No. 17-70196

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,

and

MONSANTO COMPANY,

Intervenor-Respondent.

ON PETITION FOR REVIEW FROM THE UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

PETITIONERS' OPENING BRIEF

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioners National Family Farm Coalition, Center for Food Safety, Center for Biological Diversity, and Pesticide Action Network North America certify that they have no parent corporations and that no publicly held corporation owns more than ten percent of the Petitioners.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases **Page(s)**

Federal Cases (Cont'd) **Page(s)**

Federal Cases (Cont'd) **Page(s)**

Federal Statutes

Rules

Regulations

Regulations (Cont'd) **Page(s)**

Federal Register

Other Authorities

Other Authorities (Cont'd) **Page(s)**

JURISDICTIONAL STATEMENT

This case is a petition for review of a pesticide approval by the United States Environmental Protection Agency (EPA). 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 [EPA] Administrator following a public hearing," 7 U.S.C. § 136n(b), [1] which this Court has interpreted to include holding public notice and comment, *United Farm Workers of Am. v. Envt'l Prot. Agency*, 592 F.3d 1080, 1082-83 (9th Cir. 2010). EPA solicited and responded to public comments prior to approving the challenged XtendiMax registration. *See infra* n.5. Petitioners were "a party" to the EPA proceedings, having submitted comments, and are "adversely affected" by EPA's approval of XtendiMax use on dicamba-resistant cotton and soybean. 7 U.S.C. § 136n(b); ER485-553; ER572-75; ER576-602; ER473.

Petitioners have standing. Parties have Article III standing if they are under threat of suffering an injury-in-fact that is concrete and particularized; the threat is actual and imminent, not conjectural or hypothetical; the injury is fairly traceable to the challenged action; and it is likely that a favorable decision will redress the injury. *Friends of Earth, Inc. v. Laidlaw Envt'l Serv. (TOC), Inc.*, 528 U.S. 167,

[1] All pertinent statutory provisions, regulations, and rules are included in the attached Statutory and Regulatory Addendum (A2-89). 9th Cir. R. 28-2.7.

180-81 (2000). Public interest organizations like the Petitioners have representational standing "when its members would otherwise have standing to sue in their own right, the interests it seeks to protect are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). EPA's challenged actions threaten to directly injure Petitioners' members' environmental, vocational, agricultural, recreational, aesthetic, and economic interests. *See* Bentlage Decl. ¶¶ 2-17; Buse Decl. ¶¶ 1-13; Crouch Decl. ¶¶ 2-14; Griffith Decl. ¶¶ 1-9 ; Ishii-Eiteman Decl. ¶¶ 1-11; Kimbrell Decl. ¶¶ 6-12; Newman Decl. ¶¶ 1-18; Suckling Decl. ¶¶ 2-11 (A93-147).[2]

Petitioners timely filed this petition for review. Order, ECF No. 23; ECF No. 12-1; 7 U.S.C. § 136n(b), 40 C.F.R § 23.6.

ISSUES PRESENTED

1. Did EPA violate FIFRA by approving XtendiMax:
   - using the wrong legal standard;
   - without quantifying, analyzing, or including in its analysis the socioeconomic costs of XtendiMax's drift impacts;

[2] The declarations are contained within the attached Addendum of Declarations (A92-147).

- without supporting the efficacy and feasibility of its drift mitigation measures with any data, analysis, or rationale;
- relying on Monsanto's assurances rather than EPA's own analysis; and
- in the face of significant yet unaddressed volatility risks?

2. Did EPA violate the Endangered Species Act (ESA) by failing to consult the expert wildlife agencies concerning XtendiMax's effects on threatened and endangered species and their critical habitats, despite ample evidence and the agency's admissions that its approval decision "may affect" them?

STATEMENT OF THE CASE

This action concerns a pesticide Intervenor Monsanto developed, M1768 or "XtendiMax with VaporGrip Technology" (XtendiMax), containing the weed-killing active ingredient, dicamba. *See* Excerpts of Record (ER) 002. While dicamba has been sold in other forms since 1967, ER742, XtendiMax is a "new use" registration, ER003-4, because Monsanto sought approval from EPA for an entirely novel use of it: direct, "post-emergent" application to cotton and soybean plants that Monsanto genetically engineered (GE) to survive dicamba spray. ER003-4.

I. XTENDIMAX AND GENETICALLY ENGINEERED CROPS.

Because dicamba is extremely toxic to natural cotton and soybean, the pesticide previously could be used only before these plants sprouted ("pre-emergent"), to clear a field of early season weeds. ER003-4. Genetically engineered dicamba resistance enables Monsanto's GE crops to be sprayed much later in the season, without harming the crop. ER003. Monsanto markets patented GE dicamba-resistant seeds, which are also resistant to Roundup herbicide, together with XtendiMax, as the "Roundup Ready Xtend Crop System."[3]

This crop system is Monsanto's "solution" to a problem it created. ER782-87; ER278-79. For 20 years, Monsanto has sold Roundup and seeds genetically engineered to resist Roundup's active ingredient, glyphosate. This "Roundup Ready" crop system has dramatically and controversially increased the overall pesticide output into our environment. *Ctr. for Food Safety v. Vilsack*, 718 F.3d 829, 841 (9th Cir. 2013); ER782-87. It also caused a related problem: Monsanto told farmers they could rely entirely on Roundup without weeds becoming resistant to glyphosate, contrary to weed science experts' warnings. ER552-53. But as with overusing antibiotics, Roundup overuse generated an

[3] *See* Roundup Ready® Xtend Crop System, https://www.roundupreadyxtend.com/Pages/default.aspx (last visited Feb. 8, 2018).

epidemic of glyphosate-resistant "superweeds" now infesting an estimated 100 million acres of U.S. cropland. ER595-96.

Monsanto's new business model consists of genetically engineering soybean and cotton to resist both dicamba and Roundup, enabling both to be sprayed freely without killing the crops. ER782-87. Although Monsanto presents the ability to kill glyphosate-resistant weeds with dicamba as a quick fix to the glyphosate-resistant weed epidemic, many experts predict its addition of dicamba resistance will massively increase dicamba use—nearly a 100-fold increase on soybean use alone (without glyphosate reductions)—and simply foster rapid evolution of still more intractable weeds, resistant to both.[4]

II. PROCEDURAL HISTORY: THE PROPOSED APPROVAL RAISES SIGNIFICANT DRIFT DAMAGE CONCERNS.

Monsanto first sought registrations for dicamba new use on GE soy and cotton in 2010 and 2012, ER003, originally seeking registration of a different dicamba pesticide, M1691. ER002. EPA held notice and comment several times from 2010 to 2016. ER002-3.[5] Commenters, including farmers, scientists, and conservationists supplied EPA with studies, expert opinion, and practical

[4] ER594; ER474-84; ER782-87; *see* ER635 (EPA's benefits assessment acknowledging continued use of glyphosate).

[5] ER627-28; 77 Fed. Reg. 75,153 (December 19, 2012); 77 Fed. Reg. 50,686 (August 22, 2012); 75 Fed. Reg. 51,045 (August 18, 2010).

experiential evidence warning of devastating impacts from dicamba's notorious tendency to drift off-site.[6]

The record contains copious evidence EPA knew XtendiMax posed serious risks of substantial harm to crops and other plants due to dicamba's long history of drift-related crop injury, its great volatility,[7] and many plants' extreme sensitivity to it. ER793-94, 799-803; ER742-43, 755-57; ER721-25; ER476-81; ER558-61; ER776-78. Volatile pesticides like XtendiMax evaporate from soil and plant surfaces hours to days after application, forming vapor clouds that drift and damage plants far from the application site. *See* ER347-51; ER358, 361-62; ER560. Thus the new use would dramatically increase crop injury from spray drift and vapor drift,[8] by sharply increasing dicamba use and promoting use later in the season, when it is warmer and crops are more susceptible to damage. ER560. The combination of these factors would lead to devastating consequences.

EPA was also informed the new dicamba uses might harm hundreds of endangered species and their critical habitats, as well as the environment generally.

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[6] *See* ER473-626.

[7] Vapor drift is largely a function of the pesticide's volatility and weather conditions, beyond a farmer's control. ER361-62; ER560. Spray drift (pesticide droplets blown by the wind during application) also cannot be entirely prevented. *See* EPA, *Pesticide Volatilization*, https://www.epa.gov/reducing-pesticide-drift/pesticide-volatilization (last visited Feb. 8, 2018).

[8] "Drift" as used alone means either vapor drift or spray drift or both.

ER576-90; ER492-500. The registration allows the pesticide's application on millions of acres in 34 states, and EPA knew that protected animals such as the whooping crane and grey wolf feed in sprayed crop fields, ER657, 666, and that hundreds of other endangered plants and animals are found near those fields, and will be threatened by drift. ER694-701. Others warned dicamba drift threatens flowering plants that provide nectar for pollinators and habitat for other species. ER500-01.

EPA nonetheless granted new use approval in November 2016, ER001-2, beginning a 2-year, 34-state field experiment, based on the supposition that XtendiMax is less volatile than prior dicamba formulations,[9] erroneously declaring that this, and detailed use instructions to mitigate spray drift, would "eliminate any offsite exposures." ER029; *See* ER035; ER368 ("The 2-year expiration was put in place because of the concerns about resistance and off-target movement"). EPA included a lengthy label containing use restrictions, such as tractor speed, wind

[9] M1768/XtendiMax itself was never subject to public comment (only M1691, an earlier formulation without the "VaporGrip" component). ER002. Moreover, despite that pesticide firms as a matter of course permit independent scientists to conduct tests on new products, Monsanto took the extraordinary step of prohibiting any XtendiMax drift testing by independent scientists, even though it allowed such independent testing for the pesticide's weed-killing efficacy. ER360.

direction, buffers, spray boom height, and temperature and humidity adjustments, which the agency claimed would "effectively limit" any impacts. *See* ER029-59.

Instead of consulting the expert wildlife agencies about potential harm to hundreds of endangered plants and animals and their critical habitats to "insure" none are jeopardized by the registration, as the ESA requires, EPA performed its own analyses. Using methods contrary to the ESA and assumptions lacking any scientific basis (and since proven grossly inaccurate)—*e.g.*, dicamba *would not drift at all*—EPA made the unprecedented finding the registration would have "no effect" on any of hundreds of species or habitats, leaving the expert agencies with no voice whatsoever.

Petitioners filed this petition for review on January 20, 2017. ECF No. 1-5. Petitioners moved to expedite, ECF No. 32-1, which the Court granted in part, ECF No. 61-1, while EPA took nearly a year to produce the administrative record, ECF No. 13-1 (EPA motion to extend deadlines, February 24, 2017), ECF No. 63-1 (Dec 6, 2017 filing of the initial record index).

III. THE 2017 FARMING SEASON: AN UNPRECEDENTED CATASTROPHE.

Farmers began using Monsanto's XtendiMax for the 2017 planting season. The results were disastrous. By early July, EPA's herbicide branch chief emailed EPA staff: "As I am sure all of you are aware, extremely large numbers of complaints of crop damage are being received by a number of states...." ER445. By

July 19, 2.5 million acres of soybean alone had been officially reported as damaged by dicamba drift, ER419; rising to over 3 million acres in 16 states by August, ER359-60. And these figures were substantial underestimates, as plant scientist Dr. Kevin Bradley told EPA: "[f]or every one incident case that is submitted, there are 5 that aren't." ER449. Weed scientist Aaron Hager informed EPA that an astounding 50% of the non-dicamba-resistant soybeans were injured in Illinois. ER442. Many other crops also have been damaged, including tomatoes, melons, fruit and nut trees, and vegetables, as well as residential gardens, shrubs and trees; the flower and nectar of many of these crops are vital food sources for pollinators. ER382-91; ER439, ER122; ER183-87. According to Dr. Bradley, "[w]e have never seen anything like this before … in our agricultural history." ER375.[10]

Dicamba drift threatens farmers' livelihoods, for instance by slowing soybean growth and reducing yields, costing farmers millions. ER449-50; ER442-44; ER358-61; ER372-73. Farmers were pressured to purchase patented GE dicamba-resistant soybean at a huge premium (ER356) just "to protect themselves" from dicamba drift. ER289; ER397-404; ER178 (customers switching to dicamba-resistant soybean "as a defensive measure"); ER424. The damage tore

[10] EPA was well aware of the unfolding crisis, sharing newspaper and wire reports, yet took no action. ER280-84; ER355-63; ER395-404; ER189-91; ER379-81; ER291-92; *see* ER369 (stating that EPA was "waiting on registrants to voluntarily [take action]").

apart rural communities, pitting farmer against farmer. University of Tennessee's Dr. Larry Steckel said dicamba damage has divided agriculture "like nothing I've seen," pointing to "angry" growers whose fields have suffered drift damage two or three times. ER444.

University scientists affirmed volatility, or vapor drift, as "one of the major routes" of dicamba drift injury, concluding that "our air sampling data, field volatility studies and field visits indicate that to be the case." ER378. Dr. Bradley called Monsanto's contrary claims "disingenuous at best," ER378, and shared with EPA extensive volatility test results, ER293-345, showing that, contrary to Monsanto's claims, XtendiMax volatilized "for as many as 3 or 4 days following the application." ER377-78, ER361-62 (university field test illustrating XtendiMax volatilization).

Numerous state agricultural departments reported to EPA ongoing extensive damage. ER454. University scientists expressed unanimous concern that dicamba is more volatile than manufacturers admitted. ER359-62. One of the chief messages from state and academic experts was that the label restrictions *do not work because they do not address volatility*. ER442-44; ER423 ("[B]uffers don't resolve the problem."); ER293-345 (45 pages of independent vapor drift testing by universities); ER390-91 (list of dicamba-sensitive species); *see also* ER90-91 (85 pages on how drift impacts yield). Experts visited many Missouri farmers "who

have done [dicamba application] right and still experienced" vapor drift off their fields. ER376.

At a late August meeting, EPA previewed label amendments for state officials, ER369, and the experts again responded the data "are pointing to volatilization. Many others have the same data" and "there's nothing we can do for a volatile product as far as label changes," *id.*

IV. EPA AND MONSANTO'S RESPONSE.

In August 2017, EPA briefly considered state experts' recommendations to prohibit dicamba applications after a spring "cutoff date" as the only sure means to mitigate vapor drift damage, but after Monsanto opposed it, ER355, EPA rejected this solution. ER284, ER288 (Dr. Hartzler: "Monsanto and BASF are fighting restrictions because they would 'greatly reduce the value' of their chemical and seed systems").[11]

When EPA finally acted months later, it took its orders not from the states or their experts but from Monsanto, repeatedly meeting with its lawyers and officials about how to quell the uproar. *See* ER352. [redacted]

[11] When EPA refused to require measures to address volatility, several states passed restrictions to address vapor drift, such as spray cut off dates and temperature limits. *See* AGFAX, *Dicamba, 2018: States Struggle with Application Restrictions*, http://agfax.com/2017/12/14/dicamba-2018-states-struggle-with-application-restrictions-dtn/ (December 14, 2017) ("Most of the state-by-state changes are being made, they stated, because the federal EPA labels do not address herbicide volatility.").

[redacted]; ER172-74, and Monsanto informed EPA what the "Terms and Conditions" of that new label would be, ER170-71. When EPA sent it back to Monsanto, EPA confirmed it was exactly what Monsanto had asked for. ER123 (EPA official to Monsanto: "like I said, no surprises."). In fact, when EPA tried to suggest changes to the terms and conditions, ER167-69, Monsanto dictated which suggestions would be acceptable. ER165-66.

Finally, on October 12, 2017, EPA and Monsanto amended the registration and added Monsanto's new label amendments—more applicator training, greater record-keeping burdens, and a ban on spraying dusk to dawn—none of which addressed the key issue numerous experts had pointed to: volatility and vapor drift. *See* ECF No. 57-2.

EPA declared this revised document "did not affect the conclusions in the supporting assessment of risk," and that, rather than provide *any* new data or analysis supporting the new measures' efficacy, EPA "continues to rely on all the assessments" supporting the original registration, and thus the decision "does not require a revised endangered species effects determination, nor any other new risk assessment." ECF No. 57-2 at 1; *see also* ECF No. 57-1 (same). Petitioners amended their petition for review to encompass this further EPA decision. ECF Nos. 62; 68.

SUMMARY OF ARGUMENT

In its rush to approve XtendiMax, 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 XtendiMax based on its conclusion that it 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. Second, EPA failed to analyze and weigh the significant socioeconomic and agronomic costs to farmers of destructive dicamba drift. Instead, and third, EPA relied solely on label conditions for mitigation, which was catastrophic, because the label conditions did not address vapor drift. In fact, and fourth, EPA removed the only initially-proposed label provision addressing vapor drift, relying on legally inadequate data. Fifth, EPA also unlawfully assigned to Monsanto EPA's statutory responsibility to approve XtendiMax's foreseeable use in tank mixes.

Finally, after the catastrophic 2017 farm season, EPA amended the label conditions with revisions, but without any data, analysis, or even rationale of why these additions would be successful where its initial conditions failed. Instead EPA continued to rely unlawfully on its prior analyses and determinations, even though they have now been proven tragically flawed. Worse, again EPA failed to address

the key problem: XtendiMax's volatility and consequent vapor drift. And even for the lengthy, non-vapor drift measures EPA did include, the agency never analyzed or supported with substantial evidence their efficacy or feasibility in real world farming conditions. The predictable result of EPA recklessly pushing to market a product well known to drift on to neighboring plants and damage them has been millions of acres of damaged crops, with tremendous costs, all avoidable had EPA followed the law.

The ESA required EPA to "insure" its XtendiMax registration would not jeopardize the existence of any of the hundreds of protected imperiled species it knew were in or near the areas across 34 states EPA approved for XtendiMax spraying, nor harm any of the hundreds of habitats designated as critical to their survival and recovery. 16 U.S.C. § 1536(a)(2). Similar to how it handled its FIFRA obligations, EPA approached this rigorous duty by disregarding well-settled law.

But while EPA administers FIFRA, it has no special role or authority when assessing risks to endangered species. The ESA required EPA, like every other agency whose action might have any effect whatsoever—even a beneficial one—on any such species or habitat to consult the federal agencies with wildlife expertise to insure their protection. 50 C.F.R. § 402.14(a). Instead, EPA made up its own rules. In its haste to get XtendiMax on the market with minimal oversight, EPA applied the wrong legal standards for whether to consult the expert agencies,

and employed a home-grown risk assessment process that conflicted with the ESA's requirements but allowed EPA to substitute its own uninformed guesses for those agencies' expertise. EPA not only failed to use the best available data as the ESA expressly requires, but based its assessments of potential harm to hundreds of endangered plant and animal species on grossly inaccurate factual assumptions—such as that XtendiMax would not drift at all beyond any sprayed fields, and therefore could not possibly any plants or animals beyond the fields' borders.

Following this reckless and uninformed course, EPA made the unprecedented finding that exposure to the potent chemical could not possibly affect, let alone harm, any of the many hundreds of plant and animal species at risk of extinction, nor any of their critical habitats—and that the expert wildlife agencies were not entitled to any input on the subject. This unlawfully exposed to harm vast numbers of protected species and the areas upon which they depend to survive, and continues to do so.

ARGUMENT

I. FIFRA STANDARD OF REVIEW.

To uphold this pesticide registration, the Court must find EPA supported its registration decision with "substantial evidence" in the record. 7 U.S.C. § 136n(b). Judicial review must be "searching and careful, subjecting the agency decision to close judicial scrutiny." *Containerfrieght Corp. v. U.S.*, 752 F.2d 419, 422 (9th Cir.

1985). The agency's action may be upheld only on the "basis articulated by the agency itself." *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S. vs. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983). 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.

II. 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. 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). But for a conditional "new use" registration, which EPA approved here,[12] 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 by the applicant would not significantly increase the risk of any unreasonable

[12] XtendiMax is a "new use" of registered dicamba, 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.

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.

EPA initially proposed an unconditional approval of M1691—a different dicamba pesticide—but eventually approved a conditional new use of XtendiMax. *See* ER001, 029. However, 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 XtendiMax vapor drift and tank mixtures containing XtendiMax, it lacked sufficient data to assess harm from XtendiMax's new use. *See* 7 U.S.C. § 136a(c)(7)(B); 40 C.F.R. § 152.113(a)(2); *see infra* pp. 21-26.

Second, EPA applied the *unconditional* registration standard: that XtendiMax "will not generally *cause* unreasonable adverse effects." ER029 (emphasis added). But the approval bar for conditional new use is higher: "amending the registration … would not *significantly increase the risk* of any unreasonable adverse effect on the environment." 70 U.S.C. § 136a(c)(7)(B) (emphasis added); *see also* S. Rep. 95-334, 95th Cong., 2d Sess. 10-11 (1977) ("The subcommittee agreed that the Administrator in implementing this provision

should take necessary steps to assure that conditional registrations are granted only in circumstances in which the *risk* of unreasonable adverse effects *would be minimal*.") (emphases added). EPA based its assessment, and decision, on the wrong legal standard, and never made the required legal finding.

Petitioners need not show XtendiMax will cause unreasonable adverse effects, only that XtendiMax significantly *increases the risk* of such effects. Plainly, however, EPA's decision was fatally flawed and unsupported by substantial evidence under either standard: the record shows EPA's failure to analyze risks of using XtendiMax in the manner approved *has already caused* unreasonable adverse effects, and thus the approval significantly increased the risk of unreasonable adverse effects.

III. EPA FAILED TO ACCOUNT FOR XTENDIMAX'S MASSIVE COSTS TO U.S. AGRICULTURE.

"Unreasonable adverse effect on the environment" means "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." 7 U.S.C. § 136(bb). This standard requires EPA to analyze not just the pesticide's *benefits*, but also its environmental, economic, and social *costs*, and the agency must explain how any benefits outweigh those costs. *See id.* EPA failed to support with any—let alone substantial—evidence that it adequately considered and accounted for the

foreseeable, catastrophic costs to U.S. agriculture that XtendiMax's registration is causing.

EPA's approval set in motion a 2017 farm season like nothing American agriculture had before experienced, with uncontrollable drift damaging crops on millions of acres, proliferating farmer class action lawsuits against Monsanto, farmer-to-farmer violence, and state governments implementing emergency dicamba drift measures because EPA would not. *See supra* pp. 8-11 (and citations therein). Despite this predicted disaster, EPA's 36-page registration decision, where the agency must provide its rationale, is nearly silent on these significant costs. Instead, it one-sidedly promotes alleged benefits to U.S. agriculture, ER028-29, concluding EPA "finds these benefits important," ER029.[13]

Nowhere did EPA rigorously assess XtendiMax's *costs*, such as drift damage to neighboring crops, lost sales or land use from such damage, forced protective expenditures on GE seeds, farmer vs. farmer strife, and the costs of

[13] EPA's "Review of Benefits as Described by the Registrant…" is similarly framed to ignore costs and to review only a single Monsanto document described as a "statement of benefits claimed by Monsanto." ER633. EPA also violated FIFRA by ignoring the substantial evidence that belies these assumed benefits. ER502-12. Any agronomic benefits from XtendiMax are questionable and short-term. Here, what's past is also prologue: weeds will quickly develop resistance to dicamba, just as with glyphosate. ER476-80; ER523-48; ER614 (comment from agrichemical company employee warning "[i]t would be naïve to think widespread weed resistance to dicamba will not occur.").

controlling dicamba-resistant weeds. Nor does the decision show EPA weighed these costs against any alleged benefits. Indeed, only a single paragraph in the registration decision even mentions drift costs. FIFRA requires EPA do much more: analyze and weigh these costs and support its approval decision with substantial evidence. 7 U.S.C. § 136n(b).

EPA instead relied entirely on label instructions to prevent harm. Yet EPA knew these instructions might not stop drift. The registration decision vaguely claims the label instructions would "effectively limit" drift problems, ER029, and EPA's "Benefits" assessment acknowledged these restrictions "*may reduce* the potential for drift to off-target sites." ER637 (emphasis added). That EPA anticipated XtendiMax's potential to cause drift damage is further demonstrated by the limited two-year registration, which automatically expires absent EPA's determination "that off-site incidents are not occurring at unacceptable frequencies or levels." ER035; ER368 (*EPA Responds to Dicamba Complaints*, quoting EPA's Dan Kenny: "The 2-year expiration was put in place because of the concerns about resistance and off-target movement"). EPA's expectation that dicamba drift damage might occur at "unacceptable frequencies" obligated the agency to develop credible estimates of drift costs and factor them into its FIFRA assessment before approving XtendiMax. 7 U.S.C. § 136(bb); *Pollinator Stewardship*, 806 F.3d at 532. But it did not.

Finally, that EPA's label restrictions did *not* prevent massive and widespread harm to U.S. agriculture is undeniable. *See supra* pp. 8-11. EPA's reliance on the label to stop such costs was not supported by substantial evidence, 7 U.S.C. § 136n(b). By any measure, EPA's decision was proven tragically and catastrophically wrong.

IV. EPA DISREGARDED HARM FROM XTENDIMAX VAPOR DRIFT.

Experts agree that vapor drift later in the season, when temperature and humidity are higher, is one of the major causes of the extensive dicamba drift damage in 2017. *See supra* pp. 10-11. EPA itself knew all along that XtendiMax vapor could drift off-field and destroy neighboring plants and crops. Yet in approving XtendiMax's new use, including authorizing potential use in tank mixes with other pesticides, including glyphosate, EPA disregarded record evidence demonstrating XtendiMax vapor drift would harm plants off-field, and that tank mixtures containing XtendiMax and glyphosate would amplify XtendiMax's volatility. EPA's decision to allow XtendiMax to be used in tank mixes without EPA approval violated FIFRA.

A. The Record Shows XtendiMax Vapor Drift Would Harm Neighboring Plants.

EPA knew from the outset that dicamba vapor drift was a concern. *See* ER630 (describing "high vapor drift from soybean fields resulting in non-target plant injury). Unable to ascertain the real-word effect of XtendiMax's volatility,

EPA proposed an omnidirectional buffer strip to prevent vapor drift damage.[14] ER630; ER724-25. Yet when it approved XtendiMax's new use, EPA claimed, based on additional data from Monsanto, that vapor drift was not a concern, and eliminated the omnidirectional buffer. ER460-61; ER018.

Contrary to EPA's changed position, the additional data actually showed XtendiMax vapor *could* injure non-target plants outside a sprayed field. The additional data included laboratory studies (referred to as the humidome studies) and two field studies, and additional modeling projections of XtendiMax vapor air concentrations off-field based on the data obtained from the field studies. *See* ER463-65. Importantly, EPA determined, based on the first humidome study, that the maximum allowable dicamba vapor air concentration that would not adversely affect non-target plants (referred to as the No Observed Adverse Effect Concentration or NOAEC), is 0.0177 ug/m^3. ER463. EPA then compared modeling projections of peak XtendiMax vapor off-field air concentrations against the NOAEC to predict whether XtendiMax vapor drift would harm plants. ER463-64. Critically, one of the predicted peak air concentration five meters away from the edge of a treated field was 2.08 x 10^{-2} ug/m^3 (0.0208 ug/m^3), exceeding the

[14] EPA proposed a no-spray zone—extending from the last sprayed row of crops to the edge of the field in all directions—of 100- or 220- feet—for the 0.5 lb a.e./A and 1.0 lb a.e./A application rate, respectively. ER630.

NOAEC (0.0177 ug/m^3). ER464. But instead of acknowledging that XtendiMax could injure plants off-field and assessing the magnitude of that harm, EPA simply downplayed the projection as "essentially at or below [the NOAEC]," ER464, then falsely concluded "the expected exposure at field's edge is less than the NOAEC for plant risk." ER018.

EPA's cavalier dismissal of the modeling outcome is unlawful. EPA assessed XtendiMax's volatilization risk by "determin[ing] the distance from site of application to where the NOAEC *is not expected to be exceeded*," ER018 (emphasis added); it cannot conclude there is no harm to non-target plants when one of its models showed XtendiMax vapor levels above the NOAEC beyond the treated field. *See Pollinator Stewardship*, 806 F.3d at 531 ("We cannot allow the EPA to avoid its own regulations when actual measurements trigger risk concerns, even where the measurements were 'in the neighborhood' of measurements that would not trigger such concern.") (citing *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 884 (9th Cir. 2013)). Simply put, "essentially the same" is not good enough, when the livelihood of hundreds of thousands of farmers or, as discussed below, the survival and recovery of hundreds of endangered plants and animals, are at stake.

B. The Record Shows That Tank Mixing XtendiMax and Glyphosate Increased XtendiMax's Volatility.

EPA also failed to analyze the likelihood of increased volatility from mixing XtendiMax with other pesticides in tank mixtures.[15] EPA acknowledged dicamba was designed to be sprayed along with other pesticides and chemicals, including glyphosate, the active ingredient in Monsanto's flagship herbicide Roundup. *See, e.g.*, ER714 ("It is common for products like this to be tank mixed with other products and pesticide active ingredients."). As EPA recognized, dicamba is only effective at killing some broadleaf weeds, and other herbicides would still be needed to manage other weed types. *See* ER635. [redacted]

EPA also knew tank mixes may worsen XtendiMax's effects. *See* ER022 (tank mixing could result in "enhanced activity or synergistic effects."). Specifically, [redacted] Rather than analyzing that risk, EPA's proposed registration—and all of the agency's risk assessments—relied on prohibiting tank mixing until EPA affirms a particular tank

[15] Pesticides are commonly mixed with other pesticides and chemicals in a tank prior to application. *See* ER714; ER022.

mix will not increase dicamba's volatility. *See, e.g.*, ER714 (EPA would only allow tank mixing "with products that have been tested and found not to increase the likelihood of drift/volatility."); ER457-58 (EPA addressed tank mixing increasing XtendiMax's volatility by prohibiting tank mixing).

However, the final registration authorized tank mixing without assessing XtendiMax tank mixtures' increased volatility. Instead, EPA authorized *Monsanto* alone to approve tank mix components, so long as the tank mixture has been tested for increased *spray drift*—but *not vapor drift*. *See* ER063 (requiring only "testing of tank mix products for spray drift properties"). EPA failed to require independent EPA approval of proposed tank mixes, but merely required submission of test data. *See* ER060-61.

EPA cannot register a pesticide new use without ensuring that "amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment." 7 U.S.C. § 136a(c)(7)(B). The statutory definition of "pesticide" broadly includes "*mixture of substances* intended for use as a plant regulator, defoliant, or dessicant." *Id.* § 136(u)(2) (emphasis added). Because EPA was aware tank mixes are commonly used, and that mixing XtendiMax and glyphosate could result in increased volatility, EPA was required to assess such tank mixes before allowing their use. It failed to require any such testing, or agency review. EPA's abdication of its

statutory duty to assess and consider increased harm risk from XtendiMax tank mixes violated FIFRA.

V. EPA'S OCT. 12, 2017 ACTION FURTHER PROVES THE XTENDIMAX DECISION WAS NOT SUPPORTED BY SUBSTANTIAL EVIDENCE.

The unprecedented damage forced EPA and Monsanto to act. But instead of vacating and remanding XtendiMax's registration, EPA accepted wholesale and incorporated into an amended XtendiMax registration, ECF Nos. 57-1; 57-2, [redacted]; ER394. EPA did so in response to the huge number of crop damage incidents to "further minimiz[e] [sic] off-field movement," ECF No. 57-2, at 1. This extraordinary action underscores that EPA grossly miscalculated its approval's actual costs. EPA cannot argue both 1) EPA's 2016 determination, based on the older mitigation measures alone, was supported by substantial evidence; and 2) these new 2017 revised measures are needed to address the action's consequences.

A. EPA Is Still Relying on Its Erroneous 2016 Assessments and Determinations.

While adding revised label restrictions, EPA doubled down on its original decision, underscoring it "continues to rely on all risk assessments and determinations that supported the November 9[, 2016] registration." ECF Nos. 57-1, at 1; 57-2, at 2 (claiming new measures "do not affect the conclusions in the supporting assessment of risk" and EPA "continues to rely" on that decision).

Thus, EPA did not revise its original rationale, in its November 2016 decision, despite now acknowledging its inadequacy for all practical purposes.

B. EPA Did Not Support the New Label Amendments with Any Data, Analysis, or Rationale.

At the same time, EPA conducted no analysis supporting the amended registration and new label measures it now claims will prevent recurrence of drift damage. EPA did not prepare a "revised endangered species effects determination, nor any other new risk assessment." ECF No. 57-2, at 1. Indeed, there is no new analysis of these measures' efficacy in the record: this new part of the registration is unsupported by any EPA analysis at all, only Monsanto's self-interested assurances. *See* ER355-57.[16] Empty, unanalyzed agency action is not supported by substantial evidence. Whether EPA relies on the unanalyzed and unsupported, hastily-enacted measures, or stands by its initial assessments that proved so egregiously deficient, or both, its decision-making is not supported by substantial evidence and violates FIFRA. 7 U.S.C. § 136n(b).

Further, for new use approvals, EPA must find "amending the registration *in the manner proposed by the applicant* would not significantly increase the risk of any unreasonable adverse effect on the environment." *Id.* § 136a(c)(7)(B) (emphasis added). EPA accepted Monsanto's proposed changes to the label

[16] [redacted] *Compare* [redacted] *with* ER075-121; *see* [redacted].

without new findings or analysis. EPA was required to analyze whether XtendiMax's use under the amended registration conditions, i.e., "in the manner proposed" now by Monsanto, would still significantly increase the risks of any unreasonable adverse effect. *Id.* § 136a(c)(7)(B). But in its determination to keep the product on the market and appease Monsanto while appearing to do something to address the problem, EPA simply slapped on the unanalyzed, Monsanto-drafted label additions. ER394 (EPA e-mail to Monsanto: "Our goal is to ensure these technologies are available to growers for the 2018 season" so EPA is "moving very quickly"). By relying solely on its prior analyses and determinations, analyzing a different Monsanto proposal and label, EPA violated FIFRA's plain language.

C. The New Label Still Fails to Address Vapor Drift.

Not only are EPA's supplemental label instructions lacking any analysis of their efficacy, or even any explanatory rationale, but no reason exists to believe the new measures will stop dicamba drift. Crucially, the revised label lacks any provision even purporting to address volatility or vapor drift, the harm's main wellspring according to farmers and experts. *See supra* pp. 6-11 (and citations therein); *see also supra* pp. 21-26.

As the disaster of the 2017 planting season unfolded, weed scientists confirmed to EPA that volatility was a major source of the problem and repeatedly pleaded with EPA to address it. *See supra* pp. 10-11 (and citations therein);

ER358-62; ER300-45; ER346-48; ER422. Their chief recommendation was to address volatility, such as by prohibiting use during warm-weather summer months when volatilization is more likely, as numerous states eventually did. ER369-70. Yet EPA amended the label without any measures to address it. *See* ER072-21.

Instead of addressing vapor drift/volatilization, the amended label added new peripheral use instructions, as though farmers were the problem. ER116 (the new label is "incorporating certain additional training and record keeping requirements and certain other amplifications."). These included: classifying XtendiMax as restricted use "to facilitate compliance with appropriate training and recordkeeping practices," ER116; clarified use instructions, including graphics showing buffer requirements, ER093-94; and small changes—unstudied as to efficacy—in spray volume, ER092 (compared to ER043; ER055); wind speed restriction, ER092 (compared to ER043-44; ER055-56); and time of day restriction, ER092, intended to reduce spray drift during temperature inversions, ER092-93. None of these measures even purports to address vapor drift damage, let alone stops it. At root is Monsanto's insistence that its product is flawless and farmers' errors caused the harm, so merely improving label compliance will solve everything.

D. No Evidence Supports the Changes EPA and Monsanto Did Make.

EPA not only failed to address volatility, but violated FIFRA by failing to support with substantial evidence its assumption that the byzantine measures it did include in the label will effectively prevent XtendiMax's off-field movement under real-world conditions. 7 U.S.C. § 136n(b). EPA failed to consider and analyze applicators' ability to follow the label instructions, or their effectiveness if followed. *Pollinator Stewardship*, 806 F.3d at 532.

In approving XtendiMax's new use, EPA imposed use instructions of unprecedented scope and complexity—"unlike anything that's ever been seen before," ER379 (weed scientist Bob Hartzler); for context, the 16,000-plus word revised 2017 label[17] (ER075-115) is *longer than this entire brief*. Weather restrictions permit spraying only within a narrow wind speed range of 3 to 10 mph; prohibit use when rainfall is forecast within 24 hours; bar applications dusk to dawn, and during frequently-occurring "temperature inversions" during summer days. ER377 (in Missouri, one-half to two-thirds of summer). A Missouri farmer stated: "You have to be a meteorologist to get it exactly right." ER380. A commercial applicator told EPA, "[w]e only have a very limited amount of proper

[17] *See* Monterey Language Servs., *Free Online PDF Word Count Tool*, http://www.montereylanguages.com/pdf-word-count-online-free-tool.html. This excludes a continually changing Monsanto website (part of the label) with still more requirements that must be checked within 7 days of application.

days to, by label, make applications," adding: "No matter how hard we try to do things right, there will be off target issues." ER618. Other requirements include 110ft/220ft in-field buffer zones, special spray nozzles, spray pressure limits and tractor speed restrictions. *See* ER092-94. The November 2017 additions only made the unworkable label more lengthy and complex. ER370 (state experts to EPA regarding proposed revisions, eventually adopted: the "label is too complicated now, and people are never going to comply if we make it even more complicated.").

The instructions also are contradictory. Notwithstanding explicit permission to spray at wind speeds from 3 to 10 mph with buffer zones, the label demands: "DO NOT APPLY this product when the wind is blowing toward adjacent non-dicamba tolerant susceptible crops."[18] ER094. "The applicator must also consult applicable sensitive crop registries," and not spray if he "identif[ies] any commercial specialty or certified organic crops that may be located near the application site," "near" being undefined. *Id.*

No record evidence shows EPA considered and analyzed applicators' ability to follow the incredibly lengthy and complex label instructions, or their

[18] "Susceptible crops include, but are not limited to," thirteen specific crops or crop groups; "[s]evere injury or destruction could occur if any contact between this product and these plants occurs." ER094.

effectiveness if followed. For example, despite record evidence that the ultra-low 24-inch boom height requirement to reduce spray drift is "impractical" and that "at least 3 feet" is needed because otherwise "booms break too often," ER444 (Tennessee), ER430-31 (Iowa), the record fails to show EPA analyzed the measure's feasibility. Despite expert evidence that "buffers don't resolve the problem" of drift in Iowa and "[n]o buffer size seems feasible" in Missouri, ER443, no record evidence shows EPA conducted any practical, field-level assessment of buffer zones' ability to prevent dicamba drift damage. EPA also does not account for applicators' behavior in changing weather conditions, and whether farmers could reliably abstain from XtendiMax use "if rain is expected in the next 24 hours" to prevent runoff, as the label requires. ER087. The feasibility of following the label's wind speed restrictions also was unassessed.

Thus, even for the issues the revised instructions purport to address, the record is devoid of documentation, studies, or other assessments supporting efficacy or feasibility. In fact, EPA fails even to explain its own rationale for imagining the label amendments will work. This cannot withstand judicial review. *Pollinator Stewardship*, 806 F.3d at 538 (Smith, J., concurring) ("Unless I am provided with evidence of the EPA's basis for its judgment and knowledge, I can only assume it acted with none."); *id.* at 533 ("I simply ask the EPA to explain the analysis it conducted, the data it reviewed, and how the EPA relied on the data in

making its final decision."). EPA's failings mirror those in *Pollinator Stewardship*, where it also relied on mitigation measures it failed to analyze. 806 F.3d 520. Without a realistic assessment of mitigation measures' efficacy and feasibility, risk cannot be predicted accurately and EPA's determination is not supported by substantial evidence. 7 U.S.C. § 136n(b).

VI. EPA VIOLATED THE ENDANGERED SPECIES ACT.

EPA authorized spraying XtendiMax on millions of acres across 34 states, home to hundreds of ESA-protected species, and hundreds of their designated critical habitat areas. The ESA required EPA to comply with specific processes to prevent harm to them, including, most importantly, seeking guidance from the agencies with wildlife expertise. However, EPA doggedly avoided complying with the ESA's requirements, instead applying either processes that do not apply in the ESA context, or rules it invented that apply in no context at all. By doing so, EPA circumvented ever consulting the expert wildlife agencies, before unilaterally declaring that hundreds of plants, animals, and habitats would be completely unaffected by spraying them with a toxic weed killer. EPA's unprecedented, wholesale disregard of the ESA must be reversed.

A. The ESA's Consultation Process and Standards.

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." *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 (citation omitted).

Section 7 is the "heart" of the ESA, one of the statute's most important protections for endangered species. *Cal. ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009). It mandates that each federal agency "insure" its action (here, registering an XtendiMax new use) is not likely to either jeopardize any species or adversely modify any designated "critical" habitat. 16 U.S.C. § 1536(a)(2).[19] EPA's duty to insure against jeopardy and adverse modification is "rigorous." *Sierra Club v. Marsh*, 816 F.2d 1376, 1385 (9th Cir. 1987).

Section 7(a)(2) and its implementing regulations establish a process requiring EPA to evaluate its XtendiMax registration's effects "in consultation

[19] "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).

with and with the assistance of" the agencies Congress designated as having special expertise in determining effects on endangered species: the United States Fish and Wildlife Service (FWS) (for terrestrial and freshwater species) and the National Marine Fisheries Service (NMFS) (for marine species).[20] 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b). 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.") (emphasis in original).

First, Section 7(a)(2) requires EPA to determine whether the registration "may affect" any listed species or designated critical habitat. If so, EPA then *must* consult FWS. 50 C.F.R. § 402.14(a).

Importantly, the "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 of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (en banc) (emphasis added). "*Any possible effect*,

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

whether beneficial, benign, adverse or of an undetermined character" triggers the requirement. *Id.* (quoting *Lockyer*, 575 F.3d at1018–19 (quotation omitted)) (emphasis in *Lockyer* in part, added in part). *See also W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2010) (same).

If its action meets the "may affect" threshold, EPA has only two alternatives: formally or informally consulting FWS. 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, and authorizing any incidental harm, or "take." 50 C.F.R. § 402.14(h)(3), (i).

"Informal consultation" is an exception to formal consultation. 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" them. 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 v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988), and use the best scientific and commercial data available, 16 U.S.C. § 1536(a)(2).

B. EPA Violated the ESA's Consultation Mandates.

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

EPA ignored the ESA's requirements and instead applied processes appropriate only for determining whether to register a pesticide under FIFRA. *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1033 (9th Cir. 2005) (EPA must separately comply with the ESA in pesticide registrations). However, FIFRA and the ESA reflect different policies, address different issues, apply different legal standards, and consequently assign different duties to EPA. 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, FIFRA permits—indeed, requires—EPA to weigh the costs and benefits of a pesticide when considering whether to register it, *see* 7 U.S.C. § 136(bb); *supra* p. 18, 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; *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). While pesticide regulation 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, the ESA grants EPA no special authority. It has no particular expertise in protected species' survival and recovery, nor in interpreting and applying the ESA's standards. Congress therefore explicitly demanded that EPA, like every other 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 the Fisheries Service and the Fish and Wildlife Service) are far more knowledgeable than other federal agencies about the precise conditions that pose a threat to listed species." *City of Tacoma, Washington v. F.E.R.C.*, 460 F.3d 53, 75 (D.C. Cir. 2006).

Third, EPA uses a risk assessment methodology, produced at record identifier I.1 (excerpts at ER804-12), for its FIFRA pesticide registrations that evaluates not whether the pesticide registrations "may affect" a species or habitat, but whether exposing them to a pesticide exceeds EPA's self-determined "level of concern" (LOC). An LOC is a term EPA created for the FIFRA context, and has no ESA analogue or applicability. Instead of determining whether the exposure meets

the ESA's low "may effect" standard triggering consultation, an LOC measures "adverse effects."[21]

EPA erroneously claimed the right to use this same FIFRA procedure to assess effects on ESA-protected species: instead of consulting FWS about harm risks, it simply consulted itself, using its own methodology designed to administer a very different statute. Specifically, as long as EPA's calculations yielded an acute risk quotient of >0.1 (or >.05 for aquatic animals), and a chronic risk quotient of >1, ER810-11, the agency concluded its own LOC had not been exceeded, declared "no effect," and thus excluded FWS from the process. ER651 ("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."). EPA has no such authority.

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[21] According to EPA:

> [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]. These [levels of concern] 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.

ER810 (emphases added); *see* ER703-04 (showing EPA used this risk assessment process in this case).

2. EPA's Application of Its FIFRA Process to Determine Whether to Consult Under ESA § 7(a)(2) Violates the ESA.

EPA's process, however elaborate and purportedly scientific, does not comply with the ESA. The court in *Washington Toxics Coalition v. U.S. Department of Interior*, 457 F. Supp. 2d 1158, 1179-80 (W.D. Wash. 2006), resoundingly rejected an earlier EPA attempt (even with FWS's cooperation that time) to bypass the mandated consultation process similar to the self-consultation EPA attempts now. The court explained the critical disconnect between EPA's risk assessment process and the ESA's requirements:

> 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). *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[.]'")).

Following *Washington Toxics*, the National Academy of Sciences (NAS) recommended how EPA should perform the consultation process in the context of pesticide registrations, in its report *Assessing Risks to Endangered and Threatened Species from Pesticides*.[22] EPA incorporated this advice in interim protocols EPA agreed to follow during its FIFRA-mandated registration review process.[23] But EPA deviated greatly from the *Interim Protocols* in this case, reverting to the self-consultation the court in *Washington Toxics Coalition* rejected.

EPA circumvented the consultation process by applying its internal methodologies to the ESA instead of limiting them to the FIFRA context for which they were designed. In so doing, EPA raised the consultation bar high above the ESA's "may affect" standard (as this Court and FWS have long interpreted that term) to exceeding EPA's "level of concern," which merely measures the impact

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[22] *See* National Research Council, Committee on Ecological Risk Assessment under FIFRA and ESA, *Assessing Risks to Endangered and Threatened Species from Pesticides* 10, National Academies Press (2013), https://www.nap.edu/read/18344/chapter/1.

[23] EPA, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report* (*Interim Protocols*), https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf (last visited Feb. 8, 2018). EPA assesses each registered pesticide at least once every 15 years to determine whether it continues to meet FIFRA registration standards. The ESA applies identically to EPA's registration review process and the registration at issue in this case. *Ctr. for Biological Diversity v. EPA*, 847 F.3d 1075, 1086 (9th Cir. 2017).

EPA itself considers acceptable in the FIFRA context. Instead of undergoing informal consultation and obtaining 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), EPA arrogated to itself FWS's prerogative, deciding *unilaterally* that if the registration's effects on endangered species do not exceed EPA's own "level of concern," those effects equate to "no effect," obviating any need to consult, even informally.

But those two metrics differ significantly, and as this Court has recognized, EPA lacks authority to impose its own interpretation of when consultation is triggered. ESA § 7(a)(2) does not require consultation only when an action's effects exceed EPA's "level of concern," *will adversely affect* a listed species or critical habitat, or *will affect* them at all. Instead, under the "may affect" standard, "actions 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).

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." *Id.* 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 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*.

EPA's risk assessment methodology, which seeks to determine the "likelihood of *adverse* ecological effects on non-target species," ER810 (emphasis added), thus is fundamentally and inescapably at loggerheads with the ESA's mandate to consult FWS whenever EPA's action may produce "[a]ny possible effect, *whether beneficial, benign, adverse or of an undetermined character*." *Karuk Tribe*, 681 F.3d at 1027 (emphasis added). FWS and NMFS's *Endangered Species Consultation Handbook*[24] underscores the distinction between "no effect"

[24] FWS & NMFS, *Endangered Species Consultation Handbook* (Mar. 1998) (*Consultation Handbook*), http://www.nmfs.noaa.gov/pr/pdfs/laws/esa_section7_handbook.pdf. This Court

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.24, at *xv-xvi* (italics and formatting added).

As a matter of law, therefore, an effect EPA deems 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), 02.14(b)(1). By conflating the two standards and claiming that an effect below its self-determined "level of concern" or lacking "adverse effects" has "no effect," EPA unlawfully cut FWS out of the process. The Court must set the registration aside as not in accordance with law. *See* 7 U.S.C. § 136n; *Pollinator Stewardship*, 806 F.3d at 532.

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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).

3. The Record Shows Xtendimax "May Affect" Hundreds of Endangered Species, Requiring Consultation.

EPA admitted the XtendiMax registration "may effect" hundreds of ESA-protected species and their critical habitats, but by misapplying the risk assessment framework EPA developed under FIFRA for determining whether impacts on non-target organisms are *"of concern" to EPA*, EPA erased all of these findings and converted them to "no effect" findings to avoid consultation.

Specifically, EPA in its March 8, 2011 risk assessment, ER740-73, admitted dicamba, applied at the allowed rate, may harm many protected plant and animal species; it expressly found its calculated risk quotients exceeded its own "level of concern" for all types of plants and animals. ER758-59. EPA admitted its screening analysis found "potential direct risk concerns could not be excluded for" any birds, mammals, or terrestrial plants. ER650. This list included 322 ESA-protected species within 11 states, ER708, 183 ESA-protected species within 16 additional states, ER688, and 307 ESA-protected species in 7 more states, ER684, for a total of 812 species in 34 states. Based on these admissions alone, 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. *Karuk Tribe*, 681 F.3d at 1028.[25]

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

EPA began the process of erasing these hundreds of "may affect" findings 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 environments.

However, "action area" is defined as "all areas to be affected *directly or indirectly* by the Federal Action and *not merely the immediate area involved in the action*." 50 C.F.R. § 402.02 (emphases added). EPA initially found 812 listed species were within the registration's action area. *See, e.g.*, ER704 ("322 species in the 11 states proposed for registration were identified as *within the action area*….") (emphasis added). This was appropriate, since EPA knows pesticides commonly travel well beyond sprayed fields, with harmful effects.

[25] 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.

As discussed extensively above, *see supra* pp. 6-7, 21-26, EPA also knew before this amended registration that XtendiMax is extremely drift prone, and knew even before the original registration that dicamba is: "Multiple literature studies show that there is a high vapor drift [of dicamba] from soybean fields resulting in non-target plant injury." ER746; *see* ER757 (incident data).

Yet because Monsanto purported to address this serious problem by adding "VaporGrip" to its dicamba formulation, and EPA added extraordinarily elaborate label restrictions discussed above, EPA concluded the registration would have "no effect" on any of the hundreds of species it had already identified as at-risk (except the handful expected to occur in crop fields), conclusively assuming there would be *no drift whatsoever*. EPA therefore attempted to restrict the registration's "action area" to only the fields themselves. ER653.

This culling violated the ESA definition of "action area," as well as sound science, farming realities, and the record evidence. It now is undeniable that EPA grossly miscalculated XtendiMax's vapor drift, thus exposing countless endangered plants and animals beyond field boundaries to the potent chemical. *See supra* pp. 8-11. But EPA knew before it registered XtendiMax that its laundry list of restrictions would not completely eliminate off-site drift. *See, e.g.*, ER028 (measures "*reduce the likelihood* of spray drift and volatilization" beyond fields) (emphasis added); *id*. ("if further refinements that included more realistic exposure

scenarios were conducted, these risks *would likely fall below the agency's levels of concern*.") (emphasis added); ER637 (label instruction "*may reduce* the potential for drift to off-target sites") (emphasis added).

Even before EPA's miscalculation became obvious, EPA admitted its label restrictions would only reduce drift beyond the fields' borders "to where the [No Observed Adverse Effect Concentration (NOAEC)] is not expected to be exceeded." ER018. Thus, even had EPA's drift conclusions not turned out to be so disastrously wrong, EPA's redefinition of the action area was erroneous as a matter of law. EPA defines the NOAEC as "[t]he highest level of a chemical stressor in a toxicity test that did not cause *harmful effect* in a plant or animal."[26] But the ESA mandates consultation not only when EPA's action causes "harmful effects," but when an action 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 it were not so obvious that dicamba escapes the crop fields' borders, ESA-protected species in surrounding areas consume prey—insects, rodents,

[26] EPA, *Ecological Risk Assessment Glossary of Terms*, https://iaspub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&vocabName=Eco%20Risk%20Assessment%20Glossary (emphasis added) (last viewed March 1, 2017).

reptiles—that are in the fields when they are sprayed, before moving out of the fields. EPA never considered this risk, let alone received FWS's input in consultation, and this alone renders EPA's "action area" deficient. *See Wilderness Soc. 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, the record is overwhelming that EPA's no-drift assumption and action-area manipulations were completely wrong, leaving hundreds of species and habitats on millions of acres vulnerable to the weed-killer's effects. Accordingly, EPA violated the ESA by failing to consult.

5. EPA's Conclusion that Dicamba Will Have "No Effect" Even on Protected Species Within Sprayed Fields Also was Unlawful.

Even had EPA not erred by excluding the hundreds of potentially-affected species and habitats *surrounding* dicamba-sprayed crop fields, EPA erred by then declaring the registration will have "no effect" even on the species it admitted are *in* those fields.

EPA's initial risk assessment found the proposed dicamba new use potentially harms *all* ESA-listed species that might come in contact with the pesticide. ER759 ("no species currently listed as federally threatened or endangered can be excluded from the potential for adverse effects from the

proposed new use of dicamba."). EPA was required to consult FWS at that point, and if it concluded the registration was "not likely to adversely affect" any species or habitat, it had to obtain FWS's written concurrence. Instead, EPA gerrymandered the registration's "action area" to include only the sprayed fields themselves, and thus exclude most species. But EPA admitted no drift mitigation could prevent some of America's most iconic and critically endangered animals—such as the California condor, Florida panther, and whooping crane—from ingesting dicamba, because they are "reasonably expected to occur on soybean and cotton fields." ER708-09. Again, once EPA realized listed species will be exposed to dicamba, ESA § 7(a)(2) demanded it stop and consult FWS.

In fact, the Interim Protocols EPA agreed to follow (mirroring the ESA's own requirements) unequivocally requires that EPA consult FWS regarding any listed species within the action area: "For species and critical habitats that do overlap with the action area, the call *will be 'May Affect,'* and the analysis *will proceed* with" determining whether the action is "likely to adversely affect" or "not likely to adversely affect" the species, the latter requiring FWS's written concurrence. Interim Protocols, *supra* n.23, at 7 (emphases added); *see also* 50 C.F.R. §§ 402.13(a), 402.14(b)(1).

Instead, EPA unlawfully consulted only itself, and decided the risk of harm to these protected species was not sufficiently severe to warrant consultation.

Because the "may affect" threshold is so low, to Petitioners' knowledge no court has ever upheld an action agency's "no effect" determination where endangered species are found in the action area. This Court must vacate and remand.

6. EPA's Process for Species-Specific Analysis Violated the ESA.

EPA's next step to avoid making what the ESA defines as "may effect" determinations was continuing to analyze its registration's impacts using more and more tenuous assumptions, until declaring the effects did not exceed EPA's "levels of concern"—the FIFRA-based concept at odds with the ESA. EPA then characterized these "may effect" circumstances as "no effect," sidestepping the required consultation altogether. EPA did this with many species found in crop fields, ER659-73, but its analysis of the registration's effect on whooping cranes is typical of 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,[27] and conservation efforts have led to only a limited recovery; there are now a few hundred in the wild.[28] As FWS observed: "The whooping crane is a flagship species for the North American

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

[28] *Id*. at 1.

wildlife conservation movement, symbolizing the struggle for survival that characterizes endangered species worldwide."[29]

EPA acknowledged whooping cranes "could be feeding on arthropod prey in treated cotton and soybean fields during its migration from March to May." ER656. 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 dicamba in hypothetical prey a hypothetical crane might consume. ER656.

EPA used this collection of guesses to calculate acute and chronic risk quotients, and compared these with EPA's internally-generated "levels of concern" (LOC). ER656-57. 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. If EPA believed the exposure was nonetheless "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.

[29] *Id.*

b. EPA Failed to Use the Best Scientific and Commercial Information Available.

The ESA imposes the additional, independent statutory mandate that EPA, like all federal agencies, use the "best scientific and commercial information available" when assessing 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 and other species. For example, EPA relied on its 1993 Wildlife Exposure Factors Handbook (Exposure Handbook), produced at document identifier I.3 (excerpts at ER813-824), for critical data. *See* ER656. (In contrast, FWS's latest version of its 160 page recovery plan for whooping cranes, which EPA ignored, is from 2007.[30]) The Exposure Handbook nowhere mentions whooping cranes, nor any other endangered species, because EPA never intended it to 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 narrow purpose: "to provide a convenient source of information and an analytic framework for *screening-level* risk assessments for *common* wildlife species." ER815 (emphases added). The Exposure Handbook also emphasizes the need to obtain data for the particular species being assessed. ER816 ("Exposure varies between different

[30] *See id.*

species and even between different populations of the same species….") The Exposure Handbook contains no data about any type of crane.

As discussed, once the "may affect" threshold is reached, EPA must consult FWS, not perform more refined, site-specific analyses to avoid consultation. Instead, EPA persisted in its consultation avoidance, purporting to fill the data gaps with an Exposure Handbook that instructs EPA to obtain data about local populations—specifically, *by consulting FWS*. ER818-19. Relying on this inappropriate source of critical data and its own FIFRA-based assessment methodology, EPA concluded that because the total load of dicamba it guesstimated a crane would consume was less than its own "level of concern," spraying a toxic chemical on their food would have "no effect" on any whooping cranes. ER657-58. EPA's use of patently inappropriate information and guesswork instead of even attempting to obtain the best available information independently violated Section 7(a)(2).

7. 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 XtendiMax registration will not destroy or adversely modify any habitat FWS designated pursuant to ESA § 4(a)(3)(A) as "critical" to a listed species' survival or recovery. EPA's duty to consult FWS regarding potential effects on critical habitat is separate from, but identical to the low bar controlling its duty regarding

effects on listed species themselves: EPA *must* consult FWS if its registration "may affect" a listed species' designated critical habitat.

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

EPA perfunctorily dismissed its duty to consult FWS to insure spraying millions of acres with a toxic chemical does not affect any critical habitat, falling far short of the ESA's requirements. First, EPA acknowledged FWS had designated critical habitat for 499 species in and around fields in 34 states where EPA authorized XtendiMax spraying: ER685 (for 118 listed species found in 7 states); ER705 (for 322 species in 11 additional states); and ER674 (for 59 species in another 16 states). Yet EPA then invented rules from whole cloth about when its action will trigger consultation with respect to critical habitat, and substituted them for the ESA's "may affect" standard, leading EPA to unlawfully circumvent consultation for *every single one* of 499 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. … *cotton or soybean fields are habitat for the species and there is a "may affect" determination for the species* associated with exposure to dicamba ….

> 2. … *the species uses cotton or soybean fields* and one or more effects on taxonomic groups predicted for dicamba … on cotton and soybean fields *would modify one or more of the designated PCEs.*
>
> If neither of the above conditions are met, EPA concludes "no modification."

ER692-92 (emphasis added); ER711 (emphases added).

EPA thus decided for itself that XtendiMax spraying 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 a sprayed field was part of designated critical habitat. Otherwise, the listed species for which FWS designated critical habitat that includes agricultural fields must be shown to actually use those fields, *and* EPA must find that spraying XtendiMax on the fields reduces their value as critical habitat.

This made-up formula is riddled with legally erroneous assumptions. Initially, overlap between protected species or critical habitat and the action area virtually mandates consultation because "[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character," *id.*, is almost unavoidable under such circumstances.[31] EPA not only ignored this, but contradicted it.

[31] The Interim Protocols EPA developed with input from the NAS and committed to using in its reregistration program provides "*any species or critical habitat that overlaps with the action area will be considered a 'May Affect'*)."

First, echoing the above myriad instances, EPA again awarded itself authority it does not have—here, to decide whether critical habitat is "modified." 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." 16 U.S.C. § 1536(a)(2). 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 *non sequitur*. EPA conflates risks to species with risks to habitat, and attempts to restrict its habitat consultation duties to only situations where it has already found direct species risks. But the ESA imposes on EPA independent duties for each risk. 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).

Interim Protocols, *supra* n.23, at 4 (emphasis added). *See Defenders of Wildlife v. Zinke*, 856 F.3d 1248, 1258-59 (9th Cir. 2017) (concluding FWS, in formal consultation, not required to assess adverse modification of critical habitat within action area because FWS, in informal consultation, had already agreed the projects at issue were unlikely to affect the critical habitat.).

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

b. EPA Unlawfully Excluded from Consideration All Critical Habitats Not Containing Sprayed Fields Occupied by Listed Species.

EPA's erroneous conclusion that consultation is not triggered unless a listed species "use[s] cotton or soybean fields" caused it to categorically circumvent—unlawfully—consultation on almost all of the hundreds of designated critical habitats in the action area. *See* ER711 (If any listed species is "judged to not use cotton or soybean fields," the critical habitat "assessment" for such species is automatically "no modification."); *e.g.*, ER692 ("One-hundred thirteen (113) species with critical habitat were judged to not use 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.

Whether members of an endangered species physically occupy a part of a designated critical habitat (here, cotton and soybean fields) is 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 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.[32]

Any action impairing any PCE "may affect" the critical habitat, triggering consultation. *See Consultation Handbook*, *supra* n.24, 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 determination by the Secretary that such areas are essential for the conservation of

[32] FWS, *Endangered Species Glossary*, https://www.fws.gov/nc-es/fish/glossary.pdf (last visited Feb. 8, 2018).

the species." *Id.* § 1532(5)(A)(ii) (emphasis added). *See Consultation Handbook*, *supra* n.24, 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. *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 Service*, 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."). If, for example, agricultural fields within a species' critical habitat contain the species' prey but not the species itself, then an action that reduces that prey "may affect" the habitat, triggering consultation.

Even considering the millions of acres of devastation already caused by dicamba drift that EPA was erroneously certain would never occur, whether EPA's registration will *adversely affect* (or "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" critical habitats, but instead violated the ESA as a matter of law by assuming effects on unoccupied critical habitat *cannot* trigger consultation.

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

For its assessment of critical habitats where listed species 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." ER674. Since EPA had already made erroneous "no effect" determinations for virtually all species, this had a foregone conclusion. But EPA's assessment methodology violated the ESA, since as noted above, an action "may affect" critical habitat regardless of whether it directly affects any members of the species.

EPA eventually looked at the critical habitats' PCEs, but only for those very few species actually occupying the sprayed fields found within their critical habitats. ER674. Even for those, EPA's assessment was inadequate: EPA summarily dismissed any possibility that spraying XtendiMax on fields within

critical habitat "may affect" them by declaring that, with the single exception of the whooping crane, which feeds in agricultural fields, "the PCE's are not relatable to agricultural fields." ER674. Whatever this might mean, EPA did not meet its duty to consult FWS to "insure" against adverse modification of critical habitat that includes or borders an agricultural field by declaring, without any record support or meaningful analysis, that the PCEs for those habitats are "not relatable to agricultural fields."

VII. 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 only permitted 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 Council*, 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." *Pollinator Stewardship*, 806 F.3d at 532 (internal quotation marks and citation

omitted). As to the first factor, the FIFRA violations delineated above are serious legal errors, and have caused unprecedented damage to U.S. farmers. *See*, *e.g.*, *id.* at 532-33 (vacating pesticide registration); *Nat. Res. Def. Council v. EPA*, 857 F.3d 1030, 1042 (9th Cir. 2017) (vacating the pesticide registration).

As to the ESA violations, Congress has made clear those 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

For the reasons stated above, Petitioners respectfully request the Court declare that EPA has violated FIFRA and ESA, vacate EPA's approval, and remand for further proceeding consistent with this Court's decision.

Respectfully submitted this 9th day of February, 2018.

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STATEMENT OF RELATED CASES

There are no other related cases pending in this Court.

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, this brief is proportionately spaced, has typeface of 14 points or more and contains 13,980 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

DATED: February 9, 2018.

/s/ George Kimbrell
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