Case Nos. 17-70810, 17-70817

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

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

On Petition for Review from the
United States Environmental Protection Agency

PETITIONERS' OPENING SUPPLEMENTAL BRIEF (REDACTED)

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INTRODUCTION

The gravamen of the Endangered Species Act (ESA) issues before this Court is whether Respondent EPA and Intervenor Dow can re-define the ESA's "may affect" standard to mean "some effect, but just not more than we think is of concern." They cannot. EPA violated the ESA by registering Enlist Duo without any form of consultation with the expert agencies.

EPA approved this novel pesticide with two active ingredients to be sprayed on 3 major crops for the first time, in a new way, at new times of the year, across 34 states and 185 million acres, which government studies show will increase 2,4-D use between 200-600 percent. ER353, ER414, ER443. EPA found 531 ESA-protected species and 184 designated critical habitats overlap with the action area. ER575, ER726-952. It nonetheless concluded the registration could have absolutely no possible effect on hundreds of endangered plants and animals and their critical habitats and thus had no obligation to consult the expert wildlife agencies. That unprecedented decision was contrary

to the controlling legal standards, scientific standards, and the record evidence.[1]

This Court has held that the entire registration is properly before it, including the subsumed 2014 and 2015 registrations and their supporting assessments. ECF 166. That decision underscores the following. First, EPA had multiple shots at this registration, and instead of fixing its original violations of law, the agency doubled (and tripled) down on them, while simultaneously expanding the registration. Second, none of National Family Farm Coalition *et al.* Petitioners' (NFFC) challenges fundamentally change but are only strengthened, because EPA did not meaningfully change its process or conclusions as to its ESA determination, or its challenged FIFRA determinations on volatility and tank mixing. Finally, the rightful remedy is vacatur of the entire registration.

[1] This supplemental briefing incorporates NFFC's opening briefing, ECF 64-1, and reply briefing, ECF 118.

ARGUMENT

I. EPA Violated the ESA

This case is a chapter in a two-decade saga over EPA's failure to comply with the ESA when dealing with pesticides.[2] *Wash. Toxics Coalition v. EPA*, 413 F.3d 1024, 1029 (9th Cir. 2005); *Defenders of Wildlife v. EPA*, 882 F.2d 1294, 1299-1300 (8th Cir. 1989). This includes a substantially similar prior attempt to circumvent ESA consultation duties struck down by the courts. ECF 64-1 at 27, ECF 118 at 31-32 (discussing *Washington Toxics v. EPA*, 475 F. Supp. 1158 (W.D. Wash. 2006)).

A. The National Academy of Sciences' Report

To address continuing disagreements, EPA and the wildlife agencies requested that the National Academy of Sciences ("Academy") evaluate the best scientific approach for assessing the effects of

[2] Avi Garbow & Paul Souza, *Aligning Imperiled Species Conservation and Pesticide Registrations*, 33 Va. Envtl. L. J. 172 (2015) (discussing interplay between the statutes and the role of the National Academy of Sciences); Mary Jane Angelo, *The Killing Fields: Reducing the Casualties in the Battle Between U.S. Species Protection Law and U.S. Pesticide Law*, 32 Harv. Envtl. L. Rev. 95, 111-128 (2008) (recounting litigation history).

registrations on endangered species. The 2013 Academy report[3] covering all 3 steps of the consultation process: Step 1, the "may affect" determination, Step 2, informal consultation, and Step 3, formal consultation. SBER001-195. The report has two core conclusions most relevant here.

First, with regards to Step 1, *any* potential exposure to the pesticide is a "may affect" trigger. Because of pesticides' inherent toxicity and listed species' biological expertise required for the broad and unique ESA analysis, EPA should proceed to Step 2 and at least informally consult, if there is any spatial overlap between the pesticide's potential use and the habitats of listed species. SBER028 ("Step 1 (EPA). Initial exposure modeling would answer the question, Do the areas where the pesticide will be used overlap spatially with the habitats of any listed species? … Step 2 (EPA). If area *overlaps* are identified in Step 1, EPA *would confer* with the Services …") (emphases added); SBER072 (substantially similar language); SBER051 (emphasis added):

[3] National Academy of Sciences, *Assessing Risks to Endangered and Threatened Species from Pesticides*. SBER001-195.

> In Step 1, EPA would consider whether any listed species might be harmed by the pesticide *simply by asking whether areas proposed for pesticide application and known (or suspected) species ranges or habitats coexist*. Not all listed species exist everywhere, nor are all pesticides used everywhere, so that simple formulation of the problem would help narrow the scope of later assessments. In Step 2….

Step 1 overlap analysis should lead to a "may affect" determination "almost always:"

> In Step 1, the action agency (EPA) determines whether the action 'may affect' a listed species. If the answer is yes (*as it almost always is at the screening level for outdoor-use pesticides because 'may affect' is interpreted broadly),* EPA has two options: it can enter into formal consultation or proceed to Step 2—an optional step known as informal consultation—in which it must determine whether the action is 'likely to adversely affect a listed species.'

SBER048 (emphasis added); *accord* SBER069.

Second, the Academy addressed the outmoded 2004 "Level of Concern/Risk Quotient" (RQ/LOC) FIFRA process and metrics EPA applied here, and resoundingly rejected it, concluding that it is "not scientifically defensible for assessing the risks to listed species posed by pesticides . . . ." SBER034; SBER168-169 (criticizing the use of RQ/LOCs at length, as making assumptions that are "not reliable;" with "unpredictable performance outcomes;" and as "not appropriate for assessments for listed species").

Following the Academy's report, EPA and the Wildlife Agencies published a guidance outlining pesticide consultations going forward and committing to follow the Academy's recommendations.[4] At Step 1, when EPA determines if a pesticide use authorization "may affect" any species or critical habitat, it does so based on overlap with the action area. *Id.* at 2 (Figure 1), 4. Further, following ESA regulations, the "action area" is determined by examining "potential [pesticide] use sites combined with the range of off-site transport to identify the area of potential effects in and around use sites." *Id.* at 4-5. Where there is "may affect" based on overlap, the guidance directs EPA to proceed to a second step, informal consultation or "Likely to Adversely Affect" or "Not Likely to Adversely Affect" determination, to analyze the degree to which the pesticide may impact species. *Id.* at 7. As appropriate the third step is formal consultation and preparation of a biological opinion. *Id.* at 10.

[4] U.S. Envtl. Prot. Agency, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences*, at https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf.

B. EPA's Approach Elsewhere

In stark relief to here, recent EPA biological evaluations for chlorpyrifos, malathion, and diazinon followed the Academy's scientific methodology.[5] Unlike the "no effect" conclusion for hundreds of species here, EPA determined that each pesticide resulted in not just "may affect," but "likely to adversely affect" determinations for hundreds of species. For chlorpyrifos, for use on cotton, soybeans and other crops, EPA made a "may affect" determination for 99% of listed species (1819 of 1835) and a "likely to adversely affect" determination for 97% (1778 of 1835) of listed species.[6] Similarly, for malathion, the call was "may affect" for 99% (1819 of 1835) and 97% "likely to adversely affect," (1778 of 1835).[7]

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[5] U.S. Envtl. Prot. Agency, *EPA Releases Final Biological Evaluations of Three Chemicals' Impacts on Endangered Species* (Jan. 18, 2017), *available at* https://www.epa.gov/pesticides/epa-releases-final-biological-evaluations-three-chemicals-impacts-endangered-species.

[6] U.S. Envtl. Prot. Agency, *Chlorpyrifos Executive Summary for ESA Assessment* i, iv (Tables 1 & 2), *available at* https://www3.epa.gov/pesticides/nas/final/chlorpyrifos/executivesummary.docx.

[7] U.S. Envtl. Prot. Agency, *Executive Summary for Malathion ESA Assessment* i, iv (Tables 1 & 2), *available at*

C. EPA's "No Effect" Determinations Are Contrary to Law

At issue here is simply the Step 1 "may affect" threshold, not the other consultation steps. ECF 64-1 at 17-20. If Enlist Duo "may affect" any endangered species or critical habitat, then EPA *must* consult the expert agency, Fish and Wildlife Service (FWS). 50 C.F.R. §§ 402.14(a), 402.01(b).

This Court sitting *en banc* defined the "may affect" standard, as "*any possible effect*, whether beneficial, benign, adverse, or of an undetermined character." *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (en banc); *id.* ("[A]ctions that have *any chance of affecting* listed species or critical habitat—even if it is later determined that the actions are 'not likely' to do so—*require* at least some consultation under the ESA") (emphases added).

This is also how the expert wildlife agencies define the "may affect" threshold. 51 Fed. Reg. 19,926, 19,949 (June 3, 1986).[8] As have

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https://www3.epa.gov/pesticides/nas/final/malathion/executive-summary.docx.

[8] Congress assigned FWS the job of ESA implementation, and as such FWS is entitled to deference, whereas EPA's decisions, as merely an action agency, are entitled to none in the ESA context. ECF 64-1 at 22-23.

numerous other prior panel decisions of this Court. *See, e.g., W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 496 (9th Cir. 2011); *California ex rel. Lockyer v. U.S. Dept. of Agriculture*, 575 F.3d 999, 1018-19 (9th Cir. 2009).[9]

It is intentionally a very low threshold. *Karuk Tribe*, 681 F.3d at 1027; *Lockyer*, 575 F.3d at 1018. This is because action agencies like EPA are not experts on the conservation of endangered species: The low bar to trigger the next steps—and required involvement of the expert wildlife agencies—reflects the overarching congressional intent of "institutionalized caution." *Cottonwood Environmental Law Center v. U.S. Forest Serv.*, 789 F.3d 1075, 1091 (9th Cir. 2015) (quoting *TVA v. Hill*, 437 U.S. 153, 194 (1978)). The low "may affect" threshold and strict adherence to engaging in the consultation procedure is necessary to make sure agency actions meet the substantive mandate of insuring no jeopardy to species already on the brink of extinction. *Karuk Tribe*, 681 F.3d at 1027; 51 Fed. Reg. at 19,949; *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985) ("[T]he strict substantive provisions of the ESA justify *more* stringent enforcement of its procedural requirements,

[9] ECF 64-1 at 18-20; ECF 118 at 7-9; ECF 165-1 (citing cases).

because the procedural requirements are designed to ensure compliance with the substantive provisions.") (emphasis in original); ECF 64-1 at 17-19.

1. EPA Applied an Unlawful Standard

EPA did not apply the ESA "May Affect/No Effect" standard, as defined by this Court and the expert agencies. ECF 64-1 at 21-25. Instead it applied its LOC, a FIFRA risk interpretation tool, imported into the ESA context. ECF 64-1 at 23-24; ECF 118 at 11-13; ER18-19; ER2529. For ESA-protected species found directly in Enlist Duo-sprayed fields, EPA concluded "no effect" whenever its Risk Quotient (RQ), which is the measure of harm or mortality when a species is exposed to a certain amount of pesticide, did not exceed its own Level of Concern (LOC), which represents an arbitrary level of harm or mortality acceptable to EPA. ECF 118 at 13-16; ER1045, ER2043-44.

FIFRA and the ESA are very different statutes in crucial legal and scientific ways. ECF 64-1 at 21-23 (listing differences); *Wash. Toxics*, 413 F.3d at 1032 (EPA must comply with both). They assign EPA different duties based on different policies, different scopes, and different legal standards. Under FIFRA, EPA need only determine

adverse effects are not "unreasonable" based on a policy-based weighing of costs against the benefits. 7 U.S.C. § 136(bb). Whereas the ESA is designed to insure agency actions do not push imperiled species to extinction, emphatically prohibiting such cost-benefit balancing. *Hill*, 437 U.S. at 184; *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 929 (9th Cir. 2008). EPA's fundamental error was substituting FIFRA's less protective standards and processes for the ESA's. *Wash. Toxics*, 457 F. Supp. at 1184 ("The risk framework of FIFRA (no unreasonable adverse effects) does not equate to the survival and recovery framework of the ESA."). "May affect" means "any possible effect," *Karuk Tribe*, 681 F.3d at 1027, not just what EPA decides in its balancing is adverse or unreasonable.

2. Below EPA's Level of Concern is Not the Same as "No Effect"

What EPA actually assesses with its LOC "interpretative policy" is some level of adverse effects—in other words, harm to species or habitat that EPA will tolerate—not no effect. ER2529 ("LOCs are the agency's interpretative policy" and "indicate when a pesticide used as directed has the potential to cause *adverse* effects"); ER18 ("LOCs are criteria used by the agency to indicate potential risk to non-target

organisms. The criteria indicate whether a pesticide, when used as directed, has the potential to cause *adverse* effects to non-target organisms."); ER584 (uses not expected to "directly *adversely* affect" certain taxa of species) (emphases added). Yet what EPA might unilaterally deem not an adverse or sufficiently toxic effect is not the Step 1 consultation standard of "may affect" or "any chance of affecting" species or critical habitat. *Karuk Tribe*, 681 F.3d at 1027 (consultation required even if EPA later determines the action is not likely to adversely affect species or habitat).

An RQ below the LOC does not equate to "No Effect." In fact it is a finding of a measurable potential for *harm*. In the only 23 instances in which the agency did a species-specific risk assessment, EPA actually found a measurable harm from acute and/or chronic Enlist Duo exposure for each and every one. ER654-678; *e.g.*, ER657 (Indiana Bat, "acute RQ of 0.04 does not exceed the acute listed species LOC (0.1). A chronic RQ of 0.31 does not exceed the chronic LOC of 1.0 for listed species"); ER659 (similar, Virginia big-eared bat); ER660 (similar, Gray

Wolf); ER664 (similar, Ocelot); ER668 (similar, Whooping Crane).[10] NFFC's prior briefing focused on two of the most critically endangered species, the Whooping Crane and the Indiana Bat, as telling examples of EPA's application of an unlawfully high bar, going far beyond may affect. ECF 64-1 at 37-47; *e.g.,* ER1776 (for the Indiana Bat, EPA concluding it was unable to make "a 'no effect' determination," then independently "explored the roles of various assumptions of bat biology and habitat use to evaluate the likelihood of exceeding toxic thresholds for growth and survival" rather than consult with FWS); ER1780 (finding "considerable uncertainty" of toxicity yet still not consulting).

EPA has a "No Observed Effect Level," (NOEL) that is over ten-fold lower, ER625, but did not use that as its threshold in these assessments: it used the "No Observed *Adverse* Effects Level" (NOAEL). The toxicity threshold used in the chronic effects calculations for ESA-protected mammals is 55 mg/kg/day, which it classified as the NOAEL.

[10] An acute RQ of 0.04 means that Indiana bats would be exposed to 4% of the dose of 2,4-D that would kill 50% of the population (LD50). A chronic RQ of 0.31 means that Indiana bats are exposed to 31% of the highest 2,4-D exposure level found to not cause a subset of predetermined adverse effects in long-term tests on a surrogate mammal species (rats), whereas the next higher test dose caused adverse effects. ECF 118 at 13-14.

ER626 ("adverse effects occur only at dose levels" above 55 mg/kg/day); ER657, 658, 660, 661, 662, 663, 664 (applying NOAEL in the "no effect" calculations for in-field species); ER1458-1461 (applying NOAEL to determine "no effect"). EPA's NOAEL threshold reveals it was looking for what it unilaterally deemed to be cognizable *adverse* effects—not *any* effects. This is not the proper Step 1 inquiry, which requires consultation for "any effect," not just those that EPA unilaterally would deem as adverse or toxic.[11]

Moreover, mortality is one extreme harm; the acute LOC does not account for sub-lethal harms, nor does the chronic LOC take account of potential pesticidal harms EPA does not assess, such as impairment of a fish's ability to escape predators. This mismatch means a "no effect" decision from EPA can actually have grave consequences. Consider a prior EPA attempt to declare "no effect" on ESA-protected salmon species from authorized use of certain pesticide active ingredients. The expert wildlife agency explained that EPA's approach to determine "no effect" based on exposure concentration of less than 5% of the LC50

[11] If EPA believes an effect is insignificant or discountable, that cannot be—*as a matter of law*—"no effect," because it is by definition "not likely to adversely affect," an analysis and decision that requires informal consultation and written concurrence of FWS. ECF 64-1 at 28-29.

underestimates risk to listed salmonids based on swimming behaviors.[12] After extensive evaluation of the effects using appropriate standards, status of the species and its critical habitat, and other threats to the species in the environmental baseline, the expert wildlife agency found jeopardy for some species EPA had (mis)determined "no effect."[13] This is why at least some consultation is required for *any* possible effects.

Finally, EPA record statements repeatedly acknowledged there were potential effects, which should have triggered consultation. ECF 64-1 at 31-32 (and record citations therein); *e.g.*, ER24 (endangered birds, reptiles, amphibians "could not be excluded for acute risk"). These recurrent admissions alone are as a "textual matter" enough to resolve

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[12] Nat'l Marine Fisheries Serv., ESA Section 7 Consultation Biological Opinion, EPA Registration of Pesticides Containing Azinphos methyl, Bensulide, Dimethoate, Disulfoton, Ethoprop, Fenamiphos, Naled, MEthamidophos, Methidathion, Methyl parathion, Phorate and Phosmet (Aug. 31, 2010) (Item #3), *available at* https://www.fisheries.noaa.gov/national/consultations/pesticide-consultations.

[13] For example, NMFS determined jeopardy from naled, phosmet and phorate on California Coastal Chinook; EPA had determined "no effect." *Id.* at 25 (Table 1, EPA determinations), *compare with id.* at 773 (Table 195, NMFS conclusions).

the issue and support a "may affect" conclusion. *Karuk Tribe*, 681 F.3d at 1028.[14]

D. EPA's Treatment of the Action Area Violated the ESA

Even using EPA's unlawfully flawed rubric, only a few species even received a specific ESA assessment. EPA started with 531 species "inside the action area" (ER25; ER649), but categorically excluded 501 by reducing the Action Area to just the sprayed fields. For those, EPA conducted no species-specific ESA assessment at all. This was contrary to the record as well as the controlling legal standards for "may affect" and action areas. ECF 64-1 at 33-37.

First, EPA admitted the label mitigation would only effectively *reduce*—not eliminate—the likelihood of off-field impacts, to below EPA's FIFRA LOC. ECF 64-1 at 34-35 (and record citations therein); ER19 ("reduce exposures off-site"); ER20 (same); ER29 (mitigation would "reduce the likelihood of spray drift and volatilization" beyond fields and limit "adverse effects" to the field itself); ER643 ("while there

[14] The issue is not that EPA should have made only one attempt at determining effects, as Respondents mischaracterize; it is that, once EPA found there was any potential of any effect during its assessment, it should have continued the process, but through informal consultation with FWS.

are uncertainties in the risk conclusions for terrestrial invertebrates, it is likely that the spray drift mitigation measures on ED label will serve to reduce exposures in areas off the treated site"); ER642-44 (repeatedly saying "reduce exposures"); ER77 ("will not result in drift levels that reach toxic effect for off-field listed or non-listed organisms"); ER1043 ("exposures were only above levels of concern to organisms on treated fields").

It is undisputed that some Enlist Duo will escape the fields. ECF 64-1 at 33 (and citations therein); ER1043 ("the agency makes no claim that drift and runoff do not occur" but found only that with mitigation "exposures high enough to cause acute or chronic effects are not reasonably expected to occur"); ER73 ("EPA made no assumption that spray drift will stop at field boundaries"); ER71 ("EPA does not expect spray drift to remain confined to the ED treated field."); ER23 (use restrictions will "reduce the amount available for runoff" but not eliminate it).

Again EPA was looking through the wrong lens: the Step 1 "No Effect/May Affect" standard is not just what EPA thinks is an "adverse" or "toxic" or "acute" or "chronic" effect, but "any possible effect" on or off

the fields. *Karuk Tribe*, 681 F.3d at 1027. EPA did not look for these effects and thus its "no effect" determinations were not compliant with the ESA.

Second, ESA regulations define "action area" to be "all areas to be affected directly or indirectly by the federal action and *not merely the immediate area* involved in the action." 50 C.F.R. § 402.02 (emphasis added). In other words, by definition, not just the fields, which is what EPA has tried to cut the action area down to here, eliminating 501 species from any potential consultation duty. Indeed, EPA told Congress in 2014 that the pesticide action area "will include a footprint that extends beyond the use sites to incorporate off-site transport including pesticide spray drift and runoff." ECF 118 at 23.

Third, EPA's cabining of the action area and categorical "no effect" classification for 501 species is all predicated on mitigation, the Enlist Duo label use restrictions. ER640 ("Mitigation requirements are considered adequate to achieve a drift deposition off the treated field that falls below levels of concern for non-target organisms, including effects thresholds for listed species."); ER644 ("without spray drift mitigation, direct effects are predicted" due to runoff, and mitigation

will only "reduce exposures" to "below risk concern levels" but not eliminate them).

Yet *Karuk Tribe* held that mitigation reliance like this "cuts against, not in favor of" having no duty to enter consultation and proceed to Step 2. *Karuk Tribe*, 681 F.3d at 1028. As in *Karuk Tribe*, the perceived need to reduce potential effects underscores that effects are *possible* to off-field species, which is all that is required to compel consultation. *Id.* In fact the Court zeroed in on the exact same "reduce not eliminate" agency language as here to demonstrate the agency's misinterpretation of the standard. *Id.* (miners following agency "criteria should *'reduce' – not eliminate* – the impacts to anadromous fisheries") (emphasis added).

Finally, consider the mitigation buffer on which EPA relies for its decision to categorically exclude hundreds of species: a 30-foot, *unidirectional* ("downwind") in-field buffer. ER33-34, 104-105. That means if there is an endangered species present on one or more other sides of the field, EPA refused to consider it within the action area and categorically found no effect. ER599 ("areas adjacent to treated fields could include other cultivated fields, fencerows and hedgerows,

meadows, fallow fields, grasslands, woodlands, riparian habitats, and other uncultivated areas."). Further, the buffer is only "intended to mitigate spray drift, but it is not intended to mitigate concerns from runoff" from precipitation, irrigation, or vapor drift/volatility. ER22. In addition to violating numerous ESA standards, EPA's reliance was arbitrary and capricious, failing to make a rational connection between those facts found and the "no effect" conclusion made. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm*, 463 U.S. 29, 43 (1983); ECF 64-1 at 33.[15]

E. EPA's Scope Was Unlawfully Narrow, Failing to Consider All of the Enlist Duo Pesticide

EPA's assessment also violates the ESA because of its narrowness: EPA focused solely on the 2,4-D component of Enlist Duo. ER568 (scope limited to the 2,4-D ingredient); ER24 (same). Yet EPA approved the *entire* pesticide product, Enlist *Duo*, not just the 2,4-D component. The "may affect" determination requires determining the scope of what an "effect" is, that "may affect" any protected species or habitat. "Effects of

[15] EPA also independently violated the ESA by failing to consult with FWS about designated critical habitat. ECF 64-1 at 49-56; ECF 118 at 26-28. As with its species' ESA determinations, EPA compounded its same errors of law and wrong standard in its 2014/2015 registrations again in the 2017 registration.

the action" are defined very broadly, as "the direct and indirect effects of an action on the species or critical habitat, together with the effects of other activities that are interrelated or interdependent with that action that will be added to the environmental baseline." 50 C.F.R. § 402.02; *Karuk Tribe*, 681 F.3d at 1020 ("Congress intended agency action to have a broad definition in the ESA"). The glyphosate component is not a separate agency action; EPA approved it in the same action and same product. The same is true as to the rest of the Enlist Duo product formulation, its inerts and surfactants. This failure was arbitrary and capricious and contrary to law. *State Farm*, 463 U.S. at 43 (failure to consider an important part of the problem).

F. EPA Failed to Meet its Burden to Show it Met the ESA's Best Science Mandate

The registration was also contrary to the best scientific standards for ESA pesticide consultations. Section 7 codifies that standard, requiring agencies to "use the best scientific and commercial data available" in complying with its mandates. 16 U.S.C. § 1536(a)(2). That mandate "prohibits [an agency] from disregarding available scientific evidence that is in some way better than the evidence [it] relies on." *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1080 (9th Cir. 2006).

EPA failed to provide a reasonable explanation for why its RQ/LOC approach was the best available science—particularly where EPA's own established policy recognized that the Academy approach was the best available science and where the Agency had adhered to that approach in other recent pesticide consultations. This was arbitrary and capricious. The Academy is the scientific gold standard, charged by Congress with "providing independent, objective advice to the nation on matters related to science and technology."[16] EPA knew the Academy rejected its RQ/LOC metric as "not scientifically defensible" and "not reliable." SBER034, 168. And directed the agencies to use a Step 1 "may affect" and action area approach EPA refused to use here. *See supra.*

That failure is even more egregious because EPA previously recognized the Academy approach was the best science available and followed it in the recent chlorpyrifos, malathion, and diazinon biological evaluations. [17] EPA acknowledged it "did not follow the NAS

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[16] Nat'l Academy of Sciences, *Mission*, http://www.nasonline.org/about-nas/mission/.

[17] EPA made the same promise to Congress: "The 'No Effect/May Affect' determination will largely be based on the overlap of the action area with the species' ranges and designated critical habitats (i.e., any

recommendations" with Enlist Duo, saying that by the Report's 2013 issuance, EPA already had finalized its Enlist Duo "screening level assessments" and EPA was adopting a "day forward" approach. ER1442. Yet that does not explain why EPA *still failed* to follow the Academy's recommendations in the *2017* registration decision here challenged, *4 years after* the Academy's report. EPA's use of an older, discredited, and unlawful scientific evaluation technique was arbitrary and capricious. *Sierra Club v. EPA*, 671 F.3d 955, 966-68 (9th Cir. 2012) (EPA action held arbitrary and capricious for not utilizing more recent model).

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species or critical habitat that overlaps with the action area *will be considered a 'May Affect'*)." U.S. Envtl. Prot. Agency, *Interim Report to Congress on Endangered Species Act Implementation in Pesticide Evaluation Programs* (Nov. 2014) (emphasis added), *available at* https://www.epa.gov/sites/production/files/2015-07/documents/esareporttocongress.pdf. This report also briefly mentions the Enlist Duo registration, but fails to tell Congress that EPA did not use the Academy-endorsed ESA methodology. Nor has FWS endorsed EPA's approach here in any way, contrary to Respondents' suggestion; EPA's unilateral misappropriation of the process cut FWS out of the process, leaving them no opportunity to object to EPA's conclusions.

II. EPA Violated FIFRA

A. EPA's Volatility Assessment was not Supported by Substantial Evidence

EPA's volatility assessment was supposed to determine and compare two quantities: harm threshold and vapor drift; that is: (1) the minimum concentration or dose of 2,4-D vapor that harms sensitive plants; and (2) the concentration of 2,4-D vapor that drifts beyond a sprayed field. If (2) exceeds (1), then Enlist Duo threatens off-field plants and registration would not ensure Enlist Duo would not cause unreasonable adverse effects on the environment. EPA ratified Dow's conclusion that off-field vapor concentrations "are likely below plant injury thresholds" (SER480-81), and on this basis decided no buffer zones were needed to protect plant from vapor injury. This is a critical part of the registration, given 2,4-D's notorious history of causing major drift damage (ER1959-2000; FER152, 164) and that EPA's conclusions of no unreasonable adverse effects are predicated on the assumption that harmful amounts of Enlist Duo will not leave the fields. However, the studies on which EPA relied were flawed and did not comply with

EPA's testing requirements.[18] EPA compounded its errors by doubling down on them: None of these flaws in the original 2013 assessment and 2014 registration were fixed in EPA's 2016 volatility risk assessment. *Compare* ER2082-83 *with* ER646-47.

1. 2,4-D vapor is harmful at lower concentrations than Dow-EPA estimate

EPA scientists found that Dow's vapor-phase harm threshold study (ER3190-94, the "Ouse study") was "of very limited value" due to numerous regulatory violations (ER2086-87), including failure to follow "Good Laboratory Practices" (GLP). [redacted] (SER685; SER497). The regulation-compliant repeat study EPA scientists requested (ER2086-87) was never submitted.[19] Petitioners showed that EPA's attempt to salvage the Ouse study by relating it to the entirely unrelated 1991 Ogg study was not supportable, ECF 118 at 37-39, and that EPA scientists recommended a 2,4-D vapor harm threshold [redacted] ([redacted]) than the

[18] ECF 64-1 at 59-62; ECF 118 at 36-40.

[19] The study EPA incorrectly cites as the do-over (SER448-49) is [redacted], not the requested vapor-phase harm threshold study (ER2032).

1.9 ug/m^3/h threshold that EPA management proceeded to use in the final risk assessment, ECF 64-1 at 61-62; ER3191-3192.

2. Vapor drift is greater than Dow-EPA estimate

Dow conducted a field volatility study to estimate the volatilization (flux) rates of 2,4-D choline, and computer modeling to translate the flux rates into estimates of off-field 2,4-D vapor concentrations when "commercial-size fields" are sprayed. SER480-81. This study did not comply with EPA regulations or Good Laboratory Practices: Among six deficiencies in the field study flagged by EPA scientists was the reliance on non-label application rates, violating EPA test guideline 835.8100. SER463; ECF 118 at 40.

Dow's modeling exercise was likewise flawed. Rather than model "commercial-size fields" (SER480-81), Dow modeled the vapor drift that would occur from spraying "a theoretical field of 40 acres" using the "PERFUM" model. SER517.[20] Because vapor drift increases with the size of a sprayed field, necessitating larger buffer zones,[21] and typical

[20] Modeling is needed to scale up vapor drift estimates from the tiny plots Dow sprayed in its field volatility study (1.73-2.35 hectares = 4.27-5.80 acres) to commercial-size fields. SER483-84 (Tables 1 & 2).

[21] As EPA stated in another volatilization assessment using the same model: "As field size increases so do predicted buffer zones….," where

corn, soybean, and cotton fields sprayed with Enlist Duo are many-fold larger than 40 acres,[22] Dow and EPA greatly underestimated real-world off-field vapor concentrations. EPA's volatility assessment was not based on substantial evidence. *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 529-30 (9th Cir. 2015).

B. EPA Failed to Account for Glufosinate's and Enlist Duo's Synergistic Effects

Farmers do not spray Enlist Duo alone: they often tank mix it with other pesticides. In order to support its registration with substantial evidence EPA must account for risks from Enlist Duo tank mixes intended for use. 7 U.S.C. § 136a(c)(5)(B) (in conjunction with 7 U.S.C. § 136a(c)(5)(C), (D), requires EPA to consider whether, taking

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buffer zone size reflects the distance traveled by vapor at concentrations exceeding a harm threshold. U.S. Envtl. Prot. Agency, *Iodomethane: Revised HED Human Health Assessment Which Incorporates Results of Human Iodine Monitoring*, at 68 & Fig. 22 at 61-62 (2007) *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2005-0252-0051. *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998-99 (9th Cir. 2010) (agency documents available on U.S. government websites are judicially noticeable).

[22] U.S. Dep't of Agric., Econ. Research Serv., *Farm Size and the Organization of U.S. Crop Farming* 1, 12 (2013) (Table 2) (midpoint acreage of corn (600 acres), soybean (490 acres) and cotton (1,090) farms), *available at* https://www.ers.usda.gov/webdocs/publications/45108/39359_err152.pdf.

into consideration the uses contemplated by the label, there will be unreasonable adverse effects); ER100 (tank mixing restrictions/instructions are part of the labeling).[23] EPA knows tank mix risks are within the registration's scope: EPA set up measures to account for the possibility of spray drift distance increases from tank mixing Enlist Duo. ER32; ER40-42 (requiring testing for spray drift changes before allowing pesticides to be tank mixed).

EPA also knows that synergy between pesticides can cause different risks, such as increased toxicity: that was the rationale for the *Enlist Duo I* remand, potential synergistic effects between glyphosate and 2,4-D. ER2-3; ER1003-1006 (testing for glyphosate and 2,4-D synergy).[24] Synergy is fundamentally different than increasing spray drift distance: it is increased toxicity within the same distance. ECF 118 at 44. EPA failed to apply this same diligence to tank mixing synergy concerns. EPA bears the burden to show its registration was supported by substantial evidence, and did not.

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[23] ECF 64-1 at 63-65; ECF 118 at 40-45.

[24] Despite this synergy recognition, the tank mix sections of the 2014 and 2017 decisions shows no change. *Compare* ER1404-1407 *with* ER40-44.

This failure was particularly acute because Dow's Enlist Duo business plan strategically involves a third pesticide: glufosinate. FER1. Dow went to the trouble of genetically engineering Enlist Duo crops with immunity to glufosinate, not just glyphosate and 2,4-D. ER3202, 3188-89. And the record includes evidence showing synergistic risks *specific to the use of glufosinate and Enlist Duo*. ER471-73; ER129-143. Nor is there some later process that will address synergistic effects: assuming glufosinate or another pesticide completes the spray distance testing requirement, ER32; ER40, it can then be tank mixed with Enlist Duo, with nothing further required. EPA's failure to account for these intended and foreseeable synergy risks rendered its decision unsupported by substantial evidence.

C. EPA Made a Mess of FIFRA's Registration Standards

EPA muddled the applicable registration standards, so much that at times it is unclear exactly what standard the agency claims it is using, when and how, or what part of conditional or unconditional standards it was mixing and matching and applying at various times during the registration. EPA's briefing explanations do not match the record explanations. This inconsistency, lack of record (as opposed to

post hoc) explanation, and the inability to discern the agency's path is alone grounds to vacate and remand. *Native Ecosystems Council v. U.S. Forest Serv.*, 418 F.3d 953, 965 (9th Cir. 2005) ("In an administrative appeal, we cannot divine the grounds for government decisions that are not explained or apparent.").

A lawful § 136a(c)(7)(B) conditional registration for "additional uses" of a pesticide requires both: (1) a valid underlying unconditional registration for the initial uses of the pesticide—which itself requires a determination, based on a complete dataset, that those uses would not cause "unreasonable adverse effects," 7 U.S.C. § 136a(c)(5); 40 C.F.R. § 152.112(b), (c); *and* (2) a *further* determination, based on a dataset for which certain gaps are authorized, that the additional uses will not "significantly increase the risk of any unreasonable adverse effect" beyond the baseline unconditional registration. ECF 118 at 33.

EPA failed to meet this dual requirement. The Agency impermissibly registered Enlist Duo's inaugural uses conditionally and thus failed to meet the first prerequisite for a § 136a(c)(7)(B) registration. EPA's insistence that it went above and beyond for the second prerequisite does nothing to compensate for the Agency's failure

to meet the first prerequisite: a lawful unconditional registration of Enlist Duo's initial uses. They are different, complementary inquiries. Without the required underlying unconditional registration, the 2017 approvals were unsupported by statutorily required findings and assessments.

III. The Court Should Vacate the Registration

Vacatur is the default remedy. *Alliance for the Wild Rockies v. U.S. Forest Service,* 907 F.3d 1105, 1121-122 (9th Cir. 2018) ("presumption of vacatur," unless defendants meet their burden to show otherwise); *Pollinator Stewardship Council*, 806 F.3d at 532 (remand without vacatur permitted only in "limited circumstances"); *Humane Soc. of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010) ("rare circumstances"); *Idaho Farm Bureau v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995) ("Ordinarily" vacatur applies unless "equity demands" otherwise). As such, Respondents, not Petitioners, bear the burden to show equity demands anything other than vacating the registration. They cannot. ECF 64-1 at 65-68; ECF 118 at 45-46.

Pollinator Stewardship sets forth the inquiry for the rare circumstances for remand without vacatur. 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 changed."). As to the first prong, EPA made multiple serious legal errors. The agency misapplied the FIFRA registration standard and compounded it with maladroit efforts to explain away their muddy process. EPA failed to support with substantial evidence its assumptions with regards to Enlist Duo's vapor drift and the use of Enlist Duo with other pesticides. This Court has regularly vacated similarly unlawful registrations. *Pollinator Stewardship*, 806 F.3d at 532-33; *NRDC v. EPA*, 857 F.3d 1030, 1042 (9th Cir. 2017).

Violations of the ESA's Section 7 are even graver than FIFRA violations, as "the consultation requirement reflects 'a conscious decision by Congress to give endangered species priority over the primary missions of federal agencies.' " *NRDC v. Jewell*, 749 F.3d 776, 779 (9th Cir. 2014) (quoting *Hill*, 437 U.S. at 185). And violations of Section 7 attack the very "heart of the ESA," *W. Watersheds Project v. Kraayenbrink*, 632 F.3d at 495, in a case implicating over 500 endangered species, ER575; ER24. The seriousness prong weighs heavily in Petitioners' favor.

As to the disruptive consequences prong, this Court applies it by considering "whether vacating a faulty rule could result in possible environmental harm, and we have chosen to leave a rule in place when vacating would risk such harm." *Pollinator Stewardship*, 806 F.3d at 532; *Alliance for the Wild Rockies*, 907 F.3d at 1122 (vacatur "appropriate when leaving in place an agency action risks more environmental harm than vacating it"). In *Pollinator Stewardship*, "given the precariousness of bee populations, leaving EPA's registration of sulfoxaflor in place risks more potential environmental harm than vacating it." 803 F.3d at 532. The same is true here for hundreds of endangered species, farmers, and the environment generally.

The environmentally protective remedy is vacating the unlawful approval of a novel new pesticide combination which, if not forestalled, otherwise will increase use of 2,4-D by an astounding 200% to 600% (and that is just for corn and soy) without diminishing glyphosate use. ER353; ER414; ER443 (further increases due to cotton adoption). *Pollinator Stewardship* focused on the unanalyzed risks of the specific pesticide before it, not on "other-more-toxic-pesticide substitution" speculation similar to Respondents' arguments. 806 F.3d at 532-33.

Regardless there is no record evidence vacatur will somehow lead to more environmental risk. Nor have Respondents demonstrated farmers will have to switch to more toxic pesticides; they have far safer alternatives, including those classified by EPA as reduced risk, and non-chemical options. ECF 118 at 46 & n.27.

Any claims of alleged agricultural disruption are unsupported by the record. Intervenors have not even disclosed how much Enlist Duo is currently being used to be disrupted. ER30 (no use as of 2016). Respondents have not explained why none of the many alternatives to Enlist Duo would not be viable. ECF 118 at 46 & n.27 (and citations therein). EPA, too, has options: vacatur does not mandate any new requirements, merely returning things to the *status quo ante* prior to the unlawful registration. EPA is free to propose different interim action, so long as it complies with the Court's order.

In the only case Respondents can point to where the Ninth Circuit declined to vacate and considered economic impacts even in part, *California Communities Against Toxics v. U.S. EPA*, 688 F.3d 989 (9th Cir. 2012), EPA requested a remand to reconsider a Clean Air Act rule approving an air quality plan and provided emissions credits to a

nearly-completed power plant. *Id.* at 991-92. The court found that halting the plant's construction—a "billion dollar venture"—would be "economically disastrous" and could result in blackouts that "necessitate the use of diesel generators that pollute the air, the very danger the Clean Air Act aims to prevent." *Id.* at 994. Thus vacatur was certain to cause severe economic consequences, be literally catastrophic, and occur in conjunction with environmental harm. That is a far cry from here.

Further, in remedying a violation of law courts look to the underlying purposes to be served by the statute. *Amoco Prod. Co. v. Vill. of Gambell, AK*, 480 U.S. 531, 542-43 (1987). Unlike other statutes, the ESA does not permit the weighing of economic costs. *Hill*, 437 U.S. at 184 ("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."). That is why prior ESA vacatur cases have focused exclusively on preventing irreparable harm to endangered species, only declining to vacate if vacatur itself could lead to that result. *Idaho Farm Bureau v. Babbitt*, 58 F.3d, 1392, 1405 (9th Cir.

1995) ("In the present case, concern exists regarding the potential extinction of an animal species."); *Nat. Res. Def. Council v. U.S. Dept. of Interior*, 275 F. Supp. 2d 1136, 1143-144 (C.D. Cal. 2002) (citing cases, explaining "the Ninth Circuit expressed special concern for the potentially one-sided and irreversible consequences of environmental damage prompted by vacating defective rules during remand."). The ESA's overarching purpose of "institutionalized caution" places the well-being of endangered species over any speculative disruptions to agriculture. *Cottonwood Environmental Law Center*, 789 F.3d at 1091.

Finally, the entire registration should be vacated. This Court has held that all of the registration is before it; as such, all of it is subject to remedy. The agency's violations run through their entire ESA process, skewing it as applied to all ESA species across 34 states, in all crops. The same is true for their FIFRA violations. The unlawful registration has already been in place for five years. Its reckoning is long past due.

CONCLUSION

For the foregoing reasons, as well as those set forth in NFFC's prior briefing, the Court should grant the petitions for review and vacate the registration.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, this brief is proportionately spaced, has typeface of 14 points or more and contains 6,995 words excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

DATED: July 29, 2019.

s/ George A. Kimbrell
George A. Kimbrell

CERTIFICATE OF SERVICE

I hereby certify that on July 29, 2019, I electronically filed the foregoing with the Clerk of the court using the CM/ECF system which will send notification of such filing to all registered CM/ECF users.

s/ George A. Kimbrell
George A. Kimbrell

STATUTORY AND REGULATORY ADDENDUM

All applicable statutes, etc., are contained in the addendum of NFFC Petitioner's Opening Brief, ECF No. 64-1 and the addendum of NRDC Petitioner's Opening Brief, ECF No. 63.