SUBJECT TO PROTECTIVE ORDER

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 INTERVENOR-RESPONDENT'S BRIEF (REDACTED)

CENTER FOR FOOD SAFETY
George A. Kimbrell
Sylvia Shih-Yau Wu
Amy van Saun
2009 NE Alberta St., Suite 207
Portland, OR 97211
T: (971) 271-7372
gkimbrell@centerforfoodsafety.org
swu@centerforfoodsafety.org
avansaun@centerforfoodsafety.org

CENTER FOR BIOLOGICAL DIVERSITY
Stephanie M. Parent
PO Box 11374
Portland, OR 97211
T: (971) 717-6404
SParent@biologicaldiversity.org

Counsel for Petitioners

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ARGUMENT[1]

I. THE COURT HAS JURISDICTION.

Monsanto rehashes the same timeliness argument it made in *Dicamba I*, premised on an unprecedented and textually unsupportable interpretation of 40 C.F.R. § 23.6. Order, *Nat'l Family Farm Coal. v. U.S. Envtl. Prot. Agency*, No. 17-70196 (9th Cir. Feb. 22, 2017) (*Dicamba I*), ECF 11; Pet'rs Reply 3-4, *Dicamba I*, ECF 12-1; Order, *Dicamba I*, ECF 23 (order finding the petition "timely filed"). It remains meritless.

FIFRA Section 16(b) states that a petition for review must be filed "within 60 days after the [order's] entry." 7 U.S.C. § 136n(b). 40 C.F.R. § 23.6 states in turn that "[u]nless the Administrator otherwise explicitly provides in a particular order," the "date of entry" of an order for purposes of FIFRA 16(b) judicial review is "1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is two weeks after it is signed." This registration was signed October 31, 2018. ER0001. Nowhere does the registration document otherwise "explicitly

[1] Wherever possible this reply to Intervenor-Respondent Monsanto tiers off of and incorporates Petitioners' reply to Respondent EPA, filed concurrently.

provide[]" a different "date of entry" other than the default date prescribed by 40 C.F.R. § 23.6. *See id.* Accordingly, EPA entered the registration continuation on November 14, 2018, fourteen days after that decision was signed. Petitioners filed their petition for review within 60 days, on January 11, 2019. ECF 1-6.

Monsanto (Monsanto Br. 17, ECF 62) insists that the signed "date of issuance" when a pesticide registration becomes effective, and the "date of entry" for purposes of judicial review, must be the same. Monsanto can cite no case—and Petitioners are unaware of any—where a court construed pesticide registration's *date of issue* to automatically also be its explicit *date of entry* for appellate review under 40 C.F.R. § 23.6. Rather, this Court has repeatedly rejected the premise of Monsanto's argument, including in *Dicamba I*.[2]

40 C.F.R. § 23.6 plainly states that the "date of entry" of an order is two weeks after it is signed "[u]nless the Administrator *explicitly* provides in a *particular* order." 40 C.F.R. § 23.6 (emphases added). At a minimum, EPA would need to use the words "date of entry" in the

[2] Order, *Dicamba I*, ECF 23; *See also* Order Denying Motion to Dismiss, *Nat'l Family Farm Coal. v. U.S. Envtl. Prot. Agency*, No. 17-70810 (9th Cir. June 12, 2017) (*Enlist Duo II*), ECF 43.

registration, or cite to 40 C.F.R. § 23.6, to indicate explicitly it was departing from that rule. *Powell's Books, Inc. v. Kroger*, 622 F.3d 1202, 1209 n.8 (9th Cir. 2010) ("Because the statute does not define 'explicit,' … we refer to its ordinary dictionary meaning—that is, as 'fully revealed or expressed without vagueness, implication, or ambiguity."). The registration says neither, and thus does not "explicitly" change the default date of entry specified by EPA regulations.

That is because EPA did *not* specify a different date of entry. Rather, EPA has repeatedly confirmed to this Court that it agrees with Petitioners' interpretation of its regulation.[3] Nor is this regulation unique: EPA has a host of timing regulations for statutes under its purview, in effect for well over three decades, which according to Monsanto's far-reaching argument, would be similarly invalid.[4] By setting an easily ascertainable time of entry for these orders, EPA

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[3] Pet'rs Letter, *Dicamba I*, ECF 12-1 at 2; *see also* EPA Resp., ¶ 4, *Enlist Duo II*, ECF 24; Pet. for Review, *Ctr. for Food Safety v. EPA*, No. 14-73283 (9th Cir. Oct. 30, 2014) (*Enlist Duo I)*, ECF 1-1.

[4] EPA has promulgated similar timing regulations for the Clean Water Act, the Clean Air Act, the Resource Conservation and Recovery Act, the Toxic Substances Control Act, the Safe Drinking Water Act, the Atomic Energy Act, and the Federal Food, Drug, and Cosmetic Act. *See* 40 C.F.R. §§ 23.2-23.10 (filing regulations for these statutes).

sought to bring greater fairness to "races to the courthouse," in which parties relied on complex schemes to be the first to learn of and file petitions for review. *Judicial Review Under EPA-Administered Statutes; Races to the Courthouse*, 50 Fed. Reg. 7268, 7268 (Feb. 21, 1985).[5] EPA stated in response to comments it would be an "unusual case" in which EPA would make a rule immediately reviewable. *Id.* at 7269. Exempting the entire category of pesticide registration orders from FIFRA's timing regulation, as Monsanto urges, would frustrate EPA's goals of simplifying the filing process and limiting immediate judicial review to unusual cases.

Monsanto's real quarrel (at 18-19) is with the regulation itself, not its proper application here. But courts have rejected the core premise of Monsanto's argument, that an agency decision must be immediately reviewable once it is effective. *W. Union Tel. Co. v. F.C.C.*, 773 F.2d 375,

[5] Monsanto attempts to rely on the 1985 rulemaking, but it explains specifically for FIFRA's timing regulation: "the final rule sets the trigger date at *two weeks after the date of signature*, even if the order is published in the Federal Register." *Id.* at 7270 (emphasis added). The dates of signature and issuance, and of entry for judicial review, are different, not the same. Likewise, Monsanto's reliance on *Selco Supply Co. v. U.S. Envtl. Prot. Agency,* 632 F.2d 863 (10th Cir. 1980) is wholly misplaced since it was issued before 40 C.F.R. § 23.6's promulgation.

377 (D.C. Cir. 1985) ("It is not a principle of the law that all agency action must be reviewable as soon as it is effective and ripe"). Nor is it true that the regulation attempts to reduce or alter FIFRA's 60-day jurisdictional clock; EPA's regulation simply sets when that clock begins in order to better *ensure* fair and efficient judicial review. This is very different than agencies improperly trying to shield their actions from any judicial review, to which the Court was speaking in *Kucana v. Holder*, 558 U.S. 233, 252 (2010), which Monsanto misconstrues. This Court has jurisdiction to review Petitioners' timely petition for review.

II. THE REGISTRATION VIOLATED FIFRA.

A. Required Findings and Data for Registration.

EPA failed to comply with FIFRA's conditional registration standards, as well as its own rule of decision, in the 2018 conditional registration. Pet'rs Br. 14-21, ECF 39; Pet'rs EPA Reply 23-27. Monsanto mainly parrots EPA regarding EPA's failure to make the prerequisite "no unacceptable levels of drift" determination in order to extend the registration, but adds a hyper-technical argument (at 22): the provision would apply had EPA "extended" the registration, but does not matter now because EPA "replaced" the registration. Whatever Monsanto calls it, the record shows the 2018 decision is a continuation

and *extension* of the earlier decision.[6] Indeed, EPA issued the 2018 continuation of XtendiMax, subsuming and extending the prior registration, a week before that registration would have automatically expired. But the extension could not occur, pursuant to an EPA-imposed condition, "unless EPA determine[d]" that XtendiMax drift was not happening in the fields at unacceptable levels or frequencies. ER0245. Monsanto mischaracterizes what EPA did, but whether this critical provision has meaning cannot hinge on such semantics.

Monsanto also misinterprets the import of this Court's holding *Dicamba I* moot. The Court held that the case could not be decided solely on what was before the Court previously because the 2018 registration encompassed new record materials and differences in the label. *Dicamba I*, ECF 157, at 4. The Court did not hold that everything

[6] ER0001 ("*Continuation* of Uses"), ER0003 (EPA "has decided to *extend* these registrations"), *id.* ("These registrations would have automatically expired, *unless* EPA acted to *extend* these dates on all three registrations"), ER0005 ("These registrations were time-limited with an automatic expiration date … *unless EPA granted an extension of this time limitation*"), ER0018 ("EPA will be *extending* the registrations"), ER0019 (discussing proceeding as a "registration *extension*"), ER0023 ("[T]his decision" is "*extending* the registration of dicamba OTT uses"); ER0335 ("EPA received a request to amend this registration that included *extending* the registration to December 2020") (emphases added).

in the 2016 registration and administration record, which is now a part of the record for this case and upon which Respondents otherwise continue to rely, is irrelevant and can be ignored. EPA must support its decision with substantial evidence based on review of the whole record, including following its own rules of decision for how it would continue the registration. It is telling that the same restriction is in the 2018 decision, just now with the goalposts moved back two years. ER0024. Under Respondents' reading, they could again simply ignore it as meaningless again, despite it continuing to be an enumerated registration condition.

EPA also failed to make the FIFRA-required finding that it had "satisfactory data pertaining to [XtendiMax uses]" to conclude that the continued registration of XtendiMax "would not significantly increase the risk of any unreasonable adverse effect on the environment." 7 U.S.C. § 136a(c)(7)(B).

Like EPA, Monsanto (at 20-22) erroneously insists that the additional data that EPA ordered Monsanto to submit are merely confirmatory. *See* Pet'rs EPA Reply 25-27. Monsanto (at 21 n.9) tries to dismiss the fact that EPA continued XtendiMax uses while missing

data on XtendiMax's tank mixture synergistic effects, insisting that Petitioners failed to demonstrate how tank mixture is "an important aspect of the problem." ER0070; ER0023.[7] However, EPA itself recognized in 2016 that tank mixing XtendiMax could exacerbate its effects. Further Excerpts of Record (FER)0284. Monsanto also emphasizes that EPA had reviewed some volatility studies that were conducted with tank mixtures of dicamba and glyphosate, but if anything these studies, which showed increased XtendiMax volatility from tank mixing, demonstrate that EPA needed more studies on tank mixtures before conditionally registering XtendiMax. Pet'rs Br. 19 n.12; ER0352; ER0469.

B. Label Arguments.

EPA failed to show that its 2018 label amendments would be either effective at mitigating vapor drift or feasible to follow. Pet'rs EPA Reply 28-32. Monsanto criticizes (at 31) Petitioners' reliance on record statements illustrating the previous 2016/2017 label was too complicated to follow, confusing the larger point: the 2018 label is *even*

[7] Monsanto also makes the same erroneous claim that Petitioners failed to adequately present this argument. Pet'rs EPA Reply 27 n.15.

more restrictive, lending even more credence to those concerns. Monsanto also notes that only certified applicators can spray, but the record evidence is that certified applicators themselves told EPA that they could not meaningfully follow the label. Pet'rs Br. 29-32; *see*, *e.g.*, FER0007 (comment from American Association of Pesticide Safety Educators on 2018 label noting marginal success with preventing drift "in spite of the thousands of hours of training" and urging EPA "to look in other areas, besides more training" to reduce dicamba off-field movement); ER0613; ER0637-638; ER0684; ER0758; ER0662-665.

C. Volatility Assessment.

EPA concluded that the continued registration would not cause unreasonable adverse impacts by ignoring record evidence of its significant volatility, relying instead on Monsanto's inadequate studies. Pet'rs Br. 25-29. In their briefs, Respondents double down on that reliance, with no response to the damning record evidence. Monsanto Br. 28-30; EPA Br. 36-40, ECF 48-1.[8]

[8] EPA discounts volatility evidence from 2016 (Pet'rs Br. 25; ER1574-75) as "outdated" and based on a different, "more volatile" formulation. EPA Br. 36-37. However, independent testing confirmed that formula (M1691 or Clarity) has the *same* volatility as XtendiMax,

Respondents do not contest the violation of OPPTS Test Guidelines 835.8100, which reasonably require field volatility studies in locations representing areas of major use. Pet'rs Br. 27 n.14; *Pollinator Stewardship Council v. U.S. Envt. Prot. Agency,* 806 F.3d 520, 531-32 (9th Cir. 2015) (EPA cannot avoid its own regulations or guidelines it sets itself). Respondents defend these studies as representing a range of temperature, humidity and soil pH conditions.[9] EPA Br. 39-40; Monsanto Br. 28-30. But these are not the only conditions that enhance volatility: record evidence from agronomists demonstrated that other region-specific factors (such as topography and proximity to water) enhance volatility, factors EPA ignored. FER0262; ER0464; ER1148, ER1150.

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including when mixed with Roundup. ER0772, ER0778; ER1029-33. Monsanto prohibited independent university testing of XtendiMax for volatility prior to its commercial release in 2017. FER0255. Thus, EPA had record evidence that XtendiMax was as prone to volatilization as a formulation that caused injury from ½ to over 2 miles from treated fields, yet chose to ignore it.

[9] EPA scientists themselves noted numerous deficiencies in these studies, including Texas data "discarded by the study authors," which collectively could "result in underestimates of vapor drift…." ER1217-220.

Respondents further claim that EPA considered academic studies in addition to Monsanto studies on volatility, concluding that "non-monocot plant species could experience effects of concern (a 5% reduction in plant height) up to 57 feet from the treated area," EPA Br. 38; Monsanto Br. 28-29. EPA imposed an omnidirectional 57-foot infield buffer,[10] but only in counties with ESA-listed non-monocot plants. This protection for the 218 counties with ESA-listed non-monocot plants (ER0442-459) does nothing volatility-wise to for the remaining *2,479* counties across 34 states.[11] Despite record evidence finding volatility harms off-field, EPA ignored those harms in the vast majority of counties (2,479 v. 218 counties). EPA's failure to require controlled field volatility studies in major areas of use left the Agency bereft of critical information that could have been used to craft region-specific mitigations to avert XtendiMax's unreasonable adverse effects on

[10] Not that the 57-foot buffer was sufficient to prevent harm, *see infra* pp.24-31; Pet'rs EPA Reply 14-21.

[11] U.S. Census Bureau, County and City Data Book: 2000 (Nov. 2001), *available at* https://www2.census.gov/library/publications/2001/compendia/ccdb00/2000ccdb.pdf.

non-listed crops and plants in the thousands of counties without any buffer.

In another example of EPA ignoring real-world conditions, *see* Pet'rs EPA Reply 28-32, EPA relied on "humidome" studies conducted at 40% humidity, despite much higher humidity in the states where dicamba will be used. Pet'rs Br. 28-29; ER1709; ER0353; ER1163. Respondents emphasize that the field studies captured how far dicamba vapor will travel under varying humidity levels, but the field studies do not answer the very different question served by the "humidome" studies: the level at which there is no observable plant injury from exposure to a given concentration of dicamba vapor under varying conditions, including high temperature and humidity. Scientific studies and trained applicators agreed that plant injury from dicamba vapor increases with humidity. FER0344 [redacted]; ER1075; ER0888; Pet'rs Br. 29. EPA based the no observed adverse effect level—the critical plant harm threshold—on faulty 40% humidity humidome tests, meaning that real-world

soybeans in typical high-humidity conditions will suffer more injury. Pet'rs Br. 28-29.

Finally, field size matters and both registrant and academic field studies were far too small to simulate the distance and amount of vapor drift that occurs from farms that are hundreds of acres. Pet'rs Br. 28; *see also* Br. for Dr. Mortensen as Amicus, ECF 44 at 17-21 (explaining scaling problem with only 3.4 to 9.6 acre test plots and need for plots that are hundreds of acres in size, and an accounting of landscape scale use over hundreds of fields). Monsanto does not dispute that the modeled volatility estimates for a hypothetical 80-acre field greatly underestimated the off-field vapor concentrations when real-world farms many times larger are sprayed. Pet'rs Br. 28; FER0228 (Monsanto's scientist conceded they had not "scaled up" their modeling to simulate spraying "thousands of acres").

Given the uncontested deficiencies in the data EPA relied upon, and evidence in the record of XtendiMax's volatility, EPA's determination that volatility would not cause unreasonable adverse impacts is not supported by substantial evidence.

D. XtendiMax Costs.

EPA violated FIFRA by failing to meaningfully weigh the significant cost to farmers from dicamba drift harms. Pet'rs Br. 32-35; Pet'rs EPA Reply 32-33.

Monsanto claims (at 33)—without support—that FIFRA does not require consideration of the quantifiable costs. However, *Ass'n of Pac. Fisheries v. U.S. Envtl. Prot. Agency*, is an inapposite. 615 F.2d 794, 801, 803, 809, 818 (9th Cir. 1980). Legislative history of the Clean Water Act interpreting the cost-benefit analysis for best practicable control technology is inapplicable to FIFRA.

Monsanto relies solely on cases where the harm was unquantifiable (at 34),[12] while ignoring that data on economic harm from dicamba drift is certainly not "unobtainable."[13] Indeed, the record

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[12] *Ass'n of Pac. Fisheries*, 615 F.2d at 809; *see also F.C.C. v. Fox TV Stations, Inc.*, 556 U.S. 502, 519 (2009) (harmful effect of profanity was not quantifiable, and reviewing FCC action under APA). *Wisconsin Power & Light Co. v. F.E.R.C.*, 363 F.3d 453, 464 (D.C. Cir. 2004) is similarly inapplicable, as the duties described under the Federal Power Act are different than FIFRA.

[13] The Court will certainly be doing this exercise in the class action cases against Monsanto seeking recovery from the 2016 season drift damage. *In re: Dicamba Herbicide Litigation,* No. MDL 2820 (E.D. Missouri, October 1, 2019), ECF 502 (Summary of experts to provide

is full of evidence of harm to individual farmers, including from yield reduction and millions of dollars in lost income. Pet'rs Br. 33; *see, e.g.*, ER0887-889; ER0891-894; ER0994-996; FER051-64; ER1062; ER1121; FER0206 (Arkansas soybean field yielding below 5 bushels/acre).

Respondents disingenuously suggest that high average national or state soybean yields disprove yield loss costs from dicamba drift. Not only is this fact "not informative" as to yield effects from dicamba exposure according to EPA's own scientists, ER0490 (attributing "recent high soybean yields" to "exceptionally good" weather conditions), but does not reflect costs to *individual* farmers, for whom the fact that other soybeans are not affected "is of little consolation" when their soybeans are "damaged by dicamba." ER0623.

Monsanto implies that dicamba drift somehow does not cause financial loss (at 33-34), but in reality even *infinitesimally small exposures* (as little as 1/4000th of application rate) can reduce soybean yield by 2.5%. FER0043. If just the 4.7 million acres of dicamba-injured

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reports, including calculation of damages from drift harm to farmers, *see e.g.,* Drs. Babcock, Gardisser, Knezevic, and Baldwin).

soybeans reported in 2017 and 2018 experienced this mere 2.5% yield reduction, the loss in farmer revenue would be over $54 million.[14]

Monsanto argues (at 34) that record evidence of harm may be ignored because it was attributable to the last registration. But that assumes that the label is possible to follow and that the new measures addressed volatility, neither of which is true. Pet'rs EPA Reply 28-32. Regardless, the past few years of drift harm is also part of the record of this case, and the abysmal track record is telling. Monsanto also argues (at 33) that visual injury symptoms do not predict final yield loss, but

[14] Based on 3.6 and 1.1 million dicamba-injured acres (ER890; ER732), soybean yields of 49.3 and 50.6 bushels/acre, and soybean prices of $9.39 and $9.19/bushel, in 2017 and 2018, respectively. *See* U.S. Dep't of Agric. (USDA), *Statistics by Subject*, https://www.nass.usda.gov/Statistics_by_Subject/index.php?sector=CROPS (select Crops, Field Crops, Soybeans, Price Received and Yield) (last visited Nov. 18, 2019).

While EPA cites figures for the values of the entire cotton and soy markets, EPA Br. 44, 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. *See* USDA, *Agriculture Production and Prices*, https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/agricultural-production-and-prices/ (last visited Nov. 18, 2019).

EPA's own scientists made judgments based on the reliable use of visual signs of injury. Pet'rs Br. 60-61; ER0523; ER0395-413.

Finally, Monsanto's attempts to blame older dicamba formulations for drift injury (*e.g.* applications to corn) (Monsanto Br. 10, 60) are decisively refuted by record evidence. ER0481 (*92%* of confirmed dicamba drift injury episodes in Indiana due to over-the-top (OTT)-registered formulations); FER0258-263; ER1100.

EPA's lack of quantitative assessment of costs is not cured by EPA's supposed assessment of costs to other plants, like vegetables, fruit and nut trees, and the "landscape;" its six-sentence "assessment" lacks any quantitative or meaningful data, despite evidence in the record. ER0491-492; Pet'rs Br. 34. Finally, Respondents' treatment of the benefits assessment is also unavailing: they ignore alternatives to dicamba other than 2,4-D (Pet'rs Br. 35; ER0486-487) and EPA's 2016 assessment highlighting the rapidly evolving weed resistance *to dicamba*. EPA Br. 44-45 (citing ER1389-390).

FIFRA does not allow EPA to ignore *quantifiable* evidence of harm from a pesticide while assuming benefits with no support in the record. EPA's determination that XtendiMax's benefits outweigh its economic,

social, and environmental costs was not supported by substantial evidence.

III. THE REGISTRATION VIOLATED THE ESA.

A. "May Affect" Legal Standard.

EPA's "no effect" determinations and process violated the ESA's "may affect" standard, as well as its overarching principles of institutionalized caution and ensuring no jeopardy. Pet'rs Br. 36-51; *Cottonwood Envtl. Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1091 (9th Cir. 2015); *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985). Monsanto leans on the APA standard of review applied in ESA cases in requesting deference to EPA's determinations, *e.g.*, Monsanto Br. 37, 46, but this Court has repeatedly instructed that it does not "rubber-stamp … administrative decisions that [we] deem inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute," *Nat. Res. Def. Council v. Pritzker*, 828 F.3d 1125, 1139 (9th Cir. 2016) (quoting *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 402 F.3d 846, 859 (9th Cir.2005)). EPA violated the ESA's vital Section 7 process and mandates. *See* 5 U.S.C. § 706(2)(A), (D) (requiring courts to set aside unlawful agency action if it is "arbitrary, capricious, or

otherwise not in accordance with law," or "*without observance of procedural required by law*") (emphases added).

Monsanto alone overreaches in arguing EPA only needs to consider adverse effects because the ESA requires each action agency to insure that its action is "not likely to jeopardize the continued existence of any endangered species." Monsanto Br. 44-45 (quoting 16 U.S.C. § 1536(a)(2)). 16 U.S.C. § 1536(a)(2) mandates the action agency to do so "in consultation with … [the expert wildlife agencies]." FWS has unequivocally stated that this requires an action agency "to determine whether any action *may affect* listed species or critical habitat." 50 C.F.R. §§ 402.14(a), 402.01(b) (emphasis added).

Monsanto relies heavily on *Ground Zero Ctr. for Non-Violent Action v. U.S. Dep't of the Navy*, 383 F.3d 1082 (9th Cir. 2004) but it is inapposite. There, plaintiffs argued consultation was required because the Navy's missiles might accidentally detonate, harming salmon. However, the decision to house the missiles at the navy base was made by presidential executive order, not an agency discretionary action subject to the ESA. *Id*. at 1092. Monsanto plucks the Court's observation in *dicta* that the risk of accidental explosion was so

speculative as to be "infinitesimal." *Id.* Here, EPA did not find the likelihood of exposure to be infinitesimal; rather it found that hundreds of listed species will be exposed to XtendiMax, but rounded down the resulting risk to "no effect" because it is below EPA's arbitrary policy "level of concern" that only measures "adverse effect." *See* Pet'rs EPA Reply 2-10.

Monsanto's doomsday claim (at 36) that requiring EPA to apply the lawful threshold would somehow "grind the federal government to a halt" is baseless. *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1029 (9th Cir. 2012) (addressing this concern in section entitled "Burden on the Forest Service," and explaining that "the burden imposed by the consultation requirement need not be great."). In any event, the Supreme Court has held that even a *substantiated* claim of administrative burden would not justify departure from a statutory mandate. *U.S. Envtl. Prot. Agency v. EME Homer City Generation, L.P.*, 572 U.S. 489, 509 (2014).

B. Effect Determinations.

Monsanto (at 38) spills much ink defending EPA initial assessments, but it is futile. That EPA's initial screening assessments were based on EPA's "worst-case" exposure scenarios, which are allowed by the registration, does not change that EPA concluded adverse effects for all taxa, and reached zero "no effect" findings. *See*, e.g., ER1713 ("no federally-listed taxa can be excluded…."); ER0336-337 (direct effects for all taxa at screening level). Monsanto also emphasizes that the listed species LOCs are lower than those for non-listed species, but an arbitrarily lowered LOC still does not equate to "no effect." ER1782 (LOCs part of EPA's "interpretive policy"). Monsanto also ignores that EPA applied the *same* LOC of 1.0 for ESA-listed and non-listed plants, and for chronic effects to all listed and non-listed animal taxa,[15] which makes no sense given the precariousness of ESA-listed species. *See, e.g.*, ER1960. Nor does it make sense to apply LOC across the board to conclude "no effect" for every endangered plant, from prairie fringed

[15] EPA does not reduce the chronic LOCs for listed species, meaning that EPA believes the same threshold of adverse chronic harm to be protective of the ubiquitous pigeon and of the whooping crane that has only a few hundred individuals left on earth. RER270-71.

orchids to Tennessee yellow-eyed grass. *See, e.g.*, ER1988-989 (over 40 listed plants in 16 states). Pet'rs EPA Reply 10-14.

Monsanto (at 39-40) fares no better defending EPA's refined assessments. Its discussion only makes clear that EPA drew unilateral species-specific assumptions that it had no expertise determining to reach "no effect."[16] *See Bennett v. Spear*, 520 U.S. 154, 169 (1997). More importantly, any such refined assessment can only lead EPA to a "not likely to adverse effect finding" requiring FWS concurrence, not "no effect." Pet'rs EPA Reply 12-13.

Monsanto's challenge (at 45) to Petitioners' example of the whooping crane misses its larger import: it is just one of the many examples of EPA's application of its inexpert RQ/LOC standard that misappropriates the proper ESA "no effect/may affect" standard. Pet'rs Br. 44-46. Specifically, EPA's whooping crane analysis assumes, without confirmation from the expert agency FWS, that dicamba is no more toxic to a crane than to a bobwhite quail. ER1965. EPA simply took the quail data and unilaterally "scaled from the weight of the

[16] This led to arbitrary results where EPA concluded "no effect" even though the LOCs were almost exceeded. Pet'rs Br. 45-47; ER1412; ER1977-979.

tested surrogate species (bobwhite quail) to reflect the comparatively larger actual size of the whooping crane." *Id.* Similarly, the higher an animal's metabolic rate, the more food it will consume—and the more XtendiMax along with it. EPA assumed whooping cranes' metabolic rate is 757.6 kcal/day, based on EPA's 1993 Wildlife Exposure Factors Handbook. ER1965-967. Since the Exposures Handbook contains no information about any cranes, EPA assumed a value based on another bird that happened to be in the book, in lieu of consulting FWS. FER0307-308. If this estimated value from yet another surrogate animal was low, then EPA underestimated the animal's intake of XtendiMax—and the risk. Had EPA consulted FWS, it might know better.

These are just some of the estimates and guesses EPA made; as explained elsewhere, there are many problems with the RQ/LOC method, including that it includes no analysis of mixtures, does not address all sublethal aspects of harm (like those specific to certain listed species like bird migratory patterns, bat echolocation, or essential behavioral patterns), and uses the same chronic level of concern for a species with a million individuals as those with a few hundred. *See*

Pet'rs Br. 48-49. Avoiding consultation is not "conservative," no matter if Respondents try to label it that: it is just the opposite.

C. Action Area.

EPA also unlawfully restricted the action area, applying two incorrect legal standards to formulate it—the action area standard and the may affect/no effect standard—leaving hundreds of endangered species near XtendiMax-sprayed fields without any ESA assessment at all. Pet'rs Br. 52-54.

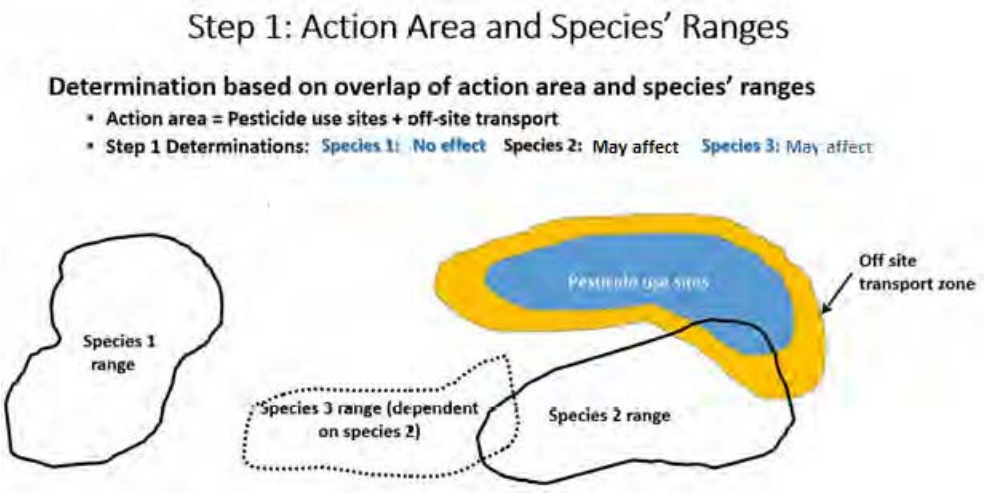
EPA admitted that the 2016 action area—limited to just the crop fields themselves—was erroneous and actually "has resulted in effects" to off-field plants. ER0012. That prior miscalculation alone was legally more than enough to trigger consultation in 2018. The 2018 action area—again just the crop fields themselves, except adding a minimal 57-foot infield buffer in only a small percentage of counties—repeated the same fundamental mistake: it culled the action area (and consequently dramatically limiting what species EPA would conduct species-specific assessment for) to just those areas that dicamba vapor, runoff, and spray would reach in amounts greater than that EPA

unilaterally determined was "below thresholds that would trigger any risk concerns." ER0017.

Yet EPA does not dispute that dicamba *will* escape beyond the fields and new buffer, aka the action area, where it could affect unanalyzed endangered species; nor does EPA dispute that its label mitigation would only *reduce*, but not eliminate dicamba movement beyond the crop field and limited buffer line. Pet'rs Br. 54 (and cites therein); *e.g.*, ER0003, ER0005, ER0017, ER0020. This is not the proper "May Affect" standard: consultation is required not just for effects from dicamba exposure that EPA inexpertly concludes are not unreasonable or of concern, but for any potential effect. Pet'rs Br. 40-41.

Contrary to Monsanto's interpretation, an action area's scope must be "*all areas* to be affected directly or indirectly," 50 C.F.R. § 402.02(d) (emphasis added), not just the narrower parts of those areas that EPA determines will be affected by dicamba drift at levels that EPA determines to be "of concern." The expert agencies' definition is abundantly clear: the action area cannot be "merely the immediate area" of the action, *id.*, which is precisely what EPA constricted it to be

here: the crop fields alone, without the surrounding areas subject to drift. EPA itself elsewhere has explained this:



[17]

Monsanto (but not EPA) urges the Court to defer to EPA's interpretation of the regulatory definition of action area, but it is not EPA's regulation to interpret, nor are they at liberty to interpret it contrary to the ESA. Pet'rs Br. 39. EPA might have discretion in calculating how far a pesticide spreads (so long as supported by the record), but it may not assume it knows what impacts those acknowledged exposures might cause to ESA-protected species or

[17] EPA, *Overview of the Draft Biological Evaluations (BEs) for the ESA Pilot Chemicals (Chlorpyrifos, Malathion, and Diazinon)* 17 (May 5, 2016), *available at* https://www.epa.gov/sites/production/files/2016-05/documents/public_webinar_overview_of_the_draft_bes_final.pdf.

habitat. *Bennett*, 520 U.S. at 169 ("species and habitat investigations [under the ESA]" are not "within the action agency's expertise").[18]

Not only was EPA's action area scope unlawfully limited, its 57-foot buffer was arbitrary and not supported by the record. Pet'rs Br. 59-65; Pet'rs EPA Reply 16-20. EPA initially concluded it must expand the action area by 443 feet (135 meters), based on 10% visual injury, after validating Dr. Norsworthy's study. ER0523-525.[19] Monsanto suggested to EPA that the study was not reliable. ER0523 ("potentially confounding issues"); ER0462-464 (similar discussion, but eliminating the conclusions concerning 10% injury threshold and the 135-m "buffer" as the protective and feasible limit). Monsanto now tries to paint Dr. Norsworthy as unsure and as stating that the study had "complicating factors." Monsanto Br. 52. To the contrary, Dr. Norsworthy indicated that this study area has frequent inversions, is close to a ridge, and the

[18] Monsanto cites *Friends of Wild Swan v. Weber*, but there the Forest Service *did* informally consult and get concurrence from FWS. 767 F.3d 936, 950 (9th Cir. 2014).

[19] EPA also ignored potential aggregate effects to species 900 feet or more from fields from dicamba off-field movement. Pet'rs Br. 63. Monsanto's citations (at 54 n.19) do not show analysis of aggregate effects of these exposure routes. EPA's failure leaves species vulnerable to harm at much greater distances than 57 feet.

soil pH is low relative to other areas of the country, all of which could contribute to extensive off-field damage, even if the combination of factors is complicated. ER0525. Monsanto (at 52) implies that damage from irrigation runoff inflated the visual damage, but EPA eliminated from consideration the only transect receiving irrigation water (where 40% of visual damaged extended about 750 feet). ER0463; ER0525. And, tank mix was not an issue (at 52-53) because plant damage was fundamentally different than what would be expected of acetochlor and the holding time did not alter the pH to enhance volatility. ER0523-524. Monsanto's attack on Norsworthy's study fails.

And while Monsanto (at 50-51) focuses on EPA's reliance on soybean injury, it is scientifically questionable whether soybean height data can be transferred to unique and sensitive plants on the brink of extinction. ER0378 (soybeans not necessarily representative of other plant species "with different growth and reproduction strategies"); ER0019 (uncertainty whether soybean studies adequately represent damage to other plants). In particular, "growth stages of listed plants in the wild will likely not always coincide with that of soybeans or other agricultural crops." ER0409. These studies are for protecting crops, but

the data must be viewed in the ESA context of "any chance" of affecting listed species, and the soybean studies do not account for different growth stages of wild listed plants, nor for the fact that visual signs of injury and height or "yield" for wild plants may be "higher or lower" than on soybeans. ER0409.

Finally, even given its unlawfully narrow scope, EPA went on to eliminate hundreds of species (all but 27) that still overlapped with its action area based on a cursory review of their habitat needs, to conclude "no effect" and avoid consultation. Pet'rs Br. 55-58. Monsanto claims (at 48) that EPA is entitled to make threshold effects determinations, but that simply begs the question of whether EPA appropriately determined "no effect" for all of these species, based on its inexpert review of the species' needs and its unlawfully high bar for "may affect." See *infra* pp.18-20; Pet'rs. EPA Reply 2-6.

The Karner blue butterfly and the rusty patched bumble bee provide good examples that EPA's "no effect" determinations based on habitat considerations are unsupported. Pet'rs Br. 55-57. While EPA offers no response, Monsanto attempts to justify the "no effect" by misinterpreting EPA's conclusion regarding terrestrial invertebrates.

Monsanto Br. 48-49 (citing SER126). It is true EPA ruled out "direct terrestrial invertebrate risks" based on its own RQ/LOC. SER126. EPA accordingly ruled out "indirect effects mediated through these organisms," meaning species that rely on terrestrial invertebrates for food or pollination would not suffer indirect effects. SER126. EPA did *not* conclude that terrestrial invertebrates would not be indirectly affected by harm to plants they rely upon. Instead, EPA expressly found that such indirect effects "*were possible* for any species." SER128 (emphasis in original); ER0009. The Karner and rusty patched both rely on plants that may be damaged by dicamba for food. Pet'rs Br. 55-57. EPA's elimination of these and other species from the action area is unsupported.[20]

Another example is the endangered Mitchell's satyr butterfly, which exists primarily in Michigan and Indiana,[21] soybean states

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[20] Monsanto's argument (at 49) that these species are located "in just a handful of states" where dicamba is registered makes no sense. Any effect on any individual of these *endangered* species has the potential to push the species to being in jeopardy of extinction. Moreover their risk is illustrative of the larger failing of law made by EPA in this case in inexpertly and unilaterally assuming no risk to hundreds of species.

[21] FWS, Mitchell's Satyr Butterfly, https://ecos.fws.gov/ecp0/profile/speciesProfile?spcode=I00K.

covered by the current registration. ER0003.[22] The butterfly has already been lost from 10 of 20 occupied sites and has "30 or fewer individuals present in many sites where it still occurs," leaving this butterfly "more vulnerable and possibly unable to adapt to long-term environmental stochastic events…."[23] Mitchell's needs habitat with "herbaceous community" dominated by sedges, ER1446, plants that may be damaged by dicamba's off-site movement. ER0737-744; ER0751-752. Yet EPA arbitrarily eliminated it from the action area without any consideration of the high risk to a species with such a precarious perch on this planet. *See, e.g.*, ER1446.

D. Whole Formula.

Monsanto's sole contribution (Monsanto Br. 57) is pointing to one graph showing some plant studies were done using XtendiMax, falsely claiming that EPA adequately assessed XtendiMax's whole formula and mixture effects; however EPA actually derived the toxicological endpoints used in its assessments from studies using other dicamba

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[22] USDA, Charts and Maps: Soybeans: Production by County, https://www.nass.usda.gov/Charts_and_Maps/Crops_County/sb-pr.php (last visited Nov. 18, 2019)

[23] FWS, Mitchell's Satyr Butterfly 5-Year Review 12, (2014), https://ecos.fws.gov/docs/five_year_review/doc5949.pdf.

formulations. RER140-143 (specifying "typical end-use product (TEP)" was used to determine toxicology endpoint for terrestrial plants, and noting different forms of dicamba used in other studies). The record elsewhere shows that the toxicity endpoints for terrestrial plants were derived from studies conducted with an older dicamba end-use product (Clarity), which lacked the "inert" VaporGrip components of XtendiMax. ER0393 (original plant toxicological endpoint study MRID 47815102 used Clarity); FER0337-333 (XtendiMax has [redacted]). EPA failed to consider the "direct and indirect effects" of XtendiMax interactions with other ingredients, in violation of the ESA. Pet'rs Br. 72-73; Pet'rs EPA Reply 22-23.

IV. THE COURT SHOULD VACATE THE REGISTRATION.

The Court should vacate the registration and remand for further agency proceedings consistent with its order. Pet'rs Br. 74-75; Pet'rs EPA Reply 33-38.

Monsanto fails to address the seriousness of violation prong, and with regard to disruptive consequences, like EPA, Monsanto improperly focuses only on alleged economic, rather than environmental, consequences from vacatur. Pet'rs EPA Reply 35-36.

Monsanto's citations to the importance of costs in the FIFRA framework omits tremendous drift damage costs to farmers from continuing the registration. Pet'rs Br. 5-12. Moreover unlike FIFRA, the ESA does not permit the weighing of economic costs. *Tenn. Valley Authority v. Hill*, 437 U.S. 153, 184 (1978) ("plain intent" of Congress is to "halt and reverse the trend toward species extinction, whatever the cost."); *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 "regardless of the expense or burden its application might impose.").

Monsanto points out that *Pollinator Stewardship* did not discuss economic costs of vacating the sulfoxaflor registration, but that omission hurts rather than helps them. Like Monsanto here, intervenor Dow made conclusory assertions of extreme disruption.[24] And Monsanto's few conclusory statements of alleged "tremendous harm" (at 58), in addition to being unsupported by any evidence, are refuted by EPA's own findings. ER489 (no evidence that "dicamba provides economic benefits of reducing growers' losses due to weeds … more

[24] Br. for Resp.-Int., *Pollinator Stewardship*, ECF 34-1, at 39 (claiming that vacatur could result in "near total crop loss" and "catastrophic loss" for growers).

effective[ly] than other weed control programs"); ER488 (explaining other "non-chemical control options"); ER486-86 (many alternatives to dicamba).

Monsanto cites the one Ninth Circuit case declining to vacate an unlawful agency approval and considering economic impacts, in part. *California Cmtys. Against Toxics v. U.S EPA*, 688 F.3d 989, 994 (9th Cir. 2012). There, EPA unlawfully approved an air quality plan for Southern California that provided credits to a nearly-completed power plant. The Court found that vacatur would cause environmental harm by delaying completion of that plant, risking the power supply and resulting in blackouts that would necessitate diesel generator use, polluting the air, "the very danger the Clean Air Act aims to prevent." *Id.* The Court also found that halting the plant's construction would be "economically disastrous" and "would likely require the California legislature to pass a new … needless and duplicative" law. *Id.* Thus the cognizable, catastrophic economic harm was certain to happen, and

occurring in conjunction with the environmental harm the Court emphasized in declining vacatur.[25]

Monsanto (at 60-61) urges the Court to wade into the evidentiary thicket to "carefully tailor" the vacatur geographically, to only certain endangered species, states, counties, or presumably even individual crop fields. But unlike an injunction,[26] vacatur simply sets aside the unlawful agency action, resetting the legal status of the issue to the *status quo ante*. If EPA subsequently wishes to take a different, narrower proposed registration, it is free to do so within the bounds of the law and the Court's order. That is why courts do not undertake detailed evidentiary hearings of scope in the first instance, and instead simply vacate unlawful agency actions. As the Ninth Circuit recently stated "[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." *Regents of*

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[25] There was also a distinct public good element to this "economic" harm, since this was about "saving the power supply," *California Cmtys. Against Toxics*, 688 F.3d at 994, not merely Intervenor Monsanto's profit margin.

[26] Monsanto cites *Califano v. Yamaski*, 442 U.S. 682 (1979) but it is an injunction, not vacatur, case.

the Univ. of California v. U.S. Dep't of Homeland Sec., 908 F.3d 476, 511 (9th Cir. 2018), *cert. granted sub nom. U.S. Dep't of Homeland Sec. v. Regents of the Univ. of California*, 139 S. Ct. 2779 (2019) (citing Nat'l *Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998)); *Desert Survivors v. US Dep't of the Interior*, 336 F. Supp. 3d 1131, 1135-136 (N.D. Cal. 2018), *appeal dismissed sub nom. Desert Survivors v. U.S. Dep't of the Interior*, No. 18-17054, 2018 WL 7117946 (9th Cir. Nov. 19, 2018) (rejecting that "the Court should place a geographical limitation on the vacatur of the SPR Policy on the basis of Article III standing."); *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 913 (1990) (Blackmum, J., dissenting) (in dissent "expressing the view of all nine justices" on the same question, stating that in vacating, "the result is that the rule is invalidated, not simply that court forbids its application to a particular individual.").

Finally Monsanto attempts to reverse the remedial burden in arguing that Petitioners must show what they call "a genuine risk of harm." Monsanto Br. 60. It is Respondents who carry the burden to escape anything but vacatur. Nor is it Petitioners' job (or the Court's) to do the very risk analysis that the expert agencies must be given the

chance to undertake during consultation. All that must be determined by the Court is whether vacating is safer for the environment and endangered species. Given the unprecedented nature and scope of the agency's approval, and shear number of endangered species at risk, the answer to that is plain.

Respectfully submitted this 18th day of November, 2019.

/s/ George A. Kimbrell
George A. Kimbrell
Sylvia Shih-Yau Wu
Amy van Saun
2009 NE Alberta St., Suite 207
Portland, OR 97211
T: (971) 271-7372
gkimbrell@centerforfoodsafety.org
swu@centerforfoodsafety.org
avansaun@centerforfoodsafety.org

/s/ Stephanie M. Parent
Stephanie M. Parent
PO Box 11374
Portland, OR 97211
T: (971) 717-6404
SParent@biologicaldiversity.org

Counsel for Petitioners

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