Case Nos. 17-70810, 17-70817

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATIONAL FAMILY FARM COALITION, et al.,
Petitioners,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents,
DOW AGROSCIENCES LLC,
Respondent-Intervenor.

NATURAL RESOURCES DEFENSE COUNCIL, INC.,
Petitioners,
v.
SCOTT PRUITT, et al.,
Respondents,
DOW AGROSCIENCES LLC,
Respondent-Intervenor.

On Petition for Review from the
United States Environmental Protection Agency

PETITIONERS' OPENING BRIEF (REDACTED)

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CORPORATE DISCLOSURE STATEMENT
REQUIRED BY FED. R. APP. P. 26.1

National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Center for Biological Diversity, Center for Food Safety, and Pesticide Action Network North America hereby certify that they have no parent corporations, and that no publicly held corporation owns more than 10% of any of the Petitioners' organizations.

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JURISDICTIONAL STATEMENT

This Court has jurisdiction under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which provides for review in the courts of appeals of "any order issued by the Administrator following a public hearing." 7 U.S.C. § 136n(b). This Court has ruled that a public comment process constitutes a "public hearing" within the meaning of Section 16(b) of FIFRA. *United Farm Workers of Am. v. U.S. EPA*, 592 F.3d 1080, 1082-83 (9th Cir. 2010). EPA solicited and responded to public comments prior to approving Enlist Duo. *See* Excerpts of Record (ER) at ER50-92. Petitioners National Family Farm Coalition, Family Farm Defenders, Beyond Pesticides, Center for Biological Diversity, Center for Food Safety, and Pesticide Action Network North America (collectively, NFFC Petitioners) may bring this challenge because they were "a party" to the proceedings before Respondent U.S. Environmental Protection Agency (EPA), having submitted substantive written comments, and are "adversely affected" by EPA's orders registering Enlist Duo. 7 U.S.C. § 136n(b); ER116-28, 308-42, 414-56, 461-70, 483-501 (comments of NFFC Petitioners).

NFFC Petitioners have standing. An individual has Article III standing if he or she is under threat of suffering an injury-in-fact that is concrete and particularized; the threat must be actual and imminent, not conjectural or hypothetical; it must be fairly traceable to the challenged action of the respondent;

and it must be likely that a favorable judicial decision will prevent or redress the injury. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000). A public interest organization like any of the NFFC Petitioners in turn has representational standing "when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). EPA's challenged actions threaten to directly injure NFFC Petitioners' members' environmental, recreational, aesthetic, and economic interests. *See* Crouch Decl. (A100-106)[1], ¶¶ 5-9 (attesting to effects of the action on her interests in whooping cranes); Buse Decl. (A93-99), ¶¶ 9-17; Limberg Decl. (A132-139), ¶¶ 6-21 (attesting to effects of the action on their interests in Indiana bats); Pool Decl. (A140-148) (attesting harm to his wine grape production), ¶¶ 8-16; Griffith Decl. (A113-118), ¶¶ 4-9; Ishii-Eiteman Decl. (A119-124), ¶¶ 6-11; Kimbrell Decl. (A125-131), ¶¶ 7-12; Suckling Decl. (A149-155), ¶¶ 4-14.[2]

[1] For the Court's convenience, copies of all concurrently-filed declarations are filed together herewith in the attached supporting Addendum of Declarations.

[2] Venue is proper because NFFC Petitioners include organizations that reside and/or have places of business within this Circuit. *See* Suckling Decl. (A149-155), ¶ 4; Ishii-Eiteman Decl. (A119-124), ¶ 2; Kimbrell Decl. (A125-131), ¶ 2.

Finally, NFFC Petitioners timely filed their petition for review within sixty days of entry of EPA's approval orders. *See* Pet. Review, No. 17-70810 (9th Cir. March 21, 2017).

ISSUES PRESENTED

1. Did EPA violate the ESA by:
   - improperly defining the "action area" for its Enlist Duo registration;
   - failing to use the best scientific and commercial data available;
   - failing to consult the expert wildlife agencies concerning Enlist Duo's potential effects on threatened and endangered species, despite ample record evidence that its registration of Enlist Duo "may affect" them; and
   - failing to consult the expert wildlife agencies concerning Enlist Duo's potential effects on designated critical habitat by relying on self-created, arbitrary rules for when EPA need not consult?
2. Did EPA violate FIFRA by approving Enlist Duo:
   - using the wrong legal standards;
   - based on inadequate data regarding 2,4-D's volatility risks; and

- for use in tank mixtures with other pesticides, including the pesticide glufosinate, without analyzing such mixtures' known synergistic effects?

STATEMENT OF THE CASE

This case challenges EPA's registration of Intervenor Dow AgroSciences' (Dow's) pesticide[3] product "Enlist Duo," containing the active ingredients 2,4-dichlorophenoxyacetic acid (2,4-D) choline salt and glyphosate dimethylammonium salt (glyphosate). ER1-36. This is the most recent of a series of EPA registrations and amended registrations of Enlist Duo. While these pesticides have been sold individually in other forms, this decision is a "new use" registration, because it approved a novel use of them: direct, "post-emergent" application to crops genetically engineered (GE) to survive being sprayed with both pesticides. ER28.

Enlist Duo and Genetically Engineered Crops

Dow's 2,4-D is a synthetic plant hormone, or auxin, that causes uncontrolled cell growth leading to plant death. *See* ER2013-14; ER2033. Glyphosate is a nonselective, systemic herbicide Monsanto developed and uses as the active

[3] Also referred to as an herbicide. "Pesticides" kill or control organisms considered to be pests, including insect and plant pests; "herbicides" are pesticides that kill plants. 7 U.S.C. § 136(u).

ingredient in its "Roundup" brand herbicides. *See* ER2141-43; ER1615; ER1620-23; ER160-63.

Because 2,4-D and glyphosate are severely toxic to natural plants, before genetic engineering, the pesticides could be used only before crops sprouted ("pre-emergent"),[4] to clear a field of early season weeds. *See, e.g.*, ER347. EPA's Enlist Duo registration entailed a "new use pattern" for 2,4-D: since 2,4-D kills natural cotton and soybean, and injures corn plants as they mature, Dow genetically engineered these crops with 2,4-D resistance to allow use of 2,4-D directly on soybean and cotton for the first time (*i.e,* "over the top"), and later in the season on growing corn plants. ER28. Dow combined its new 2,4-D resistance trait with glyphosate resistance so that all three genetically engineered Enlist crops can be sprayed with both pesticide active ingredients well into the growing season without harming them. ER2-4, 28. Consequently, the U.S. Department of Agriculture (USDA) conservatively estimates that regulatory approval of Enlist corn and soybean crops and Enlist Duo herbicide will result in a 200-600 percent increase in agricultural use of 2,4-D by 2020, ER353, and that the approval of Enlist cotton and the herbicide will result in a 5.7- to 8.6-fold increase in 2,4-D use in cotton

[4] This is true for glyphosate for all these crops. But for 2,4-D, corn has some natural resistance because it is in the grass family. Enlist corn can withstand higher doses of 2,4-D and later in the season.

production.[5] *See, e.g.,* ER4114; ER443 (projecting significant increases in 2,4-D use).

Dow markets and sells the patented GE Enlist Duo-resistant seeds (marketed as "Enlist" crops), along with its Enlist Duo pesticide, as a "weed control system."[6] Along with Monsanto's XtendiMax dicamba pesticide, Enlist Duo is the pesticide industry's quick fix "solution" to an agricultural epidemic it created with the prior generation of glyphosate-resistant GE crops: glyphosate-resistant "superweeds." ER1762-63, 68-69; ER347; ER2133. For the past twenty years, agrichemical companies have sold glyphosate-resistant GE crops, allowing growers to douse fields repeatedly with that chemical and kill weeds without killing the crop, and dramatically increasing overall pesticide output into the environment, making glyphosate the most used pesticide in history. These crops' widespread adoption also created a related problem: just as overuse of antibiotics breeds antibiotic-resistant bacteria, constant application of glyphosate to GE crop fields created an epidemic of glyphosate-resistant superweeds now infesting an estimated 100 million acres of U.S. farmland. ER448. Nor is the industry's doubling down on the

[5] USDA, *Dow AgroSciences Company Petition for Determination of Nonregulated Status of 2,4-D- and Glufosinate-Resistant DAS-81910-7 Cotton* 119 (Apr. 2015), https://www.aphis.usda.gov/brs/aphisdocs/13_26201p_fea.pdf.

[6] Dow Chem. Co., *Enlist Weed Control System*, http://www.enlist.com/en (last visited Apr. 10, 2018).

pesticide treadmill any panacea to the problems it has caused: experts predict its addition of 2,4-D resistance will massively increase 2,4-D agricultural use—without glyphosate reduction—and simply foster rapid evolution of still more intractable weeds, now resistant to both pesticides. ER416; ER448; ER455-56; *see* ER2.

Procedural History: *Enlist Duo I* and Significant Concerns Raised

This is the most recent in a series of EPA registrations and amended registrations of Enlist Duo. EPA first granted Dow's petition to register Enlist Duo on October 15, 2014. ER2. EPA's unconditional registration initially allowed its use in six states on new GE corn and soybean varieties bearing the trade name Enlist, which Dow genetically engineered specifically to be immune to 2,4-D and glyphosate. A coalition of many of the same petitioners in this case petitioned for review of that decision on October 30, 2014. Pet. Review, *Nat. Res. Def. Council v. U.S. EPA* (*Enlist Duo I*), No. 14-73353 (9th Cir. Oct. 30, 2014), ECF No. 1-1.[7]

On March 31, 2015, EPA amended its registration to allow Enlist Duo's use in nine additional states. ER2. Petitioners sought review of that decision. Pet. Review, *Ctr. for Food Safety v. U.S. EPA*, No. 15-71207 (9th Cir. Apr. 20, 2015),

[7] As in this case, NFFC Petitioners and Petitioner Natural Resources Defense Council (NRDC) separately challenged the registration. *See Ctr. for Food Safety. v. U.S. EPA*, No. 14-73359, ECF No. 1-2 (9th Cir. Oct. 30, 2014). And as here, the cases were consolidated. Order, *Enlist Duo I*, Dec. 11, 2014, ECF No. 11. All consolidated Petitioners are referred to collectively as "Petitioners."

ECF No. 1-2; Pet. Review, *Nat. Res. Def. Council v. U.S. EPA*, No. 15-71213 (9th Cir. Apr. 20, 2015), ECF No. 1-2. The cases were consolidated. Order, *Enlist Duo I*, June 2, 2015, ECF No. 66.

While Petitioners' challenge was pending, EPA announced it had discovered Dow had filed a patent application with the U.S. Patent and Trademark Office claiming Enlist Duo's two active ingredients had synergistic effects—that the two ingredients combined were more potent than would be expected from their separate effects. In its submissions to EPA, however, Dow had not included the synergy data. ER2-3.

On November 24, 2015, EPA therefore moved the Court to vacate the registration and remand it to EPA based on the synergy data, which EPA informed the Court could potentially affect EPA's assessment of the risks the pesticide poses to endangered plant and animal species. *See* Mot. Voluntary Vacatur & Remand, *Enlist Duo I*, ECF No. 121-1. On January 25, 2016, the Court granted the motion for remand but declined to vacate, so the registration remained in effect. Order, *Enlist Duo I*, ECF No.128.

On January 12, 2017, EPA:

1. reaffirmed its earlier decisions to register Enlist Duo on GE corn and GE soybean in 15 states;

2. approved Enlist Duo for use on GE corn and GE soybean in an additional 19 states, bringing to 34 the total number of states where Enlist Duo use is now authorized; and

3. approved a new use of Enlist Duo on GE cotton in all 34 states.

ER2. NFFC Petitioners filed the present Petition for Review challenging EPA's January 12, 2017 actions on March 21, 2017. Pet. Review, No. 17-70810 (9th Cir. Mar. 21, 2017), ECF No. 1-5. On May 3, 2017, the Court consolidated the present Petition for Review with *Natural Resources Defense Council v. Pruitt*, No. 17-70817 (9th Cir. Mar. 21, 2017). Order, ECF No. 14.

Enlist Duo and GE Crops

EPA acknowledged that the massive increase in 2,4-D use and extended window of its application could have significant impacts on public health, agriculture, and the environment. The approval covers 34 states with approximately 185 million acres of corn, soy, and cotton farmland.[8] The USDA conservatively estimated that the approval of Enlist crops and Enlist Duo herbicide will result in a *200-600 percent* increase in agricultural use of 2,4-D by 2020—and that was *before* EPA approved the pesticide for use on cotton. ER353. Application of 2,4-D to crops genetically engineered to withstand its application will likely accelerate weed resistance to the active ingredient, just as weed resistance to Enlist Duo's other active ingredient, glyphosate, prompted the purported need for this

[8] *See* Nat'l Agric. Statistics Serv., USDA, *Crop Acreage* (June 30, 2017), http://usda.mannlib.cornell.edu/MannUsda/viewDocumentInfo.do?documentID=1000.

registration. ER26-27 (admitting need to monitor weed resistance to 2,4-D). 2,4-D has also been associated with a wide range of human health impacts, ranging from neurological injuries to kidney, thyroid, and reproductive organ damage. ER1673-83; ER1737-39; ER2123-30. As discussed below, EPA's ecological risk assessments recognize 2,4-D is toxic to terrestrial and aquatic plants, birds, and mammals, and is known to injure such non-target organisms through volatilization of 2,4-D. ER2029-30; ER2021. EPA's own database for tracking pesticide-associated accidental kills recorded hundreds of such incidents. *See* ER2067.

Regarding glyphosate, EPA concluded that all proposed uses of Enlist Duo "on GE corn, soybeans, and cotton are already registered on other glyphosate products and are currently in use on these crops." ER3. Despite glyphosate never before having been mixed with 2,4-D for use on crops, EPA performed no new evaluation of glyphosate, which, since EPA last assessed it in 1993, has been determined to be a probable carcinogen.[9] Also since then, glyphosate has been recognized as a major cause of the precipitous, 90 percent decline of the monarch butterfly in less than twenty years, prompting the U.S. Fish and Wildlife Service

[9] *See* Press Release, Int'l Agency for Research on Cancer, World Health Org., IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides (Mar. 20, 2015), http://www.iarc.fr/en/media-centre/iarcnews/pdf/MonographVolume112.pdf.

(FWS) to determine that listing the butterfly as threatened or endangered under the Endangered Species Act (ESA) may be warranted.[10]

These harms were echoed in the public comments on the proposed registration. Commenters supplied EPA with studies, expert opinion, and practical first-hand evidence warning of devastating impacts from Enlist Duo's active ingredients. Specifically, the record contains copious evidence that Enlist Duo posed serious harm to neighboring crops and sensitive species due to 2,4-D's toxicity, its great volatility, as well as synergistic effects of using 2,4-D with pesticides.[11]

Unreasonable Adverse Effects of Enlist Duo

Despite overwhelming record evidence demonstrating harm to neighboring crops and U.S. agriculture from the use of Enlist Duo, EPA conditionally registered Enlist Duo's new uses on millions of acres across 34 states, without determining whether the massive increase and extended use of 2,4-D would "significantly increase the risk of unreasonable adverse effects" of the pesticide on the environment, the requisite finding for new use conditional registrations under

[10] 79 Fed. Reg. 78,775, 78,777 (Dec. 31, 2014).

[11] *See* ER 118-128; ER414-456; ER461-501; ER515-16; ER1356-70; ER2123-2130 (commenting on environmental and human health impacts of increased 2,4-D use); ER420-50; ER1198-1347 (harm to federally listed species); ER420-50; ER144-211 (harm from synergy with other chemicals); ER457-58; ER115-17; ER517-518; ER1195-97 (harms to agriculture and farmers).

FIFRA. *See* 7 U.S.C. § 136a(c)(7)(B). EPA instead concluded that the new uses of Enlist Duo would not have unreasonable adverse effects on the environment, and dismissed any harm from 2,4-D volatilization, even though EPA admitted it lacked sufficient data to assess such harms. EPA also authorized applications of Enlist Duo in mixtures with other pesticides, without requiring any testing of potential synergistic toxicity of such mixtures, even though synergistic effects had prompted EPA to vacate the registration previously, and in the face of identical evidence showing synergistic toxicity of 2,4-D mixtures with the pesticide glufosinate.

Endangered Species at Risk

Of the millions of acres across 34 states where Enlist Duo is used, EPA acknowledges some 531 species listed under the ESA as threatened or endangered, and 184 habitats designated as critical to their survival and recovery, are found near where EPA authorized spraying Enlist Duo. ER575. These include mammals, birds, plants, and insects, and include the whooping crane, Mexican wolf, California condor, and Indiana bat. EPA must comply with the ESA in addition to FIFRA's requirements for registering a pesticide. Section 7(a)(2) of the ESA, 16 U.S.C. § 1536(a)(2), requires that, if the Enlist Duo registration may affect any of these many species or habitats, EPA must consult the federal agencies Congress designated as having wildlife expertise—the U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS)—to "insure" EPA's action will not

likely jeopardize any of these species' continued existence nor adversely modify their habitats. *Id.*

EPA concluded that spraying a toxic weedkiller on millions of acres can have no effect on hundreds of endangered plants and animals on or near the spraying sites, *e.g.*, ER1457-67, and circumvented Congress's strict mandate that it consult the expert agencies.

EPA did this after admitting, following analysis, that registering Enlist Duo for use on millions of acres "may affect" most taxa of ESA-protected plants and animals, comprising hundreds of species. ER2030. Instead of complying with the ESA's mandate to consult the expert agencies, EPA effectively exempted itself from the law's procedural demands. EPA applied to the ESA context methods and standards EPA had developed to comply with FIFRA, a different statute with different standards, and reflecting policies different from the ESA's strict conservation mandate. EPA's "no effect" determinations therefore applied the wrong legal standards, used inappropriate data, made unsupported assumptions, and otherwise violated the ESA in the service of side-stepping EPA's obligation to obtain the expert agencies' input. As a consequence, EPA's registration threatens the continued existence of a vast array of imperiled species as well the habitats they need to survive and recover.

STANDARDS OF REVIEW

The Court may sustain EPA's Enlist Duo registration under FIFRA only if EPA's orders are "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). "The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. This is clearly the significance of the requirement … that courts consider the whole record." *Universal Camera Corp. v. Nat'l Labor Relations Bd.,* 340 U.S. 474, 488 (1951). Judicial review must be "searching and careful, subjecting the agency's decision to close judicial scrutiny." *Containerfrieght Corp. v. United States*, 752 F.2d 419, 422 (9th Cir. 1985) (internal citations and quotations omitted). Further, "the substantial evidence standard affords an agency less deference than the arbitrary and capricious standard." *Pollinator Stewardship Council v. U.S. EPA*, 806 F.3d 520, 533 (N.R. Smith, J., concurring) (citing *Universal Camera Corp.,* 340 U.S. at 477; *Union Oil Co. of Cal. v. Fed. Power Comm'n,* 542 F.2d 1036, 1040–41 (9th Cir. 1976)). Therefore, if EPA's decision is arbitrary and capricious, it cannot be supported by substantial evidence. To avoid being arbitrary and capricious, EPA "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal citations and quotations omitted). The Court's "review must not rubber-stamp ... administrative decisions that [the court deems]

inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 361 F.3d 1108, 1119 (9th Cir. 2004) (internal citations and quotations omitted). Any difference between these two standards of review is immaterial here, because EPA's decision to register Enlist Duo satisfies neither. If it finds EPA's actions violated FIFRA, this Court should set aside, or vacate, the registration. *Pollinator Stewardship,* 806 F.3d at 532-33.

EPA violated the E if its failure to consult the expert wildlife agencies in connection with its registrations of Enlist Duo was arbitrary, capricious, an abuse of discretion, or otherwise not in compliance with law. 5 U.S.C. § 706(2)(A); *see Conner v. Burford*, 848 F.2d 1441, 1453 (9th Cir. 1988). The ESA requires that federal agencies consult the expert wildlife agencies on any approval action that "may affect" any protected species or critical habitat. 50 C.F.R. § 402.14(a); *see* 16 U.S.C. § 1536(a)(2). This duty is triggered by "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (en banc) (quoting *Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018-19 (9th Cir. 2009) (quoting 51 Fed. Reg. 19,926, 19,949 (June 3, 1986)) (emphasis in *Lockyer*).

ARGUMENT

I. EPA VIOLATED THE ENDANGERED SPECIES ACT

EPA authorized spraying Enlist Duo on millions of acres across 34 states, home to hundreds of ESA-protected animal and plant species, and hundreds of their habitats that FWS specifically designated as "critical" to supporting their survival and eventual recovery. The ESA required EPA to comply with specific processes to prevent harm to these species and areas, including, most importantly, seeking guidance from the agencies with wildlife expertise before allowing the pesticide on the market. However, EPA doggedly avoided complying with the ESA's requirements, instead applying other standards that do not apply in the ESA context, or rules it invented that apply in no context at all. By doing so, EPA circumvented consulting the expert wildlife agencies Congress mandated it consult before repeatedly exposing hundreds of endangered species and habitats to a toxic weedkiller. EPA's systematic and unprecedented disregard of the ESA must be reversed.

A. The ESA's Consultation Process and Standards.

The ESA regulatory requirements with which EPA must comply when registering Enlist Duo are unambiguous. EPA has tried to circumvent them in the past and lost in the courts, but persists in essentially the same unlawful course of

conduct,[12] apparently believing it need not comply with a law Congress expressly provided applies to EPA no less than to every other federal agency.

1. Regulatory Background.

The ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978). Congress spoke "in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities, thereby adopting a policy which it described as 'institutionalized caution.'" *Id*. at 194. "[T]he plain language of the [ESA] … shows clearly that Congress viewed the value of endangered species as 'incalculable.'" *Id*. at 187.

Section 7 is the "heart" of the ESA, and one of the statute's most important protections. *Lockyer*, 575 F.3d at 1018. It mandates that "[e]ach federal agency" "insure" its action (here, registering Enlist Duo) is not likely to either jeopardize any species or adversely modify any designated "critical" habitat. 16 U.S.C.

[12] EPA also used the same unlawful approach described in this brief in its registration of the pesticide XtendiMax, as discussed in the pending *National Family Farm Coalition, et al. v. United States Environmental Protection Agency*, No. 17-70196 (9th Cir. filed Jan. 20, 2017).

§ 1536(a)(2).[13] EPA's duty to insure against jeopardy and adverse modification is "rigorous." *Sierra Club v. Marsh*, 816 F.2d 1376, 1385 (9th Cir. 1987).

2. Every Federal Agency Must Consult the Expert Wildlife Agencies Before Taking Any Action That Might Have Any Effect Whatsoever on Any ESA-Protected Species or Critical Habitat.

Of central importance to this case, Section 7(a)(2) and its regulations establish a process requiring EPA to evaluate its Enlist Duo registration's effects "in consultation with and with the assistance of" the agencies Congress designated as having special expertise in determining effects on endangered species: FWS (for terrestrial and freshwater species) and NMFS (for marine species).[14] 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b). In this context EPA is known as the "action agency," while FWS is the "expert agency." *See, e.g., Ctr. for Biological Diversity v. U.S. Forest Serv.*, 408 Fed. Appx. 64 (9th Cir. 2011). Consultation is required of "[e]ach federal agency," 16 U.S.C. § 1536(a)(2), and is "designed as an integral check on federal agency action, ensuring that such action

[13] "Jeopardize" means taking an action that "reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution…." 50 C.F.R. § 402.02. Critical habitat means "the specific areas within the geographical area occupied by the species, at the time it is listed … on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A).

[14] For simplicity, we refer to FWS as the consulting expert agency.

does not go forward without full consideration of its effects on listed species." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 603 (1992) (Blackmun, J., dissenting). This consultation process to assess the registration's effects is integral to "insuring" EPA implements the ESA's substantive protections. *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) ("[T]he strict substantive provisions of the ESA justify *more* stringent enforcement of its procedural requirements, because the procedural requirements are designed to ensure compliance with the substantive provisions.")

The first step in the Section 7(a)(2) process requires EPA to determine whether the registration "may affect" any listed species or designated critical habitat. If it *may*, EPA then *must* consult FWS. 50 C.F.R. § 402.14(a). Importantly, this "may affect" standard is extremely low:

> [A]ctions that have *any chance of affecting* listed species or critical habitat—even if it is later determined that the actions are 'not likely' to do so—*require* at least some consultation under the ESA.

Karuk Tribe, 681 F.3d at 1027 (emphases added). Further:

> *Any possible effect*, whether beneficial, benign, adverse or of an undetermined character triggers the requirement.

Id. (quoting *Lockyer*, 575 F.3d at 1018-19) (quotation omitted) (emphasis in *Lockyer*). *See also W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2011) (same).

If EPA's action meets this low "may affect" threshold, the law gives EPA only two options: it can consult FWS formally, or it can consult FWS informally. In formal consultation, FWS issues a Biological Opinion, containing FWS's expert opinion whether EPA's action is likely to jeopardize the continued existence of any species or adversely modify any critical habitat; if not, FWS may authorize any anticipated incidental harm, or "take." 50 C.F.R. § 402.14(h)(3), (i).

Informal consultation is the single exception to formal consultation where the "may affect" threshold has been reached. EPA may avoid formal consultation through informal consultation *only* if during informal consultation, FWS *concurs in writing* that while EPA's action "may affect" a species or habitat, the action is "not likely to adversely affect" it. 50 C.F.R. §§ 402.13(a), 402.14(b)(1); *Pac. Rivers Council v. Thomas*, 30 F.3d 1050, 1054 n.8 (9th Cir. 1994) ("The consulting agency [FWS] must issue a written concurrence in the determination….").

In all of these analyses, EPA must "give the benefit of the doubt to the species." *Conner*, 848 F.2d at 1454 (citation omitted). It also must use the "best scientific and commercial data available." 16 U.S.C. § 1536(a)(2).

II. EPA VIOLATED THE ESA'S CONSULTATION MANDATES

A. EPA's Roles Under FIFRA and the ESA Are Very Different.

EPA concocted its own, third alternative to Section 7(a)(2)'s consultation requirement. EPA invented an approach that allows EPA to ignore the statute's and

regulations' standards and unilaterally make determinations the law allows only FWS to make. EPA applied methods developed for registering a pesticide under FIFRA, and appropriate only in relation to species not threatened with extinction. As a matter of law, FIFRA's approach does not fulfill EPA's duties under the ESA. *Wash. Toxics Coal. v. U.S. EPA*, 413 F.3d 1024, 1033 (9th Cir. 2005) (EPA must separately comply with the ESA in pesticide registrations). This is because FIFRA and the ESA reflect different policies, address different issues, apply different legal standards, and consequently assign EPA different duties. EPA's fundamental legal error was substituting FIFRA's less protective standards and processes for the ESA's, and refusing to consult the expert wildlife agencies.

First, unlike the ESA, FIFRA requires that EPA determine whether a pesticide has any "unreasonable adverse effects on the environment," and permits—indeed, requires—EPA to weigh the pesticide's costs and benefits when making this determination. *See* 7 U.S.C. § 136(bb) ("The term 'unreasonable adverse effects on the environment' means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.").

But the ESA emphatically prohibits any such cost-benefit balancing: "The plain intent of Congress in enacting [the ESA] was to halt and reverse the trend toward species extinction, *whatever the cost*." *Hill*, 437 U.S. at 184 (emphasis

added); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 929 (9th Cir. 2008) ("ESA's no-jeopardy mandate applies to every discretionary agency action—regardless of the expense or burden its application might impose.") (quotation omitted). Similarly, while pesticide regulation under FIFRA is among EPA's many missions, the ESA affords endangered species "the highest of priorities," *Hill,* 437 U.S. at 174, and "reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies." *Id.* at 185.

Second, while EPA, by side-stepping the consultation with FWS that Congress required of "[e]ach federal agency," demonstrates it believes it has special privileges when it comes to pesticides and their impacts, the ESA grants EPA no such special authority. EPA's mandate and pesticide expertise do not extend to endangered species' survival and recovery, nor to interpreting and applying the ESA's standards, which Congress assigned to FWS. *See* 16 U.S.C. § 1532(15). Congress did not exempt EPA from its explicit command that "[e]ach federal agency" seek FWS's expertise when dealing with ESA-protected species and habitats. 16 U.S.C. § 1536(a)(2). "'[This] interagency consultation process reflects Congress's awareness that expert agencies (such as [NMFS] and [FWS]) are far more knowledgeable than other federal agencies about the precise conditions that pose a threat to listed species.'" *Nat. Res. Def. Council v. Zinke*,

Case No. 1:05–cv–01207 LJO–EPG, 2017 WL 3705108, at *5 (E.D. Cal. Aug. 28, 2017) (quoting *City of Tacoma, Wash. v. FERC*, 460 F.3d 53, 75 (D.C. Cir. 2006)).

Third, in the FIFRA context, EPA uses a risk assessment framework employing self-created "risk quotients" and "levels of concern" to determine "when a pesticide use as directed on the label has the potential to cause *adverse effects* on non-target organisms." ER2529 (emphasis added). EPA describes its scheme for assessing a pesticide registration's risks to all non-target species as follows:

> [T]he effects characterization is based on a deterministic approach using one point on a concentration-response curve (e.g., LC50). In this approach, [EPA's Office of Pesticide Programs] uses the risk quotient (RQ) method to compare exposure over toxicity. Estimated environmental concentrations (EECs) based on maximum application rates are divided by acute and chronic toxicity values….
>
> After risk quotients are calculated, they are compared to [EPA's levels of concern (LOCs)]. These [LOCs] are the Agency's *interpretative policy* and are used to analyze potential risk to non-target organisms and the need to consider regulatory action. These criteria are used to indicate when a pesticide use as directed on the label has the *potential to cause adverse effects* on non-target organisms.

ER2529 (emphases added); *see* ER18-19 (EPA used this scheme in this case). EPA uses the identical approach to assess effects on endangered species; it merely changes the threshold to assume endangered species "may be potentially affected" when acute risk quotient >0.1, ER2529, and chronic risk quotient >1, ER2530.

These "risk quotients" and "levels of concern" are based on toxicity testing using EPA guidelines that were not designed to support compliance with the ESA, but rather contain "methodologies and protocols that are intended to provide data to inform regulatory decisions under [the Toxic Substances Control Act, Federal Insecticide, Fungicide and Rodenticide Act, and section 408 of the Federal Food, Drug and Cosmetic Act]."[15] *See, e.g.*, ER2031-32 (citing toxicity tests upon which EPA relies).

EPA uses the data it obtains from such sources and calculates "risk quotients" and "levels of concern" for various species, and as long as EPA's calculations yield a "risk quotient" below the value it unilaterally decides to use, EPA concludes its own "level of concern" has not been exceeded, declares there will be "no effect," and excludes FWS from the consultation process that the ESA mandates. ER2043-44; ER1045 ("EPA determines that there is 'no effect' on listed species if, at any step in the screening level assessment, no levels of concern are exceeded.").

B. EPA's Application of Its FIFRA-based Thresholds to Determine Whether to Consult Under ESA § 7(A)(2) Violates the ESA.

EPA's process for assessing whether registering Enlist Duo "may affect" any ESA-listed species or designated critical habitat, and therefore whether it must

[15] EPA, *OCSPP 850.2100: Avian Acute Oral Toxicity Test [EPA 712-C-025]*, at i (May 10, 2012), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0010.

consult FWS, uses calculations, models, jargon, and references to laboratory studies that give it a scientific patina. Whether EPA performed its calculations accurately is beside the point, as is whether FWS might have agreed with EPA's conclusions had EPA bothered to present them to FWS during consultation. EPA's analyses, by means of which EPA rationalized failing to consult FWS and obtain FWS's written concurrence, violates the ESA as a matter of law.

The ESA does not allow an agency to apply its own "interpretative policies" regarding risk, ER2529, such that EPA may use its own "risk quotients" and "levels of concern" while the Army Corps of Engineers may use different ones it prefers, and the Department of Transportation yet others. This would completely subvert the expert wildlife agencies' statutory role in the consultation process. Similarly, no agency may unilaterally determine its action has no "potential to cause *adverse* effects" on an ESA-protected species or habitat. *See* ER2529. As explained above, the ESA mandates consultation with FWS whenever any agency's action has "any chance" of having "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character," *Karuk Tribe*, 681 F.3d at 1027. The ESA's regulations expressly provide that determining an action is not likely to cause *adverse* effects can only be made in consultation with FWS, with FWS's written concurrence, which EPA neither sought nor received in this

case for hundreds of species and habitats. 50 C.F.R. §§ 402.13(a), 402.14(b)(1); *Pac. Rivers Council*, 30 F.3d at 1054 n.8.

EPA erroneously claimed the right to use these FIFRA concepts, thresholds, and "interpretive policies" to assess effects on ESA-protected species; instead of consulting FWS about harm risks, it simply consulted itself, using its own approach designed to administer a very different statute. The ESA denies EPA such authority. These policy determinations are due no deference, and are exactly what the ESA eliminated with its directive to consult and obtain FWS's sign-off when there is "any chance" of having "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character," *Karuk Tribe*, 681 F.3d at 1027.

Moreover, EPA's use of the "risk quotients" it selects as the bright-line basis for a "no effect" determination is arbitrary. EPA has no expertise in endangered species conservation, but even where an agency has expertise, deference is not warranted unless the agency has "cogently explain[ed] why it has exercised its discretion in a given manner." *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (quoting *Motor Vehicle Mfr's Ass'n*, 463 U.S. at 48).

The court in *Washington Toxics Coalition* resoundingly rejected an earlier EPA attempt—even with FWS's cooperation that time—to bypass the mandated consultation process in a manner similar to the self-consultation EPA attempts now. 457 F. Supp. 2d at 1179-80. The court explained the fundamental disconnect

between EPA's risk assessment process and the ESA's requirements, and why the former does not satisfy the latter:

> *The risk framework of FIFRA (no unreasonable adverse effects) does not equate to the survival and recovery framework of the ESA*. The risk framework is driven by laboratory tests, models of exposure and occasionally some monitoring information. The ESA framework is an integration of status of the species, environmental background condition, the extent of the action within the action area, as well as laboratory and field testing, modeling and field validation. All of this information feeds into an analysis to support the purpose of the ESA to conserve ecosystems upon which threatened and endangered species rely.

Id. at 1184 (quoting a NMFS scientist) (emphasis added); *see also id*. at 1185 ("EPA's risk assessment, designed to answer a question posed by FIFRA (*i.e.*, whether unreasonable adverse effects would result from use of the pesticide), was not designed to answer the question posed by the ESA (*i.e.*, whether an action may be considered 'not likely to jeopardize[.]'")).

EPA unlawfully circumvented the consultation process by raising the consultation bar high above the ESA's "may affect" standard as this Court and FWS interpret that term. In finding its Enlist Duo registration would have "no effect" on hundreds of listed species and critical habitats, EPA allowed itself to avoid consultation as long as the effect did not exceed EPA's own "level of concern," which measures the "potential to cause adverse effects," ER2529. This may be EPA's boundary of acceptability, but it is not the ESA's. EPA in its risk assessments admitted it employed this unlawful standard, declaring unilaterally

that its registration will "not … adversely affect" certain taxa of endangered species—a determination that can be made only after informal consultation with FWS, with FWS's written concurrence. *See, e.g.,* ER584 ("Proposed 2,4-D choline salt uses are *not expected to directly adversely affect* freshwater or estuarine/marine fish, aquatic phase amphibians, or freshwater or estuarine/marine invertebrates") (emphasis added); ER584 (same, for aquatic plants). This flatly violates the law. 50 C.F.R. §§ 402.13(a), 402.14(b)(1); *Pac. Rivers Council*, 30 F.3d at 1054 n.8.

If EPA believed that whatever effect exposure to Enlist Duo might have on endangered species or their critical habitats was insignificant, the ESA mandates the process available: undergo informal consultation with FWS, and obtain FWS's written concurrence that EPA's action is "not likely to adversely affect" any listed species or critical habitat. 50 C.F.R. §§ 402.13(a), 402.14(b)(1). Instead, EPA arrogated to itself FWS's prerogative, declaring that if the registration's effects on endangered species do not exceed its own "level of concern" and cause no "adverse effects," those effects equate to "no effect," obviating any need to consult, even informally. But those two standards differ significantly, and EPA lacks authority to impose its own interpretation of when consultation is triggered.

FWS's and NMFS's *Endangered Species Consultation Handbook*[16] underscores the distinction between "no effect" and the "not likely to adversely affect" standard EPA effectively applied here, while calling it "no effect":

> **Is not likely to adversely affect** - the appropriate conclusion when effects on listed species are expected to be *discountable, insignificant, or completely beneficial*.
>
> **Beneficial effects** are contemporaneous positive effects without any adverse effects to the species.
>
> **Insignificant effects** relate to the size of the impact and should never reach the scale where take occurs.
>
> **Discountable effects** are those extremely unlikely to occur. Based on best judgment, a person would not: (1) be able to meaningfully measure, detect, or evaluate insignificant effects; or (2) expect discountable effects to occur.
>
> ….
>
> **May affect** - the appropriate conclusion when a proposed action *may pose any effects* on listed species or designated critical habitat….

Consultation Handbook, *supra* n.16, at *xv-xvi* (emphasis and formatting added).

As a matter of law, therefore, an effect EPA deems "not adverse," insignificant, or even beneficial *cannot be classified as "no effect."* The ESA classifies such effects as "not likely to adversely affect" the species—but only if FWS concurs in writing after informal consultation. 50 C.F.R. §§ 402.13(a), 402.14(b)(1). So regardless of the label EPA uses, the standard EPA actually

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[16] FWS & NMFS, *Endangered Species Consultation Handbook* (*Consultation Handbook*) (Mar. 1998), http://www.nmfs.noaa.gov/pr/pdfs/laws/esa_section7_handbook.pdf. This Court has relied on the *Consultation Handbook*. *See, e.g., Ctr. for Biological Diversity v. U.S. Bureau of Land Mgmt.*, 698 F.3d 1101, 1113 (9th Cir. 2012).

applied when determining risk to endangered species thus is fundamentally and inescapably at loggerheads with the ESA's mandate.

In *Karuk Tribe*, the plaintiff challenged the Forest Service's failure to consult before issuing notices of intent to conduct mining activities in ESA-protected salmon critical habitat. Mining interests argued the record contained "no evidence 'that even a single member of any listed species would be "taken" by reason' of the mining activities," and that the plaintiff had not identified "so much as a single endangered fish or fish egg ever injured by this [mining] activity." 681 F.3d at 1028 (citation omitted). This Court sitting *en banc* rejected industry's efforts to make the agency's procedural duty to consult the expert agencies dependent on evidence of actual harm, emphasizing that any risk triggers consultation. *Id.* The miners also argued that mitigation "assured" there would be "no impact whatsoever on listed species." *Id.* The Court observed that the argument "cuts against, rather than in favor of" the agency having no duty to consult, since the perceived need to reduce potential effects underscored that effects were possible, compelling consultation. *Id*.

By claiming an effect below its self-determined "level of concern," or lacking "adverse effects," has "no effect," and conflating the "no effect" and "not likely to adversely affect" standards, EPA unlawfully cut FWS out of the process

for determining the effect of EPA's Enlist Duo registration on endangered species and their critical habitats.

C. The Record Shows Enlist Duo "May Affect" Hundreds of Endangered Species, Requiring Consultation.

EPA admitted after initial risk assessments that the Enlist Duo registration "may effect" hundreds of ESA-protected species and their critical habitats. By manipulating the assessment process and utilizing the wrong standard, EPA erased all of these findings and converted them to "no effect" findings to avoid consultation.

Specifically, EPA repeatedly acknowledged that Enlist Duo, applied at the allowed rate, may affect many protected plant and animal species, even using its own "level of concern" standard. *See, e.g.*, ER2030 ("may … directly affect[]" most taxa of protected species); ER2074-75, 2079-81(EPA's "levels of concern" exceeded for many species); ER1773 (53 listed species in six states "potentially at risk," four of which remain at risk despite mitigation); ER1457 ("There are 168 species of potential concern in the 10 proposed 2,4-D choline corn and soy states …."); ER1062-63 (risks to numerous species); ER634-35 ("levels of concern" exceeded for mammals), ER642 ("Avian risk quotients exceeded the [level of concern] for acute effects on the treated field.").

Based on these admissions alone, and regardless of how EPA tries to couch its determinations, the Court must find that, as in *Karuk Tribe*, the "record in this

appeal includes ample evidence" that the action in question "may affect" endangered species. 681 F.3d at 1028. There, the Forest Service analogously admitted the mining activities "might cause" disturbance to protected salmon habitat, and the Court gave that phrase its "ordinary meaning," holding that a "may affect" conclusion had to follow "almost automatically," and ordering consultation. *Id.* at 1027 (holding that the "may affect" threshold could be resolved as a "textual matter."). The same is true of EPA's repeated admissions in this record.[17]

D. EPA Unlawfully Constricted the Registration's "Action Area."

EPA began the process of erasing these hundreds of "may affect" findings and converting them to "no effect" determinations by unlawfully redefining the registration's "action area." When evaluating whether its action "may affect" any listed species or critical habitat, EPA must examine all effects within the registration's "action area." 50 C.F.R. §§ 402.02, 402.12; *Native Ecosystems Council v. Dombeck*, 304 F.3d 886, 901 (9th Cir. 2002). EPA violated this by unlawfully constricting the registration's "action area" to just the sprayed crop fields themselves, excluding completely all surrounding areas beyond the fields' borders. However, "action area" is defined as "all areas to be affected *directly or*

[17] Similarly, as this Court held in *Kraayenbrink*, 632 F.3d at 496, the "sheer number of acres affected" by agency decisions of nationwide magnitude such as this one can "alone suggest" it "may affect" listed species. *Id.*

indirectly by the Federal Action and *not merely the immediate area involved in the action*." 50 C.F.R. § 402.02 (emphases added).

EPA initially admitted hundreds of listed species were within the registration's action area. *See, e.g.*, ER1772 ("53 species in the 6 states proposed for registration (Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin) were identified as *within the action area.*") (emphasis added); ER1456 ("168 species in the 10 [additional] states proposed for registration were identified as *within the action area.*") (emphasis added). This was appropriate, since EPA knows pesticides commonly drift well beyond sprayed fields, with harmful effects.

EPA also knew Enlist Duo specifically may travel beyond the borders of sprayed fields, ER2022 ("2,4-D is known to volatilize from the field and drift off site under certain environmental conditions."), and that it "can drift from the treated area and still be present at concentrations that exceed acute levels of concern for birds, mammals, and terrestrial plants," ER2077. In fact, the record reveals EPA was aware that by 2012, there had been thousands of reported incidents of terrestrial plants, aquatic plants, birds, fish, mammals, reptiles, and terrestrial insects having been killed by 2,4-D traveling off-site. ER2067.

EPA included label restrictions and directions for use, such as a very modest 30-foot buffer, ER20, and then concluded the registration would have "no effect" on any of the hundreds of species it had already identified as at-risk unless they

actually occupy the sprayed fields themselves. EPA therefore restricted the registration's "action area" to only the fields themselves, completely ignoring any risk to any species or habitat beyond their borders. *See* ER1457 ("157 of the 168 species originally identified as potentially at-risk can be given a 'no effect' determination based on the premise that they are not expected to occur on an action area encompassing the treated soybean and corn fields.").

This severe culling violated the ESA definition of "action area," as well as sound science, farming realities, and the record evidence. EPA knew Enlist Duo is toxic to birds, mammals, and of course (being an herbicide), plants. ER2063-64, 2067-68. EPA knew its label instructions might not eliminate all off-site drift, and therefore endangered species and their habitats might well be exposed to the toxic chemical, albeit at "reduced" levels that did not cause EPA "concern":

> While there are uncertainties in the risk conclusions for terrestrial invertebrates, it is *likely* that the spray drift mitigation measures on the Enlist Duo label will serve to *reduce* exposures to 2,4-D choline in areas off the treated site….

ER643; ER20 (buffer would "reduce" off-site exposure for birds); ER29 (measures "would *reduce the likelihood* of spray drift and volatilization" beyond fields) (emphasis added).

EPA thus could not—and did not—claim the buffers and other label restrictions would have "no effect" as the ESA and this Court define that term. To the contrary, EPA admitted its action may expose endangered plants and animals

and their critical habitats to a chemical toxic to them, and therefore there may well be effects—just not effects exceeding EPA's internal "level of concern," or that EPA considered "adverse." ER1043 ("The Agency makes no claim that drift and runoff do not occur," only that "exposures were only above levels of concern to organisms on treated fields."); ER585 (with mitigation, listed species exposure is "below levels triggering Agency risk concern"); ER29 ("these additional restrictions … limit *adverse* effects to within the treatment site itself….").

Thus, even assuming EPA's calculations were factually accurate, EPA's redefinition of the action area was erroneous as a matter of law, because it resulted in automatic "no effect" determinations for hundreds of endangered species and critical habitats exposed to a toxic chemical at "reduced levels" that EPA concluded are "unlikely" to cause "adverse" effects. An action area must include "all areas to be affected directly or indirectly by the Federal Action and not merely the immediate area involved in the action." 50 C.F.R. § 402.02. It is not limited to areas where EPA's action causes "adverse effects" or "effects above EPA's level of concern," ER29, ER1043, but where the pesticide registration may cause "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character," *Karuk Tribe*, 681 F.3d at 1027. This repeats the overarching theme of EPA's legal error: trying to jam a FIFRA square peg into an ESA round hole to avoid consultation.

Even if Enlist Duo were never to directly escape the crop fields' borders at all, the pesticide's application to the fields plainly has indirect effects on areas outside those borders. For example, ESA-protected species in surrounding areas consume prey—insects, rodents, reptiles—that may be in fields when they are sprayed, before moving out of the fields. Listed animals may drink water that flows out of sprayed fields, or eat seeds that blow out of them. EPA ignored these indirect risks, let alone declined to seek FWS's input in consultation, and this alone renders EPA's "action area" deficient. *See Wilderness Soc'y v. Wisely*, 524 F. Supp. 2d 1285, 1305 (D. Colo. 2007) (rejecting failure to consult regarding effects in broader action area); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 254 F. Supp. 2d 1196, 1212 (D. Or. 2003) (same).

In sum, EPA's action-area manipulations were wrong as a matter of law, leaving hundreds of species and habitats on millions of acres vulnerable to the weedkiller's effects. EPA had already admitted that, but for its drastic constriction of the action area, the Enlist Duo registration puts many of those species and habitats at risk, mandating consultation. *E.g.*, ER2030 (birds, mammals, terrestrial plants all "may be directly affected by the proposed uses of 2,4-D choline salt" on an acute or chronic basis, or both, and indirect effects on terrestrial invertebrates (such as honeybees) are possible). Since EPA's action area violates the ESA's

definition, EPA violated the ESA by failing to consult on any species or habitats outside the sprayed fields' borders.

E. EPA's Conclusion That Enlist Duo Will Have "No Effect" Even on Protected Species Within Sprayed Fields Also Was Unlawful.

EPA erred by excluding the hundreds of potentially-affected species and habitats surrounding Enlist Duo-sprayed crop fields. EPA again erred by then declaring the registration will have "no effect" even on the species it admitted are *in* those fields when they are sprayed, and consume food that has been sprayed with the toxic chemical.

EPA's initial risk assessment found the proposed Enlist Duo registration "may affect" virtually all of the 531 ESA-listed species that might come in contact with the pesticide. ER2030; ER649, ER621-28 (more extensive discussion of 2,4-D's toxicity). Having made these explicit "may affect" findings, ESA § 7(a)(2) required EPA to consult FWS at that point. 50 C.F.R. § 402.14(a). If EPA believed the registration was "not likely to adversely affect" any species or habitat, it had to obtain FWS's written concurrence. *Pac. Rivers Council*, 30 F.3d at 1054 n.8. It did not.

Instead, even after gerrymandering the registration's "action area" to include only the sprayed fields and thus exclude most species and habitats, EPA had to admit that no drift mitigation could prevent some of America's most iconic and critically endangered animals—such as the whooping crane, California condor,

jaguar, and gray wolf—from ingesting Enlist Duo, because they "would reasonably be expected to utilize corn, cotton, and soybean fields for resources important to the species." That is, they will be found within the shrunken action area as EPA unlawfully redefined it. ER653.

Again, once EPA realized it would be exposing endangered species to a toxic chemical, ESA § 7(a)(2) demanded it stop and consult FWS. Because the "may affect" threshold is so low, to NFFC Petitioners' knowledge no court has ever upheld an action agency's "no effect" determination where endangered species are found in the action area as EPA admits here. *See also* 50 C.F.R. §§ 402.13(a), 402.14(b)(1).

But EPA failed to do so. Instead, EPA unlawfully consulted no one but itself, and decided that whatever the risk of harm to these protected species might be, it was not severe enough to warrant seeking any input from FWS. EPA had no authority to exempt itself from the law.

1. EPA's Species-Specific Analyses Violated the ESA.

EPA's strategy to make "no effect" findings for the species found in the sprayed fields was to analyze its registration's impacts on those particular species, using more and more tenuous assumptions, until declaring the effects did not exceed EPA's "levels of concern." EPA then re-characterized these "may effect" circumstances as "no effect," sidestepping the required consultation altogether.

EPA did this with many species found in crop fields, ER653-78, but its analyses of the registration's effect on Indiana bats and whooping cranes exemplify its contortions.

a. Whooping Crane (*Grus Americana*)

The iconic whooping crane is among the world's most endangered animals. There were as few as twenty-one in 1954,[18] and conservation efforts have led to only a limited recovery; there are now a few hundred in the wild,[19] about 4 percent of its historic numbers. As FWS observed: "The whooping crane is a flagship species for the North American wildlife conservation movement, symbolizing the struggle for survival that characterizes endangered species worldwide."[20]

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[18] *See* FWS, *International Recovery Plan: Whooping Crane* (*Grus americana)* 1 (Mar. 2007), http://www.fws.gov/uploadedFiles/WHCR%20RP%20Final%207-21-2006.pdf.

[19] *Id*. at 1.

[20] *Id.*

EPA acknowledged "it is reasonable to conclude that the crane may be exposed to 2,4-D choline residues in prey on crop fields." ER667. But rather than make the required "may affect" finding and consult FWS, EPA estimated the crane's field metabolic rate, guessed the amount of prey it was likely to consume, and guessed the amount of Enlist Duo in hypothetical prey a hypothetical crane might consume. ER668.

EPA used this collection of guesses to calculate acute and chronic risk quotients, and compared these with EPA's internally-generated "levels of concern," or LOCs. *Id.* Because EPA's numbers fell below its LOC, EPA declared there would be "no effect." *Id.* But the risk quotients were not zero, *id*., and therefore required a "may effect" determination as a matter of law. *See supra* pp. 24-31. As explained above, if EPA believed the exposure was "not likely to adversely affect" the cranes, the ESA required EPA to engage in informal consultation and obtain FWS's written concurrence with this conclusion. 50 C.F.R. § 402.14(b); *Pac. Rivers Council*, 30 F.3d at 1054 n.8. EPA did not, violating Section 7(a)(2).

b. Indiana Bat (Myotis sodalis)

EPA went much further in its effort to evade consultation on the endangered Indiana bat, by cherry-picking data to help support an eventual "no effect" finding.

Indiana bats play a critical role in maintaining the balance of an ecosystem. A significant source of natural insect control, Indiana bats typically consume up to half of their body weight in insects each night. ER2238. Their population has continued to decline despite conservation and recovery efforts; less than half of those that existed when the species was listed as endangered remain. FWS's Indiana bat recovery team specifically identified pesticide contamination of the bats' food supply as a reason for their continued decline. ER2316-21.

After its screening assessment showed the Enlist Duo registration may affect the species along with other mammals, ER2079-80, EPA performed a species-specific assessment revealing the Indiana bat likely will suffer reproductive harm

by consuming 2,4-D-tainted prey, as a direct result of EPA's approval of Enlist Duo:

> A daily dose of 74 mg/kg-bw/day places the daily exposure of the bat is [sic] above the two-generation reproduction study (rat) [No Observable Effect Level] of 5 mg/kg-by/day used in the screening risk assessment, even when scaled. Consequently, *a "no effect" determination cannot be concluded for the Indiana bat* using just the lines of evidence found in the screening level risk assessment screening level risk methods.

ER1776 (emphasis added).

Again, this "may affect" determination required EPA to consult FWS. Yet, instead of either informally consulting FWS and seeking its concurrence that the registration is "not likely to adversely affect" this endangered species, *Pac. Rivers Council*, 30 F.3d at 1054 n.8, or entering formal consultation, EPA unlawfully assumed the prerogative to make all determinations itself.

EPA began the process of distancing itself from its prior analyses by declaring its underlying assumptions "conservative." ER1776. But this is exactly what the ESA requires: EPA *must* "give the benefit of the doubt to the species." *Conner*, 848 F.2d at 1454. Instead, EPA used this to justify "explor[ing] the roles of various assumptions of bat biology and habitat use to evaluate the likelihood of exceeding the toxic thresholds for growth and survival of offspring in laboratory reproduction testing." ER1776. In other words, it began trying to find a way to convert its "may affect" into "no effect."

Without expertise in bat biology, EPA guessed how often the bats were likely to visit sprayed fields, guessed how much of their diet would likely come from those fields, and guessed how much 2,4-D residue their prey likely would carry. EPA assumed no bat would obtain most of its diet from the fields, although the conservative assumption, based on the available data, would have been the opposite. ER1776-78. At no point did EPA test its assumptions with FWS.

EPA's modeling predicted the bats would be exposed to 2,4-D at levels laboratory tests showed "produced reduced pregnancies, and skeletal malformations as well as a reduction in the survival of pups." ER1780. EPA observed: "There is considerable uncertainty, in the absence of any further lines of evidence as to the toxicological significance of these short-term exposures predicted in the probabilistic model." *Id*. In the face of such "considerable uncertainty," instead of "giv[ing] the benefit of the doubt to the species," *Conner*, 848 F.2d at 1454, and consulting FWS to help resolve the "uncertainty," EPA continued its quest for a "no effect" finding.[21]

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[21] *See Wash. Toxics Coal*., 457 F. Supp. 2d at 1184-85 (quoting a NMFS scientist):

> To prevent [jeopardy to species], *the Services must treat evidence and uncertainty differently than most other agencies: to minimize risks to listed species*, we conduct our analyses and navigate our decision-making processes to avoid false conclusions at each step of a consultation ... (that is, the Services are biased to avoid the "false negative" conclusion or

EPA delved deeper into studies performed on rats (a taxonomic group only distantly related to bats) to try to determine the "toxicologically significant" dose of 2,4-D on the Indiana bat.[22] Critically, unable to avoid a "may affect" determination using the toxicity data in the rat studies on which EPA had relied for its screening risk assessment, EPA simply replaced it with a new assumption, that significantly higher doses of 2,4-D would not be toxic. EPA derived this assumption from a "hypothesis" for which EPA found support only in unpublished studies performed by the applicant, Intervenor Dow, that EPA "interpreted." ER1780. On the basis of this "hypothesis" and its "interpretations," EPA substituted a much higher toxicity threshold (55 mg/kg/day) for the significantly

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> minimize the risk of Type II error). Most other agencies, including EPA, conduct their assessments in ways that avoid concluding that agency actions had adverse effects when, in fact, such a conclusion is false (that is, they are biased to avoid the "false positive" conclusion or minimize the risk of Type I error).

Id. (emphases added.)

[22] There are a host of physiological and behavioral differences between rats and bats that make using rat toxicological data inappropriate for assessing risk to bats. Lab rats are much bigger (body mass) than Indiana bats and do not share the same physiology or locomotion. Unlike laboratory rats used in the various studies of 2,4-D toxicity, bats fly, navigate and eco-locate. If they are stressed due to chemical exposure their ability to fly and echolocate may be temporarily impaired.

lower levels EPA and other agencies had concluded would likely cause harm to small insect-eating mammals such as bats.[23] *Id.*

EPA then made more guesses of pesticide residues, the proportion of bat diet consisting of tainted insects, bat body weights, and amounts of pesticide likely to be applied, and ran more modeling runs, varying the assumptions. ER1781-83. Using habitat near agricultural fields as a surrogate for the proportion of the bats' diet originating from such fields—which obviously has a substantial impact on any calculation of pesticide load—EPA cherry-picked data to suit its purpose. The Indiana Bat Recovery Plan, ER224-2483—a standard source of "best available and current information" for species-specific assessments per EPA's policy, ER2550—reveals that from 55 to 67 percent of land near Indiana bat colonies is agricultural. ER2289. Instead of conservatively assuming bats obtain from 55 to 67 percent of their prey from agricultural land that will be sprayed with Enlist Duo, EPA

[23] *See* Forest Serv., USDA, *2,4-D Human Health and Ecological Risk Assessment Final Report*, at xxi, 3-15, 4-36 (Sept. 30, 2006) ("adverse effects could be expected" on small insect-eating mammals, such as the Indiana bat, from applications of 2,4-D at the rate EPA approved in this registration, 1 lb. a.e./acre) (emphasis added) (citing EPA's 2,4-D Reregistration Eligibility Decision (June 2005), *available at* http://www.fs.fed.us/foresthealth/pesticide/pdfs/093006_24d.pdf.)

assumed a smaller proportion. *Compare* ER1782 *with* ER1777.[24] Again, EPA left FWS out of the loop.

Applying these and other assumptions, EPA finally was able to get to the conclusion it sought: that Indiana bats would be unlikely to consume enough 2,4-D to "meet or exceed levels of toxicological concern for reproduction and development." ER1783.[25] EPA then took the toxicity threshold value of 55 mg/kg/day it derived through "hypothesis" and "interpretation" and plugged it into its risk assessments for every other endangered mammal that EPA concedes occupies and feeds in sprayed agricultural fields, and relying on that, concluded there would be "no effect" on any of them. *See, e.g.*, ER626; ER659-661 (using 55 mg/kg/day in risk assessments of endangered wolves); ER1458-61 (same for other mammals).

Importantly, EPA characterizes 55 mg/kg/day as the "NOAEL" for mammals—the level below which there is *No Observed Adverse Effect*.

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[24] *See also* ER1777 ("Old fields and agricultural areas seemed important in both studies, but bats likely were foraging most often along forest-field edges, rather than in the interior of fields, although errors inherent in determining the position of a rapidly moving animal through telemetry made it impossible to verify this."); ER1779 ("[T]he extent of foraging over agricultural land is expected to be less than the degree of foraging around the canopies of forested areas.").

[25] For its subsequent registration determination that Enlist Duo's use in additional states and on additional crops will have "no effect" on the endangered Indiana bat, EPA used the data and calculations from its previous assessment. *See* ER1459-60; ER656-57.

ER1458-61. And once again, "no adverse effect" is not the ESA standard for triggering consultation. EPA's fatal error throughout its assessments is that a "not likely to adversely affect" finding is not EPA's prerogative to make without FWS concurring in writing after consultation. 50 C.F.R. § 402.14(a), (b).

2. EPA Failed to Use the Best Scientific and Commercial Data Available.

a. EPA's Exposure Handbook Is an Inappropriate Source of Data for Assessing Risks to ESA-Protected Species.

The ESA imposes the additional, independent statutory mandate that EPA, like all federal agencies, use the "best scientific and commercial data available" when assessing its action's effects on ESA-listed species and habitats. 16 U.S.C. § 1536(a)(2). In addition to its other ESA violations, EPA violated this mandate in assessing impacts on whooping cranes, Indiana bats, and many other listed species.

For example, EPA relied on its 1993 Wildlife Exposure Factors Handbook (Exposure Handbook), produced at record identifier 6829 (ER2886-3147), for critical data. *See, e.g.,* ER656, 668 (citing USEPA 1993). The Exposure Handbook nowhere mentions whooping cranes or Indiana bats, nor any other endangered species, because EPA never intended that it be used for assessing effects on any endangered species, nor for any purpose after screening assessments show species may be affected.

On the contrary, the Exposure Handbook is designed for a different, narrow purpose: "to provide a convenient source of information and an analytic framework for *screening-level* risk assessments for *common* wildlife species." ER2592 (emphases added).

The Exposure Handbook emphasizes the need to obtain data for the particular species being assessed, ER2593 ("Exposure varies between different species and even between different populations of the same species…."), and contains no data about any type of crane or bat, let alone the endangered species for which EPA applied it.

As discussed, once the "may affect" threshold is reached, EPA must consult FWS, not perform more and more analyses until it imagines it can avoid consultation. But EPA persisted, filling data gaps with an Exposure Handbook that instructs EPA to obtain data about local populations—specifically, *by consulting FWS*. ER2595-96. Relying on this inappropriate source of critical data and its own FIFRA-based assessment standards, EPA concluded that because the total load of 2,4-D it guesstimated a whooping crane or Indiana bat would consume was less than its own "level of concern," spraying a toxic chemical on their food would have "no effect" on any of them. ER632-33. EPA's use of guesswork and data that expressly provides it is not appropriate for this purpose instead of even attempting to obtain the best available data by consulting FWS violated Section 7(a)(2).

F. EPA Also Violated the ESA by Failing to Consult the Expert Agencies About Designated Critical Habitat.

ESA § 7(a)(2) imposes an independent, additional duty on EPA to "insure" its Enlist Duo registration will not destroy or adversely modify any habitat that FWS, pursuant to ESA § 4(a)(3)(A), designated as "critical" to a listed species' survival and recovery. 16 U.S.C. § 1533(a)(3)(A). EPA's duty to consult FWS regarding potential effects on critical habitat is separate from its duty regarding effects on listed species themselves, but applies the same low bar: EPA *must* consult FWS if its registration "may affect" a listed species' designated critical habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b).

1. EPA Applied the Wrong Standard to Determine Whether Consulting on Critical Habitat is Necessary.

EPA perfunctorily dismissed its duty to consult FWS to ensure spraying millions of acres with a toxic weedkiller will not affect any critical habitat, falling far short of the ESA's requirements. First, EPA acknowledged FWS had designated 184 critical habitats for 531 species in and around fields in the 34 states where EPA authorized Enlist Duo spraying. ER679. EPA then invented rules from whole cloth about when its action will trigger consultation on critical habitat, and substituted them for the ESA's "may affect" standard, leading EPA to unlawfully circumvent consultation for *every single one* of 184 critical habitats. Here is the rule EPA created for itself:

> The Agency will conclude 'modification' of designated critical habitat if the range of designated critical habitat co-occurs with the states subject to the Federal action and one or more of the following conditions exist:
>
> 1. The available Services' information indicates that corn, cotton, or soybean fields are habitat for the species *and there is a "may affect" determination for the species* associated with 2,4-D choline salt, as labeled.
>
> 2. The available Services' information indicates that *the species uses corn, soybean, or cotton fields* and one or more effects on taxonomic groups predicted for 2,4-D choline salt on corn, cotton, and soybean fields *would modify one or more of the designated PCEs and PBFs*.
>
> If the above conditions are not met, EPA concludes "*no modification*."

ER679 (emphases added).

In other words, EPA decided that spraying Enlist Duo could not cause "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character" on critical habitat, triggering consultation, *Karuk Tribe*, 681 F.3d at 1027, unless EPA first found its action "may affect" *the listed species* for which part of its designated critical habitat is a sprayed field. Otherwise, the species must be shown to actually *use those fields*, *and* EPA must find that spraying Enlist Duo on the fields reduces their value as critical habitat. This made-up formula has nothing to do with what the ESA actually requires, and is riddled with legally erroneous assumptions.

Initially, overlap between protected species or critical habitat and the action area—which EPA admits exists here at least where sprayed fields are part of a

species' critical habitat—virtually mandates consultation because "*[a]ny possible effect*, whether beneficial, benign, adverse or of an undetermined character," *id.*, is almost unavoidable under such circumstances.

Again, echoing the above myriad instances, EPA awarded itself authority it does not have—here, to decide whether critical habitat is "modified" by the Enlist Duo spraying EPA authorized. ESA § 7(a)(2) does not mandate consultation with FWS only where EPA's action "modifies" critical habitat, nor may EPA forego consultation if it finds "no modification." The law requires consultation for all "actions that have *any chance of affecting* … critical habitat." *Karuk Tribe,* 681 F.3d at 1027 (emphasis added). EPA again applied the wrong legal standard.

Second, EPA's assertion it will consult if "there is a 'may affect' determination for the species" for which critical habitat has been designated (if the species also uses agricultural fields) is a legal *non sequitur*. EPA conflates risks to species with risks to habitat, and attempts to restrict its habitat consultation duties to only situations where it also finds species risks, thus making assessment of effects on critical habitat superfluous. But the ESA imposes on EPA independent duties for each risk. 50 C.F.R. § 402.14(a) (consulting FWS "required" if "any action may affect listed species *or* critical habitat.") (emphasis added). Critical habitat may be affected regardless of whether an action may directly affect the

species itself. *See Greenpeace v. NMFS*, 55 F. Supp. 2d 1248, 1265 (W.D. Wash. 1999) (effects on species and habitat distinct and independent).

As discussed above, EPA erroneously failed to consult FWS regarding hundreds of listed species. By predicating its critical habitat "no effect" determinations on its earlier failures to make "may affect" findings regarding the ESA-protected species, EPA merely doubled down on its unlawful conduct. But even if EPA's "no effect" species' determinations had been correct, they would be irrelevant to its independent duty to consult on critical habitat.

2. EPA Unlawfully Excluded from Consideration All Critical Habitats Except Those Containing Sprayed Fields Occupied by Listed Species.

EPA's erroneous conclusion that consultation on critical habitat is not triggered unless a listed species "use[s] corn, cotton or soybean fields" caused it to categorically ignore almost all of the hundreds of designated critical habitats in the action area as EPA ultimately defined it—the sprayed fields. *See* ER679 ("One-hundred and seventy-six (176) species with critical habitat were judged to not use corn, cotton, or soybean fields and so the critical habitat determination for these was 'no modification.'"). This is not how critical habitat or the ESA works.

As a matter of law, whether members of an endangered species physically occupy some part of a designated critical habitat (here, corn, cotton and soybean fields) is completely irrelevant to whether spraying pesticide on those fields "may

affect" the habitat, triggering consultation. Critical habitat is designated to preserve specific habitat features, known as "primary constituent elements" (PCEs), which are the "physical or biological features" "essential to the conservation of the species" and "which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A)(i); 50 C.F.R § 424.12(b). According to FWS, an area may be designated because it provides any of a wide range of features:

> [A primary constituent element is a] physical or biological feature essential to the conservation of a species for which its designated or proposed critical habitat is based on, such as space for individual and population growth, and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing of offspring, germination, or seed dispersal; and habitats that are protected from disturbance or are representative of the species' historic geographic and ecological distribution.[26]

Any action impairing any PCE "may affect" the critical habitat, triggering consultation. *See Consultation Handbook*, *supra* n.16, at 4-24 (assessing effects of an action should consider "primary constituent elements of the critical habitat, including direct and indirect effects.").

Crucially, contrary to EPA's decision, a species' physical presence is unnecessary for designation as critical habitat. Critical habitat may include "specific areas *outside the geographical area occupied by the species* ... upon a

[26] FWS, *Endangered Species Glossary*, https://www.fws.gov/nc-es/fish/glossary.pdf (last visited Apr. 10, 2018).

determination by the Secretary that such areas are essential for the conservation of the species." 16 U.S.C § 1532(5)(A)(ii) (emphasis added); *see Consultation Handbook*, *supra* n.16, at xix ("Some designated, unoccupied habitat may never be occupied by the species, but was designated since it is essential for conserving the species because it maintains factors constituting the species' habitat.").

Consequently, EPA must assess *all potentially affected* critical habitat, whether sprayed fields or not, regardless of whether members of protected species may be present in them, because the habitat nonetheless may be important for the species' survival or recovery. *See Nat. Res. Def. Council v. Kempthorne*, 506 F. Supp. 2d 322, 381-82 (E.D. Cal. 2007) (biological opinion inadequate because it failed to assess impacts on all areas of critical habitat, whether or not occupied by endangered species); *see also Gifford Pinchot Task Force v. U.S. Fish and Wildlife Serv.*, 378 F.3d 1059, 1070 (9th Cir. 2004) ("[T]he purpose of establishing 'critical habitat' is for the government to carve out territory that is not only necessary for the species' survival but also essential for the species' recovery."). One obvious example: if agricultural fields within a species' critical habitat do not contain the listed species but do contain the species' prey, which may move out of the fields where the species may then consume it, then an action that reduces that prey "may affect" the habitat, triggering consultation.

Whether EPA's registration will *adversely affect* (or even "modify") any of the hundreds of critical habitats is not before this Court; a contrary determination requires FWS's written concurrence after informal consultation, in which EPA unlawfully refused to engage. 50 C.F.R. § 402.14(b)(1). EPA did not even meaningfully consider whether spraying the fields "may affect" these critical habitats, but instead violated the ESA as a matter of law by assuming effects on unoccupied critical habitat *cannot* trigger consultation.

3. EPA Failed to Properly Assess Effects on Critical Habitat Even Where Listed Species Occupy Sprayed Fields Within Critical Habitat.

For its assessment of the 4 percent of critical habitats where listed species do occupy agricultural fields, EPA relied on its previous listed species' effects determinations "to ascertain if any [species] were determined to be at risk for direct adverse effects." ER1080. Since EPA had already made erroneous "no effect" determinations for virtually all species as discussed above, this had a foregone conclusion. But EPA's assessment methodology violated the ESA as a matter of law, since as noted, an action "may affect" critical habitat regardless of whether it directly affects any members of the species.

EPA—finally—looked at the critical habitats' PCEs for those handful of species occupying the sprayed fields that are part of their critical habitats. *Id.* EPA's assessment was inadequate: it summarily dismissed any possibility that

spraying Enlist Duo on fields within critical habitat "may affect" them by declaring (with the single exception of the whooping crane,[27] which feeds in agricultural fields), "No PCE related to agriculture." *Id.* This is flatly contradicted by EPA's own description of the Virginia big-eared bat's PCEs, which include: "Foraging habitats include woodlands, old fields, and hay fields. Agricultural and man-made areas: corn, hay, and alfalfa fields." ER978-79. The whooping crane's critical habitat also has PCEs plainly relating to agricultural fields. *Id*. at 402. The record offers no explanation for these obvious inconsistencies. On this basis as well, EPA violated ESA § 7(a)(2).

III. EPA VIOLATED THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

In approving Enlist Duo, EPA ignored and violated numerous FIFRA mandates. First, EPA applied the wrong legal standard, and never made the statutorily-mandated findings, for a conditional approval of a pesticide new use. EPA approved Enlist Duo based on its conclusion that it generally would not cause unreasonable adverse effects on the environment, when it should have weighed simply whether the pesticide's new use would significantly increase the risk of such unreasonable adverse effects occurring. Regardless, EPA's approval is

[27] Since, as discussed *supra* pp. 39-41, EPA, ignoring the ESA's standards, had already determined that the effects eating grain sprayed with 2,4-D would not rise to "a level raising a concern," EPA concluded—again ignoring the standard applicable to critical habitat—that whooping crane critical habitat would not be "modified."

unlawful under either standard, because EPA lacked evidence to support its conclusion that 2,4-D volatilization would not injure non-target organisms off-field, and entirely failed to analyze the foreseeable harms of Enlist Duo's use in tank mixtures with the pesticide glufosinate. As a result, EPA cannot find that the widespread adoption of Enlist Duo's use in agriculture would not have unreasonable adverse effects on the environment, nor significantly increase the risks of such effects, in violation of FIFRA.

A. EPA Applied the Wrong Standard and Failed to Make Statutorily Required Findings.

EPA must approve, or "register," pesticides before they are used or sold. 7 U.S.C. § 136a(a). A registration can be unconditional, *id.* § 136a(c)(5), or conditional, *id.* § 136a(c)(7). *See Nat. Res. Def. Council v. U.S. EPA*, 857 F.3d 1030, 1036-37 (9th Cir. 2017). For unconditional registrations, EPA must conclude a pesticide will, *inter alia*, "not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(D). For a conditional "new use" registration, however, which EPA approved here,[28] the standard is different. EPA must make two findings: "(i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed

[28] Enlist Duo is a "new use" of registered 2,4-D, defined as an "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.

by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment." *Id.* § 136a(c)(7)(B); *see also* 40 C.F.R. § 152.113(a)(1)-(2) (EPA can issue registration "only if" the agency has "all data," including "at a minimum, data needed to characterize any incremental risk that would result from the approval," and the approval "would not significantly increase the risk of any unreasonable adverse effect."). EPA unlawfully substituted the former standard for the latter.

The prior, 2014 registration at issue in *Enlist Duo I* was an unconditional registration. *See* ER1401. This time, EPA issued a conditional approval only. *See* ER4 (The "new use is being conditionally registered under FIFRA section 3(c)(7)(B) because of outstanding data that will be part of the registration review process."). Yet in the 2017 registration, EPA failed to find that either of the two conditional new use prerequisites were met.

First, as discussed below, EPA readily admits that, with regard to 2,4-D vapor drift and tank mixtures, the agency lacked sufficient data to assess harm from Enlist Duo's new uses. *See* 7 U.S.C. § 136a(c)(7)(B); 40 C.F.R. § 152.113(a)(2).

Second, EPA applied the *unconditional* registration standard: that Enlist Duo will not "generally cause unreasonable adverse effects." ER30. EPA based its assessment, and decision, on the wrong legal standard, and never made the

required legal finding.[29] To have their registration upheld, EPA must support with substantial evidence not only that the Enlist Duo formulation will not affirmatively and generally cause unreasonable adverse effects, but that substantial evidence supports that the new, novel use of 2,4-D over-the-top of GE crops will not even *increase the risk* of such unreasonable adverse effects occurring, or that even the risk of such adverse effects coming to pass would be *minimal*.

Finally, EPA's decision was fatally flawed and not supported by substantial evidence under either standard: the record shows EPA's failure to analyze risks of using Enlist Duo will generally cause unreasonable adverse effects, and thus the approval significantly increased the risk of unreasonable adverse effects as well.

B. EPA Failed to Ascertain That Volatilization of 2,4-D From Enlist Duo Would Not Have Unreasonable Adverse Effect on the Environment.

Volatilization of 2,4-D damages neighboring crops and plants off-field. *See* ER2032 ("2,4-D is known to volatilize from the field and drift off site under certain environmental conditions."). Nonetheless, EPA concluded, based on deficient data, that 2,4-D volatilization from Enlist Duo would not unreasonably

[29] Notably in the original 2014 Enlist Duo Registration, EPA applied the correct legal standard for a *conditional* registration. *See* ER24-25 ("Based on these considerations, consistent with the requirements of FIFRA Sec. 3(c)(7)(B), EPA concludes that (i) the Agency has satisfactory data pertaining to the expanded uses of Enlist Duo on corn and soybeans; and (ii) approving this application as set forth below will not increase the risk of any unreasonable adverse effects on human health or the environment."). This underscores the agency's application of the wrong legal standard and failure to make the statutorily required findings this time.

affect the environment. *See* ER22. EPA's conclusion lacks support in substantial evidence, in violation of FIFRA. *See Pollinator Stewardship*, 806 F.3d at 531 ("[A]n agency cannot rely on ambiguous studies as evidence of a conclusion that the studies do not support.") (citing *Tucson Herpetological Soc. v. Salazar*, 566 F.3d 870, 879 (9th Cir. 2009)).

EPA centered its entire assessment of 2,4-D volatilization on a laboratory study that EPA itself found deficient. ER2032, 2082 (describing deficient laboratory vapor-phase study); ER3190-94. The laboratory study provided visual observations of plant damage from 2,4-D vapor. ER2082. EPA used this single study to determine the acceptable threshold of harm—the highest air concentration of 2,4-D vapor that would not have unreasonable adverse effect on plants. ER2082-84. EPA then analyzed 2,4-D's volatilization risks by comparing the selected threshold against modeling projections of 2,4-D vapor concentrations. ER2082-84. The laboratory study thus supplied the guidepost for EPA's 2,4-D volatility assessment.

Yet, in its evaluation report of the study and its 2013 ecological risk assessment, EPA itself repeatedly emphasized that the submitted laboratory study was *deficient*. EPA described the study as "limited in scientific soundness," ER2020. EPA identified several critical deficiencies of the study: it was conducted without an untreated control group, nor adherence to either mandatory laboratory

practices or EPA's test guidelines. *See* 40 C.F.R. § 158.70(b) (requiring studies "adhere to the good laboratory practice (GLP) standards described in 40 CFR part 160"); ER3191 (laboratory study was "[redacted]" and "[redacted]"). Significantly, EPA acknowledged visual observations of plant damage were meaningless for its risk assessment, which requires data measuring endpoints of effect on plant growth or weight. *See* ER2082 ("Plant damage endpoints are not normally quantitatively in risk assessments, and their sensitivity, compared with growth/weight endpoints, is unknown."); ER3192 (noting "[redacted]"). EPA therefore called for an *additional* study to supply the necessary data. ER2022 (recommending another "vapor-phase study with vegetative vigor endpoints" and that "[a]t a minimum, grape and cotton should be tested as these were the most sensitive species in the submitted vapor-phase study."); ER2032 (same).

However EPA *never received such a further study*. Rather, eager to push through Enlist Duo's registration, EPA claimed the laboratory data presented the "best information available" at the time,[30] and proceeded to set the harm threshold at a 2,4-D vapor concentration of 1.9 ug/m^3/hour, the level that caused 20 percent visual physical damage for grape, the most sensitive crop tested in the study.

[30] Despite numerous additional assessments of Enlist Duo since 2013, *see supra* pp. 7-9, EPA never updated its volatility assessment.

ER2082-84. EPA claimed in its January 2013 ecological risk assessment that 20 percent was a "conservative approach" for assessing harm from 2,4-D volatilization, but its detailed evaluation of the laboratory study, finalized just three weeks later, identified [redacted]. ER3192. EPA nonetheless used the 1.9 ug/m^3/hour threshold to conclude that 2,4-D volatilization is not a concern, because various modeling projections predicted concentrations of 2,4-D vapor below that level.

EPA's analysis lacks support in substantial evidence and must be rejected. In *Pollinator Stewardship*, this Circuit rejected EPA's conclusion that the pesticide sulfoxaflor would not have unreasonable adverse effect on honey bees, where EPA's conclusion was based on deficient studies, and where EPA itself had previously called for additional studies. *See* 860 F.3d at 530. The Circuit cited many of the same deficiencies found in the laboratory study here. *See id.* at 529 ("proper controls could have been used" and "the studies could have been replicated more times"). Just as in *Pollinator Stewardship*, here EPA could have, and should have, required Dow to submit a properly conducted study that supplied the data necessary for EPA's assessment of 2,4-D volatilization. EPA did not, and its conclusion that 2,4-D volatilization would not have unreasonable adverse effect on the environment was based entirely on an unreliable harm threshold. As this

Circuit previously explained, "[t]he limitations of the underlying data … mean that no such conclusion can be reached." *Id.* at 531.

C. EPA Failed to Consider Synergistic Effects of Mixing Enlist Duo With Glufosinate.

EPA was well aware combining different pesticides and chemicals can result in synergistic effects that render the combined pesticide formulations more toxic than the individual components. ER55 (recognizing that "combined [pesticide] mixtures" may "have enhanced activity or synergistic effects."); ER3 n.1. Indeed, EPA previously vacated its registration of Enlist Duo in order to assess "possible synergistic effects" between 2,4-D and glyphosate Dow claimed in a patent application. *See supra* pp. 7-9; ER2-3.

EPA was also aware of potential synergistic effects between 2,4-D and another pesticide active ingredient, glufosinate, but failed to assess such effects. Just like the 2,4-D and glyphosate patent application, Dow had also submitted a patent application[31] claiming "synergistic weed control" of pesticide combinations containing 2,4-D and glufosinate. *See* ER122; ER471-72 ("[T]he combination of

[31] While Dow subsequently withdrew the patent application claiming synergy between 2,4-D and glyphosate, the patent application asserting synergistic effects between 2,4-D and glufosinate is still active. *See* Mann, Richard K., *Synergistic Herbicidal Weed Control From Combinations of 2,4-D-Choline And Glufosinate*, http://appft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PG01&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.html&r=1&f=G&l=50&s1=%2220150157023%22.PGNR.&OS=DN/20150157023&RS=DN/20150157023 (last visited Apr. 10, 2018).

2,4-D choline and a salt of glufosinate exhibit synergism, i.e., the herbicidal active ingredients are more effective in combination than when applied individually."). Scientific studies before EPA also indicate such synergy. *See* ER129-143. Finally, EPA also knew that Enlist crops, which are genetically engineered to withstand applications of 2,4-D and glyphosate, are also engineered to withstand applications of glufosinate. *See* ER3202 ([redacted]); ER3188-89 ([redacted]).

Yet EPA allowed mixing Enlist Duo with other pesticides and chemicals—including glufosinate—without any assessment of the mixtures' potential synergistic effects. ER32-33. Instead, Enlist Duo can be "tank mixed" as long as the mixture has been tested for increased *spray drift*—but not for any synergistic effect that increases the mixture's toxicity. *See* ER32 (authorizing products for tank mixing with Enlist Duo that have been tested and found "not to adversely affect the spray drift properties of Enlist Duo").

EPA's failures to assess synergistic effects of glufosinate and Enlist Duo, or require any such testing before allowing their tank mixing, violate its statutory duty to ensure Enlist Duo's registration "would not significantly increase the risk of any unreasonable adverse effect on the environment." 7 U.S.C. § 136a(c)(7)(B). The definition of "pesticide" plainly includes "*mixture of substances* intended for use as a plant regulator, defoliant, or desiccant." *Id.* § 136(u)(2) (emphasis added); 40

C.F.R. § 152.3 (same). EPA knew it had to assess synergistic effects when faced with *an identical claim* of "synergistic herbicidal weed control" between glyphosate and 2,4-D in a patent application. *See* ER1003-06 (requiring testing on seedling emergence and vegetative vigor to determine toxicity endpoints for the 2,4-D and glyphosate combination). In EPA's own words, without assessing such potential synergistic effects, EPA cannot "represent to the Court that its conclusions were correct regarding whether issuance of the registration met the standards in FIFRA" or "support the finding that the registration will have no effect upon threated or endangered species." Mot. Voluntary Vacatur & Remand, *Enlist Duo I*, ECF No. 121-1. EPA violated FIFRA by failing to assess whether glufosinate and 2,4-D mixtures could have unreasonable adverse effects on the environment before authorizing them.

IV. THE COURT SHOULD VACATE THE REGISTRATION

The Court should set aside, or vacate, EPA's approval. Vacatur is the express statutory remedy provided by FIFRA. 7 U.S.C. § 136n(b). Indeed, remand without vacatur is permitted only in "limited circumstances," *Pollinator Stewardship*, 806 F.3d at 532; *Humane Soc'y of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010) ("rare circumstances"), and only when the agency can show that "equity demands" a departure from this presumptive remedy, *Pollinator*

Stewardship, 806 F.3d at 532 (quoting *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)).

This Court considers whether such "rare circumstances" for remand without vacatur are met by "weigh[ing] the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be changed." *Id.* (internal quotation and citation omitted). As to the first factor, the FIFRA violations delineated above are serious legal errors. *See, e.g.*, *id.* at 532-33 (vacating pesticide registration); *Nat. Res. Def. Council*, 857 F.3d at 1042 (vacating the pesticide registration). Moreover, Congress has made clear ESA duties are even more important than EPA's FIFRA duties, weighing even more heavily in favor of vacatur. *See Karuk Tribe*, 681 F.3d at 1020 (the ESA's "consultation requirement reflects a 'conscious decision by Congress to give endangered species priority over the "primary missions" of federal agencies.'") (quoting *Hill*, 437 U.S. at 173).

In assessing disruptive consequences, this Court considers "whether vacating a faulty rule could result in possible environmental harm, and we have chosen to leave a rule in place when vacating would risk such harm." *Pollinator Stewardship*, 806 F.3d at 532; *see also Idaho Farm Bureau*, 58 F.3d at 1405-06. In *Pollinator Stewardship*, this Court held that "given the precariousness of bee populations, leaving EPA's registration of sulfoxaflor in place risks more potential

environmental harm than vacating it." 806 F.3d at 532. The exact same is true in this case for endangered species, as well as farmers and the environment more broadly.

CONCLUSION

In approving Enlist Duo for spraying on millions of acres across much of the United States, EPA violated both the ESA and FIFRA in ways that risk harm to human health, endangered species, and the environment. EPA persistently misapplied the legal standard that triggers its strict duty to consult the expert wildlife agencies to "insure" the registration does not jeopardize any listed species or harm critical habitat. Instead of consulting whenever it found the registration "may affect" a species or habitat as the ESA defines that term, EPA refused to consult unless its analyses demonstrated harm—and its analyses lacked the necessary expertise or data. With critical habitat impacts, EPA simply made up its own rules.

EPA also violated FIFRA. It applied the wrong legal standard for a conditional registration and failed to make the statutorily required findings. The agency based a critical finding that Enlist Duo's volatilization will not cause unreasonable harm by drifting on to neighboring fields on a study EPA itself acknowledged was deficient. And, despite the procedural history of this case, EPA allowed the pesticide to be tank mixed with other pesticides, such as glufosinate,

despite knowing the mixture may have synergistic effects, and therefore may cause unreasonable harm.

These ESA and FIFRA violations compel vacatur to protect health and the environment.

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