Case No. 22-70118

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Respondents,

and

SYNGENTA CROP PROTECTION, LLC,
Respondent-Intervenor.

On Petition for Review of an Order of the
United States Environmental Protection Agency

PETITIONERS' MOTION FOR SUMMARY VACATUR

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INTRODUCTION AND SUMMARY OF ARGUMENT

Petitioner Center for Food Safety (CFS) hereby moves this Court to summarily reverse and vacate the Respondent Environmental Protection Agency's (EPA or Respondent) interim registration of difenoconazole, an approval which violates both the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[1] 9th Cir. R. 3-6(a); Fed. R. App. P. 27; 9th Cir. R. 27-1.[2] Pursuant to the ESA, Respondent's flouting of its consultation duties—for a fungicide that EPA knows causes harm to federally protected endangered species—is clear error warranting summary vacatur. And under FIFRA, EPA's decision to issue difenoconazole's interim registration without critical studies on the fungicide's potential harm to public health also warrants summary vacatur.

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[1] *Difenoconazole: Interim Registration Review Decision*, Case Number 7014, EPA-HQ-OPP-2015-0401 (Interim Registration Review Decision), Attachment 1.

[2] Respondents reserve their position and Respondent-Intervenor opposes this motion. *See* 9th Cir. R. 27-1(2).

The D.C. Circuit recently granted summary vacatur in an analogous situation, for EPA's failure to comply with the ESA before registering the pesticide aldicarb, based on the "seriousness of the admitted error and the error's direct impacts on the merits of the EPA's registration decision." *Farmworker Ass'n of Fla. v. EPA*, No. 21-1079, 2021 U.S. App. LEXIS 16882 (D.C. Cir. June 7, 2021); *see* Fed. R. App. P. 32.1. The same is warranted here, for at least two reasons. First, EPA committed clear error in issuing the difenoconazole decision without ESA compliance. *Nat. Res. Def. Council, Inc. v. EPA*, 38 F.4th 34, 59 (9th Cir. 2022) (holding that interim registration review decisions like this one trigger ESA duties). And second, EPA issued its decision without critical studies that the agency itself requested over twenty years ago, studies on a topic (metabolism) which FIFRA itself requires, 7 U.S.C. § 136h(d)(1) (requiring EPA to support registrations with, *inter alia*, studies on "persistence, translocation and fate in the environment, and metabolism."). *See Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 537 (9th Cir. 2015) (holding EPA pesticide approval lacking substantial evidence and vacating under FIFRA for lack of key studies). For either or both reasons, this Court should summarily vacate the

decision and remaexnd. *Nat'l Family Farm Coal. v. EPA*, 960 F.3d 1120, 1144–45 (9th Cir. 2020).

FACTUAL BACKGROUND

Difenoconazole is a broad-spectrum systematic fungicide.[3] Fungicides are a subclass of pesticides that target fungal pests like mold and mildew. Attach 1 at 24. Systemic fungicides like difenoconazole are absorbed and distributed throughout the plant's tissue, flowers, and fruits after application, increasing persistence of the fungicide in the plant and its new growth. *Id.*

Like all pesticides, fungicides like difenoconazole are toxic substances intentionally released or sprayed to kill pests, but that also kill and harm "non-target" plants and animals. As EPA recognized, difenoconazole potentially threatens a wide variety of species, from "mammals, birds, terrestrial invertebrates, freshwater and estuarine/marine fish, and aquatic invertebrates." *Id.* at 25.

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[3] EPA, *Difenoconazole: Draft Ecological Risk Assessment for Registration Review* 5 (Sept. 16, 2020), Attachment 2.

Despite its potential harm to species and human health, over the years, EPA has approved difenoconazole use across a wide variety of landscapes. Initially approved as a seed treatment[4] on commodity crops, today the systemic fungicide is approved for many nationwide uses including: seed treatment on wheat and other cereal grains, cotton, and potatoes; direct spraying on major crops and commodities, including soybeans, sugar beets, various fruits and vegetables, tree nuts; and spraying on golf course turf grass and ornamental plants. Difenoconazole's use has increased dramatically since 2008, when EPA first approved direct spraying on soybeans, roughly 20-fold from 2008 to 2017 (from 25,000 to 500,000 lbs. per year), and continues to increase.[5] *See id.* at 12.

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[4] Seed treatments involve coating crop seeds with systemic pesticides, which are absorbed into the plants' circulatory system as the plant grows. Attach. 1 at 25.

[5] Center for Food Safety, Comments on Proposed Interim Registration Decision for Difenoconazole 2, EPA-HQ-OPP-2015-0401, Attachment 4.

PROCEDURAL HISTORY

EPA published the proposed interim registration review decision for public comment on August 3, 2021.[6] Petitioner submitted comments. *See* Attach. 4. Among other critiques, Petitioner underscored EPA's failure to comply with the ESA and consult on difenoconazole with the expert wildlife agencies and obtain the critical studies on difenoconazole's risks to public health. *Id.*

In the ecological risk assessment accompanying the proposed interim registration, EPA acknowledged that difenoconazole application exceeds EPA's own acute and/or chronic "levels of concern" (LOCs) for numerous plants and animals, including fish, estuarine/marine invertebrates, aquatic invertebrates, honeybees, aquatic plants, and birds. Attach. 2 at 7, 9-13. Exposure occurs through runoff and spray drift to water and sediment, *id*. at 43-44, with difenoconazole's noted

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[6] *Difenoconazole: Proposed Interim Registration Review Decision*, Case Number 7014, EPA-HQ-OPP-2015-0401-0049 ("Proposed Interim Registration Review Decision"); *Pesticide Registration Review; Proposed Interim Decisions for Several Pesticides; Notice of Availability*, 86 Fed. Reg. 41,838 (Aug. 3, 2021).

persistence increasing its accumulation in soil and aquatic environments. *Id.* at 8. Indeed, EPA identified chronic risk LOC exceedances for birds for up to 150 days after application in some scenarios, and after 56 days for mammals. *Id.* at 11.

In spite of these acknowledgments of harm to numerous categories of species throughout its risk assessment, EPA at the same time readily admits it has not complied with the ESA. Attach 1 at 4 ("The Agency has not yet fully evaluated difenoconazole's risks to federally listed species."); Attach. 2 at 13 ("Federally listed threatened and endangered species are not evaluated in the document."). Instead, EPA promises only to consult before its final registration decision—an entirely different federal action—and offered no timeline or work plan for when that may happen. Attach. 1 at 34-35.

EPA also issued its proposed interim registration without the critical information it requested *twenty-two* years ago on difenoconazole's potential adverse public health effects. Specifically, in 2000, EPA demanded pesticide registrants provide numerous studies to ensure that use of the fungicides in this class do not impair developing infants' brains and nervous systems, cause cancer, or disrupt hormonal

systems.[7] Then, EPA halted any further registrations of fungicides in the triazole class—to which difenoconazole belongs—over twenty years ago.[8] Attach. 1 at 9. Yet the proposed registration still contains the same glaring data gaps on difenoconazole's impacts on reproductive and developmental health.

EPA subsequently issued its final interim registration decision and finalized its draft risk assessments on March 31, 2022. Attach. 1 at 4. Regarding its ESA duties, EPA stated only that it would not undergo consultation until its separate final registration review decision, and still offered no timeline for that decision, in spite approving difenoconazole's continued use. *Id.* at 34-35. And under FIFRA, the human health studies EPA mandated more than twenty years ago still remained lacking, but EPA nonetheless issued the interim registration

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[7] *See* EPA, *1,2,4-Triazole, Triazole Alanine, Triazole Acetic Acid: Human Health Aggregate Risk Assessment in Support of Reregistration and Registration Actions for Triazole-derivative Fungicide Compounds* 6 (Feb. 7, 2006), Attachment 3.

[8] Attach. 3, at 7.

by substituting a "conservative" uncertainty factor for actual studies. *Id.* at 9.

Petitioner timely filed this petition for review. ECF No. 1-6 (June 13, 2022). Registrant Syngenta intervened. ECF No. 9 (July 13, 2022); ECF No. 15 (July 27, 2022). The parties participated in this Court's required mediation process but their discussions failed to progress. Petitioner now files this motion seeking summary vacatur of the challenged decision in light of EPA's admitted ESA violation and continued lack of substantial evidence to support the interim registration approval of difenoconazole under FIFRA.

JURISDICTION

This Court has jurisdiction under FIFRA, which provides for direct review in the courts of appeals of "any order issued by [EPA] following a public hearing." 7 U.S.C. § 136n(b); *Nat'l Family Farm Coal. v. EPA*, 960 F.3d at 1131. EPA provided a "public hearing" by holding notice and comment. *Id.* Petitioner submitted comments and timely filed this petition for review. 7 U.S.C. § 136n(b); 40 C.F.R. § 23.6.

Petitioner has standing. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000). The

environmental interests at stake are germane to Petitioner's organizational mission, and this Court can redress the injuries to Petitioner's members. [9] *Id.* The procedural nature of Petitioner's injuries (Section 7 consultation sets a strict procedure to ensure compliance with ESA's substantive commands), calls for a relaxed causation and redressability standard. *Nat. Res. Def. Council*, 38 F.4th at 54. Namely, Petitioner must only show a "reasonable probability of the challenged action's threat to [Petitioner's] concrete interest," *id.* (citations omitted), and that "the agency decision 'could be influenced' by the procedures at issue." *Id.* at 56 (quoting *Hall v. Norton*, 266 F.3d 969, 977 (9th Cir. 2001).

This low bar is easily met here: EPA's failure to fulfill its ESA obligations injures Petitioner's members who have environmental, professional, recreational, and aesthetic interests in seeing, studying, and protecting dozens of ESA-protected species—including the smalltooth sawfish, whooping crane, and Everglade snail kite—all of

[9] *See* Attach. 5, Decl. Loda; Attach. 6, Decl. Naegele; Attach. 7, Decl. Schudda; Attach. 8, Decl. Wu.

which difenoconazole harms. Crops permitted for difenoconazole spraying and seed treatment overlap with the habitats and range of many ESA-protected species for which difenoconazole exposure exceeds EPA's levels of concern. Attach. 2 at 7, 9-13. *See* Attach. 9, Sinclair Decl. (mapping overlap of difenoconazole-approved crop uses with critical habitat for six ESA-protected species). Proper ESA compliance before issuance may have resulted in protective measures included in this decision for species to protect members' interests.

And Petitioner's members' exposure to potentially harmful difenoconazole residues also meets this standard. For injuries from exposure, Petitioner only needs to show "a credible threat of harm" due to exposure to "potentially harmful" difenoconazole residues, *Nat. Res. Def. Council, Inc. v. FDA*, 710 F.3d 71, 81 (2d Cir. 2013), as amended (Mar. 21, 2013) (quoting *Baur v. Veneman*, 352 F.3d 625, 641 (2d Cir. 2003) ("[T]he relevant 'injury' for standing purposes may be exposure to a sufficiently serious risk of medical harm—not the anticipated medical harm itself."). Petitioner's members regularly consume foods with potentially harmful difenoconazole residues, which EPA might have addressed had it properly collected and considered the public health

studies. *Salmon Spawning & Recovery All. v. Gutierrez*, 545 F.3d 1220, 1226-27 (9th Cir. 2008) (Petitioner "need[s] to show only that the relief requested—that the agency follow the correct procedures—may influence the agency's ultimate decision of whether to take or refrain from taking a certain action."); *Mass. v. EPA*, 549 U.S. 497, 518 (2007) ("[A] litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant.").

STANDARD OF REVIEW

Summary reversal and vacatur is warranted when this Court concludes the respondent committed "clear error." 9th Cir. R. 3-6(a)(1); *Williams v. Hampton*, No. 19-56197, 2020 U.S. App. LEXIS 10473, at *1 (9th Cir. Apr. 2, 2020). Where, as here, the agency decision is "obviously controlled by precedent," then "summary disposition is of obvious benefit to all concerned," and should be issued. *United States v. Hooton*, 693 F.2d 857, 858 (9th Cir. 1982).

Under FIFRA, this Court may affirm EPA's difenoconazole's interim registration approval only if it is "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b).

The FIFRA substantial evidence standard "affords an agency less deference than the arbitrary and capricious standard." *Pollinator Stewardship*, 806 F.3d at 533 (N.R. Smith, J., concurring) (citing *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477 (1951); *Union Oil Co. v. Fed. Power Com.*, 542 F.2d 1036, 1040-41 (9th Cir. 1976)). Therefore, if EPA's decision is arbitrary and capricious, it cannot be supported by substantial evidence. To avoid being arbitrary and capricious, EPA "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal citations and quotations omitted).

Similarly, EPA violated the ESA if its failure to consult the expert wildlife agencies was arbitrary, capricious, an abuse of discretion, or otherwise not in compliance with law. 5 U.S.C. § 706(2)(A); *see Conner v. Burford*, 848 F.2d 1441, 1453 (9th Cir. 1988). Agency actions subject to mandatory consultation include interim registration review decisions such as this one. *Nat. Res. Def. Council*, 38 F.4th at 59. The ESA requires that federal agencies consult the expert wildlife agencies before

taking any action that "may affect" any protected species or critical habitat, 50 C.F.R. § 402.14(a); *see* 16 U.S.C. § 1536(a)(2), and to do so "at the earliest possible time." 50 C.F.R. § 402.14(a); *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1020 (9th Cir. 2012).

If the Court holds EPA unlawfully issued the interim registration of difenoconazole, it should "set aside," or vacate it. 7 U.S.C. § 136n(b); 5 U.S.C. § 706(2)(A); *Pollinator Stewardship*, 806 F.3d at 532-33; *see, e.g.*, *Farmworker Ass'n of Fla.*, 2021 U.S. App. LEXIS 16882.

ARGUMENT

I. EPA's Endangered Species Act Violation Is Clear Error.

EPA's violation of its ESA Section 7 consultation duties for difenoconazole is "clear error" that is "obviously controlled by precedent," and thus warrants summary reversal. *Williams*, 2020 U.S. App. LEXIS at *1; *Hooton*, 693 F.2d at 858.

Section 7(a)(2) is the "heart" of the ESA. *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 495 (9th Cir. 2011). It mandates that "[e]ach federal agency" "insure" that its action—here, EPA completing its interim registration review—is not likely to either jeopardize any endangered species or adversely modify any designated "critical"

habitat, by consulting with the U.S. Fish and Wildlife Service and National Marine Fisheries Service (the Expert Agencies). 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.01(b). If an action agency makes a "may affect" determination, it must then insure, through consultation with the Expert Agencies, that the action is not likely to cause jeopardy or adversely modify designated critical habitat. 16 U.S.C. § 1536(a); 50 C.F.R. §§ 402.13-.14. The ESA commands that agencies complete this review and make this determination "at the earliest possible time." 50 C.F.R. § 402.14(a); *Karuk Tribe*, 681 F.3d at 1020.

Just two months ago, this Court made plain that EPA cannot flout its ESA duties as it did here when making an interim registration review decision. Rather as this Court held, interim registration review falls squarely within the purview of "agency action" and triggers mandatory consultation. *Nat. Res. Def. Council*, 38 F.4th at 58. In *Natural Resources Defense Council*, regarding the interim registration of the pesticide glyphosate, this Court explained that interim registrations are cognizable "agency actions" triggering consultation because 1) they are "affirmative" actions, and 2) they delineate the way in which producers may continue pesticide use consistent with FIFRA.

Id. at 58-59. Through the interim registration, EPA has discretionary control to benefit protected species through mitigation measures or otherwise, like deciding which factors to consider in the ecological risk assessment. *Id.*

The present case is no different than the glyphosate interim registration. In both instances, EPA issued a so-called "interim" registration that actually *finalized* the agency's ecological and human health risk assessments, yet deferred ESA consultation until a final registration review decision at some later, undetermined time. *See id.* at 43. As this Court found in *Natural Resources Defense Council*, EPA violated the ESA by failing to comply with the ESA consultation requirements before issuing the interim registration. *Id.* at 59.

In fact, EPA's violation of the ESA here is even more egregious than in *Natural Resources Defense Council*, because unlike in that case here EPA has not even *started* a draft ESA Biological Evaluation to make the required effects determination. Accordingly, pursuant to *Natural Resources Defense Council*, the ESA and its implementing regulations' plain language, as well as numerous other ESA precedent, EPA violated the ESA. *E.g., Farmworker Ass'n of Fla.*, 2021 U.S. App.

LEXIS 16882; *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1029 (9th Cir. 2005) (failure to consult for fifty-four pesticides); *Ellis v. Housenger*, 252 F. Supp. 3d 800, 820 (N.D. Cal. 2017) (failure to consult for dozens of pollinator-harming pesticides); *Lane Cty. Audubon Soc'y v. Jamison*, 958 F.2d 290, 294 (9th Cir. 1992) (interim management strategy designed to be implemented immediately constitutes agency action triggering consultation); *Defs. of Wildlife v. Adm'r, EPA*, 882 F.2d 1294, 1301 (8th Cir. 1989) (strychnine registration violated ESA).

And *had* EPA complied with the ESA and completed a Biological Evaluation, it almost certainly would have triggered formal ESA consultation. The "may affect" threshold triggering consultation is extremely low: "actions that have *any chance of affecting* listed species or critical habitat … *require* at least some consultation under the ESA." *Karuk Tribe*, 681 F.3d at 1027 (emphasis added); *id.* ("Any possible effect, whether beneficial, benign, adverse or of an undetermined character, triggers the requirement.") (citation and quotation omitted). Here, EPA admits in its ecological risk assessment that difenoconazole, approved for dozens of crops across the country, exceeds its own toxicity level of concern for exposures when used as approved for wide

categories of species, including fish, estuarine/marine and aquatic invertebrates, honeybees, aquatic plants, and birds. Attach 2 at 7, 9-13. EPA found the level of concern exceeded for non-federally protected species, meaning that under EPA's own risk assessment framework, the same difenoconazole uses would also potentially harm federally protected species belonging to the same categories.[10]

And there are *hundreds* of endangered species that fall into these broad species categories for which EPA acknowledges risk. To give just a few examples, extensive difenoconazole use: in California's Central Valley overlaps with California condor and conservancy fairy shrimp habitat; in the Midwest with whooping crane habitat; and in Florida with smalltooth sawfish and the Everglade snail kite habitat. *See* Attach. 9, Decl. Sinclair (and exhibits). But EPA admits it failed to do *any* analysis of these risks to ESA-protected birds, fish, and other species. Attach 1 at 3.

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[10] *See* EPA, *Overview of the Ecological Risk Assessment Process* 46-47 (Jan. 2004), https://www.epa.gov/sites/default/files/2014-11/documents/ecorisk-overview.pdf (explaining that the level of concerns are set at lower thresholds for endangered species compared to their non-federally listed counterparts).

Because EPA's well-established ESA violation is "clear error" that is "obviously controlled by precedent," *Williams*, 2020 U.S. App. LEXIS at *1; *Hooton*, 693 F.2d at 858, this Court should grant summary reversal.

II. EPA's Lack of Substantial Evidence Under FIFRA Is Clear Error.

The ESA violation alone is more than sufficient ground on which to vacate the interim registration. However and additionally, EPA's failure to obtain the requisite studies on public health it mandated more than two decades ago also constitutes "clear error … obviously controlled by precedent." *Williams*, 2020 U.S. App. LEXIS at *1; *Hooton*, 693 F.2d at 858. Without these studies, EPA cannot support its interim registration decision with substantial evidence as FIFRA requires, since the need for the health data prompted EPA to issue a moratorium on further registrations in 2000. Attach. 3; *see Nat'l Family Farm Coal.*, 960 F.3d at 1124.

This is impermissible. The very purpose of registration review requires EPA to revisit studies in light of improved ability to detect risks, policy changes, changes in pesticide usage practices, and

importantly here, evolving science that has occurred since the pesticide's last review. *See Nat. Res. Def. Council*, 38 F.4th at 40 (explaining that registration review "require[s] EPA to assess any new information regarding risks to human health and the environment that has emerged … to verify that the pesticide continues to satisfy the FIFRA safety standard."). Specifically, EPA must base each re-registration on "*current* scientific and other knowledge regarding the pesticide, including its effects on human health and the environment," 40 C.F.R. § 155.40(a)(1) (emphasis added). Accordingly, EPA may identify and solicit data or information to aid in its review. *Id.* § 155.50(b)-(c). Under EPA's own FIFRA regulations, EPA must issue a data call-in "if" the agency determines that additional data "are required to maintain in effect an existing registration of a pesticide." 7 U.S.C. § 136a(c)(2)(B).

EPA did just that here. In 2000, EPA reviewed evolving science and issued a data call-in regarding the impact of 1,2,3-triazoles, a metabolite of difenoconazole and other triazole fungicides on developmental and reproductive health. Attach. 3 at 5. EPA admitted it lacked sufficient evidence for future registrations and uses to ensure

adherence to FIFRA's safety standard because available studies failed to assess risks to human health from triazole metabolites, and that additional animal studies would be required. *Id.* at 5-6 (recommending numerous toxicity animal studies on trazole metabolites as "a condition of registration"). EPA admittedly has "*no data*" to "directly evaluate the potential for carcinogenicity of 1,2.4-triazole," *id.* at 14 (emphasis added), evaluate dermal absorption of 1.2.4-triazole, *id.* at 22, or evaluate triazole alanine's potential to disrupt the nervous system. *Id.* at 79. EPA also admitted "free triazole *has not been adequately tested* in toxicity studies with the parent triazole fungicides." *Id.* at 79 (emphasis added).

EPA cannot support its decision with substantial evidence without metabolism studies like these. FIFRA makes plain that data required to support registration includes studies on pesticides' "persistence, translocation and fate in the environment, and *metabolism*." 7 U.S.C. § 136h(d)(1) (emphasis added). In turn, EPA's regulations require studies regarding metabolite toxicity to "increase[ ] the Agency's understanding of the behavior of the chemical when considering the human exposure anticipated from intended uses of the pesticide." 40 C.F.R. §§

158.130(d)(6),159.179(a); *Nat. Res. Def. Council*, 38 F.4th 34, 51 (in a pesticide registration challenge, holding that by failing to follow its own guidelines (there, cancer guidelines) EPA's interim registration of the pesticide could not survive substantial evidence review and was thus unlawful).

EPA went ahead here without the necessary studies. Attach 1 at 9. This is clear error. This Court has specifically held that EPA lacks substantial evidence when acts without necessary studies after a data call-in. In *Pollinator Stewardship*, the Court found sulfoxaflor's conditional registration unsupported because registrants had not yet submitted the Tier 2 semi-field tunnel studies on risks to pollinators the EPA had similarly identified as necessary. *Pollinator Stewardship*, 806 F.3d at 537; 40 C.F.R. § 158.630(d), (e) (requiring field testing for pollinators). There, as here, EPA's own regulations required these types of studies. And there, as here, EPA issued a data call-in to affirmatively prove that sulfoxaflor does *not* have unreasonable adverse effects on the environment after finding existing studies inconclusive.

EPA may not overcome this data requirement with its 10x database uncertainty factor and promise of future studies. In *Pollinator*

Stewardship, the Court found that lowering sulfoxaflor's maximum application rate could not overcome the data gaps because EPA still could not affirmatively prove that sulfoxaflor does not cause unreasonable adverse effects. *See Pollinator Stewardship*; *see also Tucson Herpetological Soc'y v. Salazar,* 566 F.3d 870, 879 (9th Cir. 2009) (finding that the Secretary of the Interior erred when he affirmatively relied on ambiguous and inconclusive studies to support a conclusion). The same must be true here: EPA enacted this safety factor twenty years ago solely as a temporary measure until it received the requisite studies. Attach. 3 at 67-68; *id.* at 73 ("A 10X database uncertainty factor is retained for the lack of the [mandatory] studies.").

A court should not defer to an agency's decision where, as here, the agency fails to adhere to its own regulations. *See, e.g., Pollinator Stewardship*, 806 F.3d at 537; *W. States Petroleum Ass'n v. EPA*, 87 F.3d 280, 283 (9th Cir. 1996). EPA's regulations require EPA to "[r]eview[ ] all relevant data in [its] possession " and to "determine[ ] that no additional data are necessary " to make determinations of no unreasonable adverse effects. 40 C.F.R. § 152.112(b)-(c). Accordingly, in the absence of the requisite scientific data, EPA's conclusion that

difenoconazole result in unreasonable adverse effects on the environment as unsupported by substantial evidence.

III. Vacatur Is the Proper Remedy.

Because EPA violated FIFRA and the ESA, the Court should set aside the decision. Vacatur is the default remedy for unlawful agency actions, including pesticide registrations. *All. for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1121-22 (9th Cir. 2018) ("presumption of vacatur," unless defendants meet their burden to show otherwise); *Nat. Res. Def. Council*, 38 F.4th at 51 ("[v]acatur is the traditional remedy for erroneous administrative decisions."); *Pollinator Stewardship*, 806 F.3d at 532 (remand without vacatur permitted only in "limited circumstances"); *Humane Soc'y of the United States v. Locke*, 626 F.3d 1040, 1053 n. 7 (9th Cir. 2010) ("rare circumstances"); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995) (vacatur applies unless "equity demands" otherwise).

In determining whether the Respondent can meet its heavy burden to show that a case meets the "rare" or "limited" circumstances not to vacate, courts "weigh the seriousness of the agency's errors against the disruptive consequences of an interim change that may

itself be changed." *Nat. Res. Def. Council*, 38 F.4th at 51 (quoting *NFFC*, 960 F.3d at 1144). And in environmental cases like this one, the cognizable 'disruptive consequences' to be considered are *environmental* harms that flow *from* vacatur. *Id*. at 51-52; *NFFC*, 960 F.3d at 1144-45; *Pollinator Stewardship*, 806 F.3d at 532; *All. 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").

Just like in recent pesticide cases of *NRDC* and *Pollinator Stewardship*, EPA here substantially understated or entirely failed to acknowledge the risks, including numerous ESA-protected species and risks to public health. EPA's errors are very serious: A violation of ESA's Section 7 cuts to the "heart" of the statute, *W. Watersheds Project v. Kraayenbrink*, 632 F.3d at 495, and here it was done knowingly to boot. *Nat'l Parks Conservation Ass'n v. Jewell*, 62 F. Supp. 3d 7, 20-22 (D.D.C. 2014) (agency's failure to consult under ESA a serious error justifying vacatur of underlying agency action). Human health and environmental risks are also core considerations of FIFRA. *Nat. Res. Def. Council,* 38 F.4th at 52 (finding EPA's errors in assessing human-health risk serious); *Pollinator Stewardship*, 806 F.3d at 532 (EPA's

errors in assessing risks to pollinators under FIFRA serious and vacating).

And as in *Natural Resources Defense Council*, vacating the human-health portion of EPA's IRRD would not result in disruptive consequences. 38 F.4th at 52. In both cases, this portion "clearly weighs in favor of vacatur" because it simply maintains the status quo with no new mitigation measures for human health. *Id*; *see also* Attach. 1 at 40-45.

Nor would disruptive, environmental harms flow from vacating the ecological risk assessment portion. Disruptive consequences from vacatur are "weighty only insofar as the agency may be able to rehabilitate its rationale for the regulation." *Coal. to Protect Puget Sound Habitat v. U.S. Army Corps. of Eng'rs,* 466 F. Supp. 3d 1217, 1223–24 (W.D. Wash. 2020); *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 952 (N.D. Cal. 2010). The correct inquiry asks whether the "same rule would be adopted on remand," meaning the exact same action. *Pollinator Stewardship*, 806 F.3d at 532. But here any future decision will differ both procedurally and substantively because EPA will need to incorporate the substantive results of the ESA consultation

process. When "a different result *may* be reached," such as in this case, it undermines any "disruptive consequences of an interim change that may itself be changed" and supports vacatur. *Id.* (emphasis added).

In *Natural Resources Defense Council*'s similar situation, this Court chose only to partially vacate and not to vacate the ecological risk assessment as well only for "practical reasons" not present here. 38 F.4th at 61. There, vacating may have further delayed ESA consultation beyond the Congressionally mandated October 1, 2022 deadline because the Court had not yet received responsive briefing on ecological risk assessment's sufficiency, nor held oral argument. *Id.* at 61 (refusing to vacate because "while we hesitate to reward what some might consider sloth or indolence … fully litigating the issues could result in … more, and probably unnecessary, delay."). But here, EPA has no intention of completing its final registration review by October 1, nor could it.[11] In

[11] Even for glyphosate, for which EPA completed a draft Biological Evaluation, the agency subsequently asked this Court to vacate the ecological risk assessment because EPA cannot consult by October 1, 2022. Pet. Rehearing, *Nat. Res. Def. Council* v. *EPA*, No. 20-70787, at 5-6 (9th Cir. filed Aug. 1, 2022), ECF No. 141-1 (ESA consultations for pesticides typically take *years*); *id.* at 15 (final registration review

sum, the remedy here is plain under both the ESA and FIFRA: vacate the registration.

CONCLUSION

EPA's intentional disregard for its ESA and FIFRA duties in its interim registration decision for difenoconazole is manifest clear error, contrary to its Congressional mandates, and risks irreparable harm to wildlife on the verge of extinction as well as public health. The proper outcome and remedy need not be delayed any further. For these reasons, Petitioners respectfully request the Court should grant summary reversal and vacatur.

Respectfully submitted on September 1, 2022.

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decision for glyphosate, including ESA consultation, will take until 2026); *see also* Order, *Nat. Res. Def. Council* v. *EPA*, No. 20-70787 (9th Cir. filed Aug. 5, 2022), ECF No. 142 (denying the petition for rehearing).

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been printed in 14-point Century Schoolbook font, a proportionally spaced font. I further certify that this brief complies with Circuit Rule 27-1 because it contains 4,873 words, excluding the parts of the brief exempted under Rule 32(f), according to the count of Microsoft Word. *See* 9th Cir. R. 32-3(2).

/s/ Meredith Stevenson
Meredith Stevenson

CERTIFICATE OF SERVICE

I hereby certify that, on September 1, 2022, I electronically filed the foregoing PETITIONERS' MOTION FOR SUMMARY VACATUR with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system.

I certify that all participants in the case are registered CM/ECF users, and that service will be accomplished by the appellate CM/ECF system.

/s/ Meredith Stevenson
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