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

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

Jonathan D. Brightbill
Principal Deputy Assistant Attorney General
Environment and Natural Resources Division

Michele L. Walter
Trial Attorney
J. Brett Grosko
Senior Trial Attorney
Environment and Natural Resources Division
U.S. Department of Justice
999 18th Street
Suite 370, South Terrace
Denver, Colorado 80202
(303) 844-1345 (Walter)
(202) 305-0342 (Grosko)
michele.walter@usdoj.gov
brett.grosko@usdoj.gov

Of Counsel:

Benjamin Wakefield
Michele Knorr
U.S. Environmental Protection Agency
Office of General Counsel
Pesticides & Toxics Substances Law Office
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Oct. 11, 2019

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

FEDERAL REGISTER NOTICES

OTHER AUTHORITIES

TABLE OF ABBREVIATIONS

APA	Administrative Procedure Act
BE	Biological Evaluation
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
RSBER	Respondents' Supplemental Brief Excerpts of Record
SBER	Coalition Supplemental Brief Excerpts of Record
SER	EPA's Supplemental Excerpts of Record
USDA	United States Department of Agriculture

INTRODUCTION

In response to the Court's May 30, 2019, Order, both sets of Petitioners have submitted supplemental briefs. As to the issues under the Federal Insecticide and Rodenticide Act ("FIFRA"), Petitioners' arguments either misstate or misunderstand FIFRA and the Environmental Protection Agency's ("EPA") longstanding process of issuing pesticide product licenses. Every registration action that EPA took here for Enlist Duo is consistent with FIFRA and EPA's regulations. And every action is supported by substantial evidence.

Petitioners, the 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 (collectively "Coalition") largely restate their Endangered Species Act ("ESA") arguments. They criticize EPA's level of concern-risk quotient methodology and approach for defining the action area as confined to the treated fields. Those arguments fail for the reasons EPA has stated previously. They are based on a fundamental misunderstanding of *Karuk Tribe of California v. U.S. Forest Service*, 681 F.3d 1006 (9th Cir. 2012) (*en banc*) ("*Karuk Tribe*").

The Coalition also asserts a new ESA argument concerning the glyphosate component of Enlist Duo. It waived any right to do so, however, by not presenting

it in its opening brief, and lacks standing. Even if it were properly presented, it would fail. The use of glyphosate on cotton and soybean crops that have been genetically engineered to resist the herbicide is not a "new use" under FIFRA. So no duty has arisen to consult as to glyphosate under the ESA.

BACKGROUND

I. FIFRA's Statutory and Regulatory Scheme for Pesticide Product Registration and Registration Review.

Each Petitioner has a fundamentally incorrect understanding of how FIFRA and its implementing regulations work. EPA incorporates by reference its prior discussion of FIFRA's background, *see* Brief of U.S. Environmental Protection Agency, et al. ("EPA Br.") 4-7, and provides further explanation here.

A. EPA's informal adjudication process to issue licenses for "pesticide products."

EPA registers "pesticide products" under FIFRA Section 3(a), 7 U.S.C. § 136a(a), and its implementing regulations. Under 40 C.F.R. § 152.15 ("Pesticide products required to be registered"), "[n]o person may distribute or sell any *pesticide product* that is not registered under the Act. . . ." (emphasis added). A "pesticide product" is "a 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 (emphasis added); *see* 7 U.S.C. § 136a(c)(1)(C)

(requiring draft label with application).[1] The "composition" of a specific "pesticide product" can include one or more "active ingredients." EPA Br. 4. A "pesticide product" that contains more than one "active ingredient" is a "combination" pesticide product. *Id.*

EPA must issue a registration for a "pesticide product" before the product can be sold or distributed. That "registration" is a "*license* that allows a pesticide product to be distributed or sold for specific uses under specified terms and conditions." 71 Fed. Reg. 45,720 (Aug. 9, 2006) (emphasis added); *see Reckitt Benckiser, Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010) ("A FIFRA registration is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used.").

The licensing process is an informal adjudication under the Administrative Procedure Act ("APA").[2] Through this informal adjudication process, EPA issues the pesticide product license, which is an "order" under the APA. *See* 5 U.S.C.

[1] The label provides "clear directions for effective product performance while minimizing risks to human health and the environment." https://www.epa.gov/pesticide-registration/about-pesticide-registration#registration. (last visited Oct. 7, 2019)

[2] If EPA elects to hold a public hearing for a pesticide product registration, that does not convert the registration process into formal adjudication. Where, as here, a public hearing was held, that fact is relevant only for jurisdictional purposes under FIFRA Section 16. 7 U.S.C. § 136n(b).

§ 551(6) (defining "order" as "the whole or part of a final disposition . . . of any agency in a matter other than rule making but including licensing[.]"; *see also id.* § 551(8) (defining "license" to include an "agency . . . registration . . . or other form of permission").[3] That license is the only mechanism that gives the registrant (and others) permission to sell or distribute the pesticide product.

FIFRA does not direct EPA to issue a license in any particular form. EPA therefore, as a general matter, issues a "Notice of Registration" for the initial pesticide product license. *See* 40 C.F.R. §152.117. That Notice of Registration is the "final disposition" in the informal adjudicatory process. 5 U.S.C. § 551(6); *see* EPA Br. 12, n.3. For amendments to existing licenses, EPA typically issues the amendment in the form of a letter. 40 C.F.R. § 152.117. Until a registration or amendment is granted, the registrant does not have a license to sell or distribute the pesticide product. The license is the *only* final "agency action" as defined by the APA that can be challenged. *See* 5 U.S.C. § 551(13) (defining "agency action" as "an agency rule, order, license. . . .").

The underlying rationales supporting the license are found in "Decision Documents." FIFRA does not require EPA to develop such Decision Documents

[3] Because the term "order" seems to have created confusion in earlier briefing, EPA will use the term "license" to more clearly convey the legal import of the mechanism that allows a registrant to sell or distribute a "pesticide product."

during the informal adjudication process. When such documents are developed, however, they are used to inform the final disposition on the license or amendment. Importantly, those Decision Documents are *not* the license and do *not* authorize the distribution or sale of the pesticide product. Rather, they explain EPA's underlying rationale and analysis. So even when EPA signs a final Decision Document supplying the rationale for a license or amendment, there is no license for a registrant to sell the pesticide product until EPA actually issues a Notice of Registration (license) or letter amending the license to an applicant.

B. EPA's licensing process looks at each active ingredient in a pesticide product.

When EPA receives a registration application for a pesticide product, the Agency determines whether the pesticide product contains a single active ingredient, or is a "combination" product. *See generally* ER84[4] (When "a company submits an application for a new use on a product that contains two or more active ingredients" that product is a "combination product.").

EPA also determines whether the application seeks a "new use," *i.e.*, a use that has not been previously registered, of any previously registered active ingredient. A "new use" as it pertains to "a *product containing a particular active*

[4] "ER" refers to previously filed "excerpts of record" and "SER" refers to "supplemental excerpts of record." Additional Excerpts of Record provided with this Supplemental Brief are indicated with "RSBER."

ingredient, 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 (emphasis added).

> [W]here a company submits an application for a new use on a *product that contains two or more active ingredients* . . . and the use being requested for this combination product is currently registered for one or more of the active ingredients, the EPA *only assesses the risks and benefits of the active ingredient that does not currently have products registered for that use*."

ER522 (emphasis added). When a license is sought for a combination pesticide product, EPA evaluates each active ingredient to determine whether the same uses are already registered in another pesticide product. If so, the risks and benefits for that active ingredient with respect to that use have already been assessed. So no new assessment is required.

If a "new use" is sought for an active ingredient, EPA will assess the risks and benefits of that new use. This includes whether the Agency has all the requisite data for that new use. FIFRA's regulations provide the kinds of data and information that EPA requires from applicants for the pesticide product registration process. *See generally* 40 C.F.R. Part 158; 40 C.F.R. § 158.1(a). These regulations state that EPA is not restricted in how it uses or evaluates the data and information to make its registration decisions. *Id.* § 158.1(b)(3). Indeed, EPA's regulations establish that the Agency has the flexibility to determine what data requirements are necessary on a case-by-case basis. *See id.* § 158.30(a).

Thus, EPA's longstanding practice is to review pesticide products on a "chemical-by-chemical" basis, *i.e.* on an active ingredient basis. EPA then incorporates that review into the decision for the overall pesticide product. 40 C.F.R. § 152.111; *see* 70 Fed. Reg. 40,251, 40,253 (July 13, 2005).

> *The type of review chosen depends primarily on the extent to which the relevant data base has been reviewed for completeness and scientific validity*. . . . Except for applications for registration of a new active ingredient or in special cases where it finds immediate review to be warranted, *the Agency will not commence a complete review of the existing data base on a given chemical* in response to receipt of any application for registration. *Instead the Agency will review the application using the criteria for conditional registration in FIFRA* [Section] 3(c)(7)(A) and (B).

40 C.F.R. § 152.111 (emphasis added).

Under this practice, when the application for a pesticide product contains an active ingredient for which there is an "existing database" (a database that supports a use that is already registered for that active ingredient) EPA does not conduct a new analysis of that active ingredient. Nor do EPA's regulations require additional analysis beyond the analysis previously conducted to register that use. *See* ER2; *see also* ER206 (in applications for combination products, "EPA only assesses the risks and benefits of the active ingredient that does not currently have products registered for that use.").

EPA's approach to separately consider each active ingredient fits with FIFRA's registration review process under Section 3(g). 7 U.S.C. § 136a(g).

During registration review, which takes place on a recurring 15-year cycle, EPA "evaluate[s] elements of FIFRA 3(c)(5) including the composition, labeling and other required material (including studies and other data), risks and benefits of a pesticide, and incident data or other information relating to its use." 65 Fed. Reg. 24,586, 24,587 (Apr. 26, 2000).

The purpose behind registration review is to account for "the rapid development of science and the subsequent application of that knowledge in how it impacts human health and the environment." 70 Fed. Reg. at 40,252. Registration review therefore "establishing ongoing scientific look-back procedures" to consider for this "continually evolving" landscape. *Id.* at 40,253.

FIFRA Section 3(g), however, does not specify what "unit of review" EPA should use in this process. 70 Fed. Reg. at 40,258. EPA's regulations therefore direct that registration review will be conducted for "one or more active ingredients and all the products containing such ingredient(s)." 40 C.F.R. § 155.42(a); *see* 70 Fed. Reg. at 40,258. For a combination pesticide product, that product will be assigned to the registration review case for each active ingredient. 40 C.F.R. § 155.42(a)(3).

During the registration review process, EPA may issue "data call-ins" for active ingredients that are undergoing registration review. If EPA determines that additional information is needed after receiving data in response to that data call-

in, EPA may determine that the data requirements for that data call-in are still "outstanding." As explained below, *infra* Section I.C., "outstanding data" in the context of the registration review process are different from data that may be missing from the requisite data needed to register a new use of an active ingredient.

C. EPA has discretion to issue an unconditional registration under FIFRA Section 3(c)(5) or conditional registration under Section 3(c)(7).

EPA "has discretion to review applications under either the unconditional registration criteria of FIFRA [Section] 3(c)(5) or the conditional registration criteria of FIFRA [Section] 3(c)(7)." 40 C.F.R. § 152.111. FIFRA does not dictate how EPA should exercise this discretion.

Unconditional registrations under FIFRA Section 3(c)(5), 7 U.S.C. § 136a(c)(5), can be granted for a variety of applications, including for "new uses" or new active ingredients, as long as certain criteria are met. *See* https://www.epa.gov/pesticide-registration/pesticide-registration-manual-chapter-1-overview-requirements-pesticide#unconditional. (last visited Oct. 7, 2019). Among the requirements for making a decision to issue an unconditional registration under Section 3(c)(5), EPA must determine that the pesticide product "will perform its intended function without unreasonable adverse effects on the environment," and that "when used in accordance with widespread and commonly

recognized practice, [the pesticide product] will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5); *see* EPA Br. 5.

EPA alternatively may issue a conditional registration under FIFRA Section 3(c)(7), 7 U.S.C. § 136a(c)(7). Prior to 1978, EPA could "register a pesticide only if the Agency had sufficient data to show the pesticide would not cause unreasonable adverse effects on human health and the environment when used according to the use directions and restrictions provided on the pesticide product label." https://www.epa.gov/pesticide-registration/conditional-pesticide-registration ("Conditional Registration Website") (last visited Oct. 7, 2019). Under that earlier standard, EPA "could not register a new pesticide unless its registration application was supported by all the information required under then-current scientific standards." *Id.* "Because scientific standards evolve over time, applicants seeking registration for new pesticide products were typically required to provide significantly more data than had been required in the past for virtually the same product. This led to an unfair situation." *Id.* Thus, if EPA was considering an application for Pesticide Product B, which was identical to or substantially similar to currently-registered Pesticide Product A, EPA would need to

> deny registration if the data requirements had evolved to require additional information that was not required when [P]roduct A was registered. The grounds for the denial of registration for [P]roduct B was that EPA lacked the data necessary to conclude that the new

> product met the "no unreasonable adverse effects" on human health and the environmental standard, even though an identical product, [P]roduct A, was still allowed to be sold and used.

Id.

Congress remedied that situation in 1978. It added FIFRA Section 3(c)(7), which gave EPA additional authority in two specific circumstances relevant here. Under 3(c)(7)(A), EPA can "register a pesticide product 'conditionally' . . . if it was identical or substantially similar to a currently registered product, even if there were gaps in the data, as long as EPA could make the necessary statutory findings." *Id.*; *see* 7 U.S.C. § 136a(c)(7)(A). Pesticide products that EPA registers under FIFRA Section 3(c)(7)(A) also are known as "me-too" products.

In addition, EPA can register a pesticide product under 3(c)(7)(B) "may conditionally amend the registration . . . to permit additional uses" of the pesticide active ingredient even if the "data concerning the pesticide may be insufficient to support an unconditional amendment" so long as EPA makes certain findings. Conditional Registration Website (specifying findings); *see* 7 U.S.C. § 136a(c)(7)(B). Under this conditional registration provision, the applicant must submit or cite the same data that would be required for unconditional registration of a similar product under FIFRA section 3(c)(5). 7 U.S.C. § 136a(c)(7)(B).

Through Section 3(c)(7), Congress intended to prevent the FIFRA registration program from grinding "to a virtual halt" simply because of the fast

pace at which scientific data evolves. *See* EPA Br. 35 (quoting S. Rep. No. 95-334 at 3). Thus, Section 3(c)(7) gives EPA the flexibility to grant conditional registrations when there are "outstanding data," such as in the context of registration review or that otherwise would warrant a denial of the registration. Federal Pesticide Act of 1978: Hearings on S. 1678 Before the Committee of Agriculture, Nutrition, and Forestry, 95 Cong. 69 (1979). Under Section 3(c)(7) EPA "must find that satisfactory data pertaining to the new use have been submitted. . . ." *Id.*; 7 U.S.C. § 136a(c)(7)(B). If so, the Agency may conditionally register the new use. That new use is conditional under Section 3(c)(7) based on any data concerning the active ingredient that are not yet generated, in review, or outstanding for other reasons such as in the context of a data call-in during registration review.

II. The Enlist Duo Registration and Amendments.

Because Enlist Duo is a combination "pesticide product" containing two "active ingredients" – 2,4-D and glyphosate – EPA looked to whether the application sought a "new use" for either of those active ingredients. Only 2,4-D presented a "new use" in the Enlist Duo application. ER2-4. EPA therefore was not required to conduct a new risk assessment for the existing registered uses of glyphosate for *any* of the three registration actions for Enlist Duo. EPA Br. 11 (citing ER2-4).

Through the informal adjudication process, EPA issued a Notice of Registration for its 2014 action, which is the initial *license* for Enlist Duo. ER1401; 40 C.F.R. § 152.117. The 2014 Notice of Registration states that the registration was "unconditional" under FIFRA Section 3(c)(5). ER1401. The 2014 Registration was unconditional because EPA determined that the pesticide product met the standard, *i.e.*, "no unreasonable adverse effects," from FIFRA Section 3(c)(5), and, at that time, there were no "outstanding data" identified for 2,4-D (the only active ingredient for which a "new use" was sought).

Consistent with that 2014 Notice of Registration, the Proposed Decision Document also stated that the analysis EPA conducted for this registration action supported the decision to grant an unconditional registration. RSBER27 ("Based on these considerations, consistent with the requirements of FIFRA Sec. 3(c)(5), EPA concludes that . . . approving this application as set forth below will not cause any unreasonable adverse effect on the environment.").

One document (the Final Decision Document) mistakenly refers to the 2014 registration as "conditional" (under FIFRA Section 3(c)(7)). ER1394-95. Except for the typographical error in that one document, it is clear from the record as a whole and from the substance of EPA's actions that EPA applied the *unconditional* registration standard to ensure that there were no "unreasonable adverse effects,"

and issued the registration under FIFRA Section 3(c)(5), as shown on the Notice of Registration (the actual license).

A few months later, when EPA issued the 2015 Amendment for Enlist Duo to add nine states, EPA still had not identified any outstanding data as to the new use of 2,4-D. Thus, the status of that amendment was still unconditional under Section 3(c)(5). Consistent with its regulation, *see* 40 C.F.R § 152.117, EPA issued the 2015 amendment by letter approving the additional states, which was the actual license. ER1019-40; *see* 40 C.F.R. § 152.117. The rationale supporting that Amendment is in the 2015 Final Decision Document. ER1055-60.

By the time EPA granted the 2017 Amendment for Enlist Duo, circumstances had changed. EPA determined that studies submitted in response to a data call-in for 2,4-D as part of the FIFRA registration review process did not fully satisfy the data call-in. Those studies therefore were considered "outstanding data" for *all* registered uses of 2,4-D, and *any* further registration action on the existing Enlist Duo license would have to be "conditional" under FIFRA Section 3(c)(7). The license for the 2017 Amendment is found at ER37 (Notice of Registration) and specifically states that the amended registration is conditional

under Section 3(c)(7).[5] ER37. The rationale supporting the 2017 Amendment is found in the Final Decision Document. ER28-30.

ARGUMENT

I. EPA Properly Registered Enlist Duo In 2014 As An Unconditional Registration And Subsequently Issued A Conditional Amendment To That Registration, While Consistently Applying The Most Stringent Standard To Its Actions.

Petitioner Natural Resources Defense Council ("NRDC") demands that EPA should have issued the 2014 Registration as unconditional under FIFRA 3(c)(5). NRDC Suppl. Br. 2-8. That is exactly what EPA did. Regardless of whether the 2014 Registration was unconditional or conditional, however, EPA consistently (with the exception of the one typographical error) used the most stringent substantive standard (the standard under Section 3(c)(5)) to analyze whether Enlist Duo would cause any "unreasonable adverse effects on the environment."

A. The 2014 Notice of Registration was unconditional under FIFRA Section 3(c)(5) and NRDC has waived any argument to the contrary.

The 2014 Notice of Registration (the actual license) and the Proposed Decision Document show that EPA was proceeding with an unconditional

[5] EPA exercised its discretion to issue the license for the 2017 Amendment in the form of a Notice of Registration instead of a letter given the remand of Enlist Duo (without vacatur) in the previous litigation challenging the 2014 and 2015 actions. (That litigation is referred to as *Enlist Duo I*, *see* EPA Br. 12 (providing case citations)). EPA, however, could have exercised its discretion to issue that license amendment in the form of a letter, as it did in 2015.

registration under Section 3(c)(5). *Supra* at 13. The Proposed Decision Document also shows that EPA used the standard from 3(c)(5): "consistent with the requirements of FIFRA [Section] 3(c)(5), EPA concludes that . . . approving this application as set forth below will not cause any unreasonable adverse effects on the environment." RSBER27. This totality of circumstances refutes NRDC's argument that EPA improperly issued a conditional registration in 2014.[6]

Moreover, NRDC has waived any argument that EPA issued a conditional registration in 2014. *N. Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1081 (9th Cir. 2011) ("A party waives arguments that are not raised during the administrative process."). NRDC never raised this argument until its opening brief in this current case. Indeed, when NRDC provided comments on the proposed 2015 Amendment – *after* development of the 2014 Final Decision Document and issuance of the 2014 Notice of Registration – and when NRDC provided comments on the 2017 Amendment, it *never* purported any confusion or argument about what type of registration was done in 2014 and *never* argued that the 2014 Notice of Registration was conditional rather than unconditional. ER1614-64.

[6] For these same reasons, the Coalition's argument that EPA "made a mess of FIFRA's registration standards," is incorrect. Coalition Suppl. Br. 29.

Also, when NRDC challenged the 2014 Notice of Registration and 2015 Amendment in its petition for review in *Enlist Duo I*, it *never* argued that EPA incorrectly registered Enlist Duo in 2014 under the conditional standard in (c)(7). In fact, in supporting EPA's motion for remand and vacatur of the 2014 Notice of Registration and 2015 Amendment, NRDC cited *only* Section 3(c)(5) (and not 3(c)(7)) in discussing the 2014 Registration, thereby acknowledging that the 2014 registration was an unconditional registration. *See generally* ECF #125 (Case Nos. 14-73353, 15-71213 and consolidated cases) (repeatedly citing Section 3(c)(5) instead of 3(c)(7) and acknowledging that the standard EPA applied was the "unreasonable adverse effects on the environment" standard from 3(c)(5)). NRDC's merits brief in *Enlist Duo I* also did not make any argument that the 2014 Notice of Registration was an improper conditional registration. ECF #106 (Case Nos. 14-73353, 15-71213 and consolidated cases).

Regardless, this belated argument that NRDC conjured up for the first time in this litigation is a red herring. Even *if* the Court adopts NRDC's position that EPA issued a conditional registration in 2014, the record shows that EPA applied the substantive standard from the unconditional registration provision. *See supra* at 13. NRDC and EPA agree that this is the more stringent standard. NRDC Suppl. Br. 7. Thus, any supposed error by EPA was harmless, as EPA's analysis at

the time of the 2014 Notice of Registration would not have been different even if that registration had been thought to be conditional rather than unconditional.

B. EPA's imposition of "conditions" on the registration has no bearing on whether the registration actions were unconditional under Section 3(c)(5) or conditional under Section 3(c)(7).

"EPA routinely places a variety of conditions on registrations." *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174, 181 (D.D.C. 2012). Indeed, nothing in FIFRA precludes EPA's authority to place conditions on pesticide product licenses. *See id.* at 180 (deferring to EPA's interpretation of FIFRA that EPA has the "authority to place conditions on pesticide registrations other than those specified in Section 3(c)(7)"). "The plain language of the statute does not restrict EPA's authority as to the type of conditions that may be placed on registrations." *Id.* As a practical matter, courts have recognized agency "authority to issue licenses or registrations subject to conditions." *Id.* at 181 (citing *Conn. Fund for the Env't, Inc. v. EPA*, 672 F.2d 998, 1006 (2d Cir. 1982)).

EPA's imposition of such conditions (which are unrelated to data requirements) on the registration balances the risks and benefits of the pesticide product. Those conditions, however, are *not* the same as issuing a "conditional" registration or amendment under FIFRA Section 3(c)(7). These conditions may be included on *either* an unconditional or a conditional registration or amendment.

NRDC's reliance on "conditions" that EPA imposed on the registration in issuing the 2014 license therefore has no relevance to whether the 2014 Notice of Registration was an unconditional or conditional registration. NRDC Suppl. Br. 4. In this case, EPA placed conditions on the registration concerning possible future weed resistance. ER102-3. Placing these conditions on the 2014 unconditional registration (and the amendments to that registration) was well within EPA's authority to ensure the action being granted met the registration standard. But it has no bearing on whether the registration actions were unconditional under Section 3(c)(5) or conditional under Section 3(c)(7).

C. Neither EPA's 2017 conditional Amendment nor the identification of "outstanding data" during the 2017 registration process retroactively changes the status of the previous unconditional registration actions.

NRDC further argues that because the 2017 Amendment was a conditional amendment under Section 3(c)(7) and because EPA's 2017 action did not change the 2014 Registration or 2015 Amendment, that must mean that the 2014 Registration also was conditional under Section 3(c)(7). NRDC Suppl. Br. 5. NRDC's revisionist history is incorrect. EPA has the discretion to change the status of a registration from unconditional to conditional. 40 C.F.R. § 152.111. Indeed, the purpose behind Section 3(c)(7)(B) is to authorize this exact scenario where an unconditional registration may be conditionally amended because of evolving science and data. 7 U.S.C. § 136a(c)(7)(B).

NRDC also argues that once EPA determined that there were "outstanding data" during the 2017 Amendment process, the Agency was barred from "reissuing" its 2014 and 2015 actions. NRDC Suppl. Br. 22-23. NRDC's argument is based on flawed logic that EPA "reissued" its approvals of the 2014 Registration and 2015 Amendment. *Id*. EPA does not "reissue" registrations or amendments; rather, EPA *amends* an existing license.

Here, when EPA issued the Enlist Duo license in 2014 and amended the license in 2015, those actions were *unconditional* because EPA was not aware of any "outstanding data" in the context of registration review for 2,4-D. But, when EPA issued the amendment in 2017, circumstances had changed. The Agency was then aware of outstanding data in the context of registration review with respect to the use of 2,4-D across all registered pesticide products. That 2017 Amendment therefore was conditional. The entire Enlist Duo license, as amended, is *now* conditional. That does not mean that the unconditional 2014 Registration and 2015 Amendment were invalid or that they were retroactively converted to a conditional registration and amendment. The entire Enlist Duo license, which incorporates the 2014 registered uses and the 2015 amendment, is now conditional under Section 3(c)(7) based on the existence of that "outstanding data" for 2,4-D in the registration review process.

II. Substantial Evidence Supports Each Registration and Amendment Action.

FIFRA is silent on how EPA must conduct risk assessments to balance the risks and benefits in determining whether to register a pesticide product. EPA therefore has discretion in weighing the risks and benefits associated with a pesticide product to ensure that there are "[no] unreasonable adverse effects." 7 U.S.C. § 136a(c)(5). In a "complex regulatory scheme" like FIFRA, the Court should give deference to EPA's interpretation of how to exercise this discretion. *See Wisc. Elec. Power Co. v. Reilly*, 893 F.2d 901, 906-07 (7th Cir. 1990); *see also Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 865 (1984) (giving deference to agency interpretation where "regulatory scheme is technical and complex").

Throughout *each* registration action for Enlist Duo, EPA used the more stringent standard from FIFRA's unconditional registration provision in Section 3(c)(5) to determine whether Enlist Duo would cause any "unreasonable adverse effects." NRDC does not dispute that this standard is more stringent than the standard in 3(c)(7).[7] Thus, the only question is whether, under that more stringent 3(c)(5) standard, EPA's record contains substantial evidence to support the Enlist Duo registration and amendments. The answer is yes.

[7] The Coalition disputes that the 3(c)(5) standard is more stringent, but EPA demonstrated why the Coalition is wrong. EPA Br. 33-37.

A. Substantial evidence supports the issuance of the 2014 Registration.

i. EPA reasonably looked at 2,4-D and glyphosate separately.

During a registration action, EPA will not conduct a new risk assessment for a currently-registered active ingredient just because new science has emerged since the last registration for the same uses of that active ingredient. The appropriate place for that analysis is in the context of the FIFRA Section 3(g) registration review. That is where *all* uses associated with a particular active ingredient will be assessed across *all* pesticide products containing that active ingredient.

This approach is not only consistent with the statute, but makes practical sense as well. In the more than 2,000 registration actions EPA takes each year, hundreds of them include applications for pesticide products that contain active ingredients that are already registered for the same uses. *See* https://www.epa.gov/pria-fees/annual-reports-pria-implementation. (last visited Oct. 7, 2019). Given the continuous development of scientific studies about active ingredients, it would be impracticable to demand that EPA must review all new scientific information that has been developed for every new application since the

last time an active ingredient was registered for the same uses.[8] Instead, the proper place for that updated review is in the context of Section 3(g) registration review.

To further illustrate the reasonableness of EPA's approach looking separately at each active ingredient, consider an application for a pesticide product that contains only one active ingredient. If the uses of that active ingredient have already been registered in other pesticide products, nothing in FIFRA requires EPA to conduct a new risk assessment based on scientific data that was developed after the last registration. Indeed, that approach would eviscerate Congress' concern (addressed in Section 3(c)(7)) about creating an uneven playing field between existing registrations and new registrations. *See supra* 10-12.

Contrary to this longstanding process, NRDC argues that EPA cannot separately examine each "active ingredient" in a combination pesticide product. NRDC Suppl. Br. 14-15. To that end, NRDC narrowly focuses on the definition of "pesticide," under the statute. It argues that the statute requires EPA to "analyze the entire pesticide" instead of taking an active-ingredient-by-active-ingredient

[8] EPA's approach in this regard also is consistent with FIFRA Section 4 (the re-registration program). Under that Section, EPA reregistered "each registered pesticide containing *any active ingredient* contained in any pesticide first registered before November 1, 1984 . . . ." 7 U.S.C. § 136a-1(a) (emphasis added). Consistent with the reregistration approach, under FIFRA section 3(c), EPA looks to each active ingredient in a pesticide product when registering or amending that pesticide product in the first instance.

approach. *Id.* at 14. NRDC's approach ignores the statutory definition of "pesticide," as compared to the definition of the regulatory definition of "pesticide product," and EPA's longstanding practice to separately analyze each active ingredient. *See supra* at 5-8; *see also* 40 C.F.R. § 152.111.

If NRDC's approach were used, there would be no point to reevaluating all uses for an active ingredient in the FIFRA registration review under Section 3(g). Nor would there be a reason for Congress to have allowed issuance of "me-too" registrations under FIFRA Section 3(c)(7)(A). *See supra* at 5-8. Further, an active ingredient that has been registered for the same uses would be held to different scientific review standards each time a new application is submitted for those same uses. That would eviscerate Congress' intent behind FIFRA section 3(c)(7). NRDC's approach would hold new applicants to a higher standard than previous applicants and create vast inconsistencies in regulatory decisions for the same active ingredient. It would also play havoc with EPA's ability to establish registration review schedules for orderly review of different active ingredients:

> If the Agency were required to conduct an in-depth review of all data on a pesticide each time an applicant requested unconditional registration, EPA would lose control over the order in which it reviewed chemicals. Instead, the order would be determined by the sequence in which companies submitted applications.

48 Fed. Reg. 34,000, 34,001 (July 26, 1983).

To illustrate the illogical nature of NRDC's argument, consider that in 2014, Intervenor-Respondent Dow Agrosciences LLC ("Dow") could have sought to register *just* the new uses of 2,4-D rather than the combination of 2,4-D and glyphosate in Enlist Duo. In that case, EPA could have originally registered a 2,4-D product that included the ability to tank mix it with other glyphosate pesticide products that have long been registered for these same uses. The result in that situation and in the situation of the actual combination product that was registered in 2014 would be the same: EPA would be concerned only with the unregistered *new* uses of 2,4-D, and not with the already registered uses of glyphosate.[9]

It is important to know, however, that EPA did analyze the entire pesticide product formulation for Enlist Duo. *See* SER460, 479 (field studies conducted on several combinations including 2,4-D choline and glyphosate). This is particularly evident in EPA's consideration after the remand in *Enlist Duo I* of whether there is synergy between 2,4-D and glyphosate (which there is not). ER4-5. So just as

[9] Although glyphosate itself has been registered for decades, *see* EPA Br. 11, the particular type of glyphosate used in Enlist Duo has been registered since 2007 in another pesticide product for these same uses and on these same crops. *See* RSBER33-171 (note this is "GF Registration 1280," not "GS Registration 1230" as indicated in the certified index). Thus, if a registrant submits an application for a pesticide product that only contains glyphosate as the active ingredient and there is no "new use" sought for glyphosate, EPA can issue a "me too" registration for that product. Here, EPA reviewed glyphosate "as if" the Agency was reviewing it as a me too application, ER3-4, 84, but because the only new action was the "new use" for 2,4-D, EPA did not have an obligation to fully explain that process.

NRDC demands, EPA "analyze[d] the risks associated with this entire mixture." NRDC Suppl. Br. 15. NRDC's real complaint is with the type of analysis that EPA did and whether EPA was required to conduct a new full-blown risk assessment for the already-registered uses of glyphosate. Neither the statute nor regulations require EPA to do any such thing.

ii. EPA's regulations allow the Agency to determine whether to do a new risk assessment based on whether a "new use" is sought for an active ingredient.

NRDC errs further in arguing that EPA must consider all existing evidence of Enlist Duo's risks regardless of whether the *active ingredients* have a "new use" and, thus, that "new use" is irrelevant. NRDC Suppl. Br. 16-17. For the reasons discussed above, *see supra* at 7-10, NRDC's interpretation would defeat the purpose of registration review and is not supported by the statute, congressional intent, or EPA's regulations.

NRDC further argues that EPA lacked substantial evidence to conclude that Enlist Duo would not entail any "new use" of glyphosate. *Id.* at 17-18. NRDC is wrong. The simple fact – undisputed by any evidence – is that this same form of glyphosate has been registered for these same over-the-top uses on corn, soybeans, and cotton since 2007, and glyphosate itself has been registered for these same uses for decades. *See supra* n.9.

iii. Consistent with EPA's regulations, the Agency considered "all relevant evidence" concerning the Enlist Duo registration actions.

EPA agrees with NRDC that under the Agency's regulations, EPA must consider "all relevant evidence" before granting an unconditional registration. NRDC Suppl. Br. 24; 40 C.F.R. § 152.112(b). EPA did just that. Under 40 C.F.R. § 152.112, EPA will approve an application under FIFRA Section 3(c)(5) "only if . . . [t]he Agency has reviewed all relevant data in the possession of the Agency." *Id.* § 152.112(b).[10] Where EPA disagrees with NRDC is regarding the scope of the term "relevant."

NRDC's argument in this regard focuses only on studies concerning glyphosate – not 2,4-D. Its argument is based on the mistaken notion that EPA was required to conduct an entirely new risk assessment for the same uses of glyphosate in Enlist Duo that have already been registered numerous other times. As discussed above, no such requirement exists. *See supra* at 7. The language in 40 C.F.R. § 152.112(b) does not require EPA to review emerging scientific data about an active ingredient in a pesticide product when the application does not seek a new use of that active ingredient. When read in conjunction with 40 C.F.R.

[10] Notably, this regulation applies only to *unconditional* registrations under FIFRA Section 3(c)(5) – not conditional registrations under Section 3(c)(7). Thus, NRDC's argument in this regard would only pertain to the 2014 and 2015 registration actions, which were unconditional registrations.

§ 152.111, "relevant" means that EPA determines whether the "relevant data base" for a particular "chemical," *i.e.*, the active ingredient, is being reviewed for "completeness and scientific validity" in the context of the action being requested.

As explained previously, because glyphosate was already registered for the same uses that Dow requested in the application for the 2014 and 2015 Enlist Duo registration actions, the question before EPA in reviewing those applications was to confirm that these uses were already registered and that any pertinent labeling requirements were included. EPA therefore complied with 40 C.F.R. § 152.112(b) when it reviewed "all relevant data in [its] possession" concerning the same or similar uses for glyphosate and determined that glyphosate should be treated as if it were a "me-too" registration under 3(c)(7)(A). ER3-4, 84.

For the 2,4-D component of the product, EPA considered the new use for this ingredient and conducted a full assessment under FIFRA. EPA therefore met the obligation under its regulation to consider all the relevant data. To determine that anything more was necessary for the glyphosate in Enlist Duo would undermine the Congress' intent behind FIFRA's conditional registration provision and registration review process.

The same faulty logic underlies NRDC's argument that "FIFRA required EPA to review the evidence of Enlist Duo's risks to monarchs and humans before unconditionally approving the pesticide." NRDC Suppl. Br. 10. Again, this

argument pertains only to glyphosate. And NRDC's reliance on EPA's regulations is again misplaced.[11] As explained above, there is no requirement that EPA consider additional data concerning glyphosate because there was no new use being sought for glyphosate in the Enlist Duo registration or amendments. Moreover, as EPA explained in its opening brief, the registration review process for *all* pesticide products containing glyphosate is the appropriate place for addressing the concerns and new data about potential risks to monarchs from all related registrations of glyphosate. *See* EPA Br. 6-7 (citing glyphosate registration review).[12] This is reasonable and consistent with the statute and EPA's regulations.[13]

---

[11] EPA *did* review evidence of the risks to monarchs and humans with respect to 2,4-D – the only active ingredient in Enlist Duo for which a new use was being sought, and the only relevant information as to monarchs and human health EPA was required to review prior to granting the registration for Enlist Duo. EPA Br. 74-75.

[12] NRDC's own statements about glyphosate in the registration review process show that NRDC has availed itself of the registration review process as the proper forum for addresses these concerns. *See* https://beyondpesticides.org/dailynewsblog/2019/09/health-and-environmental-groups-call-on-epa-to-revoke-glyphosates-registration/ (last visited Oct. 7, 2019)

[13] NRDC's reliance on 70 Fed. Reg. at 40,270, is misplaced. NRDC Suppl. Br. 12 (quoting *id.*) (EPA "must continue to respond to emerging risk concerns and not defer action until a pesticide's regularly scheduled registration review."). The point of the statement in the Federal Register is that the "action" that should not be deferred is registering a pesticide product that contains uses already registered. This is consistent with Congress' intent not to delay registration actions based on this evolving science.

NRDC further incorrectly relies on 7 U.S.C. § 136d(a)(2). That section provides that "at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator." NRDC Suppl. Br. 13. This statutory provision discusses the registrant's obligation after receiving a registration. But NRDC has not pointed to any evidence to show that Dow failed to provide any information required by that provision.

Finally, NRDC argues that EPA regulations require that the "applicant shall furnish with his application any factual information of which he is aware regarding unreasonable adverse effects of the pesticide on man or the environment, which would be required to be reported under [7 U.S.C. § 136d(a)(2)] if the product were registered." NRDC Suppl. Br. 13 (citing 40 C.F.R. § 152.50(f)(3)). EPA does not disagree with this requirement. However, NRDC never provides any evidence or citations to particular data that Dow allegedly failed to provide. Even so, that burden on the applicant does not change the fact that EPA is not required to continuously review evolving science every time an application is submitted for the same uses of an already-registered active ingredient.

//

//

iv. That Enlist Duo is intended to destroy weeds (including milkweed) in the field does not render any indirect effects on monarch butterflies an "unreasonable adverse effect."

NRDC's argument that EPA must evaluate indirect effects on monarch butterflies from destruction of in-field milkweed, NRDC Suppl. Br. 18-19, is really a dispute about whether EPA must consider, as a potential "unreasonable adverse effect," the effect of a pesticide on its target pests listed on the label. Milkweed is listed as an on-field pest to be controlled by Enlist Duo. FIFRA does not require that EPA consider whether the pesticide product's efficacy in controlling the target pest will have indirect effects. The issue here is whether it is a "reasonable" effect for Enlist Duo to do what it is intended to do – destroy weeds such as milkweed in the field. As far as a pesticide goes, the fact that it destroys a particular "pest," *i.e.*, milkweed, is considered a benefit to the use of the pesticide. It is also important to note that a farmer will get rid of pests (*e.g.*, milkweed) in their fields one way or another to have the greatest yield of their crop. NRDC's argument undermines the entire purpose of a "pesticide product" which is to control pests, including pests like milkweed.[14]

//

//

[14] Importantly, EPA and other federal agency partners are focusing on a broad approach to help protect the monarch butterfly. *See* EPA Br. 77-79.

v. NRDC mischaracterizes EPA's rationale for not conducting a new risk assessment for glyphosate.

NRDC's argument that "EPA must consider new evidence of Enlist Duo's harms even if market substitutes pose commensurate risks" mischaracterizes both the analysis EPA applied to Enlist Duo and the argument presented in EPA's Brief. NRDC Suppl. Br. 19-21. NRDC's assertion that EPA has argued that "Enlist Duo's adverse effects are necessarily reasonable if they are not *worse* than the harms caused by other pesticides" (*id.* at 19 (emphasis in original), *citing* EPA Br. at 75-76) mischaracterizes EPA's argument. NRDC's argument conflates the regulatory analysis EPA applied to glyphosate (relying on previous assessments conducted for the same uses of that particular active ingredient) with EPA's response to part of NRDC's argument in its Opening Brief that EPA's "no unreasonable adverse effects" finding lacked substantial evidence due to potential impacts to monarch butterflies via control of *on-field* milkweed.

As explained above, in determining whether Enlist Duo would cause "unreasonable adverse effects," EPA reviewed the application for registration that requested a new use for 2,4-D and also ensured that the same use for the glyphosate component was already registered in other existing pesticide products. Finding that the only new use was for 2,4-D, EPA appropriately only conducted new assessments for that new use.

> EPA determined that 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. That is, since there was no "new use" of glyphosate, EPA reasonably analyzed the glyphosate component of Enlist Duo as if it were a "me-too" registration application under FIFRA section 3(c)(7)(A).

Regarding the 2,4-D component of Enlist Duo, NRDC argued in its Opening Brief that EPA's analysis of 2,4-D was not supported by substantial evidence, in that EPA's findings that 2,4-D had no direct effects on terrestrial invertebrates (including monarchs) and that 2,4-D would have no off-field effects "skirted the issue" regarding monarchs due to indirect effects to monarchs via control of *on-field* milkweed. NRDC Br. 45-46. In response, EPA explained that NRDC's "theory . . . that 2,4-D use through Enlist Duo presumably will increase the effects on milkweed and, thus, on monarch butterflies" was not supported by the record. EPA Br. 75. In fact, as noted, the record shows that growers would continue to control on-field milkweed even without Enlist Duo, because milkweed is not resistant to glyphosate, and glyphosate is already registered for the same uses. *Id.* "[T]he 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 . . . 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." *Id*. at 76 (citing ER4).

Although EPA cited part of the "no new use" finding from the 2017 Final Decision Document for the proposition that the record does not support NRDC's opening argument that Enlist Duo will increase the destruction of *on-field* milkweed, EPA did not find or argue that "Enlist Duo's adverse effects are necessarily reasonable if they are not *worse* than the harms caused by other pesticides; and EPA need only assess the increment of harm that Enlist Duo poses beyond the status quo." NRDC Suppl. Br. 19 (emphasis in original). NRDC's supplemental argument in this regard mischaracterizes both EPA's regulatory finding and the argument as previously briefed.

Further, NRDC's statement that "Enlist Duo is *more* destructive to milkweed compared to other pesticides because it can be applied later in the growing season" is misleading. NRDC Suppl. Br. 21. Prior to Enlist Duo, glyphosate was already registered for control of milkweed later in the season. The registration of Enlist Duo did not affect the existing registered uses of glyphosate. For 2,4-D, this late-stage use on these crops was a new use and EPA fully evaluated that new use – which NRDC does not dispute.

B. Substantial evidence supports the 2017 conditional amendment.

As to the 2017 Amendment, NRDC's only substantive argument is that EPA "failed to consider the new evidence of Enlist Duo's harms to monarchs and people." NRDC Suppl. Br. 24. First, NRDC fails to cite any such "new evidence." But second, this argument echoes NRDC's previous argument that EPA failed to "consider all relevant data" because the Agency did not conduct a new analysis of all information generated after the 2014 and 2015 registration actions. NRDC Suppl. Br. 24 (quoting 48 Fed. Reg. at 34,001); NRDC Suppl. Br. 25 (citing 40 C.F.R. § 152.112(b)). This argument is flawed for the same reasons discussed *supra* at 27-28 because neither FIFRA nor EPA's regulations require EPA to consider new evidence for an active ingredient that has already been registered for the same uses.

NRDC relies on language from an EPA preamble to argue its point, yet leaves out pertinent language. NRDC Suppl. Br. 24 (quoting 48 Fed. Reg. at 34,001). The full text of that language (with the portion NRDC leaves out in italics) provides: "*an applicant must provide data showing that his product is acceptable for registration, including any data specifically required by EPA, and any other* available factual information concerning the adverse effects of the pesticide on humans or the environment which has not previously been submitted to the Agency." Here, the only data required was the data already in existing

databases for the same registered uses of glyphosate because Dow did not seek any new uses for glyphosate. NRDC's argument demands more of EPA than FIFRA or the regulations require and would eviscerate the purpose of FIFRA's registration review.

III. Substantial evidence supports EPA's technical determinations.

The Coalition's Supplemental Brief largely repeats technical attacks on EPA's analyses. None of these arguments has merit. Moreover, EPA deserves deference on its technical determinations. EPA Br. 58.

A. EPA's volatility analysis is supported by numerous valid studies.

EPA previously explained that it reviewed multiple studies to determine that the 2,4-D in Enlist Duo would not cause unreasonable adverse effects from volatilization. *Id*. 50-58. The Coalition's argument oversimplifies the assessment necessary to make a determination as to whether there are any alleged volatility risks of concern for Enlist Duo. Coalition Suppl. Br. 25. To this end, the Coalition's characterization tries to ignore the complexities of and the number of studies EPA considered for its volatility assessment.

After its careful analysis on the issue of volatility, EPA determined that there were no risks of concern as to volatility. Specifically, "[t]he [Probabilistic Exposure and Risk Model for Fumigants] 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.*" ER647 (emphasis added). The Coalition, however, conflates drift and volatility.[15] It references "2,4-D's notorious history of causing major *drift* damage"[16] (emphasis added) and then appears to link that alleged "drift" history to EPA not providing for a buffer as to "*volatility*." Coalition Suppl. Br. 25-25 (emphasis added). EPA, however, did separately assess "drift" potential – which is distinct from volatility. And EPA imposed a 30-foot downwind buffer to address any potential issues related to *drift*.[17]

The Coalition's inaccurate arguments regarding the Ouse Study and other studies, *id.* at 25, were previously addressed. EPA Br. 50-58. To be clear, the Ouse study which the Coalition criticizes was neither the only study nor the definitive study on which EPA relied. Instead, this study provided a reference

[15] EPA previously explained the difference. EPA Br. 50, n.17.

[16] As to the alleged "notorious history," EPA has explained that "[t]he Enlist Duo formulation is labeled with a variety of spray drift mitigation requirements designed to prevent toxicologically significant levels of exposure in areas off the treated field where non-target organisms could occur. Additionally . . . the drift and volatilization properties of this formulation are reduced relative to traditional forms of 2,4-D products." ER630.

[17] *See, e.g.*, ER640 (noting "label requirement for a 30-foot spray drift," which is adequate because "predictions say that there are no concerns for non-target organisms beyond a distance of 25 feet"); ER642 ("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.*") (emphasis added); *see also*, ER34 (requiring "30-foot downwind in field buffer…").

point for the amount of *visual plant damage* to sensitive plants from exposure to 2,4-D vapors. EPA Br. 50. But visual plant damage is not the regulatory end point that EPA used to assess the impacts from Enlist Duo – EPA used visual plant damage to determine effects on plant growth or survival. Plant growth or survival is the regulatory end point used. *Id.* 51-52. Thus, EPA used the Ouse study's data regarding the amount of visual plant damage caused by certain doses of 2,4-D vapor, and translated data into impacts to plant growth or survival. *Id*. EPA explained this, along with the limited usefulness of the Ouse study. *Id.* (citing ER3190-94). The Coalition ignores all of this, along with all of the additional studies that EPA used beyond the Ouse study. EPA Br. 52-57 (discussing six field studies and an additional vapor flux study).[18]

B. The Coalition's argument concerning synergy is unsupported by the statute and the record, both of which support EPA's approach.

The Coalition's argument concerning tank-mixing and synergy with glufosinate repeats the same irrelevant argument from its opening brief. Coalition Suppl. Br. 27-29. The fatal flaw in the Coalition's argument is that there is *no*

[18] Further, the Coalition provides no record support for its assertion that EPA's PERFUM modeling study estimated too small of a field size. Coalition Suppl. Br. 26-27. The Coalition's statements that the PERFUM modeling was "Dow's modeling exercise" and that the model utilizes a field size of "40 acres," *id*. 26, also are incorrect. EPA performed the PERFUM modeling, ER616-617, and the PERFUM model uses a field size of almost 80 acres, *see, e.g.*, ER715.

statutory or regulatory requirement for EPA to assess theoretical combinations in the field of other registered pesticides with Enlist Duo. EPA Br. 61. Nothing in the 2014, 2015, or 2017 licenses allows Enlist Duo to be tank-mixed with glufosinate. A simple reading of Enlist Duo's label conditions confirms that.

The Coalition is wrong that "to support its registration with substantial evidence EPA must account for risks from Enlist Duo tank mixes intended for use." Coalition Suppl. Br. 27 (citing 7 U.S.C. § 136a(c)(5)(B)). FIFRA Section 3(c)(5)(B), on which the Coalition relies, does not support its argument. The uses of Enlist Duo "contemplated by the label," *id.* at 27-28, do not allow tank-mixing with glufosinate or any other pesticides that have not undergone specific additional testing. EPA Br. 61-62. Nothing in FIFRA requires this additional testing prior to registering or amending a pesticide. Whether or not Dow's "business plan strategically involves a third pesticide: glufosinate" is irrelevant. FIFRA does not require EPA to consider a registrant's "business plan," or analyze what other pesticides the registrant may potentially envision being tank mixed in the future with the pesticide product undergoing registration or amendment. EPA imposes label conditions – with which Dow must comply – for any other pesticides Dow

may want to tank-mix with Enlist Duo precisely to prevent such expanded applications.[19]

IV. EPA Fully Complied With the ESA.

The Coalition reiterates the same flawed ESA mantra that it has been presenting since 2015 concerning EPA's levels of concern-risk quotient methodology: that any overlap between a project's footprint and a species habitat necessarily requires ESA section 7 consultation.[20] However, its theory hinges entirely on a misreading of *Karuk Tribe,* 681 F.3d 1006, and they fail to distinguish key cases. For example, *Friends of Santa Clara River v. U.S. Army Corps of Eng'rs*, 887 F.3d 906 (9th Cir. 2018) ("*Santa Clara*") is directly on point.

Additionally, having been unable for four years to identify any actual impacts to listed species or any meaningful criticism of EPA's levels of concern-risk quotient approach, the Coalition cites to several new documents that it now

[19] The Coalition's remaining arguments about glufosinate, tank mixing, and "synergy," Coalition Suppl. Br. 27-28 have been fully addressed by EPA. EPA Br. 13-14; *see*, *e.g.*, ER4-5.

[20] EPA incorporates by reference its responses to the Coalition's claims concerning EPA's levels of concern and risk quotient methodology, "no effect" determinations, and demarcation of the extent of the action area to encompass the treated fields. Coalition Suppl. Br. at 8-9, 10-13; EPA Br. 78-87, 89-94, 102-05. The Court previously rejected the Coalition's motion to stay the Enlist Duo registration when the Coalition made these same arguments. *Ctr. for Food Safety, et al. v. EPA*, Nos. 14-73359, 15-71207 (9th Cir.) ("*Enlist Duo I*") (ECF #94).

suggests bolster its arguments. However, none of the documents it cites do. Nor do its mischaracterizations of the 2013 National Academy of Sciences Report entitled *Assessing Risks to Endangered and Threatened Species from Pesticides* ("2013 NAS Report"), SBER001-195, the agencies' *Interim Report to Congress on Endangered Species Pesticide Evaluation Programs*[21] ("2014 Interim Report"), and EPA's *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences*[22] ("2013 Interim Approaches Document"), EPA's recent biological evaluations ("BEs") as to chlorpyrifos and malathion, and a 2010 NMFS biological opinion help it. The latter three are extra-record and irrelevant. The other documents the Coalition cites support EPA, not the Coalition. These documents prove that NMFS and FWS (the "Services") are on the same page as EPA concerning use of the levels of concern-risk quotient method. The Coalition also makes claims for the first time concerning glyphosate, but it waived that argument and lacks standing to assert it. The Court should affirm EPA's meticulous and comprehensive ESA "no effect" determinations.

---

[21] 2014 Interim Report, *available at* https://www.epa.gov/sites/production/fi07/documents/esareporttocongress.pdf (last visited Oct. 7, 2019).

[22] 2013 Interim Approaches Document, *available at* https://www.epa.gov/sites/production/files/2015-07/documents/ interagency.pdf (last visited Oct. 7, 2019).

A. The Coalition's Critique of EPA's Level of Concern-Risk Quotient Method is Undercut by This Court's Jurisprudence.

As a threshold issue, the Coalition's assessment of relevant precedent to preclude use of EPA's levels of concern-risk quotient methodology is fundamentally flawed. Coalition Suppl. Br. 8-9, 11-12, 16, 18-19, 21 (citing principally *Karuk Tribe*). Numerous cases demonstrate that EPA has the latitude to assess the potential effects of 2,4-D using the levels of concern-risk quotient method. For example, *Santa Clara*, which Petitioners do not discuss, is illustrative. In *Santa Clara*, the appellants challenged the Army Corps of Engineers' ("Corps") issuance of a Clean Water Act section 404 permit to a large development project. The permit at issue authorized the discharge of copper into the Santa Clara River. 887 F.3d at 906. As part of the Corps' ESA assessment, the agency considered the project's potential to affect listed steelhead and the species' downstream habitat through increased stormwater discharges. *Id*. at 915-16.

The fact that the project's footprint overlapped with steelhead habitat notwithstanding, the Court affirmed the Corps' "no effect" determinations.[23] *Id*. at

[23] Similar to the plaintiffs' allegations against the Corps in *Santa Clara*, here the Coalition maintains that EPA failed to consider an agency document that they believe represents the best available science. Coal. Suppl. Br. 3-5, 6-7, 14-15, 20-23. The *Santa Clara* appellants contended that the report established that sublethal impacts to steelhead smolts could occur at the levels of dissolved copper flowing from project discharges. *Santa Clara* at 924. This Court disagreed, recognizing that the determination of what constitutes the "best scientific data available"

923-26. The Court credited the Corps' data and analysis, which established that concentrations of dissolved copper in discharges would fall within the background range already observed in the river and well below the EPA's dissolved-copper criterion for the river. *Id*. at 924.[24]

The Coalition's failure to mention, much less distinguish, *Santa Clara* is not the only flaw in its analysis. Its argument also rests entirely on a fundamental mischaracterization of *Karuk Tribe*. Coalition Suppl. Br. 40-41, 54, 68. The Coalition cites to language in *Karuk Tribe* to suggest that "actions that have *any chance of* affecting listed species" require consultation. *Id.* at 40 (emphasis in original) (quoting *Karuk Tribe*); *see also id*. at 54 (same), 68 (same argument concerning effects to critical habitat). The Coalition suggests that any "possible" effect–as in any "risk" of an effect, or any "hypothetical" "hypothesized" effect, is "all that is required to compel consultation." Coalition Suppl. Br. 19.

The problem for the Coalition is that *Karuk Tribe* did not create such an illogical standard. Such a reading would be inconsistent with the ESA's implementing regulations, stripping action agencies of the ability to make "no

---

belongs to the agency's "special expertise[']" and warrants deference. *Id*. at 924-25. The Court should, as it did in *Santa Clara*, decline to substitute its scientific judgment for that of EPA.

[24] *See* EPA Br. 80-83, 95, regarding additional cases supporting EPA's argument that EPA has the latitude to use its level of concern methodology at the first of stage of ESA consultation.

effect" / "may affect" determinations under 50 C.F.R. § 402.14(a). That regulation creates a division of labor between action and consulting agencies and requiring consultation only where an agency action actually "*may affect* listed species or critical habitat." *Id.* (emphasis added). As this Court stated in *California ex rel. Lockyer*, "[a]n agency's finding that its action will have no effect on listed species or critical habitat obviates the need for consultation." 575 F.3d 999, 1019 (9th Cir. 2009) (quoting *Sw. Ctr. For Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1447-48 (9th Cir. 1996)). *Karuk Tribe* did not negate 50 C.F.R. § 402.14. The Coalition's theory would improperly obliterate the distinction between no effect and may effect.

The factual context further supports EPA. In *Karuk Tribe*, unlike here, there was no meaningful dispute that the activity at issue, suction dredge mining, would have measurable effects. A government biologist's report in the record stated that effects included, *inter alia*, (a) mortality via entrainment; (b) streambed destabilization; (c) decreases in reproductive success; (d) alteration to surface substrate composition; and (e) reduction of microhabitat availability due to sediment deposition. *Karuk Tribe* (ECF #27 at 9-12). The only argument about effects, which the Intervenors (not the government) made in one page in their brief, relied on extra record documents. *Karuk Tribe* (ECF #36 (Intervenor's answering brief) at 36-37; ECF #41 (Appellants' reply) at 31). The Court in *Karuk Tribe* had

before it concrete, discernible effects, not a mere "possible risk." *Cf.* Coalition Suppl. Br. 41, n.19.

Indeed, the gravamen of *Karuk Tribe* was not about the nature or extent of any effects to species, but rather the extent to which U.S. Forest Service retained discretionary involvement and control over the action at issue giving rise to an ESA obligation. *Karuk Tribe*, Case No. 05-16801 (9th Cir.) (ECF #27 at 15-17, 29-38; ECF #27 at 3 (no dispute USFS declined to conduct ESA analysis because it did not consider the action to be an "agency action" triggering ESA obligations, *id.* at 27-36). The Court should reject the Coalition's attempt to manufacture a new rule requiring consultation any time there is any overlap between a project's footprint and a species' habitat.[25]

B. The Court Should Defer to the Services and the EPA, not the National Academy of Sciences, as to Which Methodology Represents the "Best Available Science."

The Coalition contends that the 2013 NAS Report criticized the level of concern-risk quotient approach and the Court should therefore find EPA acted arbitrarily and capriciously. Coalition Suppl. Br. 4-6, 21-23. It maintains that the

[25] The Coalition argues that EPA's assessment was too "narrow" and should have included inert ingredients of Enlist Duo, such as surfactants. Coal. Suppl. Br. at 72. This argument fails because the Coalition does not identify any inert or surfactant that EPA allegedly did not consider or that is causing any "direct or indirect effects" on listed species or critical habitat. *Id.*; 50 C.F.R. § 402.13.

2013 NAS Report serves as the "gold standard" and embodies the best available science on how to conduct ESA pesticide assessments.[26] *Id*. at 21-23.

The Coalition's argument lacks merit.[27] The decision as to how to harmonize FIFRA and the ESA and conduct pesticides consultations is for EPA and the Services, not the NAS, to decide. Coalition Br. 8, n.8 (Coalition arguing that "Congress assigned FWS the job of ESA implementation, and as such FWS is entitled to deference . . . ."). Neither Congress nor the Services or EPA has delegated the agencies' responsibility to interpret FIFRA or the ESA to the NAS. *Lombardo v. Handler*, 397 F. Supp. 792, 793 (D.D.C. 1975), aff'd 546 F.2d 1043 (D.C. Cir. 1976) (NAS is not an "agency" under the APA). The Coalition's reliance on the 2013 NAS Report is misplaced.

---

[26] In nine briefs on this issue, the Coalition has returned to the same mantra concerning the level of concern-risk quotient issue. ECF #79, 85, 170; *Enlist Duo I* (ECF #32, 36, 55); *Nat'l Family Farm Coal., et al. v. EPA*, No. 17-70196 (9th Cir.) ("*Dicamba I*") (ECF #70-1, 133); *Nat'l Family Farm Coal., et al. v. EPA*, No. 19-70115 (9th Cir.) ("*Dicamba II*") (ECF #35). Not once has it identified any observable effect to any listed species or critical habitat. *Id.*

[27] The Coalition cursorily reiterates its objections to the manner in which EPA analyzed potential effects to two species, and its critical habitat argument, without further elucidating its flawed allegations. ECF #170 at 13, 20, n.15. EPA incorporates by reference its previous arguments as to those species and critical habitat. ECF #83 at 94-102; 105-10; *see also Weyerhauser v. FWS*, 139 S. Ct. 361, 368 (2018) (explaining that areas designated as critical habitat must also be actual habitat for the species).

In any event, the Services and EPA have appropriately considered that report and incorporated it into their deliberations in light of their decades of collective experience with pesticide consultations.[28] In March 2011, EPA, on behalf of itself, the Services and USDA, requested that a committee of the NAS convene to examine scientific and technical issues associated with determining the risk of pesticide registration and use to threatened and endangered species protected by the ESA. RER621. The agencies asked the NAS for advice on a range of subjects related to risk assessment and the ESA Section 7 consultation process. *Id.*

On April 30, 2013, the Academy provided its recommendations to the agencies. RER910. The NAS assessed the Services' and EPA's risk assessment methodologies and did not discount the usefulness of analysis of exposures, species responses to such exposures, estimated environmental concentration levels, or toxicity thresholds. SBER27 (exposure concentrations)[29]; SBER31 (species respond differently to chemical exposures); SBER052 (toxicity thresholds); SBER068 (estimated environmental concentrations); SBER112 (chemical concentrations). The NAS recommended what it called a "probabilistic approach."

[28] Unlike in other instances, Congress has not provided any particular direction to the Services and EPA as to how, or whether, to implement the 2013 NAS Report. *Cf. City of L.A. v. U.S. Dep't of Commerce*, 307 F.3d 859, 878 (9th Cir. 2002) (discussing statute requiring agency to take NAS's findings into account).

[29] "SBER" refers to the Coalition's Supplemental Brief Excerpts of Record.

SBER169-171. The NAS explicitly cabined its analysis, however, by stating that "[d]ecisions about acceptable levels of risk and how to manage risk are policy decisions that are not part of the scientific analysis." SBER063. NAS also recognized "the pragmatic demands of the pesticide-registration process" and the fact "that administrative and other nonscientific hurdles will need to be overcome to implement this approach . . . ." SBER034. The NAS envisioned coordination discussions among the agencies would occur on issues such as new approaches for exposure and effects analysis. SBER054.

While the Coalition elides this backstory, the coordination discussions the NAS envisioned have been occurring since 2013 and fully rebut the Coalition's dated argument. 2014 Int. Rep. at 4. Consistent with the 2013 NAS Report, the agencies have been collaborating to develop shared scientific approaches that reflect the advice provided. *Id.* at 4. As part of this process, the agencies published their Interim Report to Congress in November 2014. The agencies made clear that the Interim Approaches discussed in the Interim Report is not meant to be applied to all registration decisions. *Id.* at 21. The application of the Interim Approaches is an iterative process to be applied to certain pesticides as a pilot process, before applying this process to all pesticides. The Interim Report stated that EPA would complete compliant endangered species assessments in accordance with its 2004 Overview Document for all new herbicide tolerant crop uses and that

the Overview Document is the basis for EPA's ecological assessments for all chemicals other than chlorpyrifos, diazinon, malathion, carbaryl, and methomyl. *Id.* at 21, 22; RER917-18; RER3. 2,4-D was not one of the pilot chemicals to which the Interim Approaches would apply. Thus, FWS and NMFS, the agencies that the Coalition refers to as the "expert" agencies, espoused the use of the levels of concern/risk quotient approach for 2,4-D. The Interim Report went on to observe that EPA had recently registered Enlist Duo, EPA "scientists used highly conservative and protective assumptions to evaluate ecological risks for the new uses of 2,4-D." *Id.* at 21. It stated that Enlist Duo use "will be protective of non-target species, including endangered species." *Id*.

C. The Court Should Not Rely on the Extra-Record Biological Opinion and Evaluations that the Coalition Cites.

In its attempt to undermine the level of concern-risk quotient approach, the Coalition also cites to an extra-record 2010 NMFS biological opinion and two extra-record BEs assessing potential effects of chlorpyrifos and malathion. Coalition Suppl. Br. 7 (EPA BEs) 15, n. 12 (2010 NMFS Biological Opinion). The Coalition reasons as to the latter that EPA made a number of "may affect" or "likely to adversely affect" determinations in those evaluations, and should have made more here. *Id.* at 7.

The Coalition' argument fails for several reasons. As a threshold matter, the Coalition's argument is based on an extra-record material. The Court's review of

the Coalition's claims is limited to the Administrative 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). While the Coalition has made requests to add documents to the Administrative Record in this case in the past, here it did not do so. The Court should decline to rely on those documents, which were not considered by or relevant to the decision made by EPA.[30]

And in any event, any wisdom that could have been gleaned from the 2010 NMFS biological opinion that the Coalition cites, has been negated by the agencies' 2014 Interim Report to Congress. NMFS issued the 2010 biological opinion four years before EPA and the Services established that EPA would continue to use the levels of concern-risk quotient approach. *Supra* at 48-49 (discussing 2014 Int. Rep. at 21-22). The agencies decided that going forward, EPA would employ the levels of concern-risk assessment approach for use on all but a handful of pesticides consultations. *Id.* (same). 2,4-D was not one of those.

[30] To the extent the Court is inclined to consider extra record biological opinions, EPA's objection notwithstanding, NMFS frequently uses the same concepts as EPA, such as Lethal Concentration ("LC_{50}") and Lowest Observed Effect Concentration in its biological opinions. NMFS, *Biological Opinion Concerning the EPA's Registration of Pesticides Containing Chlorpyrifos, Diazinon, and Malathion* (2008), at 272, 277, 278, 279, 291, *available at* https://www.fisheries.noaa.gov/national/consultations/pesticide-consultations.

Id. The 2010 NMFS biological opinion therefore antedates the agencies' decision on how best to proceed and does not undermine EPA's use of the levels of concern-risk quotient approach in any way. *Santa Clara* 887 F.2d at 924 (deferring to Corps' technical expertise as to question concerning consideration of sublethal effects).

As to EPA's chlorpyrifos and malathion BEs, EPA and the Services agreed in 2014 that EPA would use a different methodology, the Interim Approaches, for assessing chlorpyrifos and malathion.[31] The Court should reject the Coalition's attempt to confuse the issue by claiming EPA had to follow the same approach here as it followed with respect to chlorpyrifos and malathion.

D. The Coalition Waived and Lacks Standing to Raise, and the Court Lacks Jurisdiction to Consider, its New Glyphosate Argument.

The Coalition's new claim that EPA's assessment of Enlist Duo was "incomplete" because it did not assess glyphosate is barred. Coalition Suppl. Br. 20-21. As an initial matter, the Coalition waived this argument by not raising it in its opening brief. *Rizk v. Holder*, 629 F.3d 1083, 1091, n.3 (9th Cir. 2011) (a

[31] EPA, *Biological Evaluation Chapters for Chlorpyrifos ESA Assessment*, at 4-43 (discussing use of probabilistic approach), *available at* https://www.epa.gov/endangered-species/biological-evaluation-chapters-chlorpyrifos-esa-assessment; EPA, *Biological Evaluation Chapters for Malathion ESA Assessment*, at 4-23 (same), *available at* https://www.epa.gov/endangered-species/biological-evaluation-chapters-malathion-esa-assessment (last visited Oct. 8, 2019).

petitioner waives issue by failing to raise it in its opening brief). The Coalition is incorrect when it suggests that "none of [its] challenges [have] fundamentally change[d]." Coalition Suppl. Br. 2.

The Court stated in its May 30, 2019, order that "[i]n their briefing, the parties should address *all challenges* to the initial registration (2014 order) and the original amendment (2015 order), as that registration and amendment has been reissued in the 2017 order—including challenges to all supporting documentation." ECF #166 at 8 (emphasis added). That Order concerned a jurisdictional argument EPA had made about the 2014 initial registration and 2015 original amendment. *Id*. EPA interprets the words "all challenges" to mean arguments already raised in the parties' opening and answering briefs, not "all challenges that the parties have raised or wish to raise now for the first time."

But even if the Court did so intend, the Coalition lacks standing to challenge EPA's actions as to glyphosate. 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. Def. of Wildlife*, 504 U.S. 555, 560-61

(1992)). Additionally, the Coalition 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." *Id.* at 181.

Here, the Coalition has not shown that it or its members have suffered an injury that is fairly traceable to the glyphosate component of EPA's registration decisions for Enlist Duo, or that any alleged injury would be redressed by a favorable decision. The Coalition attached seven declarations to its opening brief. The Coalition cannot rely on two of those, from Mssrs. Buse and Suckling, because they are members of two of the Petitioners, Pesticides Action Network of North America ("PANNA") and the Center for Biological Diversity, that have already entered into a settlement agreement with EPA on this issue. *Ctr. for Biol. Div., et al. v. EPA*, No. 07-cv-2794 (N.D. Cal.) ("*Bay Area Pesticides*"). Under that agreement, EPA is scheduled to complete review of glyphosate as part of registration review in June 2020. *Id.* (ECF #74).[32] PANNA and the Center for

[32] EPA recently renegotiated its June 2020 date from *Bay Area Pesticides* with the Center for Biological Diversity and PANNA in a draft pesticides settlement agreement. 84 Fed. Reg. 44,297 (Aug. 23, 2019); *Ctr. for Biol. Div., et al. v. EPA*, No. 3:11-cv-293 (N.D. Cal.) (ECF #358, 360). In it, the plaintiffs and EPA recognize that EPA will complete its BE for glyphosate in June 2021, not June 2020. The comment period closed on that draft settlement agreement on September

Biological Diversity are barred from relitigating the deadline for consultation on glyphosate here. *Tritz v. U.S. Postal Serv.*, 721 F.3d 1133, 1141 (9th Cir. 2013) ("[c]ourt-approved settlement agreements . . . have res judicata effect.").

Nor can the Coalition rely on any of the other declarations from National Family Farm Coalition, PANNA, Beyond Pesticides, or the Center for Food Safety declarants. The declarations of Ms. Eitemann (¶¶ 8-9) (Nat'l Family Farm Coalition), Ms. Crouch (¶¶ 12-13) (Beyond Pesticides), and Mssrs. Feldman (¶¶ 2, 4-5, 7-10), Kimbrell (paras. 2, 9, 11) (Ctr. for Food Safety), and Pool (¶¶ 9, 10-14, 16) (Nat'l Family Farm Coalition), all discuss the use of 2,4-D on treated fields, not glyphosate. ECF #64-1 at A92-155. Apparently the Coalition did not intend to assert a challenge regarding glyphosate when filing its opening brief, and therefore did not file declarations supporting such a challenge. *Id.* at 5, 7 (opening brief discussing 2,4-D, not glyphosate); 26-1 at 1 (Coalition discussing 2,4-D use but not mentioning glyphosate).

23, 2019. *Ctr. for Biol. Div. and PANNA v. EPA*, No. 3:11-cv-293 (N.D. Cal.) (ECF #360). None of the Coalition Petitioners commented on that settlement agreement. EPA, Docket for *Center for Biol. Div., et al. v. EPA*, 3:11-cv-293 (N.D. Cal.), *available at* https://www.regulations.gov/ docket?D=EPA-HQ-OGC-2019-0478 (last visited Oct. 8, 2019). The Court should allow EPA and the Services to complete the glyphosate consultation process in conjunction with the registration review process, as contemplated by EPA, the Center for Biological Diversity and PANNA.

The Coalition also fails to demonstrate causation. As discussed above, glyphosate has been registered in other pesticide products for the same use as is contemplated here since the 1990s. *Supra* at 5-8, 12, 22-30. Thus, the registration decisions changed nothing with respect to how, when, where, and how much glyphosate is or will be used going forward. 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. *Id*. Accordingly, there is no probative link between EPA's decision to register Enlist Duo and any ESA listed species based on its registration of glyphosate. *Lujan*, 504 U.S. 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). Thus, the Coalition cannot demonstrate the "injury" or "causation" prongs of Article III standing.

The Coalition additionally cannot meet the third prong of the Article III standing inquiry, redressability. "Redressability depends on whether the court has the ability to remedy the alleged harm." *Nuclear Info. & Res. Serv. v. NRC*, 457 F.3d 941, 955 (9th Cir. 2006). Here, even if the Court rules in the Coalition's favor on the merits of its substantive challenges to the glyphosate in Enlist Duo, the ruling would not redress its perceived harm to listed species posed by glyphosate. 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 since the 1990's. *See id.* (holding that petitioners had failed to establish redressability when there was an existing regulation); *cf.* Coalition Suppl. Br. 33 (contending use of 2,4-D would increase, but the volume of glyphosate would remain the same). Thus, as discussed further below, the Coalition' opportunity for redressability as to glyphosate use is not through a challenge to Enlist Duo. Rather, the more appropriate avenue through which the Coalition potentially could redress its alleged injuries from glyphosate is through the FIFRA Section 3(g) registration review process, where the uses of glyphosate across *all* registered pesticide products will be reviewed. Indeed, as noted above, two of the Coalition Petitioners–the Center for Biological Diversity and PANNA–are pursuing this avenue. *Bay Area Pesticides* (ECF #74).

In any event, such a challenge would lack merit. The Coalition's challenge as to glyphosate assumes that there exists an agency action triggering ESA section 7 obligations. But for that to be true, the Coalition would first have to show that EPA was required to conduct a new assessment for glyphosate under FIFRA. *See supra* at 5-8, 12, 22-30; 16 U.S.C. § 1536(a)(2). They cannot do this because Enlist Duo does not require any "new use" of glyphosate. EPA has not "authorized," "funded" or "carried out" any action with respect to glyphosate in authorizing Enlist Duo. *Id.* And the Coalition' arguments about generalized

glyphosate effects and usage do not give rise to any ESA claim. *Ctr. for Biol. Div., et al. v. EPA*, 847 F.3d 1075, 1091 (9th Cir. 2017) (because appellants Center for Biological Diversity and PANNA "fail[ed] to identify an affirmative agency action [taken pursuant to FIFRA] that would trigger a Section 7 consultation, we affirm the district court's dismissal . . . ."). The Court should therefore reject the Coalition's claims as to glyphosate and affirm EPA's comprehensive ESA assessments. EPA Br. 78-109.

V. If the Court Grants Any Aspect of the Petitions for Review, the Proper Remedy is Remand Without Vacatur.

EPA's opening brief discussed the relevant standards for vacatur, which no Petitioner has met. EPA Br. 110-11. Here, if the Court grants any aspect of the petitions for review, the Enlist Duo registration should remain in effect during any remand.

First, the disruptive consequences of vacatur on the farmers using Enlist Duo warrant remand only.[33] NRDC's claim that farmers have other "weed management tools available" misses the mark. NRDC Suppl. Br. 26. As Dow will illuminate, farmers already have invested in both Enlist Duo and seeds that are resistant to Enlist Duo. Thus, what NRDC demands is that those farmers be precluded from using the seeds and pesticide that they have already purchased *and* expend

[33] EPA understands that these repercussions on farmers will be more fully explained in Dow's supplemental brief.

additional money on alternative seeds and pesticides. Such a consequence is an overwhelming disruption for those farmers. "Equity demands" that such disruption not occur, *Idaho Farm Bureau Federation v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995), and these disruptive consequences outweigh the public health and environment concerns (which, for the reasons discussed above, are not supported by evidence) on which Petitioners rely. NRDC Suppl. Br. 27-28; Coalition Suppl. Br. 33. Moreover, any procedural defects are more appropriately addressed through remand without vacatur.

Similarly, as to the ESA issues, to extent the Court finds that EPA's Step 1 ("no effect" / "may affect") analysis did not consider a potential effect to a particular species, rendering EPA's analysis arbitrary and capricious, EPA would be able to remedy that violation by further explicating its reasoning. As such, an injunction is not warranted.

Finally, the cases on which Petitioners rely do not support vacatur in this case. For example, *Pollinator Stewardship Council v. EPA*, 806 F.3d 520 (9th Cir. 2015) contains a key statement that distinguishes that case from this situation. There, the Court's key statements supporting vacatur were the "precariousness of bee populations" *and* the fact that "on remand, a different result may be reached." *Id.* at 532. Setting aside the fact that the Court did not discuss any balancing of disruptive consequences against the concerns over the bee population, the more

telling fact is that the Court determined EPA may reach a different result on remand. Here, Petitioners have not shown any evidence or made any argument to support that EPA may reach on different result on remand with respect to Enlist Duo, *i.e.*, that EPA would decide not to issue the Enlist Duo registration or even that EPA would impose additional conditions on Dow as the registrant (nor have Petitioners actually argued that any additional conditions should be placed on Dow). Indeed, there is nothing to support the notion that any of the "fundamental flaws" argued by Petitioners "make it unlikely that the same [action] would be adopted on remand." *Id.* The fact that EPA likely would re-issue the Enlist Duo registration, combined with the disruptive consequences to farmers, undermines Petitioners' demand for vacatur.[34]

CONCLUSION

For the foregoing reasons and those stated in EPA's opening brief, EPA

//

//

//

//

[34] Further, neither of the other cases on which NRDC relies support vacatur because the Court did not address the disruptive consequence of vacatur, which is a pertinent issue here. *See* NRDC Suppl. Br. 26 (citing *NRDC v. EPA*, 857 F.3d 1030, 1042 (9th Cir. 2017); *NRDC v. EPA*, 735 F.3d 873, 884 (9th Cir. 2013).

requests that the Court deny the petitions for review.

Respectfully submitted,

JONATHAN D. BRIGHTBILL
Principal Deputy Assistant Attorney General
JEAN E. WILLIAMS
Deputy Assistant Attorney General
Environment and Natural Resources
Division

/s/ Michele L. Walter
MICHELE L. WALTER
Trial Attorney
U.S. Department of Justice
Environment and Natural Resources
Division
Environmental Defense Section
999 18th St.
South Terrace, Suite 270
Denver, Colorado 80202
(303) 844-1345

/s/ J. Brett Grosko
J. BRETT GROSKO
Senior Trial Attorney
U.S. Department of Justice
Environment and Natural Resources
Division
Wildlife and Marine Resources Section
P.O. Box 7611
Washington, D.C. 20044
(202) 305-0342

Counsel for Respondents

Of counsel

Benjamin Wakefield
Michele Knorr
U.S. Environmental Protection Agency
Office of General Counsel
Pesticides & Toxics Substances Law Office
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dated: October 11, 2019

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 13,996 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

/s/ *Michele L. Walter*

MICHELE L. WALTER

CERTIFICATE OF SERVICE

I hereby certify that on October 11, 2019, 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.

/s/ *Michele L. Walter*

MICHELE L. WALTER