

ORAL ARGUMENT NOT YET SCHEDULED

Case Nos. 19-72109, 19-72280

UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

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CENTER FOR FOOD SAFETY, *et al.*,

*Petitioners,*

v.

JANE NISHIDA, *et al.*,

*Respondents,*

and

DOW AGROSCIENCES LLC,

*Respondent-Intervenor.*

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POLLINATOR STEWARDSHIP COUNCIL, *et al.*,

*Petitioners,*

v.

JANE NISHIDA, *et al.*,

*Respondents,*

and

DOW AGROSCIENCES LLC,

*Intervenor.*

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ON PETITION FOR REVIEW FROM THE UNITED STATES  
ENVIRONMENTAL PROTECTION AGENCY

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CENTER FOR FOOD SAFETY *ET AL.* PETITIONERS' OPENING BRIEF

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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 Center for Food Safety,  
et al.*

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## GLOSSARY OF ABBREVIATIONS

2019 Registration	EPA's July 12, 2019 registration decision adding new uses of sulfoxaflor on alfalfa, cacao, citrus, corn, cotton, cucurbits, grains, pineapple, sorghum, soybeans, strawberries, and tree plantations, as well as amending preexisting uses of sulfoxaflor
Academy	National Academy of Sciences
APA	Administrative Procedure Act
CFS Petitioners	Center for Food Safety and Center for Biological Diversity, Petitioners in No. 19-72109
Dow	Respondent-Intervenor Dow Agrosciences LLC
EPA	Respondent U.S. Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FWS	U.S. Fish and Wildlife Service
GAO	U.S. Government Accountability Office
Interim Approaches	A joint guidance issued by the EPA, U.S. Fish and Wildlife Service, National Marine Fisheries Service, and the U. S. Department of Agriculture on the ESA consultation process, based on the recommendations of the National Academy of Sciences
LD <sub>50</sub>	A standard of measurement of acute toxicity used by EPA, stated in milligrams of pesticide per kilogram of body weight (mg/kg), which represents the individual dose of a pesticide required to kill 50 percent of a population of test animals
NEPA	National Environmental Policy Act

PSC Petitioners	Pollinator Stewardship Council, American Beekeeping Federation, and Jeffrey S. Anderson, Petitioners in No. 19-72280
Revised Methods	EPA's guidance on the three steps of its ESA consultation process
Wildlife Agencies	U.S. Fish and Wildlife Service and National Marine Fisheries Service

## INTRODUCTION

This petition for review challenges an unexpected July 12, 2019 decision (the 2019 Registration) by Respondent U.S. Environmental Protection Agency (EPA) to authorize the spraying of the insecticide sulfoxaflor across the United States, over major agricultural crops, such as soybean, cotton, citrus, apples, and strawberries, and without the protective measures EPA itself previously deemed necessary to prevent harm to honey bees. EPA nonetheless concluded that approving sulfoxaflor uses in this manner would not result in unreasonable adverse effects on the environment, and granted unconditional registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

EPA's conclusion is wrong and its decision unlawful, first for a simple reason that EPA has now admitted to this Court: EPA intentionally disregarded its mandatory duties under the Endangered Species Act (ESA) to *insure* that sulfoxaflor does not jeopardize the existence of endangered species, *before* issuing the 2019 Registration. This Court previously vacated the initial sulfoxaflor registration after holding EPA violated FIFRA's "unreasonable adverse effect" standard, a more lenient standard than the ESA's mandate that agencies prioritize endangered species protection. *See Pollinator Stewardship Council v. EPA (Pollinator I)*, 806 F.3d 520, 532 (9th Cir. 2015); *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 185 (1978).

The 2019 Registration is also unlawful under FIFRA. EPA issued the 2019 Registration without providing an opportunity for public input, as it was required to do under the statute. And, despite the fact that the data before EPA shows that the approved sulfoxaflor uses can harm honey bees, and pose even greater risks to other bumble bees, leaf cutter bees, native bees, and wild bees, EPA relied on an inaccurate, skewed analysis comparing sulfoxaflor to only six of the most toxic insecticides to conclude that authorizing sulfoxaflor use across the U.S. agricultural landscape would be beneficial to the environment.

Consequently, more than a decade after the initial application to register sulfoxaflor use, EPA still has “no real idea whether sulfoxaflor [would] cause unreasonable adverse effects on bees,” *Pollinator I*, 806 F.3d at 532, not to mention endangered and threatened species. EPA still has not taken the legally required steps, mandated by the ESA and outlined by EPA’s own guidance, to insure protection of our nation’s most imperiled species already in danger of extinction. This Court should grant this petition for review, hold that EPA violated FIFRA and the ESA, and vacate the 2019 Registration.

## JURISDICTIONAL STATEMENT

Petitioners Center for Food Safety and Center for Biological Diversity (collectively CFS Petitioners) seek review of the 2019 Registration by EPA to register new uses of the insecticide sulfoxaflor under section 16(b) of FIFRA. CFSE-3-32.<sup>1</sup> This Court has jurisdiction under FIFRA, which provides for review in the courts of appeals of “any order issued by [EPA] following a public hearing.” 7 U.S.C. § 136n(b), *see United Farm Workers of Am. v. Env’t Prot. Agency*, 592 F.3d 1080, 1082-83 (9th Cir. 2010). EPA’s 2019 Registration was issued with public notice and comments on EPA’s prior registrations of sulfoxaflor uses. CFSE-4-5; *see Nat’l Family Farm Coal. v. Env’t Prot. Agency*, 960 F.3d 1120, 1132 (9th Cir. 2020) (holding jurisdiction proper where challenged EPA registration followed notice and comment on a prior decision). CFS Petitioners had submitted comments on EPA’s previous sulfoxaflor decisions, and timely filed this petition for review. 7 U.S.C. § 136n(b), 40 C.F.R § 23.6; *see* CFSE-224-33; CFSE-219-23; CFSE-190-211.

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<sup>1</sup> Pursuant to Circuit Rule 30-1.4(a), CFS Petitioners include the challenged 2019 Registration in volume 1 of CFS Petitioners’ Excerpts of Record (CFSE). For other cited record documents, CFS Petitioners cite to Pollinator Stewardship Council Petitioners (PSC Petitioners)’s excerpts of record, referred to as “PSCER” along with their volume and Bates number, if they are produced therein. *See* PSC Pet’rs’ Excerpts of Record, ECF Nos. 38-1 to 38-6.

CFS Petitioners also satisfy the requirements of Article III standing for their ESA and FIFRA claims. *See Friends of Earth, Inc. v. Laidlaw Envtl. Serv. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000); *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). The challenged registration directly injures Petitioners' members' environmental and aesthetic interests in seeing and protecting federally endangered and threatened species. *See* CFS's Pet'rs' Remand Opp'n Addendum, ECF No. 59-2, at CFS\_A002-9 (Newman Decl. ¶¶ 6-29) (interests in endangered whooping crane and rusty patched bumble bee), CFS\_A012-19 (Celano Decl. ¶¶ 6-25) (interests in endangered mammals, birds, and reptiles), CFS\_A023-28 (Buse Decl. ¶¶ 9-26) (interests in endangered Indiana bat, Karner blue butterfly, Hine's emerald dragonfly, Mitchell's satyr butterfly), CFS\_A032-36 (Williams Decl. ¶¶ 5-14) (interests in endangered fishes and mussels); CFS\_A049-54 (Burd Decl. ¶¶ 23-31) (interests in the preservation of the Fender's blue butterfly, Oregon silverspot, and Chiricahua leopard frog). CFS Petitioners also have members whose recreational and vocational interests as beekeepers and gardeners in preserving the health of our nation's pollinator species are being injured by EPA's 2019 Registration. *See id.*, at CFS\_A056-59 (Burkey Decl. ¶¶ 5-14) (gardening and recreational interests in pollinator species), CFS\_A062-64 (Holterman Decl. ¶¶ 6-14) (gardening,



beekeeping, and bird-watching interests), CFS\_A068-72 (Gregory Decl. ¶¶ 6-16) (gardening and birding interests).

### ISSUES PRESENTED

1. Whether the Court should hold that EPA violated the ESA by failing to comply with the ESA's section 7 consultation procedures concerning sulfoxaflor's effects on threatened and endangered species and their critical habitats before issuing the challenged decision, where hundreds of species are potentially affected, over millions of acres, and where EPA now admits itself that it failed to so comply and is in violation of the statute;

2. Whether EPA violated FIFRA by issuing the 2019 Registration's new uses of sulfoxaflor but failed to solicit public input despite pesticide new uses requiring notice and comment;

3. Whether EPA's conclusion that the 2019 Registration authorizing sulfoxaflor spraying on numerous agricultural crops would not result in unreasonable adverse effects on the environment is supported by substantial evidence, as required under FIFRA, where EPA failed to assess the impacts of sulfoxaflor exposure on non-honey bees, and where EPA supported its registration decision with an inaccurate, flawed alternative pesticide analysis; and

4. Whether the Court should vacate the 2019 Registration, where EPA has committed serious errors of law in violating both the ESA and FIFRA and where EPA cannot meet its heavy burden to show this is the rare exceptional instance where remand without vacatur is warranted because it is the more environmentally protective remedy.

### STATEMENT OF THE CASE

#### I. Sulfoxaflor.

Sulfoxaflor is a relatively new insecticidal active ingredient, developed by Intervenor Dow Agrosciences, LLC (Dow) , which kills insects by disrupting their central nervous system. 3-PSCER-359. EPA classifies sulfoxaflor as “the only member of the sulfoxamine subclass of neonicotinoid insecticides,” a now infamous group of insecticides known for its deadly impact on honey bees and pollinator insects vital to U.S. agriculture, and on threatened and endangered species on the brink of extinction. 4-PSCER-782-83, 4-PSCER-844, 4-PSCER-880; 6-PSCER-1267; *Pollinator I*, 806 F.3d at 532 (9th Cir. 2015); 5-PSCER-960 (“Sulfoxaflor can be considered to be a neonicotinoid.”).

When bees and other pollinators forage on pollen or nectar from neonicotinoid-treated plants, or are otherwise exposed to extremely small doses of these insecticides, tremors, paralysis and death result. 4-PSCER-782; 4-PSCER-783;

4-PSCER-880. Like other neonicotinoids, sulfoxaflor is a “systemic” insecticide, meaning that it is absorbed into the treated plant and distributed via the plant’s vascular system. 4-PSCER-782. As a result, spraying a plant with sulfoxaflor not only kills insects that come into direct contact with spray droplets, but also renders the plant itself—including the leaves, stem, flowers, nectar and pollen—highly toxic to insects for long periods thereafter. *Id.*; see *Pollinator I*, 806 F.3d at 523. Consequently, the widespread use of sulfoxaflor alongside other neonicotinoids and pesticides have exacerbated the loss of bees (both honey and non-honey bees) and other vital pollinators, and have worsened the fate of endangered species already teetering on the brink of extinction. See 6-PSCER-1267.

## II. EPA’s Legal Duties in Registering Pesticides.

### A. Federal Insecticide, Fungicide, and Rodenticide Act.

FIFRA charges EPA with regulating the sale and use of pesticides. Before any pesticide can be sold or used in the United States, EPA must register the pesticide. A pesticide registration is a license that includes the terms and conditions under which the pesticide may be lawfully sold, distributed, and used, including specific uses of the pesticide, what the pesticide can be sprayed on, and instructions or limitations of the pesticide use. See 7 U.S.C. § 136a(c); 40 C.F.R. §§ 152.115, 156.10.

In passing FIFRA, Congress tasked EPA with implementing the specific data that an applicant must submit to support the pesticide use, consistent with the statute's mandates. *See* 7 U.S.C § 136a(c)(2)(A). EPA has promulgated regulations specifying “the minimum data and information EPA typically requires” to analyze and approve a pesticide registration application. 40 C.F.R. § 158.1(b)(1). EPA requires data on a pesticide's toxicology, environmental fate, and ecological effects. *See, e.g.*, 40 C.F.R. §§ 158.500-.510, 158.630-.660, 158.1300. From these and other data submissions, EPA prepares an ecological risk assessment to evaluate the risks of pesticide exposure to different taxonomic groups, including risks of pesticide exposure to endangered species.<sup>2</sup> *See, e.g.*, 4-PSCER-879-880.

EPA may only register a pesticide for a specific use if it determines, among other factors, that the proposed use of the pesticide “will perform its intended function without unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5). The meaning of “unreasonable adverse effect” is broad, and includes “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”

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<sup>2</sup> *See* EPA, *Overview of the Ecological Risk Assessment Process* 46-47 (Jan. 2004), <https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf>.

*Id.* § 136(bb) (emphasis added). Courts have interpreted FIFRA’s “unreasonable adverse effect” standard to require EPA to conduct a risk-benefit analysis “to ensure that there is no unreasonable risk created for people or the environment from a pesticide.” *Pollinator I*, 806 F.3d at 522-23; *Nat’l Family Farm Coal.*, 960 F.3d at 1142 (“FIFRA requires the EPA to consider, as part of a cost-benefit analysis, ‘any unreasonable risk to man or the environment, *taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.*’”) (quoting 7 U.S.C. § 136(bb) (emphasis in original)); *id.* at 1144 (holding pesticide registration lacked substantial evidence where EPA “substantially understated the costs it acknowledged” regarding damage caused by the pesticide registration and “entirely failed to acknowledge other costs.”).

To ensure public oversight, FIFRA also imposes procedural requirements, particularly for new pesticide active ingredients or new pesticide uses. FIFRA requires that EPA “shall publish” in the Federal Register a “notice of receipt of application” and a “notice of issuance” for every pesticide registration that utilizes a “new active ingredient” or that entails a “changed use pattern,” or “new use.” 7 U.S.C. § 136a(c)(4); 40 C.F.R. § 152.102 (“The Agency will issue in the Federal Register a notice of receipt of each application for registration of a product that contains a new active ingredient or that proposes a new use.”). EPA

defines “new use” to include “any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.” 40 C.F.R. § 152.3. New uses include uses of “new active ingredients, first food use, first outdoor use, first residential use, or other actions of significant interest.”<sup>3</sup>

### B. Endangered Species Act

The ESA is “the most comprehensive legislation for the preservation of endangered species ever enacted by any nation.” *Tenn. Valley*, 437 U.S. at 180. Congress “[made] it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities, thereby adopting a policy which it described as ‘institutionalized caution.’” *Id.* at 194.

Section 7(a)(2) of the ESA reflects Congress’s intent to “give endangered species priority over the ‘primary missions’ of federal agencies.” *Id.* at 185. It creates substantive and procedural obligations applying to every federal agency. *Nat’l Ass’n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 667 (2007). It mandates that “[e]ach federal agency” “insure” its action—here, EPA approving these sulfoxaflor uses—“is

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<sup>3</sup> EPA, *Public Participation Process for Registration Actions*, <https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions> (last visited Feb. 9, 2021).

not likely to jeopardize the continued existence of any endangered species ... or result in the destruction or adverse modification of habitat of such species.” 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.02; 16 U.S.C. § 1532(5)(A); *Sierra Club v. Marsh*, 816 F.2d 1376, 1385 (9th Cir. 1987) (ESA’s mandate is “rigorous”).

Section 7(a)(2), the “heart” of the ESA, establishes a process requiring EPA to evaluate a pesticide’s effects “in consultation with and with the assistance of” the expert wildlife agencies U.S. Fish and Wildlife Service (FWS) and National Marine Fisheries Service (collectively, the Wildlife Agencies) Congress designated as having expertise in determining effects on endangered species. *California ex rel. Lockyer v. U.S. Dep’t of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009); 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b). The consultation to assess a pesticide’s effects is integral to “insuring” EPA implements the ESA’s substantive protections. See *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985), *abrogated on other grounds*, *Cottonwood Env’t Law Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015). EPA must “give the benefit of the doubt to the species” in meeting ESA’s consultation requirements. *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988).

The first step in the Section 7(a)(2) process requires EPA to determine whether the registration “may affect” any listed species or designated critical habitat. If it *may*, EPA then *must* consult. 50 C.F.R. § 402.14(a). The “may affect” standard is

extremely low: [A]ctions that have *any chance of affecting* listed species or critical habitat—even if it is later determined that the actions are ‘not likely’ to do so—*require* at least some consultation under the ESA. *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (emphases added); *id.* (Any possible effect, whether beneficial, benign, adverse or of an undetermined character triggers the requirement) (quoting *Lockyer*, 575 F.3d at 1018-19) (quotation omitted) (emphasis in *Lockyer*).

If this low threshold for “may affect” is met, EPA must proceed to step 2 and consult the Wildlife Agencies. Consultation can be formal or informal. At the end of the consultation, the federal agency will obtain either a written concurrence from the Wildlife Agencies that the proposed action is “not likely to adversely affect” listed species or their habitat (informal consultation), 50 C.F.R. §§ 402.13, 402.14(b)(1), or a biological opinion evaluating the effects of the federal action (formal consultation). 50 C.F.R. § 402.14(a).

To address continuing disagreements over the consultation process, EPA and the Wildlife Agencies requested that the National Academy of Sciences (Academy) evaluate the best scientific approach for assessing the effects of registrations on



endangered species. The resulting 2013 report by the Academy<sup>4</sup> made clear that *any* potential exposure to the pesticide is a “may affect” trigger. Thus, if there is any spatial overlap between the pesticide’s potential use and the habitats of listed species, EPA should proceed to Step 2 and at least informally consult the Wildlife Agencies.<sup>5</sup>

Following the Academy’s report, EPA and the Wildlife Agencies jointly published a guidance document (the Interim Approaches) outlining how they would conduct pesticide consultations going forward.<sup>6</sup> Consistent with the report, the Interim Approaches provide that at the very first step, EPA is to simply determine a pesticide “may affect” any species or critical habitat if it finds species or habitats that overlap with the “potential [pesticide] use sites” and “area of potential effects in and around use sites.”<sup>7</sup> When there is a “may affect,” EPA proceeds to the second step of

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<sup>4</sup> Nat’l Academy of Sciences, *Assessing Risks to Endangered and Threatened Species from Pesticides* (2013), <https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides>.

<sup>5</sup> *Id.* at 9.

<sup>6</sup> EPA, *Interim Approaches for National-Level Pesticide Endangered Species Act Assessment Based on the Recommendations of the National Academy of Sciences April 2013 Report* (July 2017), available at <https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf> (Interim Approaches). EPA subsequently issued an updated guidance (Revised Method), which again affirmed the same three-step process. See EPA, *Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides* (Mar. 12, 2020), available at <https://www3.epa.gov/pesticides/nas/revised/revised-method-march2020.pdf>.

<sup>7</sup> *Id.* at 4-5.

entering at least information consultation—to assess in conjunction with and requiring the concurrence of the Wildlife Agencies—the degree of impacts on protected species, and if necessary continue to the third step, formally consulting the Wildlife Agencies. *Id.*

### **III. EPA’s Registration History of Sulfoxaflor.**

#### **A. The 2013 Initial Registration.**

Dow first sought registration of sulfoxaflor back in 2010, for direct spraying application, or “foliar use,” across the United States on a wide array of crops including many of most produced crops in the U.S. such as soybean, wheat, and cotton, and many specialty crops, from strawberries, citrus, melons, nuts, low growing berries, citrus, vine fruits, pome fruits, to stone fruits. 4-PSCER-803-04.

In light of the systemic nature of sulfoxaflor and its similarity with other neonicotinoid pesticides, EPA knew from the start that the Agency had to examine sulfoxaflor’s effects on “non-target” organisms, that is, those that the insecticide is not intended to kill, and specifically on bees, from honey bees to bumble bees, solitary bees, and other native and wild bees. EPA evaluated sulfoxaflor’s harm to

bees using a three-tier analysis process.<sup>8</sup> See *Pollinator I*, 806 F.3d at 524; 6-PSCER-1307-1365. As this Court previously explained:

The first “preliminary or screening-level” tier, Tier 1, is intended to identify whether potential risks to bees exist. If a risk to bees is identified in Tier 1 then the next tiers, Tier 2 and Tier 3, are intended to define when and where the risks exist and their magnitude. Tiers 2 and 3 “attempt to refine and/or characterize risk estimates to determine the conditions of risk occurrence and, when relevant, to identify spatially-and temporally-specific risks.”

*Pollinator I*, 806 F.3d at 524.

The honey bee data submitted by Dow demonstrated sulfoxaflor’s extreme toxicity to honey bees. Dow’s Tier 1 studies found a high rate of individual honey bee deaths from contact exposure and consumption of sulfoxaflor at application rates significantly lower than the requested sulfoxaflor application rates. 4-PSCER-844; 4-PSCER-785. Accordingly, EPA concluded that sulfoxaflor is “very highly toxic” to honey bees, with a similar level of acute toxicity from consumption of sulfoxaflor to bumble bees. 4-PSCER-785 (“The acute oral toxicity of sulfoxaflor to adult bumble bees (*Bombus terrestris*) is similar to the honey bee.”).

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<sup>8</sup> See EPA, *Guidance for Assessing Pesticide Risks to Bees* (June 19, 2014), available at [https://www.epa.gov/sites/production/files/2014-06/documents/pollinator\\_risk\\_assessment\\_guidance\\_06\\_19\\_14.pdf](https://www.epa.gov/sites/production/files/2014-06/documents/pollinator_risk_assessment_guidance_06_19_14.pdf).

Because the Tier 1 findings found sulfoxaflor to be extremely toxic to individual bees, EPA proceeded to Tiers 2 and 3 to evaluate the effects of sulfoxaflor on honey bee colonies. *See Pollinator I*, 806 F.3d at 525 (“Whereas the framework’s Tier 1 analysis focuses on the effects of the insecticide on individual bees, Tier 2 and Tier 3 analyses attempt to measure the effect on the colony as a whole.”). However, the Tier 2 studies that Dow submitted were either incomplete or methodologically flawed, leading EPA to conclude that “due to limitations associated with [the studies’] design and conduct,” EPA was “unable to preclude risk to [bee colony] from the proposed sulfoxaflor applications.” 4-PSCER-783.

Beyond sulfoxaflor’s harm to honey bees, commenters also warned EPA that sulfoxaflor poses threats to other bee species, birds and mammals, including endangered species and their critical habitats, and the environment generally. *See* 4-PSCER-783; CFSE-230 (“[I]t appears likely that beneficial native insects, including rare and endangered species, will face continuing jeopardy.”); 5-PSCER-914 (describing study which found pesticide drift affected native bees foraging in agricultural landscapes).

EPA’s ecological risk assessment also demonstrated that sulfoxaflor “may affect” federally protected species, triggering EPA’s consultation duties under the ESA. EPA noted in the 2013 ecological risk assessment that there were “potential

direct effects to listed species should they co-occur with application sites” for ESA-protected birds, mammals, terrestrial reptiles, terrestrial amphibians, terrestrial insects, and aquatic invertebrates. 4-PSCER-880. EPA recognized that, pursuant to step 1 of the consultation process, “[a] spatial co-occurrence analysis would be necessary to delineate the action area.” 4-PSCER-881. EPA also recognized that, in light of the proposed widespread use of sulfoxaflor, this spatial co-occurrence analysis at Step 1 would likely lead to Step 2, that is, a “may affect” finding requiring EPA to consult—at least informally—with the Wildlife Agencies. *See id.* (“[G]iven the potential widespread use of sulfoxaflor based on the proposed labels, the action area would likely encompass wide portions of the United States.”). Yet, EPA did not conduct any further analysis nor consult the Wildlife Agencies. 4-PSCER-880.

Because of the extreme risks to bees, EPA initially proposed to conditionally register sulfoxaflor at a lower application rate than that sought by Dow, and imposed use restrictions, while requiring Dow to submit additional studies on honey bees. 4-PSCER-908-09. Yet a few months later, in an abrupt about-face, EPA unconditionally approved Dow’s application, and registered sulfoxaflor uses at the lower application rate on nearly thirty agricultural crops—including soybean, various vegetables, citrus, cotton, cucurbits, strawberry, stone fruit, pome fruit, and tree nuts like almond and pistachio, even though the Agency acknowledged that the lower

application rate still posed a “potential hazard to bees from exposure.” 4-PSCER-771, 4-PSCER-769 (list of approved crop uses). EPA gave no explanation or even any mention of its failure to consult the Wildlife Agencies regarding sulfoxaflor’s potential effects on federally protected species in its registration decision.

B. Pollinator I Litigation.

On July 2, 2013, the PSC Petitioners challenged EPA’s 2013 registration decision for FIFRA violations. In 2015, this Court issued its decision, holding EPA’s 2013 registration unlawful under FIFRA. The Court emphasized that EPA’s FIFRA regulations required the Agency 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.” *Pollinator I*, 806 F.3d at 528 (quoting 40 C.F.R. § 152.112(b)-(c)) (emphases and alterations in original). The Court held that “EPA’s decision to register sulfoxaflor was not supported by substantial evidence.” *Id.* at 532. Examining the deficiencies with Dow’s Tier 2 studies, the Court concluded that the submitted data “did not support approval of sulfoxaflor” even at the reduced rate of application, since they “provided inconclusive and insufficient data on the effects of sulfoxaflor on brood development and long-term colony health.” *Id.* at 529. The Court explained that “an agency cannot rely on ambiguous studies as evidence of a conclusion that the studies do not support.” *Id.* at 531. As such, the

Court held that “[t]he limitations of the underlying data” meant that EPA could not reach a finding of no unreasonable adverse effect on bees from the registration of sulfoxaflor. *Id.* at 531. As to remedy, based on “the precariousness of bee populations,” the Court vacated the registration, and remanded the decision to EPA “to obtain further studies and data regarding the effects of sulfoxaflor on bees.” *Id.* at 532-33.

C. Dow’s 2014 Sulfoxaflor Use Application.

While the *Pollinator I* litigation was pending, EPA sought public comments on Dow’s second sulfoxaflor use application seeking to register sulfoxaflor spraying on even more crops, including alfalfa, buckwheat, cacao, corn, millet, oats, pineapple, rye and sorghum. 6-PSCER-1366-67. After this Court vacated the initial sulfoxaflor registration, rather than submitting the mandated Tier 2 studies, Dow amended its 2014 application to propose use restrictions that it claimed would reduce bees’ exposure to sulfoxaflor, such as limiting sulfoxaflor spraying on crops that bees are known to forage and collect nectar and pollen to “post-bloom,” meaning after the crops have flowered, as well as spray drift and buffer zones to reduce sulfoxaflor drift and runoff. *See* CFSE4. Nor did EPA take any steps to ascertain the potential effect of the proposed new uses on endangered species, despite recognizing the need to do so with the initial sulfoxaflor registration. Instead, EPA sat on the application until

2019, when—without any public notice—EPA unconditionally approved many of the applied uses, and without the restrictions Dow had proposed. *See infra* pp. 21-23.

D. The 2016 Registration.

It was not until May 2016 when EPA once again proposed to unconditionally register sulfoxaflor, this time for use on a wide array of agriculture crops, including barley, triticale, wheat, brassica leafy vegetables, bulb vegetables, leafy vegetables, and watercress, leaves and roots of tuber vegetables, berries (grapes, blueberries, cranberries), canola, fruiting vegetables (tomatoes, peppers, eggplants,) and okra, pome fruits, potatoes, stone fruits, succulents, dry beans, tree nuts and pistachios.<sup>9</sup> *See* 4-PSCER-747-56.

EPA acknowledged that the proposed registration would allow sulfoxaflor to be sprayed on a wide variety of crops that are very attractive to bees as food source, as well as specialty crops that depend on commercial-scale bee pollination for production, including pome fruit (apples and pears), stone fruits such cherries, and treenuts such as almond. *See* 4-PSCER-725. Nonetheless, EPA approved these sulfoxaflor uses because they are on crops that are either not foraged by bees or that are harvested before bloom, and for those crops that are foraged by bees, EPA

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<sup>9</sup> EPA also proposed unconditional registration of sulfoxaflor use on ornamental plants and on turfgrass across different landscapes. *See* 4-PSCER-747-56.



presumed any sulfoxaflor exposure would be eliminated by a ban on sulfoxaflor spraying before and during bloom. *See* 4-PSCER-723; 4-PSCER-696.

On October 14, 2016, EPA unconditionally approved sulfoxaflor uses on a variety of crops, without the additional studies this Court had required, and still without any analysis of the proposed sulfoxaflor uses on imperiled species. *See* 4-PSCER-687-97; *Pollinator I*, 806 F.3d at 532.

E. The Challenged 2019 Registration.

Even though EPA had previously provided the public with an opportunity to comment prior to issuing new sulfoxaflor use approvals, on July 12, 2019, without any prior notice, EPA announced that it was unconditionally approving additional uses of sulfoxaflor, including uses on bee-attractive crops previously vacated by this Court, and which EPA had specifically declined to approve back in 2016. CF5ER-5 (“The new uses [of sulfoxaflor] are alfalfa, corn, cacao, grains (millet, oats), pineapple, sorghum, teff, teosinte and tree plantations. This regulatory action also adds the following crops back ... : citrus, cotton, cucurbits, soybeans and strawberry.”).

EPA justified the 2019 Registration by relying in the main on new Tier 2 studies that Dow had submitted, even though EPA admitted that the studies showed that the new uses could harm honey bees on a colony level. *See* 3-PSCER-362-63

(concluding that there was “a potential for colony level risk resulting from oral exposure” for the approved sulfoxaflor uses”). EPA also noted several deficiencies of the Tier 2 studies that render their results unreliable for predicting sulfoxaflor risks. See, e.g., 3-PSCER-364 (“[T]here is a potential for the oral Tier II risk assessments results to underestimate colony-level risk to honey bees.”), 3-PSCER-571-84 (summarizing new Tier 2 studies and noting deficiencies that “limit[] [their] use in pollinator risk assessment”).

Beyond the risks to honey bees, EPA also acknowledged that non-honey bees may be at greater risk than honey bees from sulfoxaflor due to biological and behavior differences, and that its risk assessment did not account for such differences in analyzing potential unreasonable adverse effects of sulfoxaflor. See 3-PSCER-490 (“For ground nesting bees, exposure via direct contact with soil may be a major route of exposure unlike that for the honey bee.”); 3-PSCER-489 (“[T]he current risk assessment process for bees does not include a formal process that is specific to non-*Apis* bees.”).<sup>10</sup>

In addition to authorizing sulfoxaflor uses on bee-attractive crops that pose the most harm to honey bees, the 2019 Registration also removed many of the

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<sup>10</sup> In its risk assessment, EPA refers to non-honey bees collectively as non-*Apis* bees in light of the name of the honey bees’ genus name, *Apis*. See 3-PSCER-489.

mitigation measures that EPA put in place in 2016 that are intended to prevent unreasonable adverse effects on bees and other species from sulfoxaflor exposure, again without any prior opportunity for public comment. The protections that EPA removed include the requirement for a downwind, on-field buffer zone, prohibition of use on crops grown for seed, and the restriction limiting spraying on canola, fruiting vegetables, ornamentals, pome fruit, potato, and succulent and dry beans to the post-bloom period. *See* CFSER-25-29.

Finally, regarding endangered species, EPA openly admitted in the 2019 registration decision that, nearly a decade after receipt of the initial sulfoxaflor registration from Dow in 2010, it still had not undertaken even the first step in the consultation process because it “has not made an effects determination for sulfoxaflor.” CFSER-12; 4-PSCER-521 (“This ecological risk assessment for sulfoxaflor does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat.”). Instead, EPA rationalized its refusal to follow the ESA’s requirements by claiming that its belief that “as a general matter, older pesticides present a greater degree of risk to listed species than most new chemistries, including sulfoxaflor, and that it is therefore environmentally preferable in most circumstances for EPA to assess the impacts of existing pesticides sooner in the process than newer pesticides.” *Id.*

## SUMMARY OF ARGUMENTS

EPA violated the Endangered Species Act. EPA has admitted to this Court that it failed to abide by its duty under the ESA to insure that the 2019 Registration would not jeopardize the existence of any federally protected species nor destroy or modify their habitats by making an initial determination on sulfoxaflor's effects, and engaging in consultation with the Wildlife Agencies as necessary.

Therefore, as to CFS Petitioners' ESA claim, the only issue before this Court is whether vacating the 2019 Registration is the appropriate remedy. It is. Vacatur is the presumptive, default statutory remedy for EPA's legal violations in registering a pesticide use. The burden is on EPA to show why this is the rare case where equity requires anything less than vacatur, and EPA has not and cannot carry that heavy burden here. EPA's intentional violations of the ESA are very serious for purposes of the vacatur test because they go to the heart of the statutory scheme. Moreover EPA knew that sulfoxaflor threatens the existence of federally protected species, from insects, birds, mammals, to amphibians and reptiles, but went ahead and approved and expanded sulfoxaflor uses on major agricultural crops, including those posing the most threat to endangered insects. Anything short of vacatur of the 2019 Registration will simply allow EPA to continue to flout its ESA duties, to the detriment to endangered species.

The 2019 Registration also violates FIFRA's procedural and substantive requirements. Procedurally, EPA violated FIFRA's requirements for public notice and comment when it approved, without any opportunity for public comment, sulfoxaflor uses that pose the highest risk to bees and pollinators, the very uses that were previously vacated by this Court in *Pollinator I*. EPA also removed the protective measures it had previously imposed on sulfoxaflor use without any opportunity for public comment. Substantively, EPA's conclusion that the 2019 Registration would not result in unreasonable adverse effects on the environment lacks support in substantial evidence, the requisite finding for EPA's unconditional registration decision at issue here. In assessing the risks, EPA underestimated sulfoxaflor's environmental impacts by relying on a flawed alternative pesticide comparison that was improperly cabined in scope, and which did not actually assess the real-world effects of sulfoxaflor use on various species, including honey bees. EPA also entirely failed to account for the increased harm that sulfoxaflor poses to non-honey bees. As with EPA's ESA violation, the harm to bees demand that the Court vacate the 2019 Registration. *Pollinator I*, 806 F.3d at 532 (“[G]iven the precariousness of bee populations, leaving the EPA’s registration sulfoxaflor in place risks more potential environmental harm than vacating it.”).

## STANDARD OF REVIEW

The ESA requires that federal agencies consult the Wildlife Agencies on any approval action that “may affect” any protected species or critical habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14(a), 402.01(b). This duty is triggered by “[a]ny possible effect, whether beneficial, benign, adverse or of an undetermined character.” *Karuk Tribe*, 681 F.3d at 1027. EPA violated the ESA if its failure to consult the Wildlife Agencies before issuing the 2019 Registration was arbitrary, capricious, an abuse of discretion, or otherwise not in compliance with law. *Id.* at 1017; 5 U.S.C. § 706(2)(A).

The Court may sustain EPA’s 2019 Registration under FIFRA only if EPA’s orders are “supported by substantial evidence when considered on the record as a whole.” 7 U.S.C. § 136n(b). Judicial review must be “searching and careful, subjecting the agency decision to close judicial scrutiny.” *Containerfreight Corp. v. United States*, 752 F.2d 419, 422 (9th Cir. 1985). The decision may be upheld only on the “basis articulated by the agency itself.” *Pollinator I*, 806 F.3d at 532 (quoting *Motor Vehicle Mfrs. Ass’n of the U.S. vs. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983)).

“[T]he substantial evidence standard affords an agency less deference than the arbitrary and capricious standard.” *Pollinator I*, 806 F.3d at 1118 (N.R. Smith, J.,

concurring) (citing *Universal Camera Corp.*, 340 U.S. at 477 and *Union Oil Co. of Cal. v. Fed. Power Comm'n*, 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*, 463 U.S. at 43. The Court's "review must not rubber-stamp ... administrative decisions that [the court deems] inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 361 F.3d 1108, 1119 (9th Cir. 2004) (internal citations and quotations omitted).

If the Court holds EPA's 2019 Registration unlawful under either FIFRA or the ESA, this Court should "set aside," or vacate, the registration. 7 U.S.C. § 136n(b) (vesting courts with authority to "affirm or set aside" EPA's FIFRA orders in whole or in part). *Pollinator I*, 806 F.3d at 532-33; *All. for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1121-22 (9th Cir. 2018) (explaining the "presumption of vacatur" unless defendants meet their burden to show equity demands otherwise).

## ARGUMENT

### I. EPA Violated the ESA.

For the past decade, EPA has continued to disregard the ESA mandate that EPA “insure” its sulfoxaflor use approvals are not likely to either jeopardize any endangered species or adversely modify any designated “critical” habitat. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.02.

In this case, EPA has now waved the white flag on the merits of Petitioners’ claim: EPA has belatedly admitted to this Court that it agrees that the ESA required EPA determine the potential harm of sulfoxaflor to endangered species before issuing the 2019 decision and consult as necessary, and it simply violated that mandate. *See* EPA’s Mot. Remand 1, ECF No. 51-1 (“EPA recognizes that the Agency failed to comply with the ESA’s requirements prior to issuing the registration amendments for sulfoxaflor.”). EPA’s rationale for not consulting has no legal basis under the ESA’s framework establishing stringent protection of endangered species. This Court should hold that EPA violated the ESA in issuing the 2019 Registration and vacate the registration based on that violation.

#### A. EPA Has Admitted Its Flagrant Violation of the ESA.

EPA has now acknowledged to this Court that it “failed to comply with the ESA’s requirements prior to issuing the registration amendments for sulfoxaflor.”



EPA's Mot. Remand 1, ECF No. 51-1. EPA had asked that the Court remand the 2019 Registration without vacatur so that EPA can belatedly "make an 'effects determination'" regarding sulfoxaflor's effects on endangered species, "and take additional follow up action as appropriate." *Id.* The Court denied EPA's request. See Order, ECF No. 67. As a result of its failure to consult, EPA violated its substantive duty to ensure that registering sulfoxaflor uses across agricultural landscapes are not likely to jeopardize the continued existence of any endangered or threatened species, or destroy or adversely modify critical habitat. 16 U.S.C. § 1536(a)(2). Having admitted its ESA violation, EPA cannot now contest the merits of Petitioners' claim that the 2019 Registration violates the ESA. See *New Hampshire v. Maine*, 532 U.S. 742, 750 (2001) ("judicial estoppel prevents parties from playing fast and loose with the courts.") (citation omitted).

EPA's inaction is not merely procedural, but has dire consequences for protected species. For example, the fate of the endangered rusty patched bumble bee illustrates the real-world harms inflicted by EPA's indifference to its ESA duties here. In 2017, the expert FWS listed the rusty patched bumble bee as endangered, meaning it is in danger of extinction, identifying exposure to pesticides as one of the

primary causes of the endangered bees' significant decline.<sup>11</sup> The population of rusty patched bumble bee has declined by more than 87 percent in the last twenty years, and the bee now occupies only 8 percent of its historical range.<sup>12</sup> The hive populations are also dwindling; 95 percent of recently documented hives contained five or fewer individual bees.<sup>13</sup>

FWS found that pesticides like sulfoxaflor (neonicotinoids) pose an even greater threat to the rusty patched bumble bee than honey bees, because the bumble bees' smaller colony size means that the survival of a single bumble worker bee contributes much more significantly to the survival of the entire colony.<sup>14</sup> In addition to exposure to pesticide residues from nectar and pollen, because bumble bees nest underground, they are also exposed to pesticide residues in the soil.<sup>15</sup> Bumble bee larvae also consume large amounts of contaminated pollen, placing the

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<sup>11</sup> Endangered Species Status for Rusty Patched Bumble Bee, 82 Fed. Reg. 3,186, 3,187 (Jan. 11, 2017).

<sup>12</sup> FWS, *Rusty Patched Bumble Bee (Bombus Affinis) Species Status Assessment 4* (June 2016), available at <https://www.fws.gov/midwest/endangered/insects/rpbb/pdf/SSARreportRPBBwAdd.pdf>.

<sup>13</sup> *Id.* at 98.

<sup>14</sup> 82 Fed. Reg. at 3,190.

<sup>15</sup> *Id.*

survival of the next generation of rusty patched bumble bees at risk. *Id.* Crucially, much of the rusty patched bumble bees' range, as identified by the expert FWS, overlap with soybean and corn fields where sulfoxaflor can now be sprayed. See CFS's Pet'rs' Remand Opp'n Addendum, at CFS\_A095-96 (Bradley Decl., Ex. I.) (map showing crop fields and rusty patched bumble bees' range based on FWS's data).

As this Circuit has explained, “[i]f a project is allowed to proceed without substantial compliance with [the ESA’s] procedural requirements, there can be no assurance that a violation of the ESA’s substantive provisions will not result. The latter, of course, is impermissible.” *Thomas*, 753 F.2d at 764 (emphasis added). EPA’s failure to abide by the ESA’s consultation procedures has substantive impacts on the survival and existence of endangered species, and is impermissible.

B. EPA’s Justification for Its ESA Failure Has No Basis in Law or Fact.

EPA attempted to rationalize its failure to consult by stating that it was instead prioritizing ESA assessments for older pesticides currently undergoing FIFRA registration review. CFSE-11; 7 U.S.C. § 136a(g) (requiring periodic review of registered pesticides). EPA unilaterally proclaimed that “EPA *believes* [these older pesticides] to be more toxic compounds, that, among other things, pose greater risk to endangered species than does sulfoxaflor.” CFSE-12 (emphasis added). EPA

concluded that it “does not believe the environment or the public would be best served by delaying the registration of sulfoxaflor to complete consultation.” *Id.*

As an initial matter, regardless of whatever legally dubious rationale EPA gave in the 2019 Registration for its failure to consult, it has now disavowed that position to this Court in its remand motion, and admits it must consult. EPA’s Remand Mot. 1. Accordingly in this briefing the Court should not permit EPA to backtrack and now defend the 2019 administrative position that EPA has abandoned in 2020 motion practice before this Court, simply because EPA *lost* its remand motion. See *New Hampshire*, 532 U.S. at 749-50 (explaining that the doctrine of judicial estoppel “prohibit[s] parties from deliberately changing positions according to the exigencies of the moment.”) (citation omitted).

Regardless, even if the Court does countenance any backtracking of EPA’s prior admission that it violated the ESA, none of what EPA said in the 2019 registration decision is a lawful excuse for failing to consult.

First, as matter of law, EPA’s excuse—that in its view it would be better for the environment and the public to register sulfoxaflor uses without ESA consultation—finds no support in the statute. Rather, the ESA’s plain text unequivocally mandates EPA to “ensure that *none of* [its] activities ... will jeopardize the continued existence of any endangered species” by consulting with the expert Wildlife Agencies. *Babbitt*

*v. Sweet Home Chapter of Cmty. for a Great Or.*, 515 U.S. 687, 692 (1995). Nor does EPA's rationale, that registering sulfoxaflor uses may be better for "the environment or the public," have any relevance in the ESA context, where Congress made plain that the protection of endangered species be given "the highest of priorities." *Tenn. Valley*, 437 U.S. at 180; *see supra* pp. 10-14.

The D.C. Circuit has already rejected the very same excuse in a challenge to another pesticide. In *Center for Biological Diversity v. EPA*, 861 F.3d 174 (D.C. Cir. 2017), petitioner conservation groups, including CFS Petitioners, challenged EPA's registration of the pesticide cyantraniliprole, for failure to consult under the ESA. *Id.* at 177. Just as with sulfoxaflor, there EPA approved cyantraniliprole use without making an effects determination, or consulting with the Wildlife Agencies.

In the cyantraniliprole decision, EPA offered the *exact same* excuse for its failure to abide by the ESA, stating that it "does not believe the environment or the public would be best served by delaying the registration of cyantraniliprole to complete consultation." Pet'rs.' Opening Br. 13, *Ctr. for Biological Diversity*, 861 F.3d 174 (No. 14-1036), 2016 WL 675922, at \*13 (quoting EPA's registration decision document) (internal quotation marks omitted). And just like EPA did here, EPA belatedly admitted to the D.C. Circuit that its registration decision violated the ESA. *See* EPA's Answering Br. 58, *Ctr. for Biological Diversity*, 861 F.3d 174 (No. 14-1036),

2016 WL 2941537, at \*58 (“EPA does not contest that it has not made an ‘effects’ determination or initiated consultation regarding its registration order for cyantraniliprole consistent with the ESA and its implementing regulations.”).

However, despite EPA’s admission, the pesticide registrant intervenor argued that EPA’s failure was excusable since EPA was prioritizing ESA compliance of older pesticides. *See Ctr. for Biological Diversity*, 861 F.3d at 188 n.10. The D.C. Circuit resoundingly rejected the argument, holding:

In no uncertain terms, the ESA mandates that every federal agency “shall” engage in consultation before taking “any action” that could jeopardize the continued existence of any endangered species or threatened species.” 16 U.S.C. § 1536(a)(2). Absent a formal exemption under 16 U.S.C. § 1536(h), *an agency may not duck its consultation requirement, whether based on limited resources, agency priorities or otherwise. Id.*

*Id.* (emphasis added). This Court should rejected EPA’s identical excuse.

More fundamentally, whatever EPA may “believe” to be more risky for endangered species, EPA lacks the authority, mandate, and scientific expertise to determine what would put endangered species at risk. Unlike the Wildlife Agencies, EPA has no particular expertise in endangered species’ survival and recovery, nor in interpreting and applying the ESA’s standards. *See City of Tacoma, Washington v. F.E.R.C.*, 460 F.3d 53, 75 (D.C. Cir. 2006) (“This interagency consultation process reflects Congress’s awareness that expert agencies (such as the Fisheries Service and

the Fish and Wildlife Service) are far more knowledgeable than other federal agencies about the precise conditions that pose a threat to listed species.”). How risky one pesticide exposure may be to a given endangered species versus another pesticide exposure to the same endangered species is simply not a determination that Congress permitted EPA to make alone; that is exactly the point of consultation and the low threshold requiring it.

Second, EPA’s 2019 registration rationale is also wrong as a factual matter. EPA’s administration of other pesticides shows that EPA has all the data and tools needed to perform its ESA-mandated analysis. EPA simply unlawfully decided not to so act.

As EPA acknowledged, to make the initial, step 1 “effects” determination, EPA must simply determine whether sulfoxaflor use sites could overlap, or “co-occur,” with the ranges or critical habitats of endangered species. *See* 4-PSCER-881; *supra* pp. 16-17. As explained above, overlap or co-occurrence is sufficient to trigger at least informal consultation for pesticides, pursuant to the National Academy of Sciences’ seminal report and subsequent EPA and Wildlife Agency’s implementation of that report. *See supra* pp.11-14.

For several other pesticides, EPA *has already mapped out* the overlap between areas where pesticides may be present and the species’ range and critical habitats, for

many of the same crop uses EPA approved for sulfoxaflor in the 2019 Registration. See CFS Pet'rs' Remand Opp'n Addendum, at CFS\_A135-36 (Donley Decl. ¶¶ 14-15) (discussing the co-occurrence analysis EPA conducted in its biological evaluations of the insecticides chlorpyrifos, diazinon, and malathion for alfalfa, citrus, corn, cotton, cucurbits, sorghum, soybean, and strawberry). Similarly, in its registration of cyantraniliprole, EPA identified 1,377 endangered species whose range and critical habitats overlapped with areas of proposed cyantraniliprole use. See Jt. Appx., at 150-51, *Ctr. for Biological Diversity*, No. 14-1036 (D.C. Cir. filed Aug. 8, 2016), Doc. No. 1629167.

Thus EPA already had *all the information it required* to see that the 2019 Registration easily triggered the low “may affect” threshold, and that consultation of some kind was required. EPA was fully capable of making the initial “effects” determination prior to approving sulfoxaflor uses. EPA simply chose to shrug off its legal duties under the ESA, and cut off its assessment process, in order to avoid consultation with the Wildlife Agencies that it now belatedly admits it is required to undertake. The Court should not excuse EPA’s blatant disregard of the law, and instead should vacate the registration until and unless EPA complies with the ESA’s mandates.



## II. EPA Violated FIFRA.

### A. The 2019 Registration Violated FIFRA's Procedural Requirements.<sup>16</sup>

EPA violated FIFRA by failing to provide notice and opportunity for public comment on (1) Dow's application to register sulfoxaflor uses on citrus, cotton, cucurbits, soybeans and strawberry, uses that had been vacated by this Court in *Pollinator I*; and (2) EPA's removal of sulfoxaflor use restrictions that it had previously imposed in 2016.

As explained *supra*, under FIFRA, EPA must publish "a notice of [] application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern" in the Federal Register, and provide 30 days for public comment. 7 U.S.C. § 136a(c)(4); 40 C.F.R. § 152.102. Although EPA had initially registered sulfoxaflor use on citrus, cotton, cucurbits, soybeans and strawberry in 2013, this Court vacated those use approvals in *Pollinator I*. Similarly, EPA had relied on mitigation measures such as buffer zones and limiting sulfoxaflor spraying to bee-attractive crops after they have finished blooming to justify

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<sup>16</sup> CFS Petitioners join in full PSC Petitioners' argument that EPA violated FIFRA's procedural requirements on public notice and comment, and add only a few additional points here. See PSC Pet'rs' Opening Br. 20-22, ECF No. 37-1.

registering sulfoxaflor uses on a wide variety of agricultural crops in 2016, yet the 2019 Registration eliminated such protective measures. *See supra* pp. 21-23.

The new uses and removal of restrictions constitute “new uses” that triggered EPA’s duty to provide notice and comment prior to the 2019 Registration. As for the uses previously approved in 2010 and reapproved in 2013, this Court vacated them. Thus, the 2019 new uses do not have a lawful predicate and were “new uses” when EPA registered them in 2019. *See* CFSE-3 (“Decision Memorandum Supporting the Registration Decision for *New Uses* of the Active Ingredient Sulfoxaflor on Alfalfa, Cacao, Citrus, Corn, Cotton, Cucurbits, Grains, Pineapple, Sorghum, Soybeans, Strawberries and Tree Plantations and Amendments to the Labels”) (emphasis added); 40 C.F.R. § 152.3 (defining “new use” as “any ... outdoor ... use pattern” not currently registered). Indeed, Dow did not include any of the previously-approved uses when it again applied for sulfoxaflor use approval in 2016. 4-PSCER-748-49; 4-PSCER-642 (“Pollinator data submitted by the registrants in 2016, once again supported registration of sulfoxaflor, but on a limited number of agricultural sites”). Importantly, EPA’s 2019 Registration was based the new Tier 2 studies that Dow submitted *in 2018*, information and rationale that were not presented to the public back in 2010. *See supra* pp. 21-23; *see* 7 U.S.C. § 136a(c)(4)

(requiring EPA to publish public notice “promptly after receipt of ... data required” to support a pesticide registration).

For the same reason, that EPA provided public notice and comment in 2016 is no substitute for EPA’s decision to, in the 2019 Registration, remove the mitigation measures it previously sought public comments on in issuing the 2016 registration. Removal of the 2016 mitigation measures also constitutes “new use” that triggered EPA’s duty to provide notice and opportunity for public comment. See 40 C.F.R. § 152.3 (“new use” includes “additional use pattern that would result in a significant increase in the level of exposure.”).

By failing to provide public notice and comment before issuing the 2019 Registration, which approved many of sulfoxaflor’s riskiest uses for bees and pollinators, and removed mitigation measures EPA put in place for the same species’ protection in 2016, EPA violated FIFRA’s procedural mandates.

B. EPA’s Conclusion that the Approved Sulfoxaflor Uses Is Better for the Environment Is Not Supported by Substantial Evidence.

EPA’s decision to register sulfoxaflor for additional uses can only be upheld if EPA concludes that the benefits of registration outweigh the risks of the proposed uses. See *Nat’l Family Farm Coal.*, 960 F.3d at 1133 (“FIFRA uses a cost-benefit analysis to ensure that there is no unreasonable risk created for people or the environment from a pesticide.”) (quoting *Pollinator I*, 806 F.3d at 522–23). Here,

EPA found that there were serious risks from sulfoxaflor, however EPA erroneously concluded that the registration would still not result in unreasonable adverse effects, in part, because, according to EPA, sulfoxaflor nonetheless “has a better ecological and human health profile” than existing alternative pesticides. CFSER-13. EPA reached this conclusion by conducting a hazard comparison of sulfoxaflor to six other insecticides. *See* CFSER-21; 2-PSCER-340-41. However, EPA’s hazard comparison suffers critical flaws, and its conclusion that sulfoxaflor offers the benefit of better ecological profile than alternative pesticides lacks support in substantial evidence, in violation of FIFRA.

First, the scope of EPA’s hazard comparison was overly narrow. EPA only compared sulfoxaflor to six selected insecticides from three different classes of pesticides: lambda-cyhalothrin and bifenthrin, both belonging to the pyrethroid class; chlorpyrifos, acephate, dicrotophos, three organophosphate pesticides; and imidacloprid, a neonicotinoid. CFSER-21.

These six cherry-picked insecticides are, by EPA’s own admission, some of the most toxic pesticides in the marketplace today. For example, five of the six selected insecticides—lambda-cyhalothrin, bifenthrin, chlorpyrifos, acephate, and

dicrotophos—are commonly found active ingredients of “restricted use pesticides,”<sup>17</sup> so classified because EPA determined that their use “may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator.” 7 U.S.C. § 136a(d)(1)(C). EPA has also identified imidacloprid as being “very highly toxic to adult honey bees” in its proposed interim registration review of the neonicotinoid insecticide.<sup>18</sup>

EPA was well aware that other alternatives to control pests for the same crops exist, but simply chose not to include them in its hazard comparison. As EPA admitted, the six selected insecticides “account for 65% of the total acreage treated in those crops targeting sulfoxaflor’s target pest spectrum.” CFSE-19. Elsewhere in the record, EPA readily points out that there are *less toxic* alternatives. For example, EPA’s sulfoxaflor benefits assessment acknowledged that Dow had identified many “reduced risk” pesticides,<sup>19</sup> or even non-pesticide pest control methods, as

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<sup>17</sup> EPA, *Restricted Use Product Summary Report* (Oct. 24, 2019), available at <https://www.epa.gov/sites/production/files/2019-10/documents/rup-report-oct2019.pdf>.

<sup>18</sup> EPA, *Imidacloprid Proposed Interim Registration Review Decision* (Jan. 2020), available at [https://www.epa.gov/sites/production/files/2020-01/documents/imidacloprid\\_pid\\_signed\\_1.22.2020.pdf](https://www.epa.gov/sites/production/files/2020-01/documents/imidacloprid_pid_signed_1.22.2020.pdf).

<sup>19</sup> “Reduced risk” pesticides are those “that pose less risk ... than conventional alternatives.” EPA, *Conventional Reduced Risk Pesticide Program*, <https://www.epa.gov/pesticide-registration/conventional-reduced-risk-pesticide->

alternatives to sulfoxaflor. *See, e.g.*, 4-PSCER-649-50 (stating that Dow has submitted data comparing sulfoxaflor use for aphid control in alfalfa to reduced risk pesticides flupyradifurone and flonicamid), 4-PSCER-654 (“In corn, aphids are often kept below populations that would cause economic damage by natural parasites and predators....”), 4-PSCER-660-61 (listing reduced risk pesticides flupyradifurone, spinosad, spirotetramet, and tolfenpyrad as alternatives for pest control in citrus), 4-PSCER-666-67 (alternatives for pest control in cucurbits include chlorantraniliprole and flonicamid), 4-PSCER-670 (identifying flonicamid as a leading insecticide for pest control in strawberry); *see also* CFS Pet’rs’ Remand Opp’n Addendum, at CFS\_A138-39 (Donley Decl. ¶¶ 20-21), CFS\_A144-47 (Donley Decl., Exs. 1-2).

Indeed, EPA listed at least *twelve* reduced risk insecticides that are being widely used to control many of the same pests in many of the same crops (including alfalfa, citrus, cucurbits, strawberry, cacao, pome fruit, cotton) for which EPA approved or amended sulfoxaflor use in the 2019 Registration. *See* CFS Pet’rs’ Remand Opp’n Addendum, at CFS\_A138, (Donley Decl. ¶ 20), CFS\_A139-40 (Donley Decl. ¶¶ 22-24) (summarizing data from the U.S. Department of

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program#: ~:text=OP)%20Alternative%20Status-  
 ,What%20is%20the%20Conventional%20Reduced%20Risk%20Pesticide%20Prog  
 ram%3F,environment%20than%20existing%20conventional%20alternatives (last  
 visited Feb. 14, 2021).

Agriculture showing many of the reduced risk insecticides are being readily applied to treat pests in citrus, apple, strawberries, and tomatoes).

EPA has no explanation in the record as to why it only compared sulfoxaflor to six toxic insecticides, when the data before it pointed to many other, less toxic alternatives. EPA's conclusion that sulfoxaflor is "safer" based on a gerrymandered comparison to only the most hazardous alternatives renders its decision unsubstantiated by record evidence. *See Nat'l Family Farm Coal.*, 960 F.3d at 1138-39 (holding that EPA underestimated the risks associated with the pesticide dicamba where EPA ignored data in the record on, among other things, the extent of crop damage caused by dicamba drift).

Second, even accepting EPA's limited selection of alternative insecticides as sufficient, EPA's conclusion that sulfoxaflor has "a better ecological profile" still lacks substantial evidence in support, because EPA's hazard comparison did not actually compare the potential exposure and resulting risks of harm to species and the environment from the six selected insecticides. EPA's hazard comparison only discusses the insecticides' relative toxicity, and makes no mention of exposure and the resulting actual effects on species and the environment. *See* CFSE-19 ("Sulfoxaflor's toxicity to non-target organisms is generally much lower than the toxicity of these alternatives...."); 2-PSCER-340. ("The purpose of this memo is to

provide a comparison of the toxicity of sulfoxaflor ... to registered alternative compounds”).

As EPA itself recently explained in the context of similar hazard comparison for another pesticide:

Regarding the Ecological Hazard Characterization, the analysis used for comparing new active ingredients is based solely on hazard (e.g., it is based on toxicity endpoint comparisons) and *does not factor in the differential exposure and resulting risk for each of the alternatives*. The hazard assessment is intended to provide a high-level comparison and is *not intended to inform on the calculated risks that are obtained with the exposure modelling*.<sup>20</sup>

Thus, in EPA’s own words, hazard comparisons such as the one EPA conducted here “does not provide an indication of the likelihood of the adverse effect occurring on the environment.”<sup>21</sup>

Third and crucially, the hazard comparison cannot support EPA’s finding that the 2019 Registration would not result in unreasonable adverse effects on the environment, as FIFRA demands, because the hazard comparison failed to compare sulfoxaflor’s toxicity specifically to bees to that of alternative insecticides; and

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<sup>20</sup> EPA, *Response to Public Comments on EPA’s Registration of the New Active Ingredient Inpyrfluxam*, available at <https://www.regulations.gov/document?D=EPA-HQ-OPP-2018-0038-0039> (last visited Feb. 10, 2021) (emphases added).

<sup>21</sup> *Id.* at 17.



because the little data on bee toxicity that EPA did compare actually showed that even some of the toxic alternatives EPA included in the hazard comparison are less toxic to bees than sulfoxaflor.

EPA readily admits that it lacks data on honey bee toxicity for the selected alternatives. *See* CFSEER-23 (“A full comparison of honeybee toxicity for sulfoxaflor and its main alternatives cannot be made because EPA does not yet have all the data for the other insecticides.”); 2-PSCER-340-42. EPA identified risk to bees as one of the major risk factors of sulfoxaflor, yet EPA cannot know if the alternatives are safer for bees without sufficient bee toxicity data on the alternative insecticides it had identified. Instead, after acknowledging the vital role honey bees and other pollinators play to the U.S. food supply, EPA simply concluded that “EPA believes that sulfoxaflor is better for bees than the registered alternatives.” *See Pollinator I*, 806 F.3d at 532 (“Without sufficient data, the EPA has no real idea whether sulfoxaflor will cause unreasonable adverse effects on bees.”).

Moreover, EPA’s “belief” is plainly contradicted by the little data on honey bee toxicity of the alternative insecticides that EPA did possess. EPA had toxicity data for acute contact of adult bees for sulfoxaflor as well as all six alternative insecticides, expressed in the acute median lethal dose (LD<sub>50</sub>), or the amount of the pesticide that is sufficient to kill half of the individual bees tested. Whereas EPA

determined the LD<sub>50</sub> of sulfoxaflor to be 0.13 micrograms, the LD<sub>50</sub> value for two of the alternatives—acephate and dicrotophos—were much higher, at 1.2 micrograms and 0.76 micrograms, respectively. This means that the two alternatives are *less* toxic, since it takes ingesting much more of the two insecticides to kill half of the bee population tested. *See* 2-PSCER-341.

In sum, EPA's conclusion that sulfoxaflor is safer than alternative insecticides lacks substantial evidence because EPA conducted an insufficient hazard comparison that compared sulfoxaflor to only six other extremely toxic insecticides. Moreover, the insufficient hazard comparison is also deficient because: (1) it failed to take into account real-world exposure factors, but only analyzed absolute toxicities; (2) the comparison was based on incomplete bee toxicity data; and (3) the existing bee toxicity data EPA did compare actually showed that sulfoxaflor is not the least toxic insecticide for bee protection.

C. EPA Failed to Assess Sulfoxaflor Risks to Non-Honey Bees.

EPA's determination that the sulfoxaflor uses would not have unreasonable adverse effect on the environment also lacks support in substantial evidence because EPA failed to account for the increased exposure to sulfoxaflor faced by non-honey bees, including thousands of other species of native and wild bees, as well as commercially-kept non-honey bee species that, like honey bees, provide critical

pollination for agricultural crops. See 3-PSCER-489 (“[W]ithin North America alone, there are an estimated 4,000 species of bees”); CFSE-23 (“Other managed pollinators utilized by growers include alkali bees, leaf-cutting bees and bumblebees.”). As EPA acknowledges, these non-honey bees “play an important role in crop and native plant pollination, besides their overall ecological importance via maintaining biological diversity.” 3-PSCER-489.

EPA was well aware that the honey bee risk assessment framework is inadequate to capture the potential risks sulfoxaflor uses poses to non-honey bees due to the differences in biology and ecology of non-honey bees. See 3-PSCER-489.

As EPA explained in the ecological risk assessment:

Several aspects of the biology and ecology of non-*Apis* bees lead to *important differences in the route and extent to which they may be exposed to pesticides compared to honey bees. ... Specifically, many non-*Apis* bees are smaller in size and thus, would in theory receive a higher dose on a contact exposure basis (i.e., greater surface area to volume ratio) via intercepting droplets of sprayed pesticide. Most non-*Apis* bees are solitary nesting species and therefore, loss of a single nesting adult would have a much greater consequence on reproduction (at least for that nest) compared to the loss of a single adult foraging honey bee from a colony. Furthermore, the foraging range of non-*Apis* bees tends to be much smaller than that of honey bees. As a consequence, non-*Apis* bees that occupy areas adjacent to treated fields may be exposed to pesticides at a higher proportion of their foraging area compared to honey bees[.] ... For ground nesting bees, exposure via direct contact with soil may be a major route of exposure unlike that for the honey bee... . Soil and leaf material are known to be used extensively by some non-*Apis* bees for*

nest construction, which may lead to different types of exposures (e.g., contact exposure with contaminated residues on treated foliage).

3-PSCER-489-90 (emphases added). It is in recognition of these differences that EPA attempted to, in the risk assessment, compare sulfoxaflor exposure to non-honey bees with that of honey bees. *See* 3-PSCER-490.

However, EPA's comparison is critically flawed because EPA only compared honey bee and non-honey bees' relative exposure to sulfoxaflor through their consumption of nectar and pollen, and entirely failed to consider non-honey bees' contact exposure to sulfoxaflor via soil and foliar pathways, which EPA acknowledged were significant. *See* 3-PSCER-490, tbl. 11-34; 3-PSCER-491, tbl. 11-35.

The data on oral exposure shows that for adult bees, the total nectar and pollen consumption rate was comparable between honey bees and non-honey bees. *See* 3-PSCER-490, tbl. 11-34 (listing total food consumption rate at 292 mg/bee/day for honey bees, 210-402 for bumble bees, 45-193 for European mason bees, 110-165 for Alfalfa leaf-cutting bees). However, EPA also had data showing that non-honey bees would also be exposed to substantially more sulfoxaflor from contact to sulfoxaflor residue in soil and plant materials. *See* 3-PSCER-489-90. EPA pointed out in the risk assessment that, “[f]or the European mason bee, contact exposure to mud by adult

females has been estimated at 200-400 mg/bee/day,” and that “contact exposure of alfalfa leaf cutting bees has been estimated at 173 mg/bee/day.” 3-PSCER-491.

Thus, EPA’s own data showed that at least two species of non-honey bees, the European mason bee and the alfalfa leaf-cutting bee, would be exposed to significantly more sulfoxaflor via contact exposure to the insecticide’s residue in soil and on plant materials, in addition to oral exposure. *See* 3-PSCER-491. Yet, despite admitting that “soil and foliar exposure [to sulfoxaflor] ... *are likely more important* for some non-*Apis* bees,” EPA declined to analyze those exposure pathways. 3-PSCER-491 (emphasis added). Instead, EPA relied solely on its data and analysis of sulfoxaflor exposure to honey bees to summarily conclude that sulfoxaflor use would not result in unreasonable adverse effects to *all bees*. *See* 3-PSCER-496-98(basing conclusions “regarding risks to bees” on the relative risks of sulfoxaflor uses to honey bees).

Nor does EPA have any excuse for its failure to assess the unreasonable adverse effects sulfoxaflor poses to non-honey bees as part of the 2019 Registration. Commenters had repeatedly emphasized the need for EPA to assess risks to non-honey bees from soil and foliar contact to sulfoxaflor. *See, e.g.,* CFSE-192

(explaining that native solitary bees, “most of which nest in the ground, would be impacted by exposure to sulfoxaflor in the soil.”); CFSER-214-15 (“70 percent of native bee species in the U.S. have ground/soil nests where they can come into contact with pesticide residues.”); CFSER-187; 5-PSCER-913-15 (describing the risks of off-site exposure to native bees and harm to native pollinators).

In a 2016 report to Congress examining EPA’s regulatory oversight concerning bee health, the U.S. Government Accountability Office (GAO) highlighted “there are limitations to [EPA’s risk assessment for bees, *including a lack of data on pesticides’ risks to nonhoney bees.*”<sup>22</sup> Recognizing that “FIFRA authorizes EPA to require pesticide registrants to submit data from tests on nonhoney bee species using methods that meet EPA’s approval,”<sup>23</sup> the GAO recommended, “EPA ... develop a plan for obtaining data from pesticide registrants on the effects of pesticides on non-honey bee species, including other managed or wild, native

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<sup>22</sup> U.S. Gov’t Accountability Office, *Bee Health: USDA and EPA Should Take Additional Actions to Address Threats to Bee Populations* 39 (Feb. 2016), available at <https://www.gao.gov/assets/680/675109.pdf>.

<sup>23</sup> *Id.* at 53.

bees.”<sup>24</sup> EPA agreed with the GAO recommendation,<sup>25</sup> but simply failed follow through for sulfoxaflor in the 2019 Registration.

As a result of that failure, EPA’s conclusion that the approved sulfoxaflor uses would not result in unreasonable adverse effects on bees and pollinators lacks substantial evidence, because EPA entirely failed to account for sulfoxaflor’s additional risks on non-honey bees. *See Nat’l Family Farm Coal.*, 960 F.3d at 1144 (holding pesticide registration unlawful where EPA “entirely failed to acknowledge” three types of costs, including the inability of farmers to comply with the pesticide label in real world farming conditions, the anti-competitive economic effects of the registration, and social costs to farming communities).

### III. The Court Should Vacate the 2019 Decision.

As this Court explained in *Pollinator I*, vacatur is the default, presumptive remedy for an unlawful agency action, including a pesticide registration. *See* 806 F.3d at 532; *All. for the Wild Rockies*, 907 F.3d at 1121-22 (“Presumption of vacatur” unless *Defendants* meet their burden to show otherwise.).

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<sup>24</sup> *Id.* at 55.

<sup>25</sup> *Id.* at 57 (“EPA agreed with our first recommendation.”).

As such, remand without vacatur is only appropriate in “rare,” *Humane Soc’y of U.S. v. Locke*, 626 F.3d 1040, 1053 n.7 (9th Cir. 2010), or “limited” circumstances, *Pollinator I*, 806 F.3d at 532, and only when the agency can show that “equity demands” a departure from the presumptive remedy, *Pollinator I*, 806 F.3d at 532 (quoting *Idaho Farm Bureau Fed’n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)) (emphasis added). See also *Defs. of Wildlife v. U.S. Env’t Prot. Agency*, 420 F.3d 946, 978 (9th Cir. 2005) (“Typically, when an agency violates the Administrative Procedure Act and the Endangered Species Act, we vacate the agency’s action and remand to the agency to act in compliance with its statutory obligations.”), *rev’d on other grounds*, *Nat’l Ass’n of Home Builders*, 551 U.S. 644 (2007).

To determine if these “rare” circumstances are present, courts “weigh the seriousness of the agency’s errors against the disruptive consequences of an interim change that may itself be changed.” *Nat’l Family Farm Coal.*, 960 F.3d at 1144 (quoting *Pollinator I*, 806 F.3d at 532). On the latter “disruptive consequences” prong, when faced with “whether to vacate rulings by the EPA,” such as the registration here, this Court focuses on “possible environmental harm,” and has “chosen to leave a rule in place when vacating would risk such harm.” *Pollinator I*, 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”).

EPA cannot carry its heavy burden to prove that this is such a “rare” circumstance. There is no question that EPA’s violations are serious violations of law, both under the ESA and FIFRA, violations that cut to the core of the EPA’s duties under both statutes. Nor is there any question that, just as in *Pollinator I*, the environmentally protective remedy is simply vacating the registration. Permitting continuing sulfoxaflor uses in the face of EPA’s serious and longstanding violations would vitiate the purposes of the statutory schemes and further endanger ESA-protected species, native insects, pollinators critical to our food system, and other species that rely upon them. This Court should vacate the registration.

A. The Seriousness of EPA’s Violations Weighs Heavily in Favor of Vacatur.

The first prong of this Court’s vacatur inquiry, the seriousness of the agency’s legal violation, weighs heavily in favor of vacatur.

There is little question that failure to comply with the ESA’s consultation mandates is a serious error of law. The ESA’s consultation procedure—the procedures that EPA admits that it unlawfully avoided here—is the process by which agencies carry out the ESA’s substantive mandate to protect from jeopardy endangered species. 50 C.F.R. §§ 402.12-402.16; *Thomas*, 753 F.2d at 764 (“[T]he

strict substantive provisions of the ESA justify *more* stringent enforcement of its procedural requirements, because the procedural requirements are designed to ensure compliance with the substantive provisions.”) (emphasis in original). Thus, the ESA violation is both substantive and procedural in nature.

And it is hard to overstate the importance of the consultation process and standards in the ESA’s statutory scheme: Section 7 is known to be the “heart” of the ESA, *Lockyer*, 575 F.3d at 1018, *see supra* pp. 10-14, and as such disregarding it as EPA did here cuts to the quick of the statute. *See, e.g., Nat’l Parks Conservation Ass’n v. Jewell*, 62 F. Supp. 3d 7, 20-22 (D. D.C. 2014) (holding a failure to consult violation to be a serious error for purposes of vacatur and vacating the agency action).

But, of course, that is not all EPA did wrong here. EPA also unlawfully failed to hold notice and comment on the 2019 new use approvals, *see supra* pp. 37-39, a violation which would have independently been more than sufficient rationale to vacate. *See, e.g., AFL–CIO v. Chao*, 496 F. Supp. 2d 76, 91 (D.D.C. 2007) (holding that “failure to comply with the Administrative Procedure Act (APA)’s notice-and-comment requirements is unquestionably a ‘serious’ deficiency” for purposes of vacatur); *Heartland Reg’l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) (An agency’s “[f]ailure to provide the required notice and to invite public comment ... is a fundamental flaw that ‘normally’ requires vacatur of the rule”); *Nat. Res. Def.*

*Council v. U.S. Env't Prot. Agency*, 676 F. Supp. 2d 307, 313-14 (S.D.N.Y. 2009) (vacating a pesticide approval for failure to have notice and comment).

Finally, like in *Pollinator I*, EPA also failed to comply with FIFRA in its risk assessment and data regarding risks to honeybees and other bees. EPA applied an unlawfully narrow scope in failing to assess risks to non-honey bees. *See supra* pp. 46-51. EPA also failed to consider less toxic alternatives to sulfoxaflor before rationalizing its approval based on more toxic pesticides, rendering its decision without substantial evidence. *See supra* pp. 39-46. Similar FIFRA violations were sufficiently serious to vacate in *Pollinator I*, and are again now. 806 F.3d at 532; *see also Nat'l Family Farm Coal.*, 960 F.3d at 1124 & 1144-45 (vacating registration in light of EPA's substantial understatement of some risks and failure to acknowledge other risks).

EPA and Dow undoubtedly will parrot their remand motion filings, in arguing that remand without vacatur is appropriate because EPA may be able to justify or cure its procedural violations and ultimately again approve sulfoxaflor. *See* EPA Remand Mot 19; Dow Remand Resp. 7-10, ECF No. 52-1. This Court should reject those arguments again. The D.C. Circuit emphatically rejected just such a "cure" argument recently in *Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs*, --- F.3d ---, No. 20-5197, 2021 WL 244862 (D.C. Cir. Jan. 26, 2021). In *Standing Rock*, a

challenge to a pipeline easement, *id.* at \*1-3, the D.C. Circuit affirmed that the defendant agency violated the procedures of the National Environmental Policy Act (NEPA), *id.* at \*4-10. As to remedy, the intervenors argued, similar to Respondents here, that remand without vacatur was warranted because the error was “only” procedural and the Corps could “justify” its decision to grant the pipeline easement on remand. *Id.* \*at 12.

The violations here are not only procedural, *see supra*, but even if they *were*, as the D.C. Circuit explained, whether EPA will again approve sulfoxaflor “is not the question.” *Id.* Rather, “when an agency bypasses a fundamental procedural step, the vacatur inquiry asks *not* whether the *ultimate* action could be justified, but whether the agency could, with further explanation, *justify its decision to skip* that procedural step.” *Id.* (emphases added); *id.* at \*13 (“NEPA violations are serious notwithstanding an agency’s argument that it might ultimately be able to justify the challenged action.”).<sup>26</sup>

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<sup>26</sup> *Standing Rock* further noted that arguments to the contrary regarding procedural violations not being serious run headlong into the great weight of vacatur caselaw generally, like APA notice and comment violations, *see supra*, which *nearly always* warrant vacatur. *Id.* at 12 (“Otherwise, our cases explaining that vacatur is the default response to a fundamental procedural failure would make little sense.”).

Thus, the only possible “cure” aspect of the inquiry is *not* whether EPA will again re-approve sulfoxaflor uses after completing a proper risk assessment, properly holding notice and comment on new uses, and properly completing ESA section 7 consultation. It is only whether EPA could justify its current decision to *skip* ESA consultation, as well as FIFRA notice and comment, *to begin with*, before issuing the registration. And there is zero argument EPA could: As EPA already admits, it violated the ESA by issuing the registration without undertaking consultation.

In sum, given EPA’s repeated, longstanding violations of core ESA and FIFRA law, this factor must be weighed very heavily in favor of vacatur.

B. The Disruptive Consequences Prong Also Weighs in Favor of Vacatur.

First, that EPA’s ESA and FIFRA violations are so serious that EPA is unlikely to reinstate the exact same approvals should end this Court’s remedy inquiry, because consideration of potential disruptive consequences *from* vacatur “is weighty only insofar as the agency may be able to rehabilitate its rationale for the regulation.” *Ctr. for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 952 (N.D. Cal. 2010) (quoting *Comcast Corp. v. FCC*, 579 F.3d 1, 9 (D.C. Cir. 2009)). Contrary to Respondents’ mischaracterizations, the correct inquiry is limited to whether the “*same rule* would be adopted on remand,” meaning the *exact same action*. *Pollinator I*, 806 F.3d at 532 (emphasis added). On the contrary, if “a different result *may* be reached,” that

undermines any “disruptive consequences of an interim change that may itself be changed” and supports vacatur. *Id.* (emphasis added); *Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm’n*, 988 F.2d 146, 151 (D.C. Cir. 1993). And that is decidedly the case here: any future decision will be different both procedurally and substantively, since it will have to include the ESA consultation process as well as a proper FIFRA risk assessment.

Second, in environmental cases like this, in the vacatur calculus only environmental harm—not purely economic impacts—is cognizable as “disruptive.” See *Nat’l Family Farm Coal.*, 960 F.3d at 1144-45 (“[Courts] consider the extent to which either vacating or leaving the decision in place would risk environmental harm.”). That is, for the rare times to remand without vacatur, the harm to consider would be any harm to the environment from vacatur itself, making remand without vacatur more protective. *Pollinator I*, 806 F.3d at 532 (court focuses on “possible environmental harm” and has “chosen to leave a rule in place when vacating would risk such harm”); *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”) (emphasis added).

In contrast, in *Pollinator I*, despite Dow’s allegations of dramatic financial harm,<sup>27</sup> this Court did not find them worth any mention in the vacatur decision, let alone meriting any weight. See 806 F.3d at 532-33. Instead, it held that vacatur was warranted because “leaving the EPA’s registration of sulfoxaflor in place risks more potential environmental harm than vacating it.” *Id.* at 532. The same is true again here again. And in *National Family Farm Coalition*, the registrant Monsanto similarly alleged significant economic harm if the Court vacated their pesticide registration. 960 F.3d at 1144-45. The Court said it was “aware of the adverse impact” on thousands of farmers who had already bought the pesticides, but nonetheless vacated. *Id.* at 1145; see also *Ctr. for Food Safety*, 734 F. Supp. 2d at 951 (vacating and explaining “the Ninth Circuit has only found remand without vacatur warranted by equity concerns in limited circumstances, namely serious irreparable environmental injury.”).

Courts give weight to economic consequences when there is first a showing of environmental harm *from* vacatur, as in *California Communities Against Toxics v. EPA*,

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<sup>27</sup> Br. for Resp.-Int. 39, *Pollinator I*, No. 13-72346, ECF No. 34-1 (filed Mar. 7, 2014) (claiming that vacatur could result in “near total crop loss” and “catastrophic loss” for growers).

688 F.3d 174 (9th Cir. 2012).<sup>28</sup> But because these are environmental statutes, economic allegations of harm *alone* are not sufficient, which is seen by the many Ninth Circuit decisions that vacated despite severe economic ramifications. *See, e.g., Nat'l Family Farm Coal.*, 960 F.3d at 1144-45 (vacating pesticide registration covering hundred million acres and two major commodity crops); *Ctr. for Biological Diversity v. Bureau of Land Mgmt.*, 698 F.3d 1101, 1128 (9th Cir. 2012) (vacating authorization of 678-mile pipeline); *N. Plains Res. Council v. Surface Transp. Bd.*, 668 F.3d 1067, 1072, 1100 (9th Cir. 2011) (vacating construction of 130-mile railroad); *Se. Alaska Conservation Council v. Fed. Highway Admin.*, 649 F.3d 1050, 1054-56, 1059 (9th Cir. 2011) (vacating new highway and ferry terminal); *Nat. Res. Def. Council v. Houston*, 146 F.3d 1118, 1129 (9th Cir. 1998) (vacating water service contracts).

Third, purely economic disruptions have even less place where endangered species are at risk, such as here: The ESA emphatically prohibits the weighing of economic costs against the risks to protected species. *Tenn. Valley*, 437 U.S. at 194

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<sup>28</sup> *California Communities* involved a violation of the Clean Air Act, where EPA unlawfully approved an air quality plan that provided credits to a nearly-completed power plant. *See* 688 F.3d at 993-994. Unlike here, the Court found there 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.* at 994.



(“Congress has spoken in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities.”); *Cottonwood Env’t Law Ctr.*, 789 F.3d at 1091 (“[T]he equities and public interest factors always tip in favor of the protected species.”); *Nat’l Wildlife Fed’n v. Nat’l Marine Fisheries Serv.*, 524 F.3d 917, 929 (9th Cir. 2008) (“ESA’s no-jeopardy mandate applies to every discretionary agency action—*regardless of the expense or burden its application might impose.*” (quoting *Nat’l Ass’n of Home Builders*, 551 U.S. at 671) (emphasis added)).

That is why this Court has declined to vacate actions violating the ESA only if *vacatur itself* could result in harm to endangered species. See, e.g., *Idaho Farm Bureau*, 58 F.3d at 1405-06 (declining vacatur where doing so would endanger the critically endangered Spring Snail);<sup>29</sup> *Nat. Res. Def. Council v. U.S. Dep’t of Interior*, 275 F. Supp. 2d 1136, 1143-44 (C.D. Cal. 2002) (discussing cases and explaining that in environmental cases “the Ninth Circuit expressed special concern for the potentially

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<sup>29</sup> *Idaho Farm Bureau* provides a good case in point. There, the Court held that FWS violated the APA by promulgating an ESA listing decision for an endangered snail without notice and comment on a particular government report. 58 F.3d at 1395, 1403-05. However vacating the listing rule would leave the snail with no protection, potentially endangering it, so the Court left the listing in place during the remand proceedings. *Id.* at 1406.

one-sided and irreversible consequences of environmental damage prompted by vacating defective rules during remand”).

C. EPA Cannot Meet Its Burden for Remand Without Vacatur.

Thus, to avoid vacatur, EPA has to show that vacating the 2019 Registration will cause more environmental harm and risk to endangered species than remanding without vacating. *Ctr. for Env't Health v. Vilsack*, No. 15-cv-01690-JSC, 2016 WL 3383954, at \*10-11 (N.D. Cal. June 20, 2016) (applying the Ninth Circuit cases and concluding “[t]he Court is not persuaded that *vacating* [the challenged agency action] pending formal rulemaking *will result in environmental harm sufficient to warrant leaving the invalid rule in place.*”) (emphasis added). And this is a burden it cannot meet, because EPA has disregarded its duty to *actually analyze* the extent of the risks to endangered species from sulfoxaflor, as well as those to non-honey bees. *See supra* pp. 28-31. EPA admits it knows nothing about sulfoxaflor’s effects on protected species. EPA also cannot draw any conclusion from its existing FIFRA assessment, since EPA is merely an “action agency” under the ESA, not the Wildlife Agencies Congress designated, and lacks the expertise regarding ESA-protected species. *Bennett v. Spear*, 520 U.S. 154, 169 (1997) (“species and habitat investigations [under the ESA]” are not “within the action agency’s expertise”). Thus, any EPA (and Dow) allegation regarding sulfoxaflor as a safer alternative is meaningless when it comes to

ESA-protected species. *See supra* pp. 31-36; CFS Pet’rs’ Remand Opp’n Addendum, at CFS\_A129-34 (detailed critique of EPA’s FIFRA risk assessment).

Situations exactly like this—where the agency has “no real idea” of the risks, because it failed to analyze them—is precisely where this Court has held warranted vacatur time and again. *E.g.*, *Pollinator I*, 806 F.3d at 532 (vacating because agency failed to undertake required pollinator studies, and thus had “no real idea” whether the pesticide approval would cause environmental harm because of missing analysis); *All. for the Wild Rockies*, 907 F.3d at 1121-2 (vacating because defendants left some environmental risks “not addressed” and “unexplained”).

Even for non-ESA species such as non-honey bees and the environment generally, EPA still cannot show vacatur will have negative environmental consequences. As explained above, EPA relies solely on its comparison of sulfoxaflor’s toxicity to that of six of the *most toxic* alternative insecticides, even though there are numerous widely-used “reduced risk” pesticides<sup>30</sup> that are registered

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<sup>30</sup> In *Center for Biological Diversity*, the D.C. Circuit remanded EPA’s unlawful registration of the pesticide cyantraniliprole without vacating based, in part, on EPA’s classification of cyantraniliprole itself as a “reduced risk” pesticide, *unlike* sulfoxaflor here. 861 F.3d at 188-89. Just the opposite, EPA admitted sulfoxaflor poses potential risks for honeybees and birds, and numerous ESA-protected birds, mammals, reptiles, amphibians, insects, and aquatic invertebrates. *See supra* pp. 16-18. On the other hand, other courts have rejected that same argument and vacated pesticide registrations *even if* they are classified as reduced risk. *Nat. Res. Def.*

for use on many of the same crops, for many of the same pests. *See supra* pp. 39-46.

And EPA acknowledged that this comparative analysis does not analyze *actual* adverse effects of insecticide use to bees, or to the environment generally. *See id.*

Regardless of their respective toxicity profiles, that other sources of pesticide pollution may replace sulfoxaflor does not mean that it is somehow more environmentally beneficial *not* to remove a pesticide that EPA unlawfully approved—one that poses acknowledged risks to protected and other beneficial species—from the market until EPA corrects its violations of law. It is nearly always the case that there are other sources of harm or environmental pollution, and often many sources of harm to protected species and their habitat; that does not mean that courts should not remedy violations of law. Merely because vacatur will not solve all of a problem, does not mean it will not help solve a problem. *See, e.g., Massachusetts v. EPA*, 549 U.S. 497, 524 (2007) (“Agencies, like legislatures, do not generally resolve massive problems in one fell regulatory swoop.”); *Rocky Mt. Farmers Union v. Corey*, 740 F.3d 507, 511 (9th Cir. 2014) (Gould, J., concurring) (“incremental change, when aggregated, can be significant” and it would be “erroneous” to assume that an incremental step is not legally significant). Accordingly, rather than focusing on

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*Council v. EPA*, 676 F. Supp. 2d 307, 314-15 (S.D.N.Y. 2009) (vacating reduced risk pesticide registration, rejecting “substitution” arguments).

speculation about other pesticides not before the Court, the environmentally beneficial, protective result is to safeguard endangered species, other species, and the environment generally, by removing this pesticide known to be harmful to them from the market.

Finally, the ESA's overarching purpose of "institutionalized caution" places the well-being of endangered species over any speculative disruptions to agriculture. *Cottonwood*, 789 F.3d at 1091. Thus, any speculative economic injuries do not in any way trump the presumptive vacatur remedy.

### CONCLUSION

For the foregoing reasons, CFS Petitioners ask this Court to vacate the 2019 Registration approving uses of sulfoxaflor.

Respectfully submitted this 16th of February, 2021.

s/ Sylvia Shih-Yau Wu  
SYLVIA SHIH-YAU WU  
GEORGE A. KIMBRELL  
AMY VAN SAUN  
Center for Food Safety  
303 Sacramento Street, 2<sup>nd</sup> Floor  
San Francisco, CA 94111  
(415) 826-2770  
swu@centerforfoodsafety.org  
gkimbrell@centerforfoodsafety.org  
avansaun@centerforfoodsafety.org

s/ Stephanie M. Parent  
STEPHANIE M. PARENT  
Center for Biological Diversity  
P.O. Box 11374 Portland, OR 97221  
(971) 717-6404  
sparent@biologicaldiversity.org

*Attorneys for Petitioners Center for Food Safety, et al.*

### STATEMENT OF RELATED CASES

Pursuant to Ninth Circuit Rule 28-2.6, CFS Petitioners state that this case is related to, and has been consolidated with, *Pollinator Stewardship Council et al. v. Nishida et al.*, 19-72280. See Order Consolidating Cases (Nov. 4, 2019), ECF No. 18.

### CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Ninth Circuit Rule 32-1, I certify that the foregoing opening brief is proportionately spaced, has a typeface of 14 points, and contains 13,937 words, excluding the cover page, table of contents, table of citations, glossary of abbreviations, addendum, certificates of counsel, signature block, and proof of service.

DATED: February 16th, 2021.

s/ Sylvia Shih-Yau Wu  
SYLVIA SHIH-YAU WU  
Center for Food Safety  
303 Sacramento Street, 2<sup>nd</sup> Floor  
San Francisco, CA 94111  
(415) 826-2770  
swu@centerforfoodsafety.org