, *i.e.*, the less stringent standard from Section 3(c)(7)(B), does not invalidate EPA's substantive conclusions. *Cf. Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (holding that requirement to articulate satisfactory explanation for agency action "is satisfied when the agency's explanation is clear enough that its 'path may reasonably be discerned'" (quoting *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974)).

Moreover, EPA determined that Dow had submitted satisfactory data pertaining to the proposed additional use. 7 U.S.C. § 136a(c)(7)(B). EPA did not conclude (as the Coalition claims) that it lacked sufficient data to assess harm from Enlist Duo's new uses. Rather, EPA stated that "[a]lthough there are currently *no outstanding data require[d] to support the registration of this action*, the EPA has identified data that will be required in connection with registration review activities for 2,4-D." ER30 (emphasis added). EPA further stated that it "believes that the available data and scientific assessments as well as the overall considerations for

benefits for weed management in these important crops *support a FIFRA Section 3(c)(7)(B)* registration finding for the new uses." *Id.* (emphasis added). These conclusions show that EPA met the criteria under Section 3(c)(7)(B), notwithstanding that there were outstanding data issues associated with the separate registration review process. *Compare* Coalition Br. 58 (arguing EPA did not meet the two criteria under Section 3(c)(7)(B).

2. NRDC's arguments

As already established, Enlist Duo has been registered since 2014 (and was amended in 2015). Neither the Court nor EPA ever invalidated, vacated, or cancelled those prior registrations. *See supra* at 13-14. Thus, the Enlist Duo registration actions taken in 2014 and 2015 have remained in effect even after the remand in *Enlist Duo I*. *See id.* EPA therefore *only amended* the previously-amended Enlist Duo registration. These facts are undisputed, yet NRDC misleadingly asserts that Enlist Duo is a "new pesticide, never before registered" and, as such, cannot be "eligible for amended registration" under FIFRA Section 3(c)(7)(B). NRDC Br. 35. NRDC's arguments concerning the statutory interpretation of Section 3(c)(7)(B), NRDC Br. 35-43, ignore the facts and do nothing more than try to set the stage to argue that EPA should have used the standard from the unconditional registration provision in Section 3(c)(5) – which is precisely what EPA did.

a. EPA properly relied on FIFRA Section 3(c)(7)(B) when it issued a conditional amendment to the previous Enlist Duo registration.

EPA properly relied on FIFRA Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B), to grant a conditional amendment in 2017 to the pre-existing Enlist Duo registration. NRDC, however, attempts to turn back the clock to 2014 and argue that, in 2017, EPA was looking at an "inaugural use of Enlist Duo." NRDC Br. 39; *see generally id.* 35-39. According to NRDC, EPA could not rely on Section 3(c)(7)(B) in 2017 to issue an amendment because Enlist Duo was a "distinct and novel pesticide" in that glyphosate and 2,4-D had never been combined in a product before. *Id.* 38; *see also id.* 36 ("As a novel mixture of glyphosate, 2,4-D, and various inert ingredients, Enlist Duo is a new pesticide."). Under NRDC's theory, EPA could only issue a *new* registration under Section 3(c)(5) using the more stringent legal standard discussed *supra* Argument I.A.1. NRDC hinges its entire argument on incorrect factual and legal assumptions about the validity of the 2014 Registration and its 2015 Registration Amendment, by arguing there was "no lawful registration of" Enlist Duo "in the first place" and, thus, nothing that could be amended. NRDC Br. 35. NRDC's theory is wrong both factually and legally.

An Enlist Duo registration has been in effect since 2014. For the three years preceding EPA's 2017 Registration Amendment, there was never a time when Enlist Duo was not authorized under FIFRA for sale, distribution, and use on

genetically engineered corn and soybean crops in 15 states. In fact, these authorizations have remained available even during the remand in *Enlist Duo I* because the Court did not vacate the 2014 Registration or its 2015 Registration Amendment, specifically denying EPA's 2015 motion to vacate the registration. *Supra* at 13-14. When an applicant seeks to amend an existing registration and add a new use for an active ingredient (as Dow did here), EPA is not required to pretend that no previous registration exists and start a whole new registration process. Instead, EPA can proceed (as it did here), under Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B), to grant an amendment that adds a new use to a previously approved registration. Indeed, EPA explained that "[t]his final decision reaffirms the Agency's earlier decision to register Enlist Duo, on [genetically engineered] corn and soybean *that are currently registered*." ER2 (emphasis added). EPA was not required to consider a *new*, rather than *amended*, registration for Enlist Duo.

Based on this legal and factual understanding, there is no dispute that the 2014 Registration and its 2015 Registration Amendment have remained in place, even during the remand (without vacatur) from the *Enlist Duo I* litigation. Yet NRDC makes a tortured analysis of Section 3(c)(7)(B), NRDC Br. 37, claiming EPA's reliance on that section to amend the pre-existing registration amounts to a rewrite of the statute. There is no dispute here over the interpretation of Section 3(c)(7)(B), as NRDC would have the Court believe. The only dispute is whether

EPA properly relied on that provision to issue an amended registration, which it did. The Court should reject NRDC's attempt to pretend that no valid registration for Enlist Duo existed by eviscerating the Court's specific decision to *deny* EPA's motion to vacate the 2014 Registration (as amended in 2015).[13]

b. EPA provided a reasonable explanation for issuing a conditional amendment under Section 3(c)(7)(B).

NRDC next attacks EPA's reliance on FIFRA Section 3(c)(7)(B) by arguing that EPA failed to provide any reasoned explanation for issuing a conditional amendment under that Section. NRDC Br. 38-39. EPA's rationale, however, is reasonable and well-explained: there was a new use proposed for 2,4-D and EPA determined there were outstanding data during the separate 2,4-D registration review. ER30. This combination of facts prevented EPA from using any other statutory provision to amend the Enlist Duo registration.

EPA and NRDC agree that the Agency can "conditionally amend the registration of [Enlist Duo] to permit additional uses of [Enlist Duo] after Enlist Duo has already been lawfully registered." NRDC Br. 39 (internal quotation marks omitted). That is precisely what happened here – as discussed above, EPA first registered Enlist Duo in 2014, amended it in 2015, and that registration remained in effect. NRDC insists, however, that EPA could not conditionally

[13] As explained *infra* Section II.B.2.a, NRDC also is time-barred from seeking any relief as to the 2014 Registration and 2015 Registration Amendment.

amend the Enlist Duo registration in 2017 because the entire pesticide product that comprises Enlist Duo presented an "inaugural" or "novel" use for which EPA could not issue a conditional amendment under FIFRA Section 3(c)(7)(B), 7 U.S.C. § 136a(c)(7)(B). NRDC Br. 39. NRDC's argument in this regard misunderstands the distinction between review of a specific a "pesticide product" and the review of all uses for each "active ingredient" that EPA assesses during the FIFRA registration process. A brief explanation of that process therefore is helpful.

Applications for FIFRA registrations that are submitted to EPA must contain, *inter alia*, a complete formulation of the "pesticide product" for which registration is sought. Here, that formulation consists of two "active ingredients" – 2,4-D and glyphosate. If EPA determines that the application should be granted, the Agency issues a FIFRA registration under FIFRA for the "pesticide product," which is the "pesticide in the particular form (including composition, packaging, and labeling) in which the pesticide is, or is intended to be, distributed or sold." 40 C.F.R. § 152.3. Active ingredients in any particular pesticide product may already be registered for use in other pesticide products. An existing registration therefore may be amended if there is a "new use," *see supra* at 5-6 (definition of "new use" under 40 C.F.R. § 152.3) for one of the active ingredients, but not for other active ingredients. Thus, when EPA receives an application for a pesticide product that

contains more than one active ingredient, the Agency looks to whether there is "new use" proposed for any of those active ingredients.

Here, the only new use that was requested for Enlist Duo was for the 2,4-D active ingredient – not for the glyphosate active ingredient. When EPA did its first review of Enlist Duo in 2014, glyphosate had already been registered in other pesticide products for post-emergence use on genetically engineered corn, soybean, and cotton crops and has been widely used for such purposes since the 1990s. ER2.[14] Thus, the Enlist Duo registration in 2014 – as amended in 2015 and 2017 – did not expand the use sites or conditions for glyphosate on glyphosate-resistant corn, soybeans, and cotton, and the inclusion of glyphosate as an active ingredient Enlist Duo did not represent a new use for glyphosate. EPA therefore was not required to conduct any new analysis of that already registered active ingredient and, instead, reasonably relied on previous glyphosate analyses for the same uses sought. Thus, EPA's review of glyphosate was limited to confirming that the post-emergence application method, the use sites, and the use rates already registered in

[14] NRDC acknowledges this prior registration of glyphosate: "In contrast [to 2,4-D], all of Enlist Duo's uses of glyphosate on glyphosate-resistant corn, soybeans, and cotton are shared by previously registered pesticides containing glyphosate (many developed by Monsanto Co. and marketed under the trade name Roundup)." NRDC Br. 10.

other pesticide products were substantially similar to what was sought for Enlist Duo. *See* ER4.

The 2,4-D active ingredient, however, was different. Although 2,4-D had a long history of being registered in a variety of other registered pesticide products, as of 2014, this active ingredient had not previously been registered for post-emergence use on 2,4-D resistant corn or soybeans. ER3. The post-emergence use of 2,4-D on 2,4-D-resistant cotton was a "new use" that had not previously been registered in any other pesticide product. EPA's assessment of 2,4-D therefore was much more extensive than the review for glyphosate. ER2-5; ER28-30. As discussed earlier, EPA further determined that there were outstanding data in the separate FIFRA registration review process for 2,4-D in general, but that the data were not specific to the cotton use that was registered in the 2017 Enlist Duo registration action. ER4; ER30. The application for a new use and the existence of that outstanding data for 2,4-D precluded EPA from issuing another amendment for Enlist Duo under Section 3(c)(5), 7 U.S.C. § 136a(c)(5). EPA, therefore appropriately conditionally amended the pre-existing Enlist Duo registration under Section 3(c)(7)(B), *id.* § 136a(c)(7)(B).

With that correct understanding of EPA's FIFRA process, there can be no question that EPA appropriately issued a conditional registration amendment in 2017 under FIFRA Section 3(c)(7)(B) for Enlist Duo. EPA's articulation of its

rationale (ER4, ER 28-30) is eminently reasonable and provides a sound basis for upholding EPA's use of Section 3(c)(7)(B) to issue the 2017 Registration Amendment. *Compare* NRDC Br. 39 (quoting *NRDC v. EPA*, 857 F.3d 1030, 1036 (9th Cir. 2017) ("*Nanosilver II*") ("[A]n agency's action must be upheld, if at all, on the basis articulated by the agency itself.")).

c. EPA's 2017 Registration Amendment under Section 3(c)(7)(B) is consistent with the statute and Congressional intent.

As discussed above, the purpose of the conditional registration provision in Section 3(c)(7)(B) was to give EPA flexibility to issue conditional registrations where, despite outstanding data for a particular pesticide that would preclude an *unconditional* registration, there nonetheless is sufficient data on the new use to issue a conditional registration or amendment. Indeed, when "data concerning the pesticide may be insufficient to support an unconditional amendment," 7 U.S.C. § 136a(c)(7)(B), EPA does not just deny the amendment; rather, Congress gave EPA the flexibility to issue a conditional registration or amendment. *See supra* Argument I.A.1. Here, as already explained, because EPA identified "outstanding data that will be part of the registration review process" for all 2,4-D products, ER4, EPA was precluded from issuing an unconditional registration under Section 3(c)(5), as NRDC urges. NRDC Br. 42.

NRDC argues, however, that EPA's reliance on Section 3(c)(7)(B) allowed EPA to "ignore[] critical evidence of risks" posed by the glyphosate in Enlist Duo and thereby undermines FIFRA's purpose. NRDC Br. 41-43. Quite the contrary, EPA's analysis of glyphosate in 2017 was the same as it was in 2014 and 2015. Neither FIFRA section 3(c)(5) nor 3(c)(7)(B) requires a new assessment of a chemical that has already been approved and is widely used for the same uses. NRDC is wrong that EPA's reliance on the conditional registration provision "allow[s] the agency to defer evaluating relevant evidence of Enlist Duo's risks, thereby undermining the statute's core purpose to prevent unreasonable harm from pesticide use." NRDC Br. 42. Rather, EPA's reliance on the conditional registration provision is entirely consistent with the Congress' intent behind that provision – to give EPA flexibility to issue conditional registrations where there is a need for additional data, but there are satisfactory data to support the proposed use. 7 U.S.C. § 136a(c)(7)(B). Here, EPA had satisfactory data to support a conditional amendment for the new use for 2,4-D.

On the other hand, because the 2017 Registration Amendment did not authorize a new use of glyphosate, EPA was not required to conduct yet another assessment for uses of glyphosate that already have been registered – that is the very purpose of the ongoing registration review process under FIFRA Section 3(g). *See supra* Argument I.A.1; *see also* ER3-4. Indeed, nothing in Section 3(c)(7)(B)

or EPA's implementing regulation at 40 C.F.R. § 152.113 requires EPA to conduct a new assessment for an active ingredient in a pesticide product when no new use is sought for that active ingredient.

To require otherwise, as NRDC demands, would be contrary to the plain language of the statute as well as Congress' clear intent to eliminate "serious impediment[s]" to FIFRA registrations. S. Rep. No. 95-334 at 3-4; *see* 48 Fed. Reg. 34,000, 34,001 (through Section 3(c)(7)(B), Congress recognized "that a comprehensive analysis of the risks and benefits of a pesticide need not be performed until it is accomplished for all similar products already on the market.") (citing S. Rep. No. 95-334 at 20-21 and H.R. Rep. No. 95-663 at 28). NRDC argues against Congress' clear intent to forego any requirement for a comprehensive analysis in the very type of situation presented here, where an active ingredient (glyphosate) is already registered for the uses sought, and Enlist Duo along with all similar products containing glyphosate will go through a full FIFRA analysis in registration review (all uses of glyphosate will be reevaluated). As discussed, registration review is the avenue Congress intended to reevaluate already-registered products and consider whether the active ingredient continues to meet FIFRA standards. Under Section 3(g), 7 U.S.C. § 136a(g), EPA is required to reassess *all* uses of *every* pesticide product every 15 years. *Id.* § 136a(g)(1)(A)(iv). It is in that forum where all uses of glyphosate will be

evaluated. That is the appropriate time and place for reviewing this active ingredient, since the uses sought for registration were already registered on other pesticide products containing glyphosate. That registration review process for glyphosate is underway. *See* https://www.regulations.gov/docket?D=EPA-HQ-OPP-2009-0361.[15] The registration review process therefore is the appropriate forum for NRDC to raise its glyphosate concerns, where *all* glyphosate uses are being reviewed.[16] Congress simply did not intend, nor does the plain language of Section 3(c)(7)(B) or Section 3(c)(5) require, EPA to conduct a new analysis of an active ingredient contained in a combination product that was already registered for the uses sought in another pesticide product.

B. The 2017 Registration Amendment Is Supported By Substantial Evidence.

1. National Family Farm Coalition's argument

a. EPA's assessment regarding Enlist Duo's volatility is reasonable.

EPA reviewed multiple studies to determine that the 2,4-D in Enlist Duo exhibited lower volatility and off-site vapor drift than other registered forms of 2,4-

[15] Also, the registration review process for all 2,4-D products is underway and outstanding data have been identified, which is the impetus for EPA's issuance of a conditional rather than unconditional amendment here. *See* https://www.regulations.gov/docket?D=EPA-HQ-OPP-2012-0330.

[16] There are several opportunities for public input in this process. *See* 40 C.F.R Part 155.

D, and that determination was reasonable.[17] The Coalition's technical attacks on EPA's analysis are based on a fundamental misunderstanding of EPA's process and a misrepresentation of the studies on which EPA relied.

(i) The starting point of EPA's analysis was a study that examined visual plant damage from 2,4-D.

The Coalition incorrectly argues that "EPA used [a] single study" to assess the volatilization of 2,4-D choline salt. Coalition Br. 60. The sole basis of their allegation is their reference to one laboratory study submitted by Dow (hereinafter referred to as the "Ouse study."). *See* SER678-706. Contrary to the Coalition's allegation, this Ouse study merely provided a starting point – not the sole basis – for EPA's analysis.

The purpose of the Ouse laboratory study was to examine the degree of visual damage or injury, *i.e.*, "visual plant damage," (like cupping of leaves or twisting of foliage) to sensitive plants[18] caused by exposure to vapors of 2,4-D. SER685. The study developed a curve to indicate the level of visual plant injury that would occur at a particular dose of 2,4-D vapor over various lengths of time

[17] "Volatilization" or "vapor drift" means the movement of pesticide vapors through air after application. *See, e.g.*, https://www.epa.gov/reducing-pesticide-drift/pesticide-volatilization "Non-target" plants are those found off of the targeted field on which the pesticide product is being applied.

[18] The sensitive plants tested were grape, cotton, soybean, and tomato.

("dose-response curve").[19] SER685. Although identifying visual plant damage was helpful in developing this dose-response curve, the study was limited in that it did not provide the information necessary to translate visual plant damage to the necessary regulatory measure – plant growth or survival – that EPA needed to appropriately assess volatility. In other words, the study provided the dose-response curve for visual plant damage, but did not by itself tell the Agency what dose level would cause a statistically significant decrease in a plant's growth or survival rate.

EPA noted the limitations of this visual plant damage study in the Agency's "Data Evaluation Record," which represents EPA's review of that study. ER3190-3194. In that Data Evaluation Record, EPA classified the visual plant damage study as supplemental, meaning that it had limitations but was nonetheless useful to the Agency's ultimate Risk Assessment. ER3190; 3192. That limitation, however, did not mean this study had no use in EPA's assessment of 2,4-D's volatilization; rather, this visual plant damage study provided the *first* – but not the *only* – step in EPA's 2016 assessment of the volatility issue, which became part of EPA's 2016 Risk Assessment.

[19] Although the study developed a separate dose-response curve for four different plants – grape, cotton, soybean, and tomato – for convenience this document refers to a single "dose-response curve," referring to the dose-response curve for the most sensitive species: grape. SER698, Fig.4.

(ii) EPA next looked at additional studies to relate the Ouse study to plant growth and survival.

To understand the relationship of the Ouse study to EPA's volatility assessment, it is important to understand how EPA assesses risk to non-target plants from volatility. In conducting risk assessments for non-target plants (including potential risks from volatilization or vapor drift), EPA determines the pesticide dose at which statistically significant impacts to a plant's growth and survival appear, ER2484-2575, which provides a quantitative and "clearly defined assessment endpoint[]" (*i.e.*, a measurement for effects) for making that determination. ER2514 (citing "Seedling" and "Vegetative Vigor" Test Guidelines)).[20] In contrast, measures of visual plant damage (like that used in the Ouse study) are not normally used quantitatively in risk assessments. As EPA noted, because visual plant damage is not normally used quantitatively in risk assessments, EPA would need to determine the relationship to plant growth or survival. ER3191-3192; *see also* ER2082 ("Plant damage endpoints are not normally used quantitatively in risk assessments and their [sensitivity] compared with growth/weight endpoints, is unknown.").

[20] *See also* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0023 (Seedling Emergence and Seedling Growth Test Guideline at 2) (plant growth or survival includes effects on plant emergence, seedling survival, seedling length, and seedling biomass); https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0024 (Vegetative Vigor Test Guideline at 1) (effects measured include plant survival, plant height, and plant biomass).

Here, in conducting its assessment of the volatility of 2,4-D, EPA related the visual plant damage measures in the Ouse study to measures of plant growth or survival. To do so, EPA's 2016 Risk Assessment "considered potential effects from the volatilization of 2,4-D choline salt *using several lines of evidence*[,]" ER78 (emphasis added), including six publicly-available studies that related measures of visual damage to statistically significant observations of effects on plant growth or survival. ER646 (Table 35); *see also* ER1433. This process resulted in a mathematical approach for EPA to relate the visual plant damage in the Ouse study to the growth or survival endpoints needed for the Agency's quantitative ecological risk assessments. From the six additional studies relating "plant damage" to "significant effects in growth/yield," the *lowest* percentage of visual plant damage that corresponded to a statistically significant amount of growth or survival damage was 20% (on grape, the most sensitive species). ER646 (Table 35); SER436-447 ("Ogg study"). In other words, statistically significant growth or survival damage could start to be seen on the grape plant (which is more sensitive than soybean, cotton, or tomato) when the grape plant had 20% visual plant damage.

In addition, EPA looked to another study submitted by Dow, known as a "vapor flux study" (also known as the "Havens study"), which confirmed the levels of visual damage that equated to growth or survival effects. SER707-909; ER646-

648; SER472-677 ("Havens study update"); SER448-471 ("Data Evaluation Record for Havens study update).[21] The vapor flux study also confirmed that the 2,4-D choline salt is less volatile than other forms of 2,4-D. SER450. Lastly, this study demonstrated that no plant growth or survival effects would occur off the field. ER647.

(iii) National Family Farm Coalition ignores EPA's analysis of several additional studies.

National Family Farm Coalition ignores *all* of these additional studies and paints a misleading picture of EPA's volatility assessment by arguing that EPA only relied on the Ouse study. In addition, the Coalition mistakenly conflates statements in the record about the dose levels at which visual plant damage could be observed. Specifically, the Coalition argues that in evaluating the Ouse study, EPA "identified a conservative threshold at 5 percent visual plant damage, or 2,4-D concentration of 0.42 ug/m^3/h," but that "EPA nonetheless used the 1.9

[21] The Coalition incorrectly states that EPA never received the vapor flux study discussed above. Coalition Br. 61. EPA's 2013 risk assessment indicated in text and in a footnote that the vapor flux study was "in review at this time." ER2034; ER2038 (note to Table 4); ER2057-2058. The 2016 risk assessment, however, relied on the vapor flux study and did not indicate that the study was still "in review." Unfortunately, the footnote from the 2013 risk assessment (that indicated the vapor flux study was in review) was inadvertently included. Also, EPA finalized the Data Evaluation Record for the vapor flux study on Oct. 22, 2013. *See* SER448-471. The bottom line is that EPA indeed had received, completed review, and relied on the vapor flux study in the 2016 Risk Assessment.

ug/m^3/hour threshold to conclude that 2,4-D volatilization is not a concern."[22] Coalition Br. 62. The Coalition's characterization of EPA's analysis is wholly inaccurate.

For purposes of summarizing the data from the Ouse study in the Data Evaluation Record, EPA made the highly conservative *assumption* that an observation of 5% visual plant damage from 2,4-D would be the same as a 5% plant growth or survival endpoint from a guideline seedling emergence or vegetative vigor study. That assumption, however, was just a starting point because, for purposes of the Risk Assessment (as opposed to the summary of just one study), EPA went on, as explained above, to determine the dose level at which growth or survival damage occurred at statistically significant levels. ER646-647. Once EPA determined (based on the studies discussed above) that growth or survival occurred at significant levels when there was a minimum of 20% visual plant damage (on the grape plant), EPA returned to the dose-response curve in the Ouse study to find the corresponding dose level for that 20% visual plant damage. That dose level was the 1.9 ug/m^3/hour exposure threshold. SER698, Fig. 4.

This 20% visual plant damage level, based on the most sensitive plant (the grape), was the *most conservative* level of visual plant damage to determine the

[22] A pesticide dose is expressed in "ug/m^3/hour," which means the mass of pesticide (micrograms) in a cubic meter of air space to which an organism is exposed over a one-hour time period.

corresponding dose level at which statistically significant damage to growth or survival could be seen. To further underscore the conservative nature of this assessment, consider a less sensitive (but more realistically neighboring) plant, like soybean. If EPA had decided to look to the level of visual plant damage at which statistically significant damage to soybean's growth or survival occurs, that would have been 35% visual plant damage. ER64 (Table 35). Referring back to the dose-response curve from the Ouse study, the corresponding dose level for 35% visual plant damage to soybean is much higher than the 1.9 ug/m^3/hour level (in fact, greater than 10.0 ug/m^3/hour (SER698, Fig.4) that EPA determined by relying on the grape plant.

To summarize, EPA explained that it relied on data *in addition to* the Ouse study (i.e., the six field studies and the additional vapor-flux study) to determine the minimum percentage of visual plant damage that translates to a statistically significant effect on growth or survival endpoints for purposes of its risk assessment.

> EPA's risk assessment considered potential effects from the volatilization of 2,4-D choline salt using several lines of evidence. 2,4-D choline vapor flux data from a field volatility study was used to address exposure from volatilized 2,4-D to plants. First, data from a laboratory plant vapor study (MRID 48911801) indicated that grape was more sensitive to 2,4-D vapor than cotton, tomato, or soybean (this study was only available for qualitative use because of the methodology used to conduct the experiment). Second, data from several field studies related plant damage in grape, cotton, and soybean to growth or yield endpoints (Andersen et al., 2004; Everitt

> and Keeling, 2009; Kelley et al., 2005; Marple et al., 2008; Ogg et al., 1991; Robinson et al., 2013). Again, grape was the most sensitive crop with 20% damage resulting in decreases in growth and yield (cotton ranged from 58 to 66% damage and soybean from 35 to 52% damage before decreases in yield occurred).

ER78-79; *see also*, ER647 70).[23] The Coalition's argument that "EPA used [a] single study" is flatly incorrect. In the end, however, regardless of whether EPA used 5% or 20% visual plant damage as an endpoint for volatility assessment, EPA's conclusion, using multiple lines of evidence, was that there were no off-field non-target plant effects (again using the most sensitive species grape).[24]

Finally, the Coalition's reliance on *Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015), for its volatility argument is misplaced. That case involved an EPA regulation that mandated particular higher-tiered field testing

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[23] "Considering the results from the plant damage studies, the vapor-flux study, and the laboratory vapor-phase study, a conservative approach was taken in selecting endpoints to characterize risk from vapor-phase transport. At 20% physical damage, the grape had the lowest damage rate that resulted in statistically significant reductions in yield/growth. Grape was also the most sensitive species tested in the laboratory vapor-phase study. Using the percent of visual injury for grape, an endpoint of 1.9 $\mu g/m^3$/hour was visually identified as the concentration that produced 20% physical damage." ER647.

[24] *See* ER647 (in the vapor-flux field study, "[t]he only plants to show outward signs of damage [i.e., visual plant damage] were the grape (0.6% damage) and cotton (40% damage) plants *located directly on the field*.") (emphasis added); *id.* ("[t]he PERFUM model was used to estimate the off-field distances for various concentrations of 2,4-D as predicted from the vapor flux data … [and] *[t]he model predicts no adverse damage to plants off-field for any of the exposure scenarios*") (emphasis added).

when certain conditions were met. *See id.* at 531 (citing 40 C.F.R. §§ 158.630(d), (e) n.25); Coalition Br. 62. This Court found that, even where EPA might reasonably find shortcomings in the prerequisite testing, EPA was bound by its regulations to undertake the higher-tiered field testing. 806 F.3d at 531-32. Here, by contrast, there was no regulatory obligation to do more; EPA showed it received and analyzed all required data and its decision is supported by evidence that might reasonably be accepted as adequate. *See NRDC*, 735 F.3d at 877. The Coalition makes *no* argument attacking the six studies and additional plant vapor study on which EPA did rely. But to the extent there is any scientific uncertainty about that data or the conclusions EPA drew from that data, the Court must defer to EPA's expert judgment. *Id*. The Coalition's argument fails to overcome this deference or undermine the evidence on which EPA's decision was based. As explained above, EPA considered several lines of evidence before finding no plant growth or survival effects off the field. This assessment was well-reasoned and should be given deference.

b. EPA's label conditions for Enlist Duo were reasonable and the Coalition's arguments about hypothetical synergy with other pesticide products are without merit.

EPA views synergism[25] as a rare event and follows the National Research Council's recommendation that government agencies assume that the components of a pesticide product will *not* have "synergistic effects" in the absence of data showing such effects are possible. ER23. Here, the only relevant synergy issue that EPA addressed in the 2017 Registration Amendment was the potential synergism between 2,4-D and glyphosate, as discussed above, which was the basis for the remand in *Enlist Duo I*. *Supra* at 12-14. After reviewing the submitted studies, EPA determined that "the combination of 2,4-D choline and glyphosate in Enlist Duo does not show any increased toxicity to plants and is therefore not of concern." ER24. Neither Petitioner challenges EPA's conclusion as to that synergy issue nor the analysis underlying it.

Instead, the Coalition raises a different synergy argument focused on an entirely different pesticide – glufosinate – and a hypothetical mixture of that pesticide with either 2,4-D or the Enlist Duo pesticide product. That argument is speculative and not based on any actual evidence because these alleged synergistic effects could only occur if EPA allowed Enlist Duo to be used along with a

[25] *See supra* n. 5 (definition).

pesticide product containing glufosinate. Enlist Duo does not contain the pesticide glufosinate, nor has EPA registered any other pesticide product containing the combination of Enlist Duo and glufosinate. Notably, the Coalition does not provide any evidence to the contrary.[26]

The Coalition bases its synergy argument on a patent application (different from the patent application at issue in the *Enlist Duo I* remand) for a combination of 2,4-D and glufosinate filed by Dow with the United States Patent and Trademark Office.[27] This application has since been abandoned. The Coalition also cites to several articles for the proposition that studies indicate synergistic effects between 2,4-D and glufosinate. Coalition Br. 64. These articles appear to provide general discussions on the efficacy of weed control from several combinations of pesticides but do not specifically address synergy. The Coalition, however, fails to provide any specific statements in these articles to support their allegation of synergy between 2,4-D and glufosinate and, even if it did, there is no requirement that EPA had to consider the synergistic effects between a theoretical

[26] Of course, if EPA were to register such a combination, Petitioners may then be free to challenge that action.

[27] *See* Mann, Richard K., *Synergistic Herbicidal Weed Control From Combinations of 2,4-D-Choline And Glufosinate*, http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.html&r=1&f=G&l=50&s1=%2220150157023%22.PGNR.&OS=DN/20150157023&RS=DN/20150157023

combination of 2,4-D and glufosinate as part of the 2017 Registration Amendment action on Enlist Duo (which, once again, contains glyphosate, not glufosinate).

FIFRA imposes no requirement that EPA assess each theoretical combination of registered pesticide products in the field – a process known as "tank mixing." Nor does the Coalition argue that there is any such requirement. Yet, it suggests, without support, that EPA allowed the tank mixing of Enlist Duo with glufosinate and that should have assessed each theoretical tank mix of Enlist Duo with other pesticide products for potential synergistic effects. *See* Coalition Br. 64 (citing ER32-33). Such a heavy burden not only is unsupported by the statute, but is wholly unreasonable and contrary to Congress' intent to remove "serious impediment[s] in the [FIFRA] registrations program." S. Rep. No. 95-334 at 3; *see supra* Argument I.A.1.

Simply put, EPA has *not* approved the tank mixing of glufosinate and Enlist Duo.[28] Indeed, the EPA-approved product label for Enlist Duo specifically requires in the Directions for Use section that Enlist Duo "may only be tank-mixed with products that have been tested and found not to adversely affect the spray drift properties of Enlist Duo." ER100.[29] This section also states that the user cannot

[28] Again, this is a different patent application than the patent application at issue in the remand.

[29] The labeling restrictions on tank mixing ensure that any mixture with Enlist Duo will not result in the need for a different spray drift buffer. This is consistent with

tank mix any product with Enlist Duo unless they check a specific website to ensure that product is approved for tank mixing. ER100. Tank mixing Enlist Duo with a pesticide product containing glufosinate without EPA's approval would be a use inconsistent with the pesticide product's labeling and therefore illegal under FIFRA. 7 U.S.C. § 136j(a)(2)(G).

Instead, before a user could tank mix Enlist Duo and glufosinate, strict requirements would need to be met, including approval by EPA. To gain that approval, any person seeking to tank mix another pesticide with Enlist Duo must go through an evidence-based process that includes the following:

- Dow must maintain a website at http://EnlistTankMix.com that includes:
    - Information for any person seeking to tank mix a product, which includes the requirements for how testing the product must occur, and that the test data and results (along with a certification that the tests were undertaken pursuant to the protocol) must be submitted to EPA;
    - A list of the products that have been tested pursuant to EPA's approved protocol and "found, based upon this testing, not to

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EPA's concern that prompted the *Enlist Duo I* remand – consideration of whether the 30-foot spray drift buffer for the application of Enlist Duo was still adequate considering the potential synergistic effects between 2,4-D and glyphosate. The Enlist Duo product label specifically requires in the Directions for Use section that Enlist Duo "may only be tank-mixed with products that have been tested and found not to adversely affect the spray drift properties of Enlist Duo." ER100. That specific concern of the potential for spray to drift beyond the 30-foot buffer is what prompted EPA to impose the labeling restrictions and institute the evidence-based process explained above for obtaining approval to tank mix any other pesticide with Enlist Duo.

adversely affect the spray drift properties of Enlist Duo," ER38 (citing the sixth requirement in the registration);[30]

- The test data to be submitted to EPA must be accompanied with a certification "indicating whether the study was performed either pursuant to the testing protocol identified on the website or pursuant to another protocol approved by EPA and whether the results of the testing support adding the product to the list of products tested and found not to adversely affect the spray drift properties of Enlist Duo[]," ER38-39 (requirements set forth in number 7); and

- Before Dow can place the product on the list, it must receive a determination from EPA that the "product has been certified to be appropriately added to the list, and you will add appropriately certified products to the list no more than 90 days after you receive such notice from EPA." ER38-39.

See generally, ER37.

As that process makes clear, EPA not only requires that specific testing protocols be followed before any other pesticide product can be tank mixed with Enlist Duo, but that the test data and results (as well as a certification) be provided to the Agency for a determination of which pesticide products can be mixed with Enlist Duo and placed on the requisite website. ER38-39. Again, EPA has not approved the tank mixing of glufosinate with Enlist Duo. Therefore, EPA did not need to consider possible synergistic impacts that may result. EPA's restrictions on tank mixing Enlist Duo with other pesticide products were instead the

[30] *See* ER40-41 (Appendix A).

appropriate response to ensure that the mixture would not cause unreasonable adverse effects on the environment.

Notably, EPA is supported by the National Research Council's recommendation that government agencies assume the components of pesticide products will not have "synergistic effects" in the absence of data showing such effects are possible. ER23. Consistent with this recommendation, EPA was not required, as the Coalition argues (Coalition Br. 64), to address *hypothetical* synergistic effects before concluding that Enlist Duo would not have unreasonable adverse effects on the environment. Indeed, National Family Farm Coalition has not pointed to any evidence that would cast doubt on EPA's consideration of the tank mixing issue or the Agency's imposition of tank mixing restrictions. The Court therefore should reject this unfounded synergism argument.

2. NRDC's Arguments

a. Any challenge to the 2014 Registration or the 2015 Registration Amendment is time-barred.

As an initial point of clarification, NRDC cannot obtain any relief as to the 2014 Registration or the 2015 Registration Amendment because any challenge to those orders is time-barred. *See* NRDC Br. 49, n.17 (suggesting that if the Court vacates the 2017 Registration Amendment, it must also vacate the 2014 Registration and 2015 Registration Amendment so those orders are inoperative). Under FIFRA Section 16(b), 7 U.S.C. § 136n(b), any challenge to an EPA order

issued after a public hearing must be filed within 60 days after entry of that order. Petitioners timely challenged the 2014 Registration and 2015 Registration Amendment in the *Enlist Duo I* litigation. When EPA sought voluntary remand of these two decisions, however, the Court denied EPA's additional request to vacate the Enlist Duo registration (as amended in 2015). The Court also denied the petitioners' request to delay the mandate and their request to adjudicate the pending claims. *See Enlist Duo I*, ECF #132 (Case No.14-73353). The 2014 Registration (as amended in 2015) therefore remained in effect after the final judgment and remand in *Enlist Duo I*, which both Petitioners acknowledge. *See* NRDC Br. 36 ("[t]he [2017] registration challenged here is the only operative registration for Enlist Duo . . . ."); Coalition Br. 8 "[o]n January 25, 2016, the Court granted the motion for remand but declined to vacate, so the registration remained in effect.") Because the *Enlist Duo I* court did not retain jurisdiction and no actions were taken to cancel or suspend the 2014 Registration (as amended in 2015), the 60-day timeframe for challenging those earlier actions under FIFRA Section 16(b) has run. 7 U.S.C. § 136n(b). Thus, the only registration action that could have and has been timely challenged here is the 2017 Registration Amendment to add the post-emergence use on genetically engineered corn and soybean in 19 states and the post-emergence use on genetically engineered cotton in 34 states.

b. NRDC lacks standing to raise any arguments concerning glyphosate.

NRDC does not have standing to challenge EPA's actions as to glyphosate in the 2017 Registration Amendment. *See* NRDC Br. 47-49. To establish Article III standing, a claimant must show "(1) it has suffered an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992)). Additionally, NRDC may assert standing on behalf of its members as long as the "members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Friends of the Earth*, 528 U.S. at 181.

Here, NRDC has not shown, nor can it show, that it or its members have suffered or will suffer an injury that is fairly traceable to the glyphosate component of EPA's 2017 Registration Amendment for Enlist Duo, or that any alleged injury would be redressed by a favorable decision on that registration alone. This is because glyphosate has been registered in other pesticide products for this same

post-emergence use as an herbicide on genetically engineered corn, soybeans, and cotton crops that were modified to be resistant to glyphosate (*i.e.*, the same type of use pattern) since the 1990's. ER2. Indeed, these same authorized uses of glyphosate were registered before Enlist Duo. *See infra* at 70-71 (citing statistics on glyphosate use on corn, soybean, and cotton crops). Thus, the 2017 Registration Amendment of Enlist Duo (and indeed, even the 2014 Registration and 2015 Registration Amendment) changes nothing with respect to how, when, where, and how much glyphosate is or will be used going forward.[31]

> The registration of Enlist Duo does not represent any new exposures or increase in exposures for glyphosate. Glyphosate is already used on the majority of corn and soybean production acres in the United States today. Glyphosate is presently being applied in the same fields where Enlist Duo applications would be expected, using the same application methods as registered for Enlist Duo.

ER1445. In other words, the 2017 Registration Amendment of Enlist Duo authorizes the same uses as prior (and still existent) registrations of pesticide products containing glyphosate. Accordingly, there is no probative link

[31] Although the 2014 Registration and 2015 Registration Amendment are not subject to review, NRDC does not have standing to challenge the glyphosate component of Enlist Duo in either of those actions, for the same reasons discussed *supra* Section II.B.2.b. Thus, even if NRDC's challenge is viewed as a challenge to all three of EPA's registration actions relating to Enlist Duo, there is no standing to challenge EPA's treatment of glyphosate in any of those orders given all the prior registrations of glyphosate as an active ingredient pesticide in other pesticide products that are used on these same crops.

between EPA's decision to amend the Enlist Duo registration (or even to register Enlist Duo in the first instance) and the current plight of the monarch butterfly or any alleged human health risk posed by glyphosate. *Lujan*, at 560 ("injury has to be 'fairly . . . traceable to the challenged action of the defendant, and not . . . the result of the independent action of some third party not before the court'") (citation omitted). Indeed, the alleged injuries NRDC claims cannot be caused by the 2017 Registration Amendment because these uses of glyphosate have been authorized for use and have been widely used since the 1990's. Thus, NRDC cannot demonstration the "injury" and "causation" prongs of Article III standing.

NRDC also cannot establish the "redressability" prong of Article III standing. "Redressability depends on whether the court has the ability to remedy the alleged harm." *Nuclear Info. and Res. Serv. v. NRC*, 457 F.3d 941, 954 (9th Cir. 2006). Here, even if the Court rules in NRDC's favor on the merits of NRDC's substantive challenges to the glyphosate in Enlist Duo, the ruling would not redress NRDC's perceived harm to the monarch butterfly or alleged human health risk posed by glyphosate. That is because other pesticide products containing glyphosate would continue to be sold, distributed, and used on these same crops in accordance with the previously-approved registrations that authorized these uses as early as the 1990's. *See*

id. (holding that petitioners had failed to establish redressability when there was an existing regulation). Thus, as discussed further below, the more appropriate avenue through which NRDC potentially could redress its alleged injuries from glyphosate is through the FIFRA Section 3(g), 7 U.S.C. § 136a(g), registration review process, where the uses of glyphosate across *all* registered pesticide products is currently being reviewed, not through the instant Enlist Duo registration challenge.

c. The administrative record does not support that there will be increased glyphosate usage.

Even if NRDC has standing to challenge EPA's assessment of glyphosate, this challenge has no merit. 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. NRDC Br. 47-49. As discussed above though, EPA was not required to do so. Thus, NRDC's arguments about increased glyphosate usage find no support in the record.

NRDC insists that EPA ignored evidence that use of glyphosate "would decrease but for EPA's registration of Enlist Duo." NRDC Br. 47; *see id.* at 14 ("Enlist Duo is likely to perpetuate glyphosate use at levels well above what would otherwise be expected."). NRDC's arguments are pure speculation unsupported by any evidence in the record. EPA has explained: "If widely adopted by growers,

the herbicide combination in this weed control systems approach *could potentially prolong the effectiveness of the glyphosate technology* if the two herbicides are controlling weeds that are not resistant to either herbicide." ER28 (emphasis added)). However, "potentially prolonging the effectiveness" of glyphosate, while authorizing no new use or application method, is not an "increase" in usage.

Moreover, EPA's 2017 Registration Amendment does not change any already-authorized use of glyphosate:

> the glyphosate in Enlist [Duo] would not cause unreasonable adverse effects on the environment because the use conditions authorized under the Enlist [Duo] registration are identical or substantially similar to use conditions already authorized for glyphosate in other existing glyphosate registrations, and the EPA does not expect the registration of enlist Duo to significantly change the locations, methods, or volume of glyphosate used on corn, soybeans, or cotton.

ER4. "Thus, 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." *Id.*

Indeed, the use of glyphosate prior to Enlist Duo was pervasive: "[D]uring the 2010-2014 period, the percent of corn treated one or more times with glyphosate ranged from 80 to 85 percent, the percent of soybeans treated one more times with glyphosate is approximately 95 percent, and the percent of cotton treated one or more times with glyphosate ranged from 75 to 90 percent." ER558 n.3. NRDC even cited similar statistics in its comments. ER157 (stating "as of

2016, 89% of corn and cotton crops, and 94% of soybean crops, were glyphosate-resistant"). Thus, NRDC's own statistics support that the use of glyphosate on these crops was already nearly ubiquitous before the 2014 Registration, and there is no evidence to indicate that glyphosate usage would increase even more because of Enlist Duo.[32] Without Enlist Duo, farmers would continue to have access to and use other registered pesticide products containing glyphosate on these same crops and in the same manner authorized by Enlist Duo to control milkweed (which has not developed resistance to glyphosate). To control milkweed in fields with corn, soybean, or cotton that has been genetically engineered to be resistant to glyphosate and 2,4-D, farmers either will likely use glyphosate alone in other registered pesticide products, or Enlist Duo (which is a combination of glyphosate and 2,4-D). There simply is *no* evidence in the record that glyphosate usage will increase because of Enlist Duo, particularly where glyphosate usage has been and will continue to be pervasive, with or without Enlist Duo.

NRDC's additional arguments concerning the health effects of glyphosate and effects of glyphosate on monarch butterflies are irrelevant both to NRDC's actual argument that glyphosate usage will not decrease and to whether substantial evidence supports EPA's 2017 Registration Amendment. Interestingly, NRDC

[32] *See* NRDC Br. 47-48 (citation omitted) ("as of 2016, 89% of corn and cotton crops, and 94% of soybean crops, were glyphosate-resistant").

spends significant time citing evidence that allegedly shows such effects. NRDC Br. 47-48. Those studies, however, do not support NRDC's claim that EPA failed to consider whether glyphosate usage will change or increase. To that end, NRDC's reliance on *Nanosilver II* is misplaced. That case involved an entirely new pesticide, not a new use of a previously registered pesticide. Under FIFRA Section 3(c)(7)(C), 7 U.S.C. § 136a(c)(7)(C), EPA had to make a public interest finding for that new pesticide, which was not required here.

Finally, registered uses of glyphosate (including those in Enlist Duo) are being reevaluated through the FIFRA Section 3(g) registration review process. *See supra* at 6-7. That is the appropriate forum in which NRDC's concerns about health effects and impacts to monarchs will be evaluated. EPA therefore appropriately did not address such concerns during this FIFRA process to issue the 2017 Registration Amendment. Those concerns have no bearing here on whether EPA's 2017 Registration Amendment was supported by substantial evidence.

d. EPA's analysis of 2,4-D was reasonable.

EPA conducted a robust analysis of the new use of 2,4-D for the 2017 Registration Amendment, and NRDC fails to mount any credible attack on that analysis. First, it should be noted that NRDC's brief does not contain any argument concerning EPA's analysis of the human health effects of 2,4-D. Rather, in NRDC's "Statement of the Case," NRDC summarily states that EPA's "analyses

are flawed" regarding the human health risks of 2,4-D, mentioning "thyroid problems and Non-Hodgkin lymphoma," "carcinogenicity and thyroid toxicity," "individuals' aggregate exposures," and "health risks … to pregnant women and children." NRDC Br. 23 (citing ER182-197 and ER463-467). Beyond that, NRDC provides no argument concerning these assertions. Thus, NRDC has waived any argument about EPA's analysis of the human health effects of 2,4-D. *See, e.g.*, *NW. Acceptance Corp. v. Lynwood Equip., Inc.*, 841 F.2d 918, 923 (9th Cir. 1988) (failure to present an "intelligible argument in support of [a party's] contention" fails to comply with Federal Rule of Appellate Procedure 28(a)(4) and waives the argument).[33]

Second, the only substantive argument NRDC makes regarding EPA's analysis of the effects of 2,4-D concerns the alleged impact on milkweed – and thus on monarch butterflies – from a purported "expansion" of 2,4-D use. NRDC Br. 44. At the heart of NRDC's argument is the complaint that Enlist Duo – and in particular, the 2,4-D component – does what it is intended to do: control target

[33] Despite NRDC's failure to develop any intelligible argument concerning its allegations about the human health effects of 2,4-D, EPA points out that it did address NRDC's concerns during the process for the 2017 Registration Amendment. *See, e.g.*, ER51-52 (responding to comments about thyroid toxicity); *id.* at 3 (responding to comments about cancer); ER1424-1425 (responding to comments about Non-Hodgkin's Lymphoma); ER56-57 (responding to comments about exposure to infants and children); ER1414-1454, ER50-92 (responding to NRDC's various comments regarding health risks to pregnant women and children).

weeds like milkweed in all crops including in genetically engineered corn, soybean, and cotton. Beyond that, nothing in NRDC's argument calls into question EPA's analysis of the effects of 2,4-D.

The record demonstrates that EPA assessed the risks to both monarch butterflies and to off-field milkweed (as opposed to milkweed in the actual crop fields on which Enlist Duo would be intended for use). For example, EPA

> completed a non-target direct effects risk assessment for terrestrial invertebrates, specifically referencing monarch butterflies as a member of this taxa . . . and finds no concerns for terrestrial invertebrates (including monarchs). . . . EPA has also conducted a risk assessment for the combined toxic effects to non-target plants (a grouping that includes plants important to monarchs) . . . [concluding] that effects to non-target plants, under application conditions prescribed on the label, would be limited to the treated field itself.

ER64.

NRDC argues that these responses "skirted the issue" because the alleged "risk to monarchs" arises by virtue of Enlist Duo's purported "expansion of 2,4-D use," including both a "rise in use" and "changes in how [2,4-D] can now be used." NRDC Br. 44-45. The gravamen of NRDC's concerns seems to be that milkweed will be targeted at all – including in farmers' crops – thereby posing a risk to monarch butterflies. The theory appears to be that 2,4-D use through Enlist Duo presumably will increase the effects on milkweed and, thus, on monarch butterflies. The record does not support NRDC's presumption. EPA acknowledged that "the registration of Enlist Duo . . . will result in an increased

usage of 2,4-D because applications will now be allowed [post-emergence] on [genetically engineered] cotton, there will be a longer period of time that applications can be made on [genetically engineered] corn, and for the first time, up to two applications can be made over-the-top on [genetically engineered] soybeans." ER83. That fact, however, does *not* mean that *more* milkweed will be controlled overall because of Enlist Duo. Enlist Duo simply provides *another tool* for the control of weeds (including milkweed) in farmers' fields. That does not lead to the conclusion that *more* milkweed will somehow be controlled than before the 2017 Registration Amendment (or, for that matter, the original 2014 Registration or the 2015 Registration Amendment). Farmers have been using various methods (including the application of other herbicides) to control weeds (including milkweed) in their fields to acceptable levels at the same crop growth stages before Enlist Duo was registered, and farmers will continue to do so even if Enlist Duo is not available. Farmers will control milkweed on their field either through Enlist Duo's combination of 2,4-D and glyphosate, or through some other herbicide. NRDC's concerns about using 2,4-D to control milkweed therefore are misplaced.

Indeed, EPA has explained that "the use conditions authorized under the Enlist Duo registration are identical or substantially similar to use conditions already authorized for glyphosate in other existing glyphosate registrations, and the

EPA does not expect the registration of Enlist Duo to significantly change the locations, methods, or volume of glyphosate used on corn, soybean, or cotton." ER4. Although some weeds are resistant to glyphosate, milkweed is not. So absent Enlist Duo, farmers will use other registered pesticide products containing glyphosate that are authorized for use to control milkweed in precisely the manner for which Enlist Duo is authorized. Simply put, nothing in the record disputes that farmers will control the same amount of milkweed on their crop fields through the use of herbicides or other means and at the same crop growth stages, with or without Enlist Duo.

Finally, NRDC's apparent concerns about the use of 2,4-D to do what it is intended to do (control weeds on farmers' crop fields) and any associated impacts of the use of pesticide products containing 2,4-D, are not specific to the new use of Enlist Duo on cotton (or even limited to Enlist Duo at issue), but are directed to 2,4-D generally. Here again, the appropriate forum for NRDC to raise these issues is during the ongoing "registration review" of 2,4-D pursuant to FIFRA Section 3(g), under which review EPA considers all uses of 2,4-D. EPA expects to issue a Proposed Interim Decision for 2,4-D for public comment through the registration review process in the near future. *See* https://www.epa.gov/pesticide-reevaluation/registration-review-schedules (EPA's "2018 Registration Review Schedule for Conventional Cases (as of 04/27/2018)"). The issue of whether and

to what extent the use of 2,4-D in farmers' fields affects terrestrial invertebrates and their habitat, including monarch butterflies, and if so, how to address that (which is the true gravamen of NRDC's argument), is more appropriately addressed during the registration review process. This considers 2,4-D across all approved uses and provides the appropriate forum for NRDC to provide input on its concerns about monarch butterflies and other invertebrates, as it relates to 2,4-D, generally.

Importantly, protection of pollinators, including monarch butterflies, and their habitat is a larger issue than the Enlist Duo registration, or even 2,4-D (or any other herbicide) in registration review. Such protection is consistent with priorities identified by the federal government, as evidenced by the efforts of the Canadian/Mexican/US Trilateral Committee for Wildlife and Ecosystem Conservation and Management, and by the May 19, 2015, Presidential Memorandum on the National Strategy to Promote the Health of Honey Bees and Other Pollinators, *available at* https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf.[34] EPA is and will continue to be a partner

[34] The "National Strategy" document identified three overarching goals, including one specific to monarch butterflies: "Increase the Eastern population of the monarch butterfly to 225 million butterflies occupying an area of approximately 15 acres (6 hectares) in the overwintering grounds in Mexico, through

in these national and international efforts to protect the monarch butterfly. The primary concern for monarch butterflies being the availability of milkweed (which is necessary for their life-cycle), taking any action on one herbicide product or one active ingredient would likely not address the issue, as other herbicides (registered for similar uses) could fill the void left by that one action. Rather, EPA and other federal agency partners are focusing on a broader approach to help protect the monarch butterfly. To this end, EPA has issued a Federal Register notice seeking information and public input on EPA's Risk Management Approach to Identifying Options for Protecting the Monarch Butterfly. *See* https://www.regulations.gov/docket?D=EPA-HQ-OPP-2015-0389.

III. EPA FULLY COMPLIED WITH THE ESA

The Coalition raises six ESA arguments. First, they object to EPA's toxicological "level of concern" approach to assessing potential effects to ESA-listed species. Coalition Br. 21-31. Second, they allege that Enlist Duo "may affect" certain ESA-listed species because the area where EPA expects growers to

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domestic/international actions and public-private partnerships, by 2020." National Strategy at i. To that end, USDA's Natural Resources Conservation Service has taken the lead on increasing milkweed available to monarchs, developing "the framework of a Monarch Butterfly Habitat Development Project through which [the Natural Resource Conservation Service] will work cooperatively with private landowners to increase monarch habitat in a 10-state region." NRCS Monarch Butterfly Habitat Development Project at 3, *available via* https://www.nrcs.usda.gov/wps/portal/nrcs/detail/national/plantsanimals/pollinate/?cid=nrcseprd402207.

sue Enlist Duo will overlap with those species' habitat. *Id.* at 31-32. Third, they contend EPA incorrectly identified the potentially affected "action area" because it assumed that Enlist Duo would not drift off of the fields where it is applied. *Id.* at 32-37. Fourth, they maintain that Enlist Duo also "may affect" two species occurring on fields where Enlist Duo is applied, the Whooping crane and Indiana bat. *Id.* at 37-47. Fifth, they argue–without identifying any other source it allegedly should have used–that EPA failed to use the best scientific and commercial data by utilizing its 1993 Wildlife Exposure Factors Handbook. *Id.* at 47-48. Finally, they challenge EPA's determination that Enlist Duo will not modify any species' designated critical habitat. *Id.* at 49-45. None of the Coalition's arguments has merit.

A. EPA Applied The Correct Methodology.

EPA complied with the ESA when it correctly applied the step-by-step "level of concern" approach to the new uses at issue.

1. EPA's methodology fully comports with the ESA and pertinent regulations.

Contrary to the Coalition's suggestion, the ESA requires action agencies to make threshold effects determinations. Coalition Br. 21-25; *Defenders of Wildlife v. Flowers*, 414 F.3d 1066, 1069-70 (9th Cir. 2005). The ESA mandates that action agencies shall "insure that any action [it] authorize[s] . . . is not likely to jeopardize the continued existence" of any ESA-listed species. 16 U.S.C.

§ 1536(a)(2). Federal regulations oblige agencies to "review [their] actions . . . to determine whether any action may affect listed species or critical habitat." 50 C.F.R. § 402.14(a). They confirm that *if* an action agency first decides that an action "may affect" a listed species, it may, with the Service's concurrence, determine that the action is "not likely to adversely affect" listed species. *Id.* § 402.13(a). That is what EPA did here. EPA's tiered analysis—which it conducted with a conservative threshold inquiry and proceeded, if necessary, to a species-specific assessment–was the most effective and efficient method to conduct the threshold inquiry, and fully complied with the Agency's statutory obligations.

2. EPA's approach was entirely consistent with judicial authority.

Caselaw supports EPA's method. For example, in *Flowers*, 414 F.3d 1066, this Court upheld the U.S. Army Corps of Engineers' determination that two residential development projects would have no effect on the ESA-listed pygmy owl. *Id.* at 1070. The Court did so even though FWS had objected to the Corps' "no effect" determination. *Id*. at 1068-69. FWS had—unlike here—objected that the project area served as a movement corridor and likely also nesting, roosting, and foraging habitat, confirming potential overlap between the project footprint

and species' habitat.[35] *Id.* The Court nevertheless upheld the Corps' determination because the Corps' analysis was based on a "firm foundation." *Id.* at 1070. Judicial authority does not support Petitioners' contention that any overlap between an ESA-listed species and an action area—such as the pesticide footprint—automatically triggers consultation. *Id.*; *Friends of the Santa Clara River v. U.S. Army Corps of Eng's*, 887 F.3d 906, 923-27 (9th Cir. 2018) (affirming "no effect" determination for listed steelhead because concentrations of dissolved copper in discharges would be within background range already observed in river and well below the dissolved-copper criterion for river).

Similarly, in *Ground Zero Center for Non-Violent Action v. U.S. Dep't of the Navy*, 383 F.3d 1082, 1092 (9th Cir. 2004), this Court upheld the United States Navy's "no effect" determination concerning the effects of potential missile explosions where the Navy determined that risks of explosion were remote at best. *Id.* According to the Coalition's viewpoint, even that remote possibility of an effect would have resulted in a "may affect" determination, requiring informal or formal consultation. Instead, the Court agreed that the action agency had ample latitude to bring its expertise to bear, assess the potential risk, and could reasonably

[35] The Court should reject any argument in the Coalition's reply that no individual members of the listed species at issue existed near the action. There–unlike here–FWS had specifically stated that there *were* members of the listed species within the project footprint. *Flowers*, 414 F.3d at 1068-69.

determine that the action would have "no effect" on listed species. *Id.* Allowing EPA to make "no effect" determinations as to pesticides makes sense because EPA has substantial expertise in evaluating how a pesticide will be used and the toxicology of those pesticides.

This Court should reject any argument that the Court's finding was not meant to be binding. The Court did observe that certain aspects of the Navy's operations were non-discretionary and not subject to the ESA. *Id.* The Court went on to note, however, that there were other aspects of the Navy's operation that *were* subject to the ESA. *Id.* Nevertheless, because the "risk of an accidental explosion of a Trident II missile" was "remote" or even "infinitesimal," the Court found the Navy's "no effect" determination was not "arbitrary and capricious." *Id.*

Likewise, in *Newton Cty. Wildlife Ass'n v. Rogers*, 141 F.3d 803, 811 (8th Cir. 1998), the court deferred to the action agency's "no effect" determination where the project at issue was alleged to overlap with the habitat and have effects on ESA-listed bald eagles. The court did not, however, find that any such overlap necessitated a "may affect" determination. *Id.*; *see also Conservation Congress v. USFS and USFWS*, No. 16-cv-864, 2018 WL 2427640, (E.D. Cal. May 30, 2018) (upholding "no effect" determination and rejecting claims that timber operation would affect the gray wolf); *Ctr. for Biological Diversity v. U.S. Army Corp. of Eng'rs*, No. 14-cv-01667, 2015 WL 12659937, at *22-23 (C.D. Cal. June 30,

2015) (upholding "no effects" determination as to Newhall Ranch despite potential overlap).

The Court should reject any argument that the case at bar is distinguishable from *Newton County* because in that case, USFS had not made a "no effect" determination. The Eighth Circuit clearly noted that USFS *had* made, as EPA did here, a "no effect" determination. 141 F. 3d at 810 ("[t]he Forest Service prepared a detailed biological 'evaluation' for each sale and *found there was no effect* on any listed or endangered species. A finding of no effect obviates the need for consultation with the Fish and Wildlife Service).

The cases the Coalition cites, moreover, do not help them. *Karuk Tribe*, on which the Coalition chiefly relies, does not support the Coalition's argument. Coalition Br. 26, 32, 35, 50, 51 (relying on *Karuk Tribe*, 681 F.3d 1006). To be clear, in *Karuk Tribe*, the action agency – the U.S. Forest Service – did not make a "no effect" determination and then seek to defend that decision. 681 F.3d at 1021-24. The Forest Service never made an ESA determination as to the mining project at issue. Instead, the agency argued that its approval of a company's notice of intent to engage in mining activities on Forest Service lands did not constitute "agency action" and contended that it had no duty to assess whether the mining would impact listed species. *Id.* at 1021-24.

Once the Court declined to adopt this argument, *id.* at 1024, the Forest Service did not dispute that the mining activities at issue "may affect" listed species. *Id*. at 1027, 1030 ("The Forest Service does not dispute that the mining activities it approved in this case 'may affect' critical habitat of coho salmon in the Klamath River system."). Because record evidence included information about the effects of suction dredge mining on threatened species, the Court found the action may affect listed species. *Id.* at 1028-29.

Indeed, if anything, *Karuk Tribe* supports EPA's approach. Through its careful level of concern methodology, EPA determines whether there is any "chance of affecting" listed species by determining whether the pesticide's use would have any observable physiological or biological effect. 681 F.3d at 1027. Below the level of concern, there is no scientific evidence of "any possible effect." *Id.*; ER 72-73, 88, 90. And the Coalition has not identified "any possible effect" on any species that they contend EPA did not consider. *Id.*; Coalition Br. 21-56. *Karuk Tribe* does not stand for the position that action agencies must prove such a negative. *Karuk Tribe* supports EPA's use of levels of concern to conduct its ESA analysis.

Similarly, *Washington Toxics Coal. v. U.S. Dep't of the Interior*, 457 F. Supp. 2d 1158, 1179-80 (W.D. Wash. 2006), is inapposite. Coalition Br. 20. There, the lower court invalidated a portion of EPA's counterpart regulations,

which EPA established with FWS and NMFS for pesticide consultations. These regulations, however, concerned a subsequent step in the consultation process. As the court stated, the regulations allowed EPA to "to make unilateral [Not Likely to Adversely Affect determinations—*i.e.*, not a "no effect" determination] and to permit those . . . determinations to be equivalent to a finding of 'not likely to jeopardize' [listed species] . . . ." *Id*. at 1182, 1188. The court did not suggest that action agencies do not have discretion to make their own threshold "no effect" determination. *Id.* Neither EPA's level of concern approach nor a "no effect" determination was at issue in *Washington Toxics*, 457 F. Supp. 2d at 1179-80.

The Coalition's reliance on *Western Watersheds Project v. Kraayenbrink*, 632 F.3d 472 (9th Cir. 2011), in which the plaintiff challenged the Bureau of Land Management's "no effect" finding as to certain regulatory changes, is also misplaced. Coalition Br. 20. First, FWS objected to the Bureau of Land Management's "no effect" determination. *Id*. at 497. Second, record evidence contradicted that determination. *Id*. at 496-97. The Court remanded the determination due to a lack of a reasoned explanation. Here, however, FWS has not objected to EPA's carefully documented determination that the registration decisions would have no effect on listed species, and no record evidence contradicts that determination. ER10-129, 183-224, 1043-1196, 1202-1323.

Next, *California ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999 (9th Cir. 2009), concerning the Forest Service's determination that the roadless area rule for the management of national forests would have "no effect" on listed species, is not on point. *See* Coalition Br. 16, 20; *Lockyer*, 575 F.3d at 1005, 1018-19. In its brief, the Forest Service contended that the rule created a new administrative procedure that by itself would have no effect on the environment. *Id.* at 1019. Later, at oral argument, the agency reversed course and conceded that the new rule would in fact reduce protections for listed species. *Id.* Here, EPA has demonstrated that the new use will have no effect on listed species. SER82-114. Upon reaching this "no effect" determination, EPA was not required to consult with FWS. *Friends of the Santa Clara River*, 887 F.3d at 923-27; *Sw. Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1449 (9th Cir. 1996) (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). In short, caselaw supports EPA's reasonable level of concern approach.

3. EPA's Level of Concern Approach allows EPA to scientifically and thoroughly assess potential effects.

The Level of Concern approach is not only consistent with caselaw, but also makes eminent practical sense. The Level of Concern methodology allows EPA to accurately and efficiently gauge the potential effects of pesticides to listed species over large areas. The levels of concern are criteria used to indicate potential risk to

non-target organisms. SER16, 35, 139-140. The criteria indicate when a pesticide, used as directed, has the potential to cause undesirable effects on non-target organisms. To determine if a level of concern has been exceeded, a risk quotient must be derived and compared to the levels of concern. SER16, 35. A risk quotient is calculated by dividing an appropriate exposure estimate by an appropriate toxicity test effect level. SER35, 64. When the risk quotient exceeds the level of concern for a certain category, potential risk to that particular category is presumed to exist. *Id.* Notably, the Coalition has not objected to any specific scientific aspect of EPA's methodology. Coalition Br. 21-56. They do not (a) question EPA's assumptions about species' bodyweight, diet, or its use of surrogates; (b) argue that EPA's levels of concern are too high or that lower levels could actually harm or effect a species; or (c) assert that EPA miscalculated its risk quotients. *Id*. Nor do they challenge any facet of the application of the 2004 Overview Document, which set forth EPA's methodology for making effects determinations. *Id.*; *see also* ER2484 *et seq*. This belies their contention that EPA should always find that any overlap must result in a "may affect" finding.

4. EPA correctly relied upon the Wildlife Exposure Factors Handbook.

The Coalition's argument that EPA's reliance on its Wildlife Exposure Factors Handbook renders EPA's analysis arbitrary lacks merit. Coalition Br. 47-48. The Coalition claims that the Wildlife Exposure Handbook was meant only for

screening level risk assessments and that EPA used it in a more refined ESA level assessment. *Id*. at 47. To the contrary, the Handbook was written as a framework to "guide development of exposure factors and assessments for species of concern in a risk assessment." ER 2598; *see also id.* ("[S]pecies selection criteria for site-specific risk assessment might include the following considerations: . . . Local species that are of concern to Federal and state regulatory agencies (*e.g*., endangered and threatened species)"). EPA determined that it could be used on species other than those specifically listed. ER 3076 ("Values for key contact rate factors such as food and water ingestion rates have been measured for few wildlife species. In this section, we describe allometric equations that can be used to estimate several exposure factors on the basis of animal body weight using models derived from taxonomically similar species."); *see also* ER 3077 ("Allometric equations can be used to estimate parameter values for species for which measured values are not available."). The Handbook was used by EPA to measure the dietary exposure of wildlife individuals from the use of the 2,4-D component within Enlist Duo. SER87, 118. EPA's use of this resource was reasonable and the agency's expertise in determining the best available information for its ESA assessments should be given deference.

B. EPA's "No Effects" Determinations Are Fully Supported by the Record.

In its various refined and careful ESA analyses, EPA concluded that the new use would have "no effect" on a number of species and those species' critical habitat. Because ESA Section 7's consultation requirement applies only where agency action "may affect" a species, EPA was not required to consult with FWS concerning those species or their critical habitat. *See* 50 C.F.R. § 402.14; *Sw. Ctr. for Biological Diversity*, 100 F.3d at 1447-48.

1. EPA's ESA 2016 Ecological/ESA Assessment fully demonstrates that Enlist Duo would have no effect on listed species.

National Family Farm Coalition claims that Enlist Duo may affect certain identified species and their critical habitat and, therefore, that EPA was required to consult. Coalition Br. 45. The record, however, contains ample support for EPA's determination that the new cotton use for 2,4-D will not affect listed species or their critical habitat. EPA thoroughly considered all potential mechanisms for interaction between Enlist Duo and listed species, including runoff, spray drift, and volatilization. SER52-82 (screening level ESA assessments, including potential indirect effects for species with dependencies on other species (e.g., food, shelter, habitat).

EPA also conducted multiple detailed analyses for hundreds of listed species. SER82-114, 159-407 (explaining rationale for each "no effect"

determination for 531 listed species). Where, based on its ecological risk assessments, EPA concluded that Enlist Duo would have "no effect" on listed species, it ended its endangered species assessment. Where EPA concluded that the new use "may affect" but was "not likely to adversely affect" a species, it conducted further analysis and informally consulted with FWS, and imposed label restrictions preventing application in these relevant counties. ER107 (approving Enlist Duo in certain states subject to county-by-county restrictions), 575; *see also supra* n.10.

The Coalition incorrectly asserts that EPA failed to consider potential effects to prey species. Coalition Br. 36, 40, 42-43, 45, 54. The Coalition claims that "[e]ven if Enlist Duo were never to directly escape the crop fields' borders at all, the pesticide's application to the fields plainly has indirect effects on areas outside those borders." *Id.* at 36. They argue that "ESA-protected species in surrounding areas consume prey – insects, rodents, reptiles – that may be in fields when they are sprayed, before moving out of the fields." *Id.* The Coalition does not mention, however, that the administrative record is replete with analysis of potential impacts to prey. ER023 (indirect effects risk concerns were identified for any species that have dependencies on mammals, birds, reptiles, terrestrial-phase amphibians, or terrestrial plants that are directly affected); SER48 (consumption of exposed arthropods); 67-68 (same), 75 (same), 89, 91, 101, 103-104, 109, 134-46

(considering residues in arthropods as a dietary item for birds and mammals consuming insects that have consumed corn/soybean/cotton tissues with Enlist Duo residues). The Court should reject the Coalition's contention that Enlist Duo "may affect" listed species where EPA determined "no effect."

2. EPA's screening analysis was not tantamount to a "may affect" determination.

The Coalition's assertion that EPA "admitted" in doing its ESA analysis that Enlist Duo may harm listed plant and animal species because those species exceeded EPA's level of concern misses the mark. Coalition Br. 13, 28, 31, 35, 36. EPA's pesticide program made five "likely to adversely affect" or "not likely to adversely affect" determinations. *See supra* n.10. That alone demonstrates that EPA's Level of Concern worked as it was supposed to–to identify when EPA could identify any ascertainable effects, so that it could take further action. EPA either went on to consult with FWS or in some instances changed the labels to preclude use of Enlist Duo in those counties where those species live, resulting in a "no effect" determination. *Id.* The Coalition does not challenge or even mention those determinations. Coalition Br. 16-56. As to the balance of the potentially affected species, EPA did not "admit" that Enlist Duo may affect any of those species. SER82 (explaining that taxa could not be excluded from potential direct or indirect effects at screening level without further refinement). EPA considers environmental effects to occur when exposure to Enlist Duo reaches levels where

the available exposure and toxicity data indicated that effects on organisms can reasonably be expected to occur. Here, after applying its exceedingly protective screening level analyses – which allow EPA to save its scarce resources by identifying those species for which it need not conduct a more refined analysis– EPA performed a refined risk assessment for listed species that did not pass the conservative screening analysis. SER37 ("Risk assessment guidance indicates that the most sensitive species of a taxonomic group are to be used for screening level risk assessments.").

This assessment explains how the Agency determined which listed species fell within the action area and how EPA made its effects determinations for those species. SER82-114. Those refined assessments replaced EPA's conservative default assumptions at the screening level with pesticide- and species-specific information. This gives EPA a more accurate assessment, but takes additional time and resources. The resulting risk quotients here were well below EPA's established level of concern. *Id.* Below that level, there is no evidence of "any possible" discernible effect to that species. *Karuk*, 681 F.3d at 1027; ER72-73 (FWS and NMFS stating if no "plausible" effect or species or habitat will not respond in any manner, then "no effect" determination is appropriate), ER88, ER90; *cf.* Coalition Br. at 18, 20-21, 23, 25, 30, 49, 67 (referring to FWS and NMFS as the "expert" wildlife agencies). The Coalition seeks to have EPA argue

in the abstract to justify its approach based on "effects" that they presumably believe are observable below EPA's Level of Concern. Yet without identifying what those effects are, the Coalition cannot show that EPA failed to consider any aspect of the Enlist Duo registration. *Id.* The Court should reject the Coalition's arguments.

At bottom, the Coalition contends that EPA should only get one chance to consider possible effects. If it begins with conservative default assumptions, and cannot rule out the possibility of a potential effect, they argue, then EPA must make a "may affect" determination based on those conservative assumptions. The Coalition cites nothing in the statute, regulations, or caselaw to support this argument. Regardless, the issue is not what EPA's initial assessment reveals, but whether EPA can ultimately support its "no effect" decision with the detailed information in the record, which it does. SER82-122, 159-431. Indeed, if the Coalition was to prevail, and EPA were not allowed to use its toxicological expertise to save resources and make effects determinations based on the best available information, then every pesticide (by its very nature) would be an automatic "may affect." That may be the Coalition's desired outcome, but it is not what FWS, NMFS, or Congress envisioned.

For these reasons, the agency's expert determination should be upheld. *Friends of the Santa Clara River*, 887 F.3d at 915-16, 923-27 (affirming "no

effect" determination based on Corps of Engineers' expertise); *All. for Wild Rockies v. Weber*, 979 F. Supp. 2d 1118 (D. Mont. 2013) (upholding no effect as to bull trout or its critical habitat), *aff'd*, 639 Fed. App. 498 (9th Cir. May 6, 2016); *Sw. Ctr. for Biological Diversity*, 100 F.3d at 1447-48.

3. The Administrative Record Amply Supports EPA's Determinations as to the Whooping Crane and Indiana Bat.

a. Whooping Crane

EPA applied its careful, refined ESA assessment methodology to the Whooping crane. SER100-101. After seeking a remand of the original Enlist Duo registration to review potential synergistic effects, EPA completed a new, revised and updated refined ESA assessment on October 19, 2016. SER1-435. To conduct its species-specific assessment, EPA calculated the crane's metabolic rate, the mass of prey the crane consumes daily, the mass of 2,4-D in the crane's daily diet, and used these values to calculate the daily dose of 2,4-D a crane would receive. SER100-101. This approach includes conservative input, in that EPA's analysis assumed that the crane would eat only one food item, arthropods, on exposed fields. *Id.* This assumption was conservative because cranes also feed on other vertebrates with lower pesticide residues than arthropods. SER104 ("In evaluating 2,4-D residues from the screening risk assessment, the residues in terrestrial arthropods exceeded those of terrestrial vertebrate species."); *cf. Newton Cty. Wildlife Ass'n*, 141 F.3d at 810-11. Even with these conservative

assumptions, EPA found that the potential exposure to the Whooping crane was orders of magnitude below the level at which a Whooping crane might be affected by Enlist Duo registration (0.04 vs. 0.1 risk quotient). SER101. EPA therefore reasonably concluded that Enlist Duo would have "no effect" on the species. *Id.*; *see also* ER20 (2,4-D is "'practically non-toxic' on an acute dietary basis to birds"). The Court should accordingly uphold EPA's findings as to the crane.[36]

The Coalition raises two principal complaints about EPA's Whooping crane analysis, neither of which is valid.

First, these Petitioners misquote EPA's 2016 Ecological/ESA Assessment. The Coalition suggests that EPA "acknowledged" that Enlist Duo may affect the crane because it stated, "it is reasonable to conclude that the crane may be exposed to 2,4-D choline residues in prey on crop fields." Coalition Br. 40. However, EPA never concluded that Enlist Duo would affect the crane. The Coalition omits the latter part of EPA's statement, which reads: "it is reasonable to conclude that the crane may be exposed to 2,4-D choline residues in prey on crop fields, *therefore EPA conducted the following species-specific analysis for the crane*." SER100

[36] While FWS recognized that additional research is necessary, there is no evidence that pesticide use is a significant threat to Whooping cranes. FWS, Int'l Whooping Crane Recovery Plan at 29 (2007) ("Recovery Plan"), *available at* https://www.fws.gov/refuge/Aransas/wwd/science/intl recovery plan.html. Moreover, the Whooping crane has a long-term annual population increase of 13.9%, the highest of any North American crane population. Recovery Plan at 11. The Court may take judicial notice of the Recovery Plan.

(emphasis added). The latter portion of EPA's statement clarified that EPA had not concluded its analysis or made any effect determination at that stage. *Id*.

Second, the Coalition mischaracterizes the discretion that action agencies like EPA have to make effects determinations. Petitioners suggest that if "the risk quotients [are] not zero" as to a pesticide, EPA must make a "may affect" determination. Coalition Br. 40. To the contrary, risk quotients below the level of concern establish that use of a given pesticide will produce no discernible effect on the listed species. *See supra* at 20-21, 92; ER 72-73 (FWS and NMFS stating if no "plausible" effect, or species or habitat will not respond in any manner, then a "no effect" determination is appropriate), 88 (citing NMFS guidance), 90 (citing FWS guidance). EPA logically may conclude that a risk quotient between zero and its level of concern means that the pesticide would have no effect on the species at issue. Indeed, FWS and NMFS have espoused EPA's use of the level of concern approach. In a 2014 report to Congress, FWS and NMFS confirmed that the level of concern approach applied to pesticides like Enlist Duo.[37] The agencies jointly stated that EPA's 2004 Overview Document, which described the level of concern

[37] EPA, FWS, and NMFS, Interim Report to Congress on Endangered Species Act Implementation in Pesticide Evaluation Programs at 20, 22 (Nov. 2014) (Interim Report), *available at* https://www.epa.gov/sites/production/files/2015-07/documents/ esareporttocongress.pdf. The Court may take judicial notice of the Interim Report; *cf.* Coalition Br. at 18, 20-21, 23, 25, 30, 49, 67 (referring to FWS and NMFS as the "expert" wildlife agencies)

approach, "is the basis for all ecological assessment for all chemicals other than chlorpyrifos, diazinon, malathion, carbaryl, and methomyl." Interim Report at 20, 22. Accordingly, EPA correctly relied on the level of concern approach.

b. Indiana Bat

EPA also used a careful, data-driven approach to make its effects determination as to the Indiana bat. As stated previously, after seeking a remand of the original Enlist Duo registration to review potential synergistic effects, EPA completed a new, revised and updated refined ESA assessment on October 19, 2016. SER1-435. The 2016 Ecological/ESA Assessment included a new screening level analysis, revised and updated effects determinations, and new critical habitat determinations. ER570-71. In its refined ESA analysis, EPA considered the bat's metabolic rate (kilocalories/day), the daily mass of prey consumed, the mass of 2,4-D in its insect diet, the daily dose ingested (mg/kg-body weight/day), and the dose level at which there are no observed adverse effects ("NOAEL")–(55 mg/kg-body weight).[38] It then calculated the applicable

[38] EPA fully documented its NOAEL for small mammals of 55 mg/kg-body weight in the administrative record. EPA noted that 2,4-D is well absorbed orally by small mammals, undergoes limited metabolism, and is eliminated quickly from mammalian bodies. SER59. It emerges unchanged in the animal's urine. *Id.* Fifty-five mg/kg/day is the dose level at which the animal's ability to eliminate 2,4-D from its system begin to become overwhelmed. *Id*. Doses at and greater than 55 mg/kg/day are therefore of concern. *Id*. Below this level, there is no observable effect on that species. ER72-73 ("no effect" determination appropriate where there is no "plausible" effect), 88, 90.

risk quotient to be 0.04 (less than half of the acute Level of Concern) and 0.31 (less than one third of the chronic Level of Concern). *Id.* EPA reasonably and correctly concluded that Enlist Duo would not affect the species. *Id.*

The Coalition makes six principal arguments concerning the Whooping crane and Indiana bat, all of which miss the mark. Coalition Br. 41-47.

Most fundamentally, these Petitioners cite the wrong document. They cite to EPA's *February 2014* ESA Addendum, not the updated 2016 ESA Addendum. Coalition Br. 42 (citing ER1776), 43 (citing ER1780), 44 (citing 1780), 45 (citing 1781-83), and 46 (citing 1782, 1777, 1783). Only in a footnote does the Coalition acknowledge that EPA actually completed an updated refined ESA assessment in 2016. *Id.* at 46, n. 25 (citing SER89-90). Even there, they do not address EPA's 2016 Ecological/ESA Assessment, which included the best available science for the 2017 Amended Registration. *Compare* ER1771 *et seq.* (2014 six-state ESA assessment), ER1455 *et seq.* (2014 ten-state ESA assessment), *with* SER3 ("this *updated* assessment includes *new Effects Determinations* for listed species in all of the states in which Enlist Duo is proposed for use on corn, cotton and soybeans" including "*updated*" screening level and species-specific effects determinations and critical habitat modification determinations (emphasis added)); SER4 (listing eight differences between 2016 and previous ESA analyses, including terrestrial exposure modeling and a new evaluation of

mammalian developmental, reproduction, and metabolism information used to establish a threshold for reproductive effects for the crane and bat). EPA relied on its 2016 Ecological/ESA Assessment, which referenced and relied, when appropriate, on its earlier 2014 findings. EPA did not, as the Coalition contends, base its assessment on its work from 2014, in approving the 2017 Amended Registration. ER26 (Enlist Duo Decision Document basing ESA analysis on 2016 Ecological/ESA Assessment ("for more details on [the foregoing] findings, refer to the" 2016 Ecological/ESA Assessment)). The Coalition's contentions are based entirely on data and analysis that was not the "best available science."

The Coalition's next argument – that EPA's 2014 screening level assessment "showed that the Enlist Duo registration may affect the species . . ." – also fails. Coalition Br. 41. The screening assessment was merely the *beginning* of EPA's analysis, not the end. *Id.* (citing ER2079-80). It did not determine whether Enlist Duo use will affect the bat, but rather whether EPA would need to continue with its efficient, stepwise, refining approach. ER1776 (stating screening assessment was premised on "just the lines of evidence found in the *screening level risk assessment* . . .").

The Coalition also misses the mark when it incorrectly suggests that the FWS 2007 draft recovery plan found that "pesticides," including pesticides like Enlist Duo, are one cause of the Indiana bat's decline. Coalition Br. 41 (citing

ER2316-21). In fact, FWS stated that *organochlorines* and *pyrethroids*–not all pesticides–may be impacting Indiana bats. ER2316. Neither component of Enlist Duo is an organochlorine or pyrethroid pesticide. 2,4-D is a synthetic auxin and glyphosate is a glycine that inhibits a certain enzyme in plants. ER5, 93.

The Coalition next contends that EPA's 2014 modeling "predicted" that the Indiana bat would be subject to 2-4, D exposure levels that could produce reduced pregnancies, deformities, and reduced survival of pups. Coalition Br. 43 (citing 2014 ESA Assessment, ER1780). That is not accurate. In fact, the quote that these Petitioners cite makes clear that EPA was merely noting that *to the extent the dose reaching an individual animal were to reach 80 mg/kg/day*–a level that was 25 mg/kg/day higher than the level EPA actually used–such effects could occur. ER1780. EPA was not suggesting that use of Enlist Duo per the requirements of the registration would result in dose levels of 80 mg/kg/day. *Id.*

The Coalition's contention that EPA should have employed a NOAEL lower than 55 mg/kg-bw for the Indiana bat because the U.S. Forest Service used a smaller figure in a 2006 report concerning 2,4-D use in Forest Service operations fares no better. Coalition Br. 45, n.23. First, this report, by another agency relied on older information and was not considered by EPA. The report that these Petitioners cite is not in the administrative record. It was not before EPA at the time it approved Enlist Duo in 2017. The Court should accordingly not rely on it.

Fla. Power & Light Co., 470 U.S. at 743–44; *Lands Council*, 395 F.3d at 1030. Even if the Court were to consider it, the Coalition is attempting to compare apples to oranges. The Forest Service did not prepare the 2006 USDA Report to make effects determinations under the ESA. USDA Report xiv-5-50, Table 3-3 (Tables 16-17). Nor does it mention the Indiana bat. *Id.* at xxi, 3-15, 4-36. Finally, while it is unclear whether the Forest Service considered the data available in 2006, EPA was not in 2016 at liberty to use only 2006-vintage data. EPA had to use all of the information at its disposal in 2016. By 2016, EPA's toxicological interpretation had evolved. *Id.* at 1-1 (noting the report even in 2006 was not, and was not intended to be, a "comprehensive summar[y] of all of the available information" and even in 2006 did not "cover all of the available literature in detail"). The Forest Service in 2006, unlike EPA in 2016, did not have the benefit of EPA's latest data or its interpretation of all available data. For all of these reasons, the 2006 Forest Service Report is irrelevant.

Finally, National Family Farm Coalition contends that because up to 67 percent of the land near Indiana bat colonies is agricultural, the EPA should have assumed that 67 percent of its prey would come from agricultural land treated with Enlist Duo. Again, Petitioners' comparison is based on the wrong document. In the 2016 Ecological/ESA Assessment–not the 2014 ESA Assessment Petitioners cite–EPA observed that it expected "the extent of foraging over agricultural land to

be less than the degree of foraging around the canopies of the forested areas." SER89. While it could have reduced the percentage of prey taken from treated fields from 100% to 67%, EPA did not do so. EPA conservatively assumed that 100% of the bat's diet would come from treated agricultural areas. SER89-90. Contrary to the Coalition's contentions, EPA did not "assume[ ] a smaller portion"–*i.e.*, less than 100%–of the species' diet would come from treated fields. Coalition Br. 46; *see also* SER89-90.

For these reasons, the Court should uphold EPA's meticulous assessments of potential effects to the Whooping crane and Indiana bat.

C. EPA Properly Defined the Action Area.

The Coalition next challenges EPA's definition of the "action area" for Enlist Duo as the fields on which growers apply it in the 34 states where EPA has approved it for use. *See* Coalition Br. 32-37. According to the Coalition, EPA "unlawfully constrict[ed] the registration's 'action area' to just the sprayed crop fields themselves, excluding completely all surrounding areas beyond the fields' borders." *Id.* at 32-33. Once again, the Coalition's arguments are meritless.

Contrary to the Coalition's arguments, EPA correctly defined the action area to include treated fields. Its method was fully consistent with the ESA's implementing regulations, which define "action area" as "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(c), (d), (g), 402.14(g)(1). For Enlist Duo, EPA limited the "action area" to treated fields based on careful findings that 2,4-D choline, when used as directed on the label, would prevent offsite migration and prevent direct or indirect effect on ESA-listed species. ER22-23, 25-26, 70-72, 1043, 1049-50. In so doing, "EPA used the best available information to quantitatively evaluate the extent of spray drift" given the Enlist Duo label's strict use conditions. ER73. The EPA then compared those results to available effect thresholds and found that non-target organism exposures would be below effects thresholds beyond treated fields. *Id.* This "logically resulted in the confinement of the area where effects could reasonably be expected to occur to the treated field itself." *Id.*

The Coalition argues that EPA's limitation of the "action area" to the treated fields was unlawful because EPA "knows pesticides commonly drift well beyond sprayed fields, with harmful effects," and "knew Enlist Duo specifically may travel beyond the borders of sprayed fields." Coalition Br. 33. This argument misses the mark. First, the Coalition ignores the use requirements included in the Enlist Duo label, which were designed to prevent the product from migrating off treated fields. ER93-113 (label). The Coalition has not identified any record evidence showing that, when growers comply with the label's use restrictions, Enlist Duo will move off of treated fields and affect ESA-listed species or critical habitat.

The Coalition also contends that even if it were to never directly escape the fields' borders, Enlist Duo "plainly has indirect effects on areas outside" of the fields' borders. Coalition Br. 36. The Coalition, however, does not cite any record evidence for this argument, and also disregard record evidence that EPA considered both potential direct and indirect effects to ESA-listed species. ER72 (EPA concluding that "the direct *and indirect* effects to any taxa would be limited to areas within the confines of treated fields.") (emphasis added).

They similarly cite to evidence that refers to previous formulations of 2,4-D. They argue that "2,4-D" is prone to migrate through spray drift and volatilization. Coalition Br. 33 (citing ER2022 for the proposition that "*2,4-D* is known to volatilize from the field and drift off site under certain environmental conditions.") (emphasis added); *id.* (citing ER2067 for the proposition that "EPA was aware that by 2012, there had been thousands of reported incidents of terrestrial plants, aquatic plants, birds, fish, mammals, reptiles, and terrestrial insects having been killed by *2,4-D* traveling off-site") (emphasis added). However, Enlist Duo contains a newer formulation of 2,4-D that is less prone to volatilization. ER28 ("the choline salt is less volatile than other forms of 2,4-D"). The Court should reject the Coalition's attempted sleight of hand, which is based on a pesticide active ingredient that is not a component of Enlist Duo.

In sum, the administrative record evidence fully supports EPA's reasonable assumption that Enlist Duo would remain on the treated fields. *See supra* Section II.B.1.a (discussing EPA's assessment of volatility); SER15, 26-27, 63, 75 ("Spray drift analysis indicates that spray drift mitigations on the current label for Enlist Duo would reduce exposures off site to levels well below risk concern levels for listed and non-listed species, thereby containing risks to the treatment site itself."), 79, 81 ("Analysis of volatilization information for the 2,4-D choline products indicates that volatilization from the treatment site to off-site areas is not of concern."), 82 ("risks for non-target plants will not extend to off-treatment site areas"), 83. The Court should accordingly find that there is "a rational connection between the facts [EPA] found and the choices [it] made." *Arrington v. Daniels*, 516 F.3d 1106, 1112 (9th Cir. 2008) (internal quotation marks and citation omitted); *Friends of the Wild Swan v. Weber*, 767 F.3d 936, 950 (9th Cir. 2014) ("[T]he choice of appropriate action areas requires application of scientific methodology and, as such, is within the [action] agency's discretion."); *cf. Bear Lake Watch, Inc. v. F.E.R.C.*, 324 F.3d 1071, 1077 ("'We defer to agency expertise on questions of methodology . . . .'").

D. EPA correctly gauged potential impacts to critical habitat.

EPA carefully considered potential impacts to designated critical habitat. EPA used a logical, refining approach to ascertain whether the new use on cotton

and the expansion to 19 additional states for soybean and corn would affect any species' critical habitat. First, EPA identified those species for which FWS or NMFS had designated critical habitat. SER112-114. EPA completed this step by asking whether there was any co-occurrence between the designated critical habitat and the 34 states subject to the registration. *Id.* This first step is akin to the cautious screening level analysis in the "level of concern" approach for effects to the species. *See supra* at 20-22. If the answer to the first inquiry is no, EPA determines there will be no adverse modification of critical habitat. SER112-114.

However, if the answer to the threshold inquiry is yes, EPA asks if either of the following is true: (a) the species uses corn, cotton or soybean fields as habitat *and* EPA has already made a "may affect" determination for the species; *or* (b) the species uses corn, cotton or soybean fields *and* the effects from the new uses would affect one of that species' primary constituent elements. *Id.* The first prong identifies situations where EPA needs to look more closely at potential effects to habitat because the species occur on affected fields and EPA has already found that the species itself is affected by the pesticide. *Id.* This prong requires EPA to consider whether a pesticide is not only directly or indirectly affecting the species, but also its critical habitat. Even if the answer to this question is no, however, EPA continues with its analysis. EPA also asks whether the species occurs on corn, soybean or cotton fields and the pesticide would affect one or more of the primary

constituent elements of that species' critical habitat. Primary constituent elements are features that support the life-history needs of the species, such as water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. *Implementing Changes to the Regulations for Designating Critical Habitat*, 81 Fed. Reg. 7414, 7426, 7432 (Feb. 11, 2016) ("*Changes*"); *see also* 50 C.F.R. § 424.12(b)(1)(ii). Concrete examples of primary constituent elements might include gravel of a particular size required for spawning, alkali soil for germination, protective cover for migration, or susceptibility to flooding or fire that maintains early-successional habitat characteristics. *Changes*, 81 Fed. Reg. at 7432. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a maximum level of nonnative species consistent with conservation needs of the listed species. *Id*. Thus, while not required to do so, EPA based its critical habitat analysis on whether any potential effect existed on primary constituent elements of species' critical habitat. *Alliance for the Wild Rockies*, 979 F. Supp. 2d at 1130-31 (not requiring analysis of primary constituent element when assessing potential effects to critical habitat in context of a "no effect" determination).

The Coalition's argument that EPA "invented [these] rules from whole cloth" is incorrect. Coalition Br. 49. EPA's approach to assessing effects to

critical habitat dates back to 2004. The 2004 EPA Overview Document explains that, because pesticides directly impact living organisms, critical habitat analysis for pesticides focuses chiefly on those primary constituent elements that are of a biological nature—*i.e.*, the biological resource requirements for the listed species associated with the critical habitat. ER2534; ER 72-73, 88, 90. That is precisely what EPA did here. SER112-114 (assessing potential effects to 187 critical habitats); SER159-431 (explaining rationale for critical habitat "no effect" determinations).[39] FWS and NMFS have acknowledged and endorsed the 2004 Overview Document's primary constituent element-based approach in the 2014 report to Congress. *Supra* n.37. The Court should defer to the considered judgment of EPA as to how to conduct its endangered species analysis.

The Coalition's argument that EPA incorrectly determined that Enlist Duo would have no effect on species or critical habitat for those species occurring on the fields of application also fails. It is a rehash of their action area argument. It lacks merit for the same reasons. Coalition Br. 46. Based on the information that it had before it, EPA rigorously analyzed the likelihood of off-site movement. *See supra* Section II.B.1.a (FIFRA argument demonstrating volatilization and spray drift were not a concern for 2,4-D). EPA reasonably relied on data and modeling

[39] Contrary to the Coalition's contention, EPA considered potential exposure of prey species. *See supra at* 90-91, 107-108; ER2549.

analyses to impose a downwind buffer to ensure that there would be no effects to non-target plants outside of the treated area. *Id.*[40] The Court should decline the Coalition's invitation to second-guess EPA's expert judgment.

The Court should also reject the Coalition's suggestion that EPA failed to consider species' primary constituent elements. First, the Coalition ultimately concedes that EPA did consider primary constituent elements. *Compare* Coalition Br. 53, *with id.* 55-56 ("EPA–finally–looked at the critical habitats' [primary constituent elements] . . . ."). Indeed, the record demonstrates that EPA considered primary constituent elements in excruciating detail. SER112, 162, 165, 172, 173, 411-412) (considering primary constituent elements of numerous species).[41] Notably, Petitioners do not identify a single primary constituent element – of the Whooping crane, the Indiana bat, or any other species – that EPA allegedly did not consider. In short, the record demonstrates that EPA did not "rel[y] on factors which Congress has not intended it to consider, entirely fail[] to consider an important aspect of the problem, offer[] an explanation for its decision that runs counter to the evidence before the agency or is so implausible that it could not be

[40] Other terms or condition of registration to ensure no off-field movement include restrictions regarding droplet size, ground-boom height, wind speed and direction, irrigation timing, anticipated weather, and a prohibition against aerial application. ER31-36.

[41] Appendix M of the 2016 Ecological/ESA Assessment discusses critical habitat elements, generally, and specifically states when it is discussing PCEs that FWS has officially identified. SER411-431.

ascribed to a difference in view or the product of agency expertise." *League of Wilderness Defenders Blue Mountains Biodiversity Project v. Allen*, 615 F.3d 1122, 1130 (9th Cir. 2010) (citing *Lands Council v. McNair*, 537 F.3d 981, 987 (9th Cir. 2008)).

IV. ALTHOUGH THE PETITIONS SHOULD BE DENIED ON THE MERITS, THE COURT SHOULD PERMIT THE PARTIES TO BRIEF REMEDY SEPARATELY IF NECESSARY OR, ALTERNATIVELY, NARROWLY TAILOR ITS RELIEF.

For all the reasons stated above, the Court should deny the petitions for review on the merits. Should the Court grant the petitions in whole or in part, however, EPA respectfully requests that the parties be permitted to brief the issue of remedy separately or, alternatively, narrowly tailor any relief.

Enlist Duo has important agricultural uses that could be disrupted by vacatur of the 2017 Amended Registration. The decision whether to vacate depends on (1) the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and (2) the "'disruptive consequences of an interim change that may itself be changed.'" *Cal. Communities Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (quoting *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993)). "A flawed rule need not be vacated." *Id.* Indeed, "when equity demands, the regulation can be left in place while the agency follows the necessary procedures" to correct its action. *Id*.

Here, it is impossible to ascertain the "seriousness" of any "deficiency" until the Court renders a decision on the merits. Yet, the likely "disruptive consequences" of vacatur – both to farmers who already have purchased genetically engineered seeds formulated for Enlist Duo, and state and federal regulatory programs – would be significant. Additional briefing as to EPA's court-ordered responsibilities, priorities, and funding would also aid the Court in assessing an appropriate remedy under the ESA.

Moreover, any remedy should be tailored to the actual injuries Petitioners have adequately shown in their standing declarations. As this Court and the Supreme Court have held, petitioners must demonstrate standing separately for each form of relief sought. *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650-51 (2017); *Friends of the Santa Clara River*, 887 F.3d at 917; *Los Angeles Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 655 (9th Cir. 2011)). Limiting any remedy to the injury that forms the basis for standing is necessary to "insure[] the framing of relief no broader than required by the precise facts to which the court's ruling would be applied." *Schlesinger v. Reservists Comm. to Stop the War*, 418 U.S. 208, 221-22 (1974); *see also Los Angeles Haven Hospice*, 638 F.3d at 664. In particular, NRDC's standing declarations fail to show alleged injuries that have been caused by EPA's treatment of glyphosate in the 2017 Amended Registration or that any such injuries would be redressable injuries that

justify a vacatur. *Lujan*, 504 U.S. at 560. Indeed, FIFRA's judicial review provision expressly contemplates such tailoring of judicial relief. *See* 7 U.S.C. 136n (providing that reviewing court may "set[] aside" the challenged order "in whole or in part").

Accordingly, it would be appropriate to have further briefing to assist the Court in constructing a remedy tailored to the Court's opinion on liability and the actual scope of the Coalition's cognizable injuries.

CONCLUSION

For the foregoing reasons, the Court should deny the petitions for review and uphold EPA's 2017 Registration Amendment. To the extent the Court does not affirm EPA's decision, EPA requests an opportunity to submit further briefing on remedy.

Respectfully submitted,

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STATEMENT OF RELATED CASES

There are no other related cases pending in this Court.

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and Circuit Rule 32-1 because it contains 26,394 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

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CERTIFICATE OF SERVICE

I hereby certify that on July 11, 2018, I electronically filed the foregoing brief with the United States Court of Appeals for the Ninth Circuit by using the CM/ECF system. I certify that all case participants are registered for the Appellate CM/ECF System and that they will be served by the CM/ECF system.

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