No. 19-70115

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' REPLY TO RESPONDENTS' BRIEF

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INTRODUCTION

The central ESA theme of this case is whether EPA can re-define the Endangered Species Act's (ESA) "may affect" standard to mean "some effect, just not more than we think is of concern." It cannot. EPA violated the ESA by registering XtendiMax without consultation with the expert agencies.

The scope of this case is worth reiterating: EPA approved the dramatically increased spraying of a toxic pesticide, predicted to increase its use over 88-fold on soybean and 14-fold on cotton,[1] covering nearly 100 million acres across 34 states,[2] overlapping with several hundred endangered species and their critical habitat.[3] Respondents can point to no decision ever signing off on a "no effect" determination of this magnitude. Nor can they point to any case affirming their "level of concern" standard. No such case exists, because the proper standard mandates consultation.

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[1] Further Excerpts of Record (FER) 298-99.

[2] U.S. Dep't of Agric., 2019 Acreage Report 15, 20 (June 28, 2019) (89,196,000 acres of soybeans and 13,802,000 acres of cotton planted in 34 states in 2019), *available at* https://www.nass.usda.gov /Publications/Todays_Reports/reports/acrg0619.pdf.

[3] ER1693; ER1800; ER1584; ER2057; ER1823; ER1602.

And the FIFRA side mirrors that conclusion: The EPA/Monsanto experimental approval created a wave of pesticide drift damage never before seen, with millions of acres damaged, emergency state protections instituted, thousands of farmers bringing class action lawsuits, and continuing uproar. If there ever was a case in which EPA should have had to quantify costs to farmers, and support with substantial evidence whether its label mitigations were actually feasible in the real world, and make sure it had all the critical data the law requires before rushing to extend the registration, this is it. But EPA did not. These and Respondents' other violations of law compel vacatur.

ARGUMENT

I. THE REGISTRATION VIOLATED THE ESA.

A. EPA Applied an Unlawful Standard.

It is undisputed that EPA's ESA determinations were made using the agency's FIFRA risk assessment approach (the RQ/LOC approach). EPA also admits that under this approach, it found "no effect" for any ESA-protected species found in or near XtendiMax-sprayed fields where the "risk quotient" ("RQ")—EPA's assigned measures of mortality and harm from dicamba exposure—did not exceed the levels of mortality

and chronic harm that EPA unilaterally deemed acceptable as a matter of "interpretative policy," ER1782, aka the "level of concern" ("LOC"). EPA Br. 47, ECF 48-1 (LOCs "indicate when a pesticide . . . has the potential to cause *undesirable* effects on non-target organisms"); RER270 (LOCs "indicate when a pesticide use as directed on the label has the potential to cause *adverse* effects on non-target organisms.") (emphases added); Pet'rs Br. 44, ECF 39.

Respondents insist requiring EPA to consult on anything more than potential adverse effects it deems sufficient sets the bar too high, but the "may affect" threshold has already been defined—by the expert agencies and this Court—to include "any possible effect, whether beneficial, benign, adverse or of an undetermined character." *Karuk Tribe of California v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (*en banc*); 51 Fed. Reg. 19926, 19949 (June 3, 1986). The low threshold, requiring "at least some consultation" for "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," is not merely Petitioners' contention: it is the plain and consistent holding of this Circuit. *Id.* at 1027; *California ex rel. Lockyer v. USDA*, 575 F.3d 999,

1018 (9th Cir. 2009); *e.g., Ecological Rights Found. v. Fed. Emergency Mgmt. Agency*, 384 F. Supp. 3d 1111, 1121-122 (N.D. Cal. 2019) (applying *Karuk* standard). Pet'rs Br. 40-42. This low bar gives the benefit of the doubt to species on the brink of extinction. *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988).

B. EPA Receives No Deference and Violated the ESA's "Best Available Science" Mandates.

Action agencies like EPA receive no ESA deference. *Trustees for Alaska v. Hodel*, 806 F.2d 1378, 1384 n.10 (9th Cir. 1986) (regulated agencies get no deference in interpreting statutes regulating them); *Parola v. Weinberger*, 848 F.2d 956, 959 (9th Cir. 1988); *Conservation Law Found. v. Ross*, No. 18-1087 (JEB), 2019 WL 5549814, at *11 (D.D.C. Oct. 28, 2019) (rejecting deference argument, explaining "it is not the *action* agency that is the expert as to its duties under the ESA ….''). The Fish and Wildlife Service (FWS) and National Marine Fisheries Service (NMFS) are the expert agencies responsible for administering the ESA, and defined the "may affect" threshold as low. *Supra* 2-3; Pet'rs Br. 38-42.

EPA did not just exclude the expert agencies, it also ignored the expert scientific recommendations it sought: EPA utilized its RQ/LOC

approach here despite knowing that it was specifically rejected by the National Academy of Sciences (NAS) as "*not scientifically defensible* for assessing the risks to listed species posed by pesticides … "[4] Elsewhere, EPA agreed to use NAS's recommended 3-step approach, which begins with the "no effect" or "may affect" determination, based solely on overlap between areas where use is authorized and species ranges and critical habitat. The latter scenario is followed by informal consultation, and if necessary, formal consultation. RER324 ("The Agencies are implementing the [Academy's] recommended three-step consultation approach."); RER324-27.

NAS did not "cabin" its recommendations, as EPA claims. While acknowledging that there may be "administrative and nonscientific hurdles" to implementation, NAS concluded the scientifically sound

[4] Nat'l Acad. Of Sci., Assessing Risks to Endangered and Threatened Species from Pesticides 15, NAT'L. ACAD. PRESS (2013) [hereafter NAS Recommendations], *available at* https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides (emphasis added).

approach "is *possible and necessary* to provide realistic, objective estimates of risk."[5]

EPA offers no scientific explanation for sticking with its outdated RQ/LOC approach, other than pointing to a 2014 report where EPA restates a policy decision not to implement all aspects of the NAS Recommendations to all registrations immediately. But that same report explained: "[t]he expectation is that [the interim approach EPA and the wildlife agencies adopted] can be incorporated into the risk assessment process on a 'day forward approach.'" RER329. Whatever might have been appropriate pre-2014, the 2014 report cannot justify why EPA, when it recognized "the need to reevaluate" its prior ESA assessments after two disastrous seasons of reported dicamba drift damage, *continued to use an approach the Academy rejected*. Nor does that report establish FWS "endorsed" EPA's current assessments; it only states that "EPA intends" to ignore the NAS approach in favor of the outdated 2004 Overview for herbicide-tolerant crop uses. RER342. This failure to use the best available science violates the ESA and is entitled to zero deference.

[5] NAS Recommendations at 15 (emphasis added).

C. The Caselaw Supports Petitioners.

Respondents' attempts to factually distinguish *Karuk Tribe* fail; it controls here. Although the Forest Service in *Karuk Tribe* did not make a "no effect" determination, it approved mining activities that "'might cause disturbance of surface resources" without ESA consultation. 681 F.3d at 1013. And while the agency took no position on whether "may affect" was met, the "no effect/may affect" standard was squarely presented and necessarily decided by the Court, because the intervenor miners vigorously disputed on appeal that the record showed the "may affect" threshold was met. *Id.* at 1027. This Court sitting *en banc* held that the Forest Service violated its duty to consult, rejecting the intervenor's arguments. *Id.* at 1027-1029. The Court further explained that because the Forest Service acknowledged the *potential* for disturbance of surface resources from the approved mining activities, the "may affect" threshold was triggered "as a textual matter." *Id.* at 1027. Here, EPA's own assessment documents made numerous similar textual admissions, Pet'rs Br. 49-51, *and* the measure of harm was higher, because EPA compared its estimates of potential exposure of

listed species against "adverse" or "undesirable" levels.[6] Pet'rs Br. 43-45.

Respondents' attempt to factually distinguish other cases also fails. EPA notes *Washington Toxics* invalidated a regulation allowing EPA to unilaterally make "not likely to adversely affect" determinations, but, for all practical and legal purposes, that is what EPA did here, when it failed to consult on exposure risks to listed species below EPA's LOCs. Pet'rs Br. 44, 49-51. More generally, the *Washington Toxics* cases illustrate the impropriety of EPA's transposition of FIFRA harm standards into its ESA duties. Pet'rs Br. 43. Similarly, that FWS had objected to the "no effect" findings in *Kraayenbrink* and that the action agency conceded to effects on ESA-protected species in *Lockyer* cannot erase the numerous EPA admissions that XtendiMax uses "may affect"—rather than would have "no effect"—on listed species. *See, e.g.*, RER010-11 (birds "at risk of mortality" from XtendiMax-sprayed fields); Pet'r Br. 50-51. EPA misses

[6] Even EPA's brief repeatedly shows they applied a higher standard than the *Karuk*/FWS "any effect" standard. EPA Br. 2 ("observable" effects), 21 ("discernable"), 47 ("undesirable" effects); 62, 65, 75 ("discernable" and "observable").

the larger point: These decisions articulate that a lawful "no effect" determination is lower than the "adverse/undesirable effect" approach EPA unlawfully applied.

Respondents instead rely heavily on *Friends of the Santa Clara River v. Corps of Eng'rs*, 887 F.3d 906 (9th Cir. 2018), but even they cannot claim that *Santa Clara* somehow raises the established low consultation threshold set in *Karuk Tribe*.

In *Santa Clara*, plaintiffs challenged the action agency Army Corps' "no effect determination" where its proposed project would, during storm events, discharge materials containing dissolved copper into the Santa Clara River. 887 F.3d at 923. The Court upheld the "no effect" finding because it was undisputed that the concentration of discharged dissolved copper would be well-below background levels already in the river and therefore would not increase fish exposure. *Id.* at 924; *Ctr. for Biological Diversity v. U.S. Army Corp. of Eng'rs*, No. 14-cv-01667, 2015 WL 12659937, at *14-16 (C.D. Cal. June 30, 2015) (court below explaining the discharges actually *lower* risk by diluting copper concentration). Nothing indicates EPA's approval would somehow *decrease* dicamba exposures for endangered species. The last two

seasons of damage prove the *opposite*: unprecedented, massive increases in exposure to dicamba, in ways and at times never before permitted before. Pet'rs Br. 3-12.

The other cases Respondents cite are inapposite. *Defenders of Wildlife v. Flowers,* 414 F.3d 1066, 1070 (9th Cir. 2005) (no members of the listed species existed near the action area); *Southwest Ctr. for Biological Diversity v. Glickman*, 932 F. Supp. 1189, 1194 (D. Ariz. 1996), *aff'd*, 100 F.3d 1443, 1445-446, 1148 (9th Cir. 1996) (Rescissions Act of 1995, in which Congress exempted timber sales from ESA compliance). In reality, no court has signed off on a "no effect" determination like the one attempted here, because it is unlawful. *Washington Toxics Coal. v. Dep't of Interior*, 457 F. Supp. 2d 1158, 1184 (W.D. Wash. 2006) ("The risk framework of FIFRA … does not equate to the survival and recovery framework of the ESA.").

D. EPA's "No Effect" Conclusions Are Contradicted by the Record.

EPA offers no explanation for how its repeated "may affect" admissions equate to "no effect" other than citing to its ESA assessments. EPA Br. 60-62; *see* Pet'rs Br. 49-51. The assessments collectively establish that EPA found XtendiMax adversely affected

hundreds of species, but "refined" away any such effects by relying on its unworkable label restrictions to limit the action area, and applying EPA's own assumptions about some of the species' behaviors and diet to calculate RQs for each species, then comparing the RQs to EPA's own LOCs. Pet'rs Br. 45-47.

Nor does EPA explain how the RQ/LOC approach could account for potential *indirect* pesticide effects beyond direct mortality and chronic harm, such as effects to a listed species' behaviors or needs. Pet'rs Br. 48. EPA (at 58-59) objects to a NMFS biological opinion finding harm from pesticides to listed salmon, overturning EPA's "no effect" determinations. Pet'rs Br. 48 n.24. However this Court "may consider evidence outside of the administrative record" in reviewing the ESA claim. *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 497 (9th Cir. 2011). That biological opinion illustrates the real-world threats to species under EPA's unilateral approach, which leaves out a panoply of harm types and routes.

EPA insists its assessments were "refined and careful," but its interpretation warrants no deference. *Bennett v. Spear*, 520 U.S. 154, 169 (1997). EPA unlawfully ended its process with "no effect" findings

after making uniformed guesses about species' behaviors, relying on unworkable label instructions to deduct species exposures, and arbitrarily applying EPA's own policy about acceptable risk levels.

Both EPA's textual admissions, no matter how couched, and its reliance on mitigation, mean the threshold was breached. *Karuk Tribe*, 681 F.3d at 1029 (mining activities that "might cause" surface disturbance trigger ESA consultation "as a textual matter"); *id.* at 1028 (reliance on mitigation measures "does not mean that the 'may affect' standard as not met" but instead "suggests exactly the opposite").

EPA's bald assertion, that there is "no evidence of any discernible effects to species" below its species-specific RQ and LOC, is even belied by its own 2004 interpretation of the RQ/LOC approach. EPA Br. 62. That document provides that, where EPA's "screening-level chronic [and acute] RQs for a given animal group equal or exceed the endangered LOC," as was the case here, EPA may use further refinement "to determine if a rationale for a *not likely to adversely* effect [sic] determination"—not a no effect finding—"is possible." RER273 (emphasis added); RER289-90. EPA's refined analyses at the species-specific level can only assure EPA dicamba exposure is, at best, "not

likely to adversely affect" that species, which requires it to consult FWS and obtain concurrence. 50 C.F.R. § 402.13(c).[7]

The Court should also reject EPA's strawman (at 48-49) that Petitioners' process—which is really the *NAS's process*, and EPA's *own* process elsewhere—would eliminate the effects determination or EPA's role. The law merely requires that, once EPA made a "may affect" determination using the proper legal standard, it continues any further refinement with the input of the expert wildlife agencies. *Karuk Tribe*, 681 F.3d at 1027. To the extent that there would likely be some consultation where a pesticide's use overlaps with listed species habitat, EPA *itself* agreed that "any species or critical habitat that overlaps with the action area will be considered a 'May Affect.' " RER325; NAS Recommendations at 29 (EPA should "*almost always*" find "may affect"

[7] Of the many hundreds implicated, EPA informally consulted for only three species. For two, rather than consult further, EPA agreed to prohibit use in the species' counties, ER1173; for the third (eskimo curlew), FWS concurred, but *not* because exposures would not be harmful, because the bird is presumed already extinct. ER1416; ER1955-1957.

for "outdoor-use pesticides because 'may affect' is interpreted broadly.") (emphasis added).

E. EPA's Action Area Violated the ESA.

The "may affect" threshold is low precisely to avoid the inexpert errors EPA made here, eliminating hundreds of species from the action area to make unsupportable "no effect" determinations. Pet'rs Br. 52-66; *see also* Pet'rs Monsanto Reply 23-25.

1. EPA Failed to Evaluate Direct and Indirect Effects on Species Other than Plants.

In 2018, EPA expanded the action area based on its belated acknowledgement that dicamba does not stay on the fields. Not only did EPA not expand the action area enough, *infra,* EPA did not consider the direct and indirect effects on species other than listed plants within the expanded action area, making its "no effect" determinations for all but 69 plant species not only arbitrary, but factually false.

First, EPA previously eliminated most species from the action area based on its expectation that dicamba would not overlap with their habitat. ER1614-1697; ER1836-1939; ER1990-2056; *see also* ER0009 (direct rick concerns could not be precluded for ESA-protected mammals, birds, reptiles, or amphibians before re-drawing action area).

But, when it had to expand the action area in 2018, EPA *never evaluated* direct effects on those ESA-protected species that may live within the expanded action area. ER0341 ("previous listed species effects determinations" made in initial assessments "maintained"). These prior "no effect" determinations are not supportable with an expanded action area.

Second, EPA never evaluated indirect effects on species that rely on plants within the expanded, off-field action area. Again, EPA generally acknowledged that indirect effects "*were possible* for any species" dependent on terrestrial plants for food or habitat, but it never evaluated those indirect effects in the expanded action area. SER128 (emphasis in original); ER0009. The western yellow-billed cuckoo is an example of a bird that may suffer direct effects from exposure and indirect effects from damage to plants it relies on for habitat (including the plants needed by the caterpillars it eats). The rusty patched bumble bee also relies on plants to survive. Pet'rs Br. 65-66. Respondents fail to show EPA evaluated the effects on many species that rely upon plants for habitat, such as the rusty patched bumble bee, listed butterflies, the cuckoo, and other wildlife that may be in the expanded action area. *See*

e.g., ER1444 (Bachman's warbler breeds in palustrine forested wetlands); ER1445-446 (black-capped vireo breeds in shrublands); ER1449 (Hine's emerald dragonfly needs plants and vegetation for foraging). EPA's failure to evaluate the effects, direct and indirect, on all species within the expanded action area is arbitrary.

2. EPA's 57-Foot "Buffer" is Not Supported by the Record.

First, as a matter of law, any injury to plants, whether visually estimated at 5% or 10%, is "any chance" of harm to endangered plants or other plants that endangered species rely upon for food, shelter, or nesting. EPA cannot conclude "no effect" based on a 57-foot buffer that it selected based on an arbitrary level of effects—5% reduction in plant height—while ignoring data showing injury at much farther distances. EPA's reliance on 5% reduction in plant height as the only measure of "effect" for purposes of expanding the action area violates the "may affect" standard. *Karuk Tribe*, 681 F.3d at 1027.

Second, factually, the record shows that EPA needed to expand the action area hundreds of feet from the fields. EPA scientists concluded that academic study data required an "expansion of the dicamba action area" by *443 feet* (135 meters) beyond fields to establish

"a protective and technically defensible limit" for ESA effects determinations. ER0525 (expanding from preliminary 196 feet (60m) following validation of Norsworthy study). The 57-foot "buffer" is unsupportable. EPA disregarded measurements of visual signs of injury to plants hundreds of feet from fields in favor of a few studies that directly measured plant height.

Almost all the studies show plant injury well beyond the 57-foot expanded action area. The maximum distance to 10% visual injury is 136m/446ft in the Norsworthy field study and 34m/111ft in the Young study. ER0417. Six others are reported as "average" distances, meaning some measurements of injury were higher, and range from 131 to 226 feet. ER0417 (Jones 59m/193ft; Norsworthy Engenia 40m/131ft; Norsworthy Xtendimax 52m/170ft; Kruger Engenia 67m/219ft; Kruger Xtendimax 69m/226ft; Bradley Xtendimax 41m/134ft). Three others are closer, but still exceed 57 feet. ER0418 (Young 20m/65ft; Sprague 25m/82ft; Steckel 18m/59ft).

EPA protests (at 65) that the Kruger study shows only "[s]light visual symptomology" about 250 feet beyond the edge of the field, ER0368, but some effects 250 feet away is *not* "no effect." Moreover, the

data also show 45-50% visual injury at more than 45 feet from the field, ER0368 (Figure 19); ER0418, meaning it is highly likely that 10% visual injury is well beyond 57 feet.

EPA argues (at 66) the Purdue study supports the 57-foot buffer because the "average" distance was 31 feet to where more than 30% visual injury occurred. However, the data show visual injury between 10% and 30% observed up to 141 feet (43m) and 108 feet (33m) on Plot 1. ER0370. Some injury was observed up to 164 feet (50m) away. ER0370.

EPA argues (at 65) that 20% signs of visual injury is "the threshold that EPA used to approximate discernible effects on plant apical endpoints (5% plant height inhibition)."[8] *Any* injury to plants—especially if a particular plant is an obligate species for a listed insect—is a sufficient chance of injury to meet the low "may affect" standard for consultation; 5% plant height is EPA's arbitrary FIFRA-based standard of what it believes is "reasonable." Faced with "a registrant-suggested 20% visual signs of injury threshold," EPA scientists' evaluated "all available visual signs of injury measurements compared with height

[8] Eventually, EPA discarded all the visual injury studies. *See infra* 19.

and yield effects measurements" and concluded that "a reasonable and protective threshold for visual signs would be 10%." ER0523. Respondents are off-base in asserting that 20% was "the only metric EPA viewed as even potentially relevant…." Monsanto Br. 52, ECF 62. The record does not support 20% injury as the threshold for effects to endangered species, nor is it a lawful standard. *Karuk Tribe*, 681 F.3d at 1027.[9]

Shortly after validating Norsworthy's study, Pet'rs Br. 61-62, Monsanto and EPA management found a way to avoid all the damning data documenting visual injury signs hundreds of feet from fields. EPA used only the "Direct Field Study Approach," rejecting "Visual Signs of Injury," which the majority of academic studies utilize. ER0380-381; ER0395-413; ER0381 (EPA arrived at 57 feet expanded action area using direct measurement). Thus EPA limited itself to *just four studies* with direct plant height measurements. ER0380. Relying on limited data "from four field studies has uncertainties related to study conduct

[9] Distances of even 20% injury also far exceed 57 feet. ER0417 (Jones 38m/124ft; Young 33m/108ft; Norsworthy 24m/78ft; Kruger 36m/124ft; Norsworthy 31m/101ft; Kruger 43m/141ft; Bradley 19m/62ft; Norsworthy 82m/269ft).

as well as geographical and environmental variability." ER0395-396. "Visual signs of injury" is not "subjective and arbitrary," as Respondents mischaracterize; it is a well-established method of drift harm measurement that the majority of the academic studies implemented. For example, Dr. Norsworthy used two methods to score visual signs of injury, and the results of both were in "close agreement . . . at each point along the transects." ER0524. Crucially here, visual injury certainly is relevant for an ESA effects determination. EPA ignored documented injury to avoid expanding the action area beyond 57 feet, in violation of the ESA.

F. EPA's "No Modification" Determinations for Critical Habitat are Arbitrary.

EPA's response (at 69-71), thrice repeating the same list of unrevealing record citations, fails to show lawful evaluation of whether dicamba's new uses "may affect" critical habitat, much less any analysis in "excruciating detail." EPA (at 69) limited its view of critical habitat to whether a species uses cotton or soybean fields, rather than answer the appropriate question: whether new uses of dicamba trigger the low "may affect" critical habitat threshold, as designated by FWS, regardless of species presence. Congress did not delegate to EPA the

authority to determine critical habitat (or which features of critical habitat may be harmed); that is reserved for FWS to designate by regulation or determine through consultation.[10] 16 U.S.C. § 1533(a)(3)(A). EPA's conclusion that most critical habitats would not be modified based on species presence on fields is inconsistent with FWS designations of critical habitat and the ESA.

In 2018, EPA determined that dicamba new uses would affect 12 of 14 critical habitats in the expanded action area, but did not revisit its erroneous "no modification" determinations for all other critical habitats that include the fields. ER0451-459. Moreover, based on academic studies and other reports, *supra*, dicamba will affect plants well past 57 feet so the buffer does not mitigate to "no effect" for those critical habitats.

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[10] EPA (at 71) overreaches in its interpretation of *Weyerhaeuser Co. v. U.S. Fish & Wildlife Serv.*, 139 S.Ct. 361 (2018) The Court did not hold what constitutes critical habitat; it remanded for the lower court to interpret "habitat" in the first instance to determine whether critical habitat could include areas that "would require some degree of modification to support a sustainable population of a given species," as FWS argued. *Id.* at 369.

G. EPA Failed to Assess Effects of XtendiMax Whole Formula and Mixtures.

EPA was well-aware of the unknown effects of dicamba interactions with other chemicals. *See* FER0284-285 ("[T]he topic of synergy and multiple stressors is an uncertainty in assessing risk to non-target plants *including endangered species*.") (emphasis added); *'Ilio'ulaokalani Coal. v. Rumsfeld*, 464 F.3d 1083, 1093 (9th Cir. 2006) (no need to comment to preserve issue of which agency had "independent knowledge"). Regardless, Petitioners preserved this issue. ER1341 (Center for Biological Diversity comment: "EPA must consider during the consultation process the effects of these 'inert' or 'other' ingredients together with the active ingredient on listed species…."); ER1251 (Center for Food Safety (CFS) urged EPA to assess the "toxicity of all the components of likely end-use products.").

EPA's argument that petitioners failed to name specific inactive ingredients is also meritless. Pesticide formulas are proprietary information that are not disclosed to the public. FER0332-333 (whole formula confidential). Moreover, CFS specifically identified glyphosate and glufosinate as ingredients for which EPA must assess synergistic

effects. ER1251-252. EPA points to nothing in the record indicating that such analyses were done.

II. EPA VIOLATED FIFRA.

A. EPA Failed to Make Requisite Determinations for 2018 Registration.

EPA had to support with substantial evidence that "(i) [Monsanto] had submitted satisfactory data pertaining to the proposed additional use[s];" and (ii) XtendiMax uses "would not significantly increase the risk of any unreasonable adverse effect on the environment." 7 U.S.C. § 136a(c)(7)(B). And pursuant to the registration terms it self-imposed, EPA also had to determine that "off-site incidents are not occurring at unacceptable frequencies or levels." ER0245; ER0282. EPA failed in all three respects. Pet'rs Br. 12-20.

EPA extended XtendiMax uses despite copious evidence establishing that XtendiMax off-site drift incidents were occurring at unacceptable levels.[11] EPA claims (at 24-25) it can ignore the condition because it was not set by Congress in FIFRA. That is akin to saying the

[11] ER0724-725; ER0656 ("[T]he amount of off-target damage observed in 2017 and now in 2018 remains unacceptably high.…); ER0509; ER0510-514; ER0612-614; ER0627; ER0745-776; FER0041-045.

agency has no authority to tailor the registration with any mitigation because those measures are not stated in FIFRA. By requiring itself to make a determination about the level of XtendiMax drift in the XtendiMax license,[12] EPA made it *part of* its registration decision, and a prerequisite for its continuation beyond November 2018.

EPA's position is also flatly contrary to *Pollinator Stewardship* and *NRDC*; both hinged on analogous "rules of decision" standards the agency set and then similarly tried to evade. Pet'rs Br. 17 (citing *Pollinator Stewardship Council v. U.S. Envtl. Prot. Agency,* 806 F.3d 520, 531-32 (9th Cir. 2015); *Nat. Res. Def. Council (NRDC) v. U.S. Envtl. Prot. Agency*, 735 F.3d 873, 884 (9th Cir. 2013)).

EPA (at 25) unsuccessfully characterizes the required finding as mere explanation of the automatic expiration, but the registration plainly states that it cannot be extended "*unless the EPA determines*" that drift is not occurring at unacceptable levels or frequencies. ER0245 (emphasis added). ER1072 (EPA official explaining the automatic expiration "could be removed if everything is working well," but in the

[12] The provision is Part D of the registration's *conditions*, along with the other mitigations, such as use and geographic restrictions. ER0237-246; *accord* ER0016-24 (same part in 2018 registration).

"worst-case the risks outweigh the benefits, and the registration expires"). EPA failed to *determine* anything on this score.[13]

Nor did EPA support with substantial evidence the two statutorily-required findings before conditionally extending the registration. 7 U.S.C. § 136a(c)(7)(B). EPA claims (at 27-28) that it had "satisfactory data pertaining to the proposed additional use[s]" because Monsanto had complied with all of its data requirements listed under 40 C.F.R. part 158, but EPA's regulations make clear those requirements are "minimum data." 40 C.F.R. §§ 158.1(b)(1); 158.30; 158.75 ("The data routinely required by this part may not be sufficient to permit EPA to evaluate every pesticide product."). Nor did Monsanto meet them: Monsanto's field volatility studies violated EPA's testing guidelines. Pet'rs Br. 27 n.14-15; Pet'rs Monsanto Reply 9-13 (filed concurrently). That Monsanto complied with most of EPA's minimum data requirements does not amount to "satisfactory data" for XtendiMax's conditional registration. Pet'rs Br. 7-12.

[13] Webster's Third New Int'l Dictionary, *Determine*, https://www.merriam-webster.com/dictionary/determine.

The additional new studies EPA required show EPA could not conclude that XtendiMax would not "significantly increase the risk of any unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(7)(B). Respondents' attempt to downplay these studies as a part of a regular practice to "confirm" registrations finds no support in FIFRA or its regulations. The word "confirmatory" is not used in FIFRA. EPA regulations limit "confirmatory" testing to elaborate upon previously-submitted studies only for testing a pesticide's mutagenicity, 40 C.F.R. §§ 158.230(d)(9); 158.500(e)(30), not for studies ascertaining a pesticide's mobility (including volatility), environmental fate, and ecological effects, the attributes EPA seeks to understand with the additional studies. *Id.* §§ 158.630(e); 158.660(e); 158.1300(e).[14]

To meet FIFRA's standard, these future "confirmatory" studies should have been provided before EPA's approval, to address long existing uncertainties around dicamba's off-site movement. Pet'rs Br. 12-14. Instead, for the *first* time, EPA is requiring field studies to assess yield loss from dicamba off-site movement, its potential to injure plants

[14] The regulations limit this use of "confirmatory" to "confirmatory trials" by an independent laboratory to validate testing methodologies. *See* 40 C.F.R. §§ 158.630(e)(7); 158.660(e)(7); 158.1300(e)(7).

through irrigation water, and impacts on "sensitive tree/shrub/woody perennial species." ER0070; ER0378 ("There were no studies that assessed yield"); ER0023 (ordering "new data"). EPA is also belatedly requiring Monsanto to comply with its testing guidelines, and conduct field studies in locations of XtendiMax use. ER0070. Similarly, EPA has known since 2016 that XtendiMax's volatility could be exacerbated in tank mixtures, but is only now requiring Monsanto to study it. ER0070; FER0284.[15]

EPA lacked substantial evidence that XtendiMax would not "significantly increase the risk of" its unreasonable adverse effects, and that XtendiMax offsite drift incidents are not happening at unacceptable levels.[16]

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[15] Respondents ask this Court to disregard Petitioners' tank mixture arguments based on *United States v. Strong*, 489 F.3d 1055 (9th Cir. 2007). There the Court disregarded new claims in a footnote without any citations to the relevant legal authority. *Id.* at 1060 n.4. Here, Petitioners adequately raised the issue by specifically naming "enhanced volatility via tank mixing" in its paragraph describing data that EPA's conditional registration under 7 U.S.C. § 136a(c)(7)(B), and provided more explanation and further record evidence demonstrating this problem in a footnote. Pet'rs Br. 19 & n.12.

[16] EPA (at 21, 29, 41) seeks broad deference, but substantial evidence review is far from so toothless. *Pollinator Stewardship*, 806 F.3d at 535 (Smith, J., concurring) ("searching and careful review" that grants

B. EPA Failed to Analyze the Efficacy and Feasibility of 2018 Label Amendments.

In 2018, EPA further complicated XtendiMax's already unprecedented instructions, but still failed to address volatility (aka vapor drift) *or* assess the feasibility of actually following the label in the real world. Pet'rs Br. 21-25, 29-31. Under FIFRA, the label is the law, but if the label is impossible to follow, then EPA's decision that use in accordance with that label meets the FIFRA safety standard is unlawful. The same is true when EPA ignores record evidence from certified applicators that the *product* is volatile, instead only imposing measures to "reduce misapplication." EPA Br. 36.

Use instructions are mitigation measures to prevent unreasonable adverse effects. Respondents do not attempt to rebut that EPA has a duty to analyze whether its label could be followed in the real world. *Pollinator Stewardship*, 806 F.3d at 538 ("[p]rofessional judgment and knowledge do not meet the substantial evidence standard independent of data and facts" regarding effectiveness of mitigation measures); *S. Fork Band Council of W. Shoshone of Nevada v. United States Dep't of*

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agencies even "less deference than the arbitrary and capricious standard").

Interior, 588 F.3d 718, 727 (9th Cir. 2009) (disapproving mitigation measures that lacked efficacy assessment). If the practicability/feasibility of label measures could pass muster automatically, there is no stopping point: presumably EPA could "mitigate" with a label of "do not spray unless unicorns are present."

Unlike the missing use instructions addressing volatility, or any feasibility analysis, the record *does* contain evidence that XtendiMax is volatile and that—even if the 2018 amendments would prevent all drift harm—the label is nearly impossible to follow. ER1100 (volatility "one of the major routes" of dicamba injury); ER0688 (although EPA derides it as "an opinion survey," (at 32), professional certified applicators identified volatility as the primary factor in drift injury *54%* of the time, compared to 16% of the time for spray drift); Pet'rs Br. 8-9, 11 (volatility); Pet'rs Br. 30-31 & n.17 (label impossibility); ER0684 (Illinois professional applicator stating "I believe it is impossible to make an on-label application as the label is written[.]"); FER0033-034 ("This was probably the most complex label I had ever seen in my 40-year career"); ER0756; ER0651.

EPA's claim that its 2017 changes resulted in overall complaint reduction is contradicted by its admission elsewhere that *state*-issued use restrictions resulted in this modest decline in incidents. EPA Br. 26, 34. Indeed, the four states with the greatest reductions in 2018 (Arkansas, Minnesota, Missouri, and Tennessee) had *their own* cutoff dates in place. ER0529-531; FER0311-331. EPA has no response to the fact that dicamba injury *increased* in five leading soybean states. Pet'rs Br. 10 (citing ER0529-531).

Contrary to Respondents' mis-framing, Petitioners do not challenge EPA's 2018 amendments as unreasonable individually, but as a whole, because they do not address the main concern of volatility, and only make the label more impossible to follow. Even if the 2018 amendments addressed volatility, Respondents cannot point to *any* analysis, study, or explanation addressing whether users can follow the label, given farming conditions like geography and weather. *See* EPA Br. 42-43; Monsanto Br. 31. Critical questions remain unanswered: how many days would allow lawful application, *i.e.* without temperature

inversions;[17] or wind speeds in the narrow 3-10 mph window;[18] or no rain forecast within 24 hours?[19] Or even sufficient *hours* to spray in a month, as was the case for Indiana?[20] Can applicators really apply a "downwind"-only buffer against changing wind,[21] or comply with the ultra-low 24" boom (sprayer) height requirement to mitigate spray drift?[22] While EPA may rely on its label as part of its rationale for why its decision will not cause unreasonable environmental effects, it may not ignore real-world evidence that the complex label could not mitigate

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[17] ER0745-746; FER0028-030 (inversions often occur afternoon to mid-morning); *id.* (inversion predictions not accurate); FER0023-025 (inversions "should be constantly monitor[ed]")

[18] ER0715 ("Any time we had average wind speeds over 5 MPH, we had gusts over 10 MPH"); FER0014-017 ("days when wind speeds and gusts are below 15 mph are rare" in central Illinois); FER0036 (average Iowa wind speed is 14 mph); ER0634 (10 mph wind in Western Texas "a fairy tale").

[19] FER0005 ("excessive rainfall" prevented application).

[20] ER0614 (Indiana weather data show only less than 50 hours for legal applications in June 2018); FER0019-020 (same for 2017 and previous 5 years); *see also* FER0008-011.

[21] FER0024 (wind "can also change direction rapidly"); *id.* (recommending monitoring wind speed and direction throughout application due to frequent changes).

[22] ER1145 (cannot comply with height restriction without damaging equipment); ER1151 ("cannot use booms at 24 inches" with hilly terrain, "need at least 3 feet").

XtendiMax's harms. 7 U.S.C. § 136n(b); *Nat. Res. Def. Council (NRDC) v. U.S. Envtl. Prot. Agency,* 857 F.3d 1030, 1041-1042 (9th Cir. 2017).

C. EPA's Failed to Assess Dicamba Costs.

EPA also undertook no meaningful assessment of drift injury costs; the Court cannot "defer to a void." *Oregon Nat. Desert Assn. v. Rose*, 921 F.3d 1185, 1191 (9th Cir. 2019). Regulations require EPA "[r]eview[ ] all relevant data in [its] possession," including evidence of the extent of damages to farmers and the environment from dicamba drift. *Pollinator Stewardship,* 806 F.3d at 528 (citing 40 C.F.R. § 152.112(b)-(c)).

Respondents cite no precedent allowing EPA to tout the supposed benefits of a new use while ignoring quantifiable costs. FIFRA mandates EPA "gather data to determine if the benefits of a particular pesticide product outweigh its 'economic, social, and environmental costs.' " *Ctr. for Biological Diversity v. U.S. Envtl. Prot. Agency*, 847 F.3d 1075, 1085 n.9 (9th Cir. 2017) (citing 7 U.S.C. §§ 136a(c)(3)(A), (c)(5)(C); 136(bb)).

EPA argues it assessed costs to other plants, but its six-sentence "assessment" lacks any quantitative data, despite evidence in the

record. ER0491-492; Pet'rs Br. 34. While EPA cites (at 44) figures for the values of the entire cotton and soy markets, these are irrelevant to XtendiMax, as EPA's own scientists ascribe *no yield benefits* to XtendiMax (ER0489-490), and EPA failed to acknowledge the $53 billion worth of fruit, nut, and vegetable crops threatened by dicamba drift.[23] *See also* Pet'rs Monsanto Reply 14-17.

III. THE COURT SHOULD VACATE THE REGISTRATION.

Respondents do not meet their heavy burden to show this is one of those "rare circumstances" in which "equity demands" remand without vacatur. *Pollinator Stewardship*, 806 F.3d at 532; *Humane Soc'y of U.S. v. Locke*, 626 F.3d 1040, 1053. n.7 (9th Cir. 2018); *Idaho Farm Bureau v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995); Pet'rs Br. 74-75.[24]

Pollinator Stewardship sets forth the inquiry. 806 F.3d at 532 ("weigh[ing] the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be

[23] U.S. Dep't of Agric., Agricultural Production and Prices, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/agricultural-production-and-prices/.

[24] Petitioners oppose Respondents' supplemental briefing request as unnecessary and further delaying of this expedited case.

changed."). As for the first factor, EPA's attempt to minimize its fundamental FIFRA flaws fails: this Court vacates registrations for similar or less. *Id.* at 532-33; *NRDC*, 857 F.3d at 1042. The ESA violations are even graver, as "the consultation requirement reflects a conscious decision by Congress to give endangered species priority over the primary missions of federal agencies." *Nat. Res. Def. Council (NRDC) v. Jewell*, 749 F.3d 776, 779 (9th Cir. 2014) (internal quotation omitted). EPA downplays its ESA violations as "largely procedural" but the Section 7 *procedure* is the very "heart of the ESA," *Kraayenbrink*, 632 F.3d at 495, vital to its substantive no jeopardy mandates. *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).

EPA implies (at 76) it will again register XtendiMax, but it is unlikely EPA could register the same label, as any subsequent registration will require addressing the deficiencies, including: undertaking and supporting with substantial evidence the missing FIFRA analyses and findings; applying a lawful, not-impossible label; addressing volatility and actually weighing costs to farmers; as well as undergoing the ESA consultation process; and establishing new use limits, to protect farmers and ESA-species. Accordingly, even more so

than in *Pollinator Stewardship*, on remand "a different result may be reached," 806 F.3d at 532. The seriousness prong weighs heavily in Petitioners' favor.

As for 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." *Id.* at 532; *All. for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1122 (9th Cir. 2018) (vacatur "appropriate when leaving in place an agency action risks more environmental harm than vacating it"). The environmentally protective remedy is vacating an unlawful action projected to increase soybean and cotton use of dicamba by 88 and 14.3 times, respectively, with combined use having already risen 12-fold in 2017. Pet'rs Br. 4, ER0477; FER0289-299.

Respondents have entirely failed to carry their burden to show any negative environmental consequences *from* vacatur. Instead EPA (at 75) mistakes vacatur and injunctions—diametrically different remedies—in arguing Petitioners must show irreparable harm in order for the Court to vacate. First, given the presumption of vacatur, *All. for the Wild Rockies*, 907 F.3d at 1122, anything other than vacatur is

Respondents' burden, not Petitioners'. Second, if there is any irreparable harm role, it is the prerequisite for remand without vacatur: in ESA cases courts have only declined to vacate if vacatur itself could lead to that result. *Idaho Farm Bureau*, 58 F.3d at 1405 ("concern exists regarding the potential extinction of an animal species"); *see, e.g.*, *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 951 (N.D. Cal. 2010) ("[T]he Ninth Circuit has only found remand without vacatur warranted by equity concerns in limited circumstances, namely serious irreparable environmental injury.").

EPA instead makes conclusory allegations of economic disruption, but even assuming they alone are cognizable, that does not approach its evidentiary burden. Any reliance interests are necessarily limited: there is no guarantee EPA continues the registration post-2020. Nor is it true that farmers do not have multiple other weed management options, including less toxic ones.[25]

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[25] EPA accords "reduced risk" status to 7 other herbicides for cotton (4) and soybean (4), with one registered for both. U.S. Envtl. Prot. Agency, *Reduced Risk and Organophosphate Alternative Decisions for Conventional Pesticides*, https://www.epa.gov/pesticide-registration/reduced-risk-and-organophosphate-alternative-decisions-conventional (last updated June 2018).

Finally, EPA's strained efforts (at 75-76) to distinguish *Pollinator Stewardship* fail. This case is *Pollinator Stewardship*, but on steroids: there, only one "precarious" but not (yet) endangered type of insect (bees) were potentially at risk, and only one key study was missing. Here, *hundreds* of already endangered species are at similar risk, and EPA has failed to consult for *all* of those species and *many* risks are left unanalyzed due to the failure to consult.

CONCLUSION

Vacatur is required because "leaving [the registration] in place risks more potential environmental harm than vacating it." *Pollinator Stewardship*, 806 F.3d at 532. That conclusion is underscored by the continued 2019 drift evidence,[26] and the repeated admissions of risks to

[26] Steve Davies, *Dicamba's off-target effects continue for third year*, AGRIPULSE COMMUNICATIONS (Oct. 9, 2019), https://www.agri-pulse.com/articles/12691-dicambas-off-target-effects-continue-for-third-year-in-row; Emily Unglesbee, *EPA Gets Limited Dicamba Data: As Dicamba Injury Complaints Rise, States' Communication with EPA Declines*, DTN (Aug. 20, 2019), https://www.dtnpf.com/agriculture/web/ag/crops/article/2019/08/20/dicamba-injury-complaints-rise-epa; Dan Charlies, *Rogue Weedkiller Vapors Are Threatening Soybean Science*, NAT'L PUB. RADIO (July 19, 2019), *at* https://www.npr.org/sections/thesalt/2019/07/19/742836972/rogue-weedkiller-vapors-are-threatening-soybean-science; Emily Unglesbee, *Off-Target, Once Again: Herbicide Injury Heats Up Across the Country*,

endangered species. EPA has failed to show equity demands the Court not vacate the registration.

Respectfully submitted this 18th day of November, 2019.

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DTN (July 25, 2019), https://www.dtnpf.com/agriculture/web/ag/crops/article/2019/07/25/herbicide-injury-heats-across.

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