FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CENTER FOR FOOD SAFETY; CENTER FOR BIOLOGICAL DIVERSITY,

Petitioners,

v.

MICHAEL S. REGAN, in his official capacity as Administrator; U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondents,

CORTEVA AGRISCIENCE LLC,

Respondent-Intervenor.

No. 19-72109

EPA No. 62719-625

OPINION

POLLINATOR STEWARDSHIP COUNCIL; AMERICAN BEEKEEPING FEDERATION; JEFFERY S. ANDERSON, *Petitioners*, v. MICHAEL S. REGAN, in his official capacity as Administrator; U.S. ENVIRONMENTAL PROTECTION AGENCY, *Respondents*, CORTEVA AGRISCIENCE LLC, *Respondent-Intervenor*.	No. 19-72280 EPA Nos. 62719-625 62719-623 62719-631

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

Argued and Submitted January 19, 2022
Honolulu, Hawaii

Filed December 21, 2022

Before: Diarmuid F. O'Scannlain, Eric D. Miller, and Kenneth K. Lee, Circuit Judges.

Opinion by Judge Lee;
Partial Concurrence and Partial Dissent by Judge Miller

SUMMARY*

Pesticide / Environmental Protection Agency

The panel granted in part and denied in part petitions for review brought by Center for Food Safety and Pollinator Stewardship Council challenging the 2019 amended registration of the pesticide sulfoxaflor, which was created by Dow Agrosciences LLC.

A company seeking to register a pesticide must obtain approval from the Environmental Protection Agency (EPA), which in turn must comply with the Endangered Species Act (ESA), and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In 2010, Dow submitted an application for sulfoxaflor. In January 2013, EPA announced and invited public comment for a proposed conditional registration at lower application rates with some mitigating measures. Less than seven months later, EPA decided to unconditionally register sulfoxaflor. In *Pollinator Stewardship Council v. EPA (Pollinator I)*, 806 F.3d 520 (9th Cir. 2015), this court vacated the sulfoxaflor registration because of Dow's flawed and limited data for

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

honeybees. In 2016, EPA registered sulfoxaflor for limited use without the additional court-ordered studies. In 2019, in a surprise announcement, EPA unconditionally registered sulfoxaflor.

The panel held that EPA violated the ESA's mandate that it determine whether the pesticide may affect endangered or threatened species or their habitat, and (if so) consult other wildlife agencies to consider its impact on endangered species. Although EPA admitted it did not comply with the ESA, EPA alleged it lacked the resources to do so. The panel held that EPA cannot flout the will of Congress just because it contends it is too busy or understaffed. The panel further held that EPA's repeated violations of the ESA undermined the political structure.

The panel held that EPA failed to meet FIFRA's notice and comment requirement because it did not allow the public to comment on Dow's requested amendments to the 2016 registration to reinstate expanded usage of sulfoxaflor. EPA cannot rely upon Dow's original application for sulfoxaflor to support the registration amendments. Because Dow requested, and EPA approved, "new uses" for sulfoxaflor, EPA should have solicited public comments.

The panel, however, did not vacate the agency's decision because a vacatur might end up harming the environment more and disrupting the agricultural industry. The panel instead remanded it to EPA for further proceedings. The panel directed EPA to act immediately address the deficiencies and complete the ESA "effects determination and consultation" requirements, as well as the FIFRA notice and comment obligation, within 180 days of the mandate being issued in the case.

Judge Miller concurred in part and dissented in part. He agreed with the majority's holding that the EPA acted unlawfully by failing to engage in consultation or provide public notice and an opportunity to comment before it approved the expanded use of sulfoxaflor. He dissented from the majority's decision to leave the EPA's action in place, and he would instead vacate the order under review.

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OPINION

LEE, Circuit Judge:

It's déjà vu all over again. The U.S. Environmental Protection Agency (EPA) comes before this court once more because of its failure to abide by the law.

Before a company can introduce a pesticide to the market, it must obtain approval from EPA. 7 U.S.C. § 136a(a). And EPA, in turn, must comply with the Endangered Species Act (ESA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) before it can provide its stamp of approval for the pesticide. Broadly, these two statutes require the agency to consider the impact on the environment and threatened species.

Seven years ago, this court vacated EPA's approval of sulfoxaflor, a new pesticide created by Dow Agrosciences LLC. We held that EPA erred because Dow had not provided sufficient scientific evidence that this pesticide would not harm honeybees. After Dow agreed to limit the type and scope of usage for sulfoxaflor, EPA in 2016 greenlit it for "limited uses" even without additional studies. Then in 2019, EPA made a surprise announcement that it had reviewed additional studies provided by Dow and had given "unconditional approval" for sulfoxaflor on various usages that it had earlier canceled. This 2019 amended registration of sulfoxaflor led to the challenge before us.

We hold that EPA violated ESA's mandate that it determine whether the pesticide may affect endangered or threatened species or their habitat, and (if so) consult other wildlife agencies to consider its impact on endangered species. EPA admits it did not comply with the ESA but

defends itself by claiming that it lacks the resources to do so. EPA cannot flout the will of Congress—and of the people—just because it thinks it is too busy or understaffed.

EPA also failed to meet FIFRA's notice and comment requirement because it did not allow the public to comment on Dow's request to reinstate expanded usage of sulfoxaflor. Because Dow requested and EPA approved "new uses" for sulfoxaflor, EPA should have solicited public comments. We, however, do not vacate the agency's decision because a vacatur may end up harming the environment more and disrupting the agricultural industry. We instead remand it to EPA for further proceedings.

BACKGROUND

I. A company seeking to register a pesticide must obtain approval from EPA, which in turn must comply with ESA and FIFRA.

To understand this case, we need briefly to recap the regulatory framework for approving pesticides. Under FIFRA, a company must first file a statement and submit data supporting the pesticide registration to EPA. 7 U.S.C. § 136a(c). The statement must include "a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use;" "the complete formula of the pesticide;" and "a full description of the tests made and the results thereof upon which the claims are based" or, alternatively, citations to public literature or previously submitted data. 7 U.S.C. § 136a(c)(1)–(2).

FIFRA then requires EPA to "promptly" publish in the Federal Register "a notice of each application for any pesticide if it contains any new active ingredient or if it would entail a changed use pattern." 7 U.S.C. § 136a(c)(4).

The agency must provide for a 30-day comment period, *id.*, and "respond to comments received on the notice of application" when it notifies the public of the registration, 40 C.F.R. § 152.102.

Before it can register a pesticide, EPA must conduct a "cost-benefit analysis to ensure that there is no unreasonable risk created for people or the environment from a pesticide." *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005), *abrogated on other grounds as recognized in Cottonwood Env't L. Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075, 1089 (9th Cir. 2015). EPA may deny an application to prevent "unreasonable adverse effects," which means "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide." 7 U.S.C. §§ 136a(a), 136(bb).

Finally, EPA must comply with the ESA, which requires EPA first to make an "effects" determination on whether the pesticide "may affect [a] listed species or critical habitat." 50 C.F.R. § 402.14(a). If yes, EPA must then consult another agency to see if the pesticide is "[l]ikely to jeopardize" the species or critical habitat. *Id.* § 402.14(h)(1)(iv)(A).

II. Dow submits an application for sulfoxaflor, but EPA asks Dow to submit more data before suddenly registering it for unconditional use anyway.

In 2010, Dow Agrosciences LLC sought to register three insecticides containing the chemical sulfoxaflor, a new and highly effective "active ingredient" for killing insects that are difficult to control. Sulfoxaflor is unique compared to other registered insecticides. It kills the insects by interfering with their central nervous system, causing

tremors, paralysis, and death. But unlike other insecticides in its class, sulfoxaflor has a distinct mechanism for acting on insects, which makes it effective while other insecticides are not. To apply it, growers spray the product onto plants, and the plants absorb it into the tissues, pollen, and nectar. Insects die by either touching the insecticide or ingesting a plant that has absorbed it. *Pollinator Stewardship Council v. EPA* (*Pollinator I*), 806 F.3d 520, 523 (9th Cir. 2015). As part of its application, Dow submitted several scientific studies supporting the registration of sulfoxaflor.

EPA noticed the public and invited comment on Dow's sulfoxaflor application on December 22, 2010, as required by FIFRA. Pesticide Products; Registration Applications, 75 Fed. Reg. 80,490 (Dec. 22, 2010). EPA's notice disclosed that Dow sought to register its sulfoxaflor products for use on diverse crops, including citrus, cotton, cucurbits (*e.g.*, squash and cucumbers), berries, and soybeans. 75 Fed. Reg. at 80,491–92. And the agency gave the public 30 days to submit comments. *Id.* at 80,490.

EPA then analyzed the studies submitted by Dow "using a new framework it had recently developed to better analyze the risks to bees" due to "growing concerns about the rapid decline in bee populations." *Pollinator I*, 806 F.3d at 524. The framework involves a three-tiered analysis. At Tier 1, EPA identifies whether there is a potential risk to bees. *Id.* at 524–25. If the agency identifies a risk, then Tier 2 and Tier 3 define the risks and their magnitude, respectively. *Id.* "[W]hereas the 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." *Id.* at 525.

In EPA's analysis of sulfoxaflor studies, it identified a

"potential for risk to honey bees" under Tier 1. But EPA found the Tier 2 studies insufficient, as they were "unable to preclude risk to developing brood or long-term colony health from the proposed sulfoxaflor applications due to limitations associated with their design and conduct." EPA thus concluded that new data was needed.

While EPA did not unconditionally approve sulfoxaflor because of the gaps in data, it still conditionally approved its registration to obtain more data. *Id.* at 526–27; *see also* 7 U.S.C. § 136a(c)(5). FIFRA allows the agency to "conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data . . . on the condition that by the end of such period [the agency] receives such data and the data do not meet or exceed risk criteria enumerated in regulations . . . ." 7 U.S.C. § 136a(c)(7)(C). But EPA may only conditionally register a pesticide if it "determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest." *Id.*

So, in January 2013, EPA announced and invited public comment for a proposed conditional registration at lower application rates with some mitigating measures. EPA conditioned registration upon Dow providing more studies. Although EPA announced its proposed decision conditionally to register sulfoxaflor in January 2013—pending receipt of more data—EPA less than seven months later decided to "unconditionally" register sulfoxaflor, meaning that EPA "necessarily" had "sufficient data to evaluate the environmental risks." *Pollinator I*, 806 F.3d at 523, 527. But "Dow never completed the requested additional studies." *Id.* at 527. EPA still "gave its approval

to usage under modified circumstances," *id.*, and concluded that sulfoxaflor applied according to the label would "not present unreasonable adverse effects against bees."

III. The Ninth Circuit vacates the sulfoxaflor registration because of Dow's flawed and limited data for honeybees.

In response, commercial beekeepers and beekeeping organizations petitioned this court to review EPA's unconditional registration decision. *Id.* at 528. They argued that EPA's decision was based on insufficient data to assess the risk to honeybees. *Id.* We agreed and held that "EPA's decision to unconditionally register sulfoxaflor was based on flawed and limited data." *Id.* at 522. We explained that "[w]ithout sufficient data," EPA had "no real idea whether sulfoxaflor will cause unreasonable adverse effects on bees, as prohibited by FIFRA." *Id.* at 532. We vacated the 2013 registration and ordered additional studies to assess the risk to honeybees. *Id.* at 532–33.

Right after we issued our decision, EPA stopped manufacturers from selling and distributing sulfoxaflor. The agency issued "a final cancellation order for all pesticide products containing the active ingredient sulfoxaflor." The order explained that "vacatur of the sulfoxaflor registration" meant that "the registrations were no longer in effect under FIFRA, and no new sulfoxaflor material could or can lawfully be released for shipment by manufacturers unless and until new registrations are issued."

IV. EPA registers sulfoxaflor for limited use without the additional court-ordered studies.

Dow then "amended the remanded sulfoxaflor application to add restrictions that eliminated [sulfoxaflor]

exposure to pollinators," such as limiting sulfoxaflor spraying to "post bloom" (that is, after flowering) on crops that attract bees and requiring spray drift and buffer zones. In other words, Dow decided to limit the proposed use of sulfoxaflor rather than provide more studies that would allow more expansive use of it.

In May 2016, EPA invited public comment on its proposed decision to register sulfoxaflor. The proposed decision stated:

> Specifically addressing the Ninth Circuit Court of Appeals' direction to "obtain further studies and data regarding the effects of sulfoxaflor on bees are required by EPA regulations," EPA finds that given the parameters of this proposed decision, there is no need for additional data to be submitted.

EPA also included an addendum to the agency's 2013 risk assessment that analyzed the risk based on the proposed revised labels.

In October 2016, EPA unconditionally registered sulfoxaflor for "limited uses" with restrictions. The registration did not include "indeterminate blooming crops" (citrus, cotton, cucurbits, soybeans, and strawberry), which were vacated with the 2013 registration. And for those crops registered, EPA explained that, given the court's directive, "a buffer is required to eliminate exposure to bees at a level that could be expected to cause adverse effects" until Dow submitted, and EPA reviewed, more pollinator studies.

V. EPA in a surprise announcement unconditionally registers sulfoxaflor products in 2019.

Sometime later, Dow apparently requested that EPA expand its sulfoxaflor registrations. It is unclear from the record how Dow went about making the request, and the parties could not provide more context at oral argument. What we do know is this: On July 12, 2019, without notice to the public about Dow's request, EPA announced that it was unconditionally approving new uses of sulfoxaflor under § 3(c)(5) of FIFRA. EPA added new uses that Dow had applied for in 2014, added back the indeterminate blooming crops (that is, citrus, cotton, cucurbits, soybeans, and strawberry) from the vacated registration, and removed certain restrictions that EPA had required when it reregistered crops in 2016.

EPA cited two previously noticed applications—one in 2014 and the other in 2018—to meet its notice and comment obligations under FIFRA. *See* 7 U.S.C. § 136a(c)(4). It did not, however, provide notice and comment on the newly authorized uses for indeterminate blooming crops or on the removal of the 2016 restrictions.

Before issuing the new registration, EPA conducted another ecological risk assessment to evaluate "the likelihood that exposure to one or more pesticides may cause harmful ecological effects" and a benefits analysis to determine whether the expanded registration posed any unreasonable adverse effects to the environment. In its assessment, EPA relied on new studies that Dow had submitted with its request. Dow had submitted three new Tier 1 studies; three new Tier 2 semi-field tunnel studies and two new Tier 2 colony feeding studies, each of which evaluated long-term effects on honeybee colonies; and

fourteen other Tier 2 field residue studies for assessing oral exposure to sulfoxaflor.[1] EPA concluded that it "ha[d] adequate data to demonstrate that there will be no unreasonable adverse effects to honey bees resulting from the expanded registration of sulfoxaflor" and that the pest-control benefits outweighed the risk to the bee population. EPA decided, however, to not make an "effects determination" for sulfoxaflor, meaning that the agency did not determine whether the new proposed uses "may affect" or are "not likely to adversely affect" an endangered or threatened species or its habitat, as required by federal regulation. 50 C.F.R. §§ 402.14(a), 402.13(c).

After EPA announced its final decision unconditionally to register sulfoxaflor again, the Center for Food Safety (CFS), Center for Biological Diversity, Pollinator Stewardship Council (PSC), American Beekeeping Federation, and Jeffery Anderson filed timely petitions for review with this court, alleging that the 2019 sulfoxaflor registration violated the ESA, 16 U.S.C. § 1531 *et seq.*, and FIFRA, 7 U.S.C. § 136a *et seq.*[2] Dow, now known as Corteva, intervened in support of EPA.[3] EPA admits that it committed "legal error" by disregarding the ESA.

For the FIFRA claims, Petitioners argue that EPA had to conduct notice and comment before it could approve the

[1] The semi-field tunnel studies place bees in tunnel enclosure and feed them pesticide-treated crops. *Pollinator I*, 806 F.3d at 525.

[2] We have jurisdiction under 7 U.S.C. § 136n(b) to review the ESA and FIFRA claims. *See Ctr. for Biological Diversity v. EPA*, 847 F.3d 1075, 1088–90 (9th Cir. 2017).

[3] While Dow is now known by Corteva Agriscience LLC, we refer to the Intervener as "Dow" for consistency.

2019 registration amendments authorizing use on indeterminate blooming crops and removing restrictions from the 2016 registration. Petitioners also argue that EPA's decision to amend the sulfoxaflor registration is not supported by substantial evidence.

EPA and Dow defend the registration, claiming that the agency complied fully with FIFRA's procedural requirements. EPA does, however, concede that its rationale could be more "detailed" when explaining third-party economic costs. The agency requests voluntary remand or, in the alternative, that we remand without vacatur. But Dow makes no such concession and argues that EPA considered all relevant factors and provided a comprehensive explanation for its decision.

STANDARD OF REVIEW

"Because the ESA does not specify a standard of review, we review EPA's compliance under the [Administrative Procedure Act] and uphold agency action unless it is arbitrary, capricious, an abuse of discretion, or contrary to law," and we review EPA's compliance with FIFRA for "substantial evidence when considered on the record as a whole." *Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 914, 923 (9th Cir. 2020).

ANALYSIS

This litigation presents two separate procedural challenges to EPA's 2019 registration of sulfoxaflor. First, we must decide whether EPA complied with the ESA. Second, we must decide whether EPA complied with FIFRA's notice and comment requirement. We hold that it failed to comply with either.

I. EPA violated the Endangered Species Act by not making an effects determination for sulfoxaflor.

EPA admits that it violated the ESA by not making an "effects" determination for sulfoxaflor and not conducting any potentially required agency "consultation" before registering the chemical.

A. EPA has disregarded Congress's legislative command to ensure its actions do not jeopardize endangered species and their habitats.

Federal agencies must comply with the ESA's procedural requirements, which seek to protect endangered or threatened species. *Id.* at 922; *see also* 16 U.S.C. § 1531. Section 7(a)(2) of the ESA mandates that federal agencies must ensure that their actions are "not likely to jeopardize" endangered species or their habitats by consulting the appropriate wildlife agency. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 17.11. This process is called "consultation."

"The threshold for triggering" consultation is "relatively low." *California ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009). For each proposed action, a federal agency must determine "at the earliest possible time" whether it "may affect a listed species or critical habitat" (that is, make an effects determination). 50 C.F.R. § 402.14(a). Should the agency determine that its proposed action—such as a pesticide registration—would have no effect, further action is unnecessary. *Id.* § 402.14(b)(1). But if the agency determines that its proposed action may have such an effect, then it triggers the consultation requirement. *Id.* § 402.14(a). The agency must then consult the appropriate wildlife agency, which usually prepares a "biological opinion" on whether the proposed action is "[l]ikely to jeopardize the continued existence of listed

species or result in the destruction or adverse modification of critical habitat." *Id.* § 402.14(h)(1)(iv)(A).

In approving the amended registration of sulfoxaflor in 2019, EPA did not make an effects determination for sulfoxaflor, nor did it estimate when it would comply with any consultation requirement (if necessary). Rather, EPA acknowledged its noncompliance and granted the unconditional registration of sulfoxaflor. The agency's actions violated § 7(a)(2). *See Ctr. for Biological Diversity*, 847 F.3d at 1091 (stating that "Section 7 consultation" is "triggered by an affirmative agency action").

EPA's reasons for not making an effects determination are unpersuasive. The agency explained that it was "focusing most of its resources" on registered pesticides for which EPA had not yet made an effects determination. EPA further claims that it did not "believe" that "the environment or the public would be best served by delaying the registration" to comply with the consultation requirement. It warned that, were the agency to focus its "limited resources" on the consultation of sulfoxaflor, it "would by necessity come at the expense of . . . evaluating . . . what EPA believes to be more toxic compounds that, among other things, pose greater risk, to endangered species than do sulfoxaflor."

But an agency cannot ignore the will of Congress just because it genuinely believes that it has a good reason or excuse for doing so. As the Supreme Court recently reminded us, "our system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2490 (2021) (citing *Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 582, 585–86 (1952)); *cf. FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125

(2000) ("Regardless of how serious the problem an administrative agency seeks to address, however, it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'").

Simply put, EPA must make an effects determination at "the earliest possible time," not when the agency believes the public or environment may be best served by it. 50 C.F.R. § 402.14(a). The "language" of the statute "admits of no exception." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 173 (1978); *cf. id.* ("One would be hard pressed to find a statutory provision whose terms were any plainer than those in § 7 of the Endangered Species Act."). Nor has EPA qualified for any formal exemption under 16 U.S.C. § 1536(h) to avoid the consultation requirement. *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 188 n.10 (D.C. Cir. 2017).

We doubt that EPA would be as forgiving if companies justified their failure to abide by environmental laws with a similar excuse that they lack the resources or that the government regulation asks the impossible. *Cf. Niz-Chavez v. Garland*, 141 S. Ct. 1474, 1486 (2021) ("If men must turn square corners when they deal with the government, it cannot be too much to expect the government to turn square corners . . . ."). Government regulators would likely be displeased by the lack of progress and would require companies to double their efforts to comply with the law—or face severe consequences. EPA cannot set two standards of compliance under environmental law: a lenient standard for itself, and a stricter one for companies and individuals.

To be sure, we recognize that an "agency confronting resource constraints may change its own conduct" within its

authority. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 327 (2014). But prioritizing pressing matters does not mean agencies have license to ignore the law. Simply put, "[a]bdication of responsibility is not part of the constitutional design." *Clinton v. City of New York*, 524 U.S. 417, 452 (1998) (Kennedy, J., concurring). The ESA commits agencies to make certain that its actions do not jeopardize threatened or endangered animals. *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 667 (2007) ("To 'insure' something . . . means '[t]o make certain, to secure, to guarantee (some thing, event, etc.).'" (alteration in original) (internal quotation marks omitted)); *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 928–29 (9th Cir. 2008) (holding that consultation is required so long as the agency could comply with both the ESA and other statutory requirements).

B. EPA's repeated violation of the ESA undermines the political structure.

Equally troubling is EPA's apparent habit of ignoring ESA's effect determination and consultation requirements. Five years ago, the D.C. Circuit chastised EPA for not making an effects determination for another pesticide and failing to consult other federal agencies in approving a pesticide. *See Ctr. for Biological Diversity*, 861 F.3d at 188.[4]

[4] EPA also has settlement agreements and is embroiled in litigation for not complying with the consultation process before registering other pesticides. Proposed Settlement Agreement; Biological Evaluations, 85 Fed. Reg. 81,205, 81,205–06 (Dec. 15, 2020) (proposing a settlement agreement to make an effects determination for five different active ingredients).

Yet EPA did it again. And it did so by recycling the same argument that another circuit court rejected. In *Center for Biological Diversity*, the D.C. Circuit rejected the argument that "EPA's failure to consult [was] excusable because it" had "fulfilled the 'purpose' of the ESA by 'devis[ing] a rational solution to prioritize its resources and avoid delaying the availability of reduced risk [pesticide].'" 861 F.3d at 188 n.10 (second alternation in original). The D.C. Circuit warned that "an agency may not duck its consultation requirement, whether based on limited resources, agency priorities or otherwise." *Id.* We agree. Resource constraints and agency priorities do not justify an agency's noncompliance with federal law.

EPA explains that it has a backlog because FIFRA predates the ESA, and the agency has "many hundreds" of registered pesticides. But a half century has passed since the statute's enactment. *See* Pub. L. No. 93-205, 87 Stat. 884 (1973). How long does the agency expect us to excuse its failure to follow the law? "Once Congress, exercising its delegated powers, has decided the order of priorities in a given area, it is for the Executive to administer the laws and for the courts to enforce them when enforcement is sought," no matter "[o]ur individual appraisal of the wisdom or unwisdom of a particular course consciously selected by the Congress." *Tenn. Valley Auth.*, 437 U.S. at 194.

When an agency deliberately ignores Congress's legislative command, it undermines the will of the people and ultimately our constitutional structure of government. "Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided." *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 142 S. Ct. 661, 665 (2022) (per curiam). The consultation requirement compels

federal agencies to review its actions. *See Lopez v. Davis*, 531 U.S. 230, 241 (2001) (noting Congress's "use of a mandatory 'shall' . . . to impose discretionless obligations"). Thus, when EPA does not comply with the ESA's consultation requirement, the agency effectively exceeds its authority. *See City of Arlington v. FCC*, 569 U.S. 290, 297 (2013) ("Both [agencies'] power to act and how they are to act is authoritatively prescribed by Congress, so that when they act improperly, no less than when they act beyond their jurisdiction, what they do is ultra vires.").

EPA assures us that Congress is aware of EPA's backlog and is pushing the agency to comply with the consultation process.[5] Congressional oversight of administrative agencies' decision-making is not only desirable but also central to our structure. But despite Congress's efforts, EPA's pesticide registrations are not in compliance with the law. That Congress is trying to make the agency comply with its legislative command clearly does not excuse EPA from compliance with the law.

Over a decade has passed since Dow submitted its initial application for sulfoxaflor, yet EPA has still not finalized an effects determination for the chemical. Shortly before and after oral argument, EPA submitted correspondence promising that it will issue an effects determination soon. While we welcome such a development, EPA appears to be

[5] In 2014, Congress ordered EPA to report on its compliance with the consultation process. Pub. L. No. 113-79, § 10013, 128 Stat. 649 (2014). Congress acted again in 2018 and established an interagency working group that is tasked with improving compliance with the consultation process. Pub. L. No. 115-334, § 10115, 132 Stat. 4490 (2018). As part of its oversight, this working group is to submit progress reports to Congress. *Id.*

engaging in a whack-a-mole strategy for complying with the ESA: It does little to comply with the law and then devotes resources once it has been sued—and then this process repeats itself. Parties should not have to file a lawsuit to compel EPA to follow the law. EPA must not delay to comply with the ESA's effects determination/consultation requirement. § 7(a)(2).

II. EPA violated FIFRA by failing to conduct notice and comment on Dow's requested amendments to the 2016 registration.

Petitioners also argue that EPA violated FIFRA when it approved Dow's request for an amended registration for sulfoxaflor in 2019. Specifically, EPA removed restrictions for sulfoxaflor usage imposed in the 2016 application and added back indeterminate blooming crops—without providing notice and an opportunity for public comment on Dow's latest request.

The parties disagree about the scope of our prior vacatur from our 2015 decision. *See Pollinator I*, 806 F.3d at 532–33. CFS argues that our vacatur essentially voided the original application, which had gone through notice and comment. They thus argue that Dow's 2019 request to remove restrictions and add back indeterminate blooming crops—in whatever form it was submitted to the agency—was effectively a new application. EPA disagrees. The agency contends that there was no new application because the court vacated only the registrations, not the application. EPA thus argues the agency treated the original application as "pending" because the court did not address the status of the application. So, no new application, no need for additional notice and comment under FIFRA, according to EPA.

We need to clarify the scope of our prior vacatur and the record before we decide whether Dow's requested amendments triggered notice and comment under FIFRA.

A. EPA cannot rely upon Dow's original application for sulfoxaflor to support the registration amendments.

Federal courts have equitable power to award an appropriate remedy where an agency commits error or exceeds its statutory authority. *See Franklin v. Gwinnett Cty. Pub. Sch.*, 503 U.S. 60, 70–71 (1992) ("The general rule . . . is that absent clear direction to the contrary by Congress, the federal courts have the power to award any appropriate relief in a cognizable cause of action brought pursuant to a federal statute."). When a court orders vacatur, it sets aside or invalidates an agency decision or order. *See Action on Smoking & Health v. C.A.B.*, 713 F.2d 795, 797 (D.C. Cir. 1983) (per curiam) ("To vacate . . . means 'to annul; to cancel or rescind; to declare, to make, or to render, void; to defeat; to deprive of force; to make of no authority or validity; to set aside.'" (citation omitted)). The scope of our vacatur is determined, in part, by our jurisdiction in each controversy.

Here, our vacatur and remand of the 2013 registration did not impact Dow's original application for sulfoxaflor. In *Pollinator I*, the petitioners requested that we vacate the registration. 806 F.3d at 528. Indeed, they could not have asked us to vacate the application because we had jurisdiction only to review "the validity of any order issued by the [EPA] following a public hearing." 7 U.S.C. § 136n(b). An application is not such an order. Our decision states several times that we were vacating registration but never mentions the fate of the application. *See, e.g.*,

Pollinator I, 806 F.3d at 522, 528. And we asked only that "EPA to obtain further studies and data regarding the effects of sulfoxaflor on bees." *Id.* at 533. We did not ask EPA to instruct Dow to resubmit its application. So, our vacatur and remand of the 2013 registration invalidated only the sulfoxaflor registrations.

But EPA's argument that it treated the original application as pending is unsupported by the record. Following our vacatur and EPA's final cancellation order in 2015, Dow "amended the remanded sulfoxaflor application to add restrictions that eliminated exposure to pollinators." The amended application did not include indeterminate blooming crops, which are attractive to bees. EPA "reevaluated this application," asked for notice and comment on it, and then reregistered sulfoxaflor with its limitations on usage. Therefore, Dow did not leave the application pending in its original form.[6]

EPA also points to no authority that permits the agency to keep an incomplete application pending. By EPA regulation, if EPA determines that an application for registration is incomplete, and the applicant fails to complete it, the agency will "terminate any action on such application, . . . treat the application as if it had been withdrawn by the

[6] On appeal, EPA argues that it took additional comment in 2016 under its "transparency policy" and not under 7 U.S.C. § 136a(c)(4). But the agency's record citation does not prove or disprove its assertion. We cannot rely on EPA's representation because it did not rely on itself when issuing the registration. *See Nat'l Fam. Farm Coal.*, 966 F.3d at 917; *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("We may not supply a reasoned basis for the agency's action that the agency itself has not given." (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947))).

applicant," and "[a]ny subsequent submission relating to the same product must be submitted as a new application." 40 C.F.R. § 152.105.

We thus conclude that EPA cannot avoid further public scrutiny by relying on the 2010 application to support the sulfoxaflor registration amendments.

B. Dow's request to add indeterminate blooming crops and remove restrictions from the already-registered uses triggered notice and comment under FIFRA.

We next consider whether the vacated uses that Dow requested trigger notice and comment under FIFRA. EPA's actions are not governed by the Administrative Procedure Act's notice and comment requirements but by the procedures set forth in FIFRA. Neither FIFRA nor its implementing regulations set forth procedures for the remand. *See* 7 U.S.C. § 136n. EPA thus must provide notice and comment only where required by FIFRA.

"As always, we begin with the text of the statute." *Friends of Animals v. U.S. Fish & Wildlife Serv.*, 879 F.3d 1000, 1003 (9th Cir. 2018) (quoting *Limtiaco v. Camacho*, 549 U.S. 483, 488 (2007)). FIFRA requires EPA to "promptly" publish in the Federal Register "a notice of each application for any pesticide if it contains any new active ingredient or if it would entail a changed use pattern." 7 U.S.C. § 136a(c)(4). EPA's position is that the public has no right to know about Dow's request to remove the

restrictions because the public received notice of Dow's original application from nine years ago. We disagree.[7]

The record does not explain how Dow went about requesting that EPA add the cancelled uses back to the 2016 sulfoxaflor registration. At oral argument, Dow pointed to its 2010 application, but—as we just explained—the application was not pending in its original form. When we pressed Dow about how it actually requested that EPA add back the indeterminate blooming crops and remove the restrictions to the 2016 sulfoxaflor registration, it did not know the answer.

So, we look to the regulations for ways in which Dow could have asked EPA to add the cancelled uses back. There are three ways, and all require notice and comment. The first two ways were for Dow to submit a new application, 40 C.F.R. § 152.42, or an application for amended registration, *id.* at § 152.44 (to relabel the pesticide to include more uses). Both would have triggered EPA's notice and comment obligations if the cancelled uses entailed "new use[s]." *Id.* at § 152.102. In this context, "new use" means, in part: "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

[7] EPA also argues that the public does not have a right to notice and opportunity for comment on the new court-ordered Tier 2 studies. We agree. FIFRA typically does not require new notice and comment every time the agency receives new data, *see* 7 U.S.C. § 136a(c)(4), but Dow did not merely submit additional data to support an existing application, *see, e.g.*, 40 C.F.R. § 152.92 ("An applicant may demonstrate compliance for a data requirement by submitting a valid study that has not previously been submitted to the Agency."). Instead, the company submitted to EPA the court-ordered Tier 2 studies *and* requested that EPA amend the sulfoxaflor registration.

organisms." *Id.* § 152.3. Alternatively, but unlikely, Dow could have claimed that the cancelled uses were a minor modification under § 152.46(a)(1). That subsection, too, would have required EPA to conduct notice and comment. *Id.* EPA does not represent that it waived the application requirement, *see* 40 C.F.R. § 152.44, so the question before us is whether the amended uses are "new uses."

We hold that Dow's request to add back indeterminate blooming crops and remove restrictions on already-registered uses falls under "new use." Indeterminate blooming crops are attractive to bees and thus were not included in the registration until Dow submitted more data on the potential effects on bees. Similarly, Dow added the restrictions to labels because they "eliminated exposure to pollinators." Removing those restrictions and adding bee-attractive crops would therefore cause a "significant increase in the level of exposure" of sulfoxaflor to pollinators. 40 C.F.R. § 152.3. Thus, no matter how Dow asked EPA to remove restrictions on already-registered crops and add indeterminate blooming crops back, the agency should have allowed the public to weigh in.

We reject EPA's argument that Dow's request contained no new uses because those uses were previously registered. *Cf. Auer v. Robbins*, 519 U.S. 452, 462 (1997) (explaining that courts may defer to an interpretation made in a legal brief so long as it is not a "post hoc rationalization advanced by an agency seeking to defend past agency action against attack" (cleaned up)). EPA documents repeatedly refer to the 2019 amendments as "new uses." For example, the agency stated in its decision memorandum that it was "unconditionally granting *new uses* for sulfoxaflor under section 3(c)(5) of FIFRA." Those uses included indeterminate blooming crops. While EPA distinguished

between "entirely new uses" and "new uses that had been previously granted and vacated," the regulations do not permit this distinction. *See* 40 C.F.R. § 152.3.[8] We hold that EPA had to conduct notice and comment on the addition of indeterminate blooming crops and removal of the restrictions in the 2019 registration.[9]

III. Vacatur of the 2019 sulfoxaflor registration is not warranted.

EPA admits to having made two errors and requests voluntary remand to comply with the ESA and FIFRA. First, as discussed, EPA acknowledges that it has not made an effects determination as required by the ESA. *See* 16 U.S.C. § 1536(a)(2).[10] The agency filed two declarations

[8] When evaluating an application for registration of a pesticide involving use of the pesticide that EPA has suspended or cancelled, the agency must follow the regulations in "subpart D of part 164," which sets forth rules for reversing or modifying a suspension or cancellation order. 40 C.F.R. §§ 152.100(b); 164.130. EPA issued a final cancellation order under section 6 of FIFRA for all relevant sulfoxaflor registrations. Therefore, we ordered supplemental briefing asking the parties whether EPA should have followed the regulations for reregistering uses that were subject to a cancellation order. Dk. 161. But we do not need address this issue because the parties have waived any argument that EPA was required to follow subpart D of part 164. *See WildEarth Guardians v. EPA*, 759 F.3d 1064, 1072 n.3 (9th Cir. 2014).

[9] Because we find that EPA procedurally violated FIFRA, we do not reach whether EPA's registration decision is supported by substantial evidence.

[10] At oral argument, EPA's counsel represented that the agency would complete an effects determination by the end of Spring 2022. On July 19, 2022, however, EPA filed a Federal Rule of Appellate Procedure 28(j) letter notifying the court that is has completed a draft effects determination, but it still needed at least six months to finalize it.

acknowledging its responsibilities under the statute and setting forth a timeline for the agency to complete an effects determination. Second, EPA concedes that its rationale "could be more detailed" when explaining third-party economic costs. On remand, EPA offers to "explicitly address why the economic and social costs of the registration amendments, on balance support registration." Petitioners, however, request that this court vacate the 2019 sulfoxaflor registration, which both the agency and Dow oppose.

We leave invalid agency action in place "'when equity demands' that we do so." *Pollinator I*, 806 F.3d at 532 (quoting *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)). When determining whether an agency's action should remain in effect on remand, we apply a two-factor balancing test first outlined in the D.C. Circuit's *Allied-Signal* decision: We weigh the seriousness of the agency's errors against "the disruptive consequences of an interim change that may itself be changed." *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (quoting *Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993)).[11]

[11] CFS urges us to follow *Standing Rock Sioux Tribe v. U.S. Army Corps of Engineers*, 985 F.3d 1032 (D.C. Cir. 2021), but this court is not bound by that case, and we decline to adopt the rule that "[w]hen 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." 985 F.3d at 1052. We further question whether *Standing Rock* represents a new standard for vacatur even in the D.C. Circuit, as argued by CFS. Since *Standing Rock* has been issued, the D.C. Circuit has repeatedly relied on the *Allied-Signal* test. *See, e.g., Am. Pub. Gas Ass'n v. U.S. Dep't of Energy*, 22 F.4th 1018, 1030 (D.C. Cir.

A. EPA's errors do not warrant vacatur because the agency could likely adopt the same registration decision on remand.

When weighing the seriousness of the errors, we look to "whether the agency would likely be able to offer better reasoning or whether by complying with procedural rules, it could adopt the same rule on remand, or whether such fundamental flaws in the agency's decision make it unlikely that the same rule would be adopted on remand." *Pollinator I*, 806 F.3d at 532; *see also Nat'l Fam. Farm Coal.*, 966 F.3d at 929–30.

EPA's failure to comply with the ESA—while serious—does not warrant vacatur based on the record before us. Our case is analogous to *Ctr. for Biological Diversity*. *See* 861 F.3d at 188. In that case, EPA failed to make an effects determination for cyantraniliprole. *Id.* The D.C. Circuit, however, did not vacate EPA's registration because "[n]otwithstanding the EPA's failure to make an effects determination and to engage in any required consultation, it did not register [the pesticide] in total disregard of the pesticide's potential deleterious effects." *Id.* Here, too, EPA did not greenlight sulfoxaflor in "total disregard" of its potential harm. The agency conducted a new ecological risk assessment, which "evaluate[d] the likelihood that exposure to one or more pesticides may cause harmful ecological effects," based on the new data that Dow submitted. EPA concluded that sulfoxaflor has a better ecological profile than other main alternative pesticides—similar to the pesticide in *Ctr. for Biological Diversity*. *See id.* at 189.

2022); *Long Island Power Auth. v. FERC*, 27 F.4th 705, 717 (D.C. Cir. 2022).

EPA conducted a hazard comparison for sulfoxaflor that compared the toxicity of sulfoxaflor to six alternative registered pesticides. The agency found that "[s]ulfoxaflor's toxicity to non-target organisms is generally much lower than the toxicity of [its] alternatives and in some cases by many orders of magnitude lower." CFS asserts the hazard comparison is insufficient because it compared sulfoxaflor only with "other extremely toxic insecticides." The comparison was not, however, "cherry picked." EPA explained that it chose those six pesticides because they "are the most commonly used broad-spectrum insecticides currently registered for the proposed uses of sulfoxaflor and they account for 65% of the total acreage treated in those crops targeting sulfoxaflor's target pest spectrum." Contrary to CFS's claim, the agency did not intentionally omit other known, less toxic alternatives to "control pests for the same crops" from its hazard comparison." Some of these alternatives have problems, such as causing aphid flares and killing natural predators like lady bugs. Despite our serious concern that EPA has continued to flout the ESA, we ultimately conclude that EPA could maintain the same registration decision once it makes an effects determination and engages in any required consultation. *See Pollinator I*, 806 F.3d at 532.

EPA's failure to comply with FIFRA's notice and comment requirement also does not warrant vacatur, "especially in light of" EPA's "substantial compliance" with FIFRA. *Nat'l Fam. Farm Coal.*, 966 F.3d at 929. Notice and comment goes to the heart of agency accountability and assists judges with reviewing agency action. When considering whether notice and comment can cure the defect, the "touchstone" of the court's inquiry is thus the "agency's open-mindedness, because the concern is that an

agency is not likely to be receptive to suggested changes once the agency puts its credibility on the line in the form of final rules." *Advocs. for Highway & Auto Safety v. Fed. Highway Admin.*, 28 F.3d 1288, 1292 (D.C. Cir. 1994) (internal quotation marks omitted). We do not, however, require vacatur whenever an agency breaches its notice and comment obligations. Thus, where an agency is likely to be able to offer better reasoning and adopt the same rule on remand, vacatur for failure to provide notice and comment is not required. *See Idaho Farm Bureau Fed'n*, 58 F.3d at 1401–02 (declining to vacate where the agency failed to provide the public with the opportunity to review a report, while acknowledging that the procedural error was significant).

Though EPA failed to provide notice of Dow's request to amend the sulfoxaflor registrations, its ecological risk assessment and decision memorandum reflect that the agency considered sulfoxaflor's impact on bees. *See Daimler Trucks N. Am. LLC v. EPA*, 737 F.3d 95, 103 (D.C. Cir. 2013) (vacating where the "EPA entirely failed to provide notice of its intention to amend its regulation . . . and offered no persuasive evidence that possible objections to its final rule have been given sufficient consideration" (cleaned up)). And Petitioners' objections to sulfoxaflor have not changed since its initial registration. *See generally Pollinator I*, 806 F.3d 520.

EPA therefore could likely "adopt the same rule on remand." *Id.* at 532.[12] In *Pollinator I*, we vacated EPA's

[12] In EPA's 28(j) letter, it also notified the court that it is working with Dow on mitigating measures for the 2019 sulfoxaflor registration. But our review is limited to the record before us. *See San Luis & Delta-Mendota Water Auth. v. Locke*, 776 F.3d 971, 992–93 (9th Cir. 2014).

sulfoxaflor registration because, upon further studies, the agency could decide to change the maximum application rate or find that it could not be "registered at all because of its effects on brood development and long-term colony strength." *Id.* at 532–33. Six years later, EPA has received all necessary data and found no negative effect on brood development or long-term colony strength.

Petitioners' assertions that EPA lacks enough data to support its registration decision are without merit. First, there are not "critical shortcomings" in Dow's new tunnel studies. Dow submitted three new Tier 2 tunnel studies for EPA review. "Importantly, these new tunnel studies evaluated long-term effects on colonies at the proposed application rates of sulfoxaflor, thereby addressing limitations identified in the previous 6 tunnel studies." The studies monitored hive strength, brood development, and colonies' ability to survive through winter (called "overwintering"). EPA's risk assessment concluded that sulfoxaflor "did not result in long-term effects on colonies, as indicated by colony strength and brood development."

PSC disputes this conclusion by arguing that EPA could not assess sulfoxaflor's effect on colonies' ability to survive through winter. But EPA did assess overwintering. While two of the studies were inconclusive because the control group (the group not sprayed with sulfoxaflor) failed to overwinter in adequate numbers, the third study determined that low application rates of sulfoxaflor did not affect overwintering. And one of the new Tier 2 colony feeding studies successfully examined overwintering. EPA was satisfied with its findings and continues to represent that there is no need for further overwintering studies. Thus, "where, as here, a court reviews an agency action 'involv[ing] primarily issues of fact,' and where 'analysis of

the relevant documents requires a high level of technical expertise,' we must 'defer to the informed discretion of the responsible federal agencies.'" *Sierra Club v. EPA*, 346 F.3d 955, 961 (9th Cir. 2003) (alteration in original) (quoting *Marsh v. Oregon Nat'l Res. Council*, 490 U.S. 360, 377 (1989)).

EPA also relied on other data to inform its conclusion on the long-term effects of sulfoxaflor. The agency found that "no long-term colony-level effects were observed prior to overwintering and submitted studies from other insecticides that act on the [same] receptor indicate that effects on colonies post overwintering are not more sensitive than those expressed prior to overwintering." It thus concluded that "the relatively short duration (3 days or less) of forager mortality and quantifiable residues of sulfoxaflor in pollen and nectar are not suggestive of long-term exposure."

Second, PSC challenges the new colony feeding studies. Dow submitted two new colony feeding studies, which evaluated effects of oral exposure to sulfoxaflor. EPA found one of the studies acceptable for quantitative use in risk assessment and the other "supplemental (qualitative) due to uncertainties associated with actual exposures that hives received during the study." The agency concluded that there is "a low potential for colony-level risks to honey bees indic[a]ted from oral exposure to contaminated pollen and nectar for canola, corn, cotton, pome fruit, and sorghum." For the remaining crops, EPA found "a potential for colony-level risk" when "conservatively assuming that bees feed exclusively on the treated crop."

PSC focuses on the "potential for colony level risk," but their framing of the data is inappropriate. EPA did not find that there is an "adverse effect on the entire colony if the

colony forages for up to 10 days on crops." The colony feeding studies were based on a ten-day oral exposure to sulfoxaflor, and the ecological risk assessment found:

> If honey bee colonies were to become exposed to sulfoxaflor for periods lasting *substantially longer* than 10 days and such longer exposures led to greater sensitivity of colonies, there is a potential for the oral Tier II risk assessments results to underestimate colony-level risk to honey bees.

Longer exposure could result from "a potential for repeated applications of sulfoxaflor to honey-bee attractive crops during or near bloom" and honeybee colonies pollinating multiple crops in success. Since honeybee colonies pollinate multiple crops in succession, this could "potentially" expose the bees to sulfoxaflor "for combined time periods lasting longer than 10 days."

PSC also omits a key assumption. EPA's risk assessment is conservative because it assumes that bees feed exclusively on treated crop. Bees in the Tier 2 studies were fed a pesticide-treated diet, so the results of those studies reflect exposures that are higher than that expected from real world conditions. This is true of both the feeding and tunnel studies. And for the tunnel studies EPA noted that "the exposure of bees within the tunnel is considered a *reasonable worst case scenario* since applications were made while bees were actively foraging on the treated crop over the duration of the exposure (7-10 days) and bees were forced to forage only on treated crop." Therefore, any potential risk is based on a conservative assessment.

Third, EPA did not "entirely fail" to assess the risk to non-honeybees. *Nat'l Fam. Farm Coal. v. EPA*, 960 F.3d

1120, 1124–25 (9th Cir. 2020). Consistent with EPA's 2014 Guidance, the agency analyzed the risk to non-honeybees by using honeybee data as a surrogate for non-honeybees because of limits in testing. Risk assessments focus on honeybees because (1) "honey bees are widely recognized as the most important managed pollinator in most regions of the world . . ." and (2) "standardized test methods for evaluating exposure and effects of chemicals in a regulatory context are more developed with the honey bee compared to non-*Apis* bees . . . although recent progress has been made on test method development for bumble bees." "We defer to agency expertise on methodology issues, unless the agency has completely failed to address some factor[,] consideration of which was essential to [making an] informed decision." *Brower v. Evans*, 257 F.3d 1058, 1067 (9th Cir. 2001) (second alteration in original) (internal quotation marks). And a "reasonable mind might accept" EPA's reliance on honeybee studies "as adequate to support a conclusion" that sulfoxaflor does not pose "unreasonable adverse effects on the environment." *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013).

Finally, contrary to PSC's assertion, EPA's decision to waive Tier 3 field testing was reasonable. EPA may waive data requirements because they "will not always be appropriate for every product." 40 C.F.R. § 158.45(a). The agency explained that, in some cases, Tier 3 studies have limited utility because "there has been difficulty in controlling the extent to which free-foraging bees utilize the treated crops." The agency's 2014 and 2016 guidance therefore "narrowed and clarified" when Tier 3 testing is recommended. EPA now recommends Tier 3 testing only "in situations where important uncertainties or risk hypotheses could not be adequately addressed by data from

lower tier assessments."

For its evaluation of sulfoxaflor, EPA concluded that Tier 3 studies would "not add meaningful input to [its] conclusions." Dow's Tier 2 semi-field and residue studies were "sufficient to characterize colony-level risks to honey bees with an appropriate level of confidence."[13]

EPA, though, admits that it "could explain more clearly why harm to beekeepers is not likely from the uses of sulfoxaflor authorized by the 2019 registration amendments." In its decision, EPA acknowledged the economic value that beekeeping adds to agriculture each year and stated that the agency "believes that sulfoxaflor has less of an impact on bees than its main alternatives." But it did not identify the potential economic cost to beekeepers. EPA points to a response it made in 2016 to public comments as proof that it considered the economic cost to beekeepers. The agency's response, however, largely repeats its conclusion in the 2019 decision memorandum and could not have addressed beekeeper costs based on the new Dow studies submitted in 2018.

While EPA was aware of the third-party costs and yet failed to address them in its analysis, *see Nat'l Fam. Farm Coal.*, 960 F.3d at 1142–43, this is not an error serious enough to warrant vacatur because the registration already has precautions for beekeepers. EPA found that, when sulfoxaflor was directly sprayed on foraging honeybees, "the

[13] Pollinator full-field study designs "have varied considerably and overall their utility has been limited" due to "confounding influence of other stressors including disease, pests, poor nutrition, climate, other pesticides; insufficient statistical power due to practical limitations to replicating study sites; insufficient characterization of exposure; [and] limited ability to extrapolate results to other crops or other regions."

impacts of sulfoxaflor [were] short-lived (3 days or less) and long-term effects on the colonies [were] not indicated." Even so, the sulfoxaflor product labels advises growers of bee-attractive crops that "[n]otifying known beekeepers within 1 mile of the treatment area 48 hours before the product is applied will allow them to take additional steps to protect their bees" and that "limiting application to times when managed bees and native pollinators are least active, *e.g.* 2 hours prior to sunset or when the temperature is below 50°F at the site of application will minimize risk to bees." A more thorough explanation of the costs to beekeepers would cure the defect on remand.

In sum, the seriousness of EPA's errors does not support vacatur.

B. The possible environmental harm and disruptive impact of vacatur warrant leaving the faulty registration undisturbed.

Under the second prong of the *Allied-Signal* test, "we consider whether vacating a faulty rule could result in possible environmental harm," *Pollinator I*, 806 F.3d at 532, and the disruptive impact of vacatur, *Cal. Cmtys. Against Toxics*, 688 F.3d at 992.

Remand without vacatur here maintains "the enhanced protection of the environmental values covered by [the registration]" because sulfoxaflor has a more favorable toxicological profile compared to alternatives. *Ctr. for Biological Diversity*, 861 F.3d at 188; *see Idaho Farm Bureau Fed'n*, 58 F.3d at 1405–06. As discussed above, "[s]ulfoxaflor's toxicity to non-target organisms is generally much lower than the toxicity of these alternatives and in some cases by many orders of magnitude lower." While EPA could not make a "full comparison of honey bee

toxicity for sulfoxaflor and its main alternatives," it looked at toxicity from contact exposure and the dissipation rate. The "residual toxicity time" (RT25) is the time that the pesticide remains acutely toxic and results in 25% mortality. And beekeepers have shared that "RT25" data on pesticide persistence are "one of the most important pieces of information for the protection of honey bees." Based on the data, EPA concluded that the dissipation rate for sulfoxaflor is significantly shorter than its alternatives.[14]

To reevaluate sulfoxaflor's ecological impact, EPA conducted a second ecological risk assessment and benefits assessment for the 2019 registration amendments. This "significant expenditure of public resources . . . would be unnecessarily wasted if we affirm the decision to set aside the [registration] when a more closely tailored remedy is available." *Idaho Farm Bureau Fed'n*, 58 F.3d at 1405–06; *cf. Cal. Cmtys. Against Toxics*, 688 F.3d at 994 ("While we have only ordered remand without vacatur in limited circumstances, if saving a snail warrants judicial restraint, . . . so does saving the power supply.").

Finally, vacatur is a disruption to the agricultural industry. "[T]here is evidence of potentially serious disruption if a pesticide that has been registered for over [many years] can no longer be used." *Nat'l Fam. Farm Coal.*, 966 F.3d at 929–30. And vacating the sulfoxaflor registration would disrupt many agricultural sectors, which could cause "yield quantity losses."

[14] Sulfoxaflor remains acutely toxic for less than 3 hours as compared to 8 hours (imidacloprid), more than 24 hours (chlorpyrifos), 24–48 hours (bifenthrin), and 54 hours (lambda-cyhalothrin).

We thus reluctantly remand without vacatur for EPA to make an effects determination for sulfoxaflor, solicit additional notice and comment for the sulfoxaflor amendments, and address the economic costs to beekeepers in determining whether the registration will cause "unreasonable adverse effects." 7 U.S.C. §§ 136a(a); 136(l). We "expect and urge EPA to move promptly on remand." *Nat'l Fam. Farm Coal.*, 966 F.3d at 930.[15]

EPA should act immediately to address these deficiencies and complete the ESA "effects" determination and consultation requirements, as well as the FIFRA notice and comment obligation, within 180 days of the mandate being issued in this case. *See In re Core Commc'ns, Inc.*, 531 F.3d 849, 861–62 (D.C. Cir. 2008).

CONCLUSION

Petitioner CFS's petition for review is **GRANTED** in part and **DENIED** in part. Petitioner PSC's petition for review **GRANTED** in part and **DENIED** in part. The case is **REMANDED WITHOUT VACATUR** to EPA.[16]

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[15] The partial dissent argues that we should vacate based on EPA's failure to abide by the law. There is indeed a strong case for vacatur, given EPA's history of noncompliance. But we ultimately believe that a remand without a vacatur—even if it appears to allow "EPA to escape[] any serious consequence"—is appropriate under the unique facts here because a vacatur would likely harm the environment more and disrupt the agricultural industry. *Cf. Ctr. for Biological Diversity*, 861 F.3d at 188–89 (remanding without vacatur).

[16] The motions for leave to file *amicus curiae* filed by (1) Conservation Law Foundation, et al. (Case No. 19-72109, Dkt. 41 and Case No. 19-72280, Dkt. 41), (2) National Cotton Council, et al. (Case No. 19-72109, Dkt. 93 and Case No. 19-72280, Dkt. 91), and (3) CropLife America

MILLER, Circuit Judge, concurring in part and dissenting in part:

The court correctly holds that the Environmental Protection Agency acted unlawfully by failing to engage in consultation or provide public notice and an opportunity to comment before it approved the expanded use of sulfoxaflor. But rather than set aside the EPA's action, the court leaves it in place, gives the EPA a disapproving wag of a finger, and asks the agency to spend the next six months trying harder. I would instead vacate the order under review.

When a court determines that an agency has erred, the normal practice is to vacate the agency's action. "[V]acatur of an unlawful agency action normally accompanies a remand." *Alsea Valley All. v. Department of Com.*, 358 F.3d 1181, 1185 (9th Cir. 2004); *see United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019) ("The ordinary practice is to vacate unlawful agency action."). Although we have held that a court has discretion to remand without vacating, doing so is appropriate only in "limited circumstances." *California Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 994 (9th Cir. 2012). Our discretion is guided by two factors: "the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Allied-Signal, Inc. v. NRC*, 988 F.2d 146, 150–51 (D.C. Cir. 1993) (quoting *International Union, United Mine Workers of Am. v. Federal Mine Safety & Health Admin.*, 920 F.2d 960, 967 (D.C. Cir. 1990)); *see California Cmtys. Against Toxics*, 688 F.3d at

(Case No. 19-72109, Dkt. 95 and Case No. 19-72280, Dkt. 93) are **GRANTED**.

994 (adopting the *Allied-Signal* test). Here, both factors counsel in favor of vacatur.

I begin with the agency's errors. The court is unanimous in holding that the EPA violated the Endangered Species Act of 1973 (ESA), 16 U.S.C. § 1531 *et seq.*, and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq.*, in three ways.

First, the ESA requires federal agencies to engage in "consultation" to ensure that their actions are not "likely to jeopardize" endangered or threatened species or "result in the destruction or adverse modification" of the "critical" habitat of such species. 16 U.S.C. § 1536(a)(2). The regulations elaborate on that requirement by specifying that an agency must determine whether its proposed action "may affect a listed species or critical habitat." 50 C.F.R. § 402.14(a). If the agency determines that the action would have no effect, it need not proceed with further ESA analysis. *Id.* § 402.14(b)(1). But if it determines that the action might have such an effect, then "formal consultation is required." *Id.* § 402.14(a). In this case, the EPA did not make the required determination before it approved the amended registration of sulfoxaflor in 2019, nor did it engage in consultation. As the EPA now concedes, its failure to consult violated the ESA.

Second, FIFRA requires the EPA to publish "a notice of each application for any pesticide if it contains any new active ingredient or if it would entail a changed use pattern," and to allow a period of at least 30 days for public comment on the application. 7 U.S.C. § 136a(c)(4). Although the EPA provided public notice after the initial application to register sulfoxaflor, we vacated the registration that resulted from that application. *Pollinator Stewardship Council v. EPA*,

806 F.3d 520, 533 (9th Cir. 2015). Thus, as the court explains, the EPA was required to undertake notice and comment before it approved the 2019 amended registration. It did not do so.

Third, FIFRA permits the EPA to register a pesticide only if it determines that the use of the pesticide will not have "unreasonable adverse effects on the environment," 7 U.S.C. § 136a(c)(5)(D), which the statute defines to include "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," *id.* § 136(bb). The statute thus requires the agency to consider "risks of economic and social costs." *National Fam. Farm Coal. v. EPA*, 960 F.3d 1120, 1142 (9th Cir. 2020). But, in part as a result of its failure to provide notice and allow for public comment, the EPA did not discuss the costs that registering sulfoxaflor might have on commercial beekeepers. The EPA does not quite concede that it erred, but it does acknowledge that its "rationale describing why the amendments satisfy the FIFRA standard could be more robust."

The agency's errors were serious. We have described the ESA's consultation requirement as the "heart of the ESA." *Karuk Tribe of Cal. v. United States Forest Serv.*, 681 F.3d 1006, 1019 (9th Cir. 2012) (en banc) (quoting *Western Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 495 (9th Cir. 2011)). An agency's failure to comply with it "cannot be considered a *de minimis* violation." *Thomas v. Peterson*, 753 F.2d 754, 763 (9th Cir. 1985), *abrogated on other grounds as recognized by Cottonwood Env't L. Ctr. v. United States Forest Serv.*, 789 F.3d 1075, 1092 (9th Cir. 2015). Likewise, notice-and-comment procedures are critical "to ensure fairness to affected parties" and "to give affected parties an opportunity to develop evidence in the

record to support their objections to the rule and thereby enhance the quality of judicial review." *International Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005). An agency's "[f]ailure to provide the required notice and to invite public comment" is therefore "a fundamental flaw that 'normally' requires vacatur of the rule." *Heartland Reg. Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) (quoting *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002)).

These deficiencies are not merely technical or formal; they raise significant doubts about the EPA's choices. *See Allied-Signal*, 988 F.2d at 150. It is the EPA's job, not ours, to assess the risks of a pesticide. But it is difficult for us to know whether the EPA did so correctly when its errors obscure our view of the alternatives. I do not share the court's confidence that the EPA's violations could not have made a difference.

The record reveals that the EPA overlooked important risks. A Tier II ecological assessment found "a potential for colony-level risk" to honeybees from exposure to sulfoxaflor for periods longer than ten days. Longer exposure is a real possibility because growers of blooming crops like citrus and strawberries may repeatedly apply sulfoxaflor and because some colonies pollinate multiple crops in succession. The court dismisses these findings largely because the study "conservatively assum[ed] that bees feed exclusively on the treated crop." But the potential exposure extends beyond the study's assumptions, and the EPA cautioned that the potential for risk remained even "at lower dietary concentrations." The conservative study design thus does not erase a legitimate cause for concern. *See Pollinator*

Stewardship Council, 806 F.3d at 531; *NRDC v. EPA*, 735 F.3d 873, 883–84 (9th Cir. 2013).

The record also suggests risks for other species of bees. As compared to honeybees, many non-honeybees are smaller, so they are exposed to a higher dose of pesticide from a given spray. In addition, most are solitary, so as the EPA acknowledged, the death of a non-honeybee "would have a much greater consequence on reproduction." The court accepts the EPA's analysis of the risks to non-honeybees because the agency did not "entirely fail" to assess them. But total ignorance is not necessary for vacatur; an erroneous or incomplete assessment will also do. *See Pollinator Stewardship Council*, 806 F.3d at 532–33. That the EPA did not completely neglect the risks does not mean the agency would necessarily make the same decision if it understood them better.

As for beekeepers, the EPA's approach was one of thorough disregard. The agency "entirely failed" to assess the costs they would incur. *National Fam. Farm. Coal.*, 960 F.3d at 1145. The court recognizes the agency's failure but excuses it because sulfoxaflor's labeling advises users that "[n]otifying known beekeepers . . . before the product is applied will allow them to take additional steps to protect their bees." The labeling does not even inform the beekeepers directly, let alone hint at what the costs to them might be. It is not a meaningful substitute for an assessment of economic harm.

The EPA's serious errors have raised correspondingly serious questions about its decision. The unresolved risks to bees and beekeepers mean that "[o]n remand, a different result may be reached." *Pollinator Stewardship Council*, 806

F.3d at 533. These deficiencies should lead us to follow the ordinary course of vacating the agency's action.

Vacatur would not pose a risk of "disruptive consequences of an interim change that may itself be changed." *Allied-Signal*, 988 F.2d at 150–51. As the District of Columbia Circuit has recognized, "a quintessential disruptive consequence arises when an agency cannot easily unravel a past transaction in order to impose a new outcome." *American Great Lakes Ports Ass'n v. Schultz*, 962 F.3d 510, 519 (D.C. Cir. 2020); *see*, *e.g.*, *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002) ("The egg has been scrambled and there is no apparent way to restore the status quo ante."); *Heartland Reg. Med. Ctr.*, 566 F.3d at 198 (determining that remand without vacatur was justified because "vacatur of the . . . requirement would have raised substantial doubt about HHS's ability to recoup payments it made for years prior to reinstatement of that requirement"). Here, by contrast, there is little evidence that the "interim change" created by vacatur of the registration would have disruptive consequences. The agency has not disbursed funds based on the registration, nor has anyone taken irreversible actions in reliance on it.

To be sure, sulfoxaflor offers benefits to the farmers who use it, and vacatur would make those benefits unavailable while the agency reconsiders the registration. The Department of Agriculture submitted a declaration stating that vacating the registration would disrupt "numerous agricultural sectors" and increase "the likelihood of yield quantity losses (for some crops)." Thus, it may be true that sulfoxaflor is economically beneficial, and it may also be true, as the EPA suggests, that it is environmentally beneficial because it displaces older, more hazardous

pesticides. It is appropriate to view that argument with at least some skepticism because it is based on an incomplete record: The costs to beekeepers and the risks to bees are unknown and may chip away at the claimed benefits, whether or not they cancel them out. *See Pollinator Stewardship Council*, 806 F.3d at 532. But if the EPA's factual predicates are valid, they are a reason for Congress to amend the ESA and FIFRA to make new pesticides easier to approve. They are not a reason to excuse the EPA's decision to ignore the requirements of statutes that are currently on the books. *See National Fam. Farm Coal.*, 960 F.3d at 1145 (vacating the registration of an herbicide even though doing so meant that growers would be forced to purchase alternatives, thus incurring costs "through no fault of their own"). Had the EPA simply announced at the outset that it thought sulfoxaflor was so useful that it should be registered without complying with the statutory procedures, we would not uphold the agency's action. But that is the practical effect of our decision not to vacate the registration.

And that is undoubtedly how the EPA will understand our ruling. *Cf. NRDC, Inc. v. EPA*, 489 F.3d 1250, 1264 (D.C. Cir. 2007) (Randolph, J., concurring) (observing that "[a] remand-only disposition is, in effect, an indefinite stay of the effectiveness of the court's decision and agencies naturally treat it as such"). The EPA has a long history of violating the ESA by not preparing effects determinations. Although it says that it is working to remedy its pattern of noncompliance, it admits that it has a backlog of "[m]any hundreds of pesticides [that] have been approved and are available for use that have not undergone ESA review." In circumstances such as these, remand without vacatur "invites agency indifference." *In re Core Commc'ns, Inc.*, 531 F.3d 849, 862 (D.C. Cir. 2008) (Griffith, J., concurring);

see Oglala Sioux Tribe v. NRC, 896 F.3d 520, 537 (D.C. Cir. 2018) ("We have never turned merely to a remand remedy when an agency refused to adhere to a statutory command in such an across-the-board fashion.").

The court recognizes the EPA's history of noncompliance, offering a Ciceronian denunciation of the agency's behavior: "How long does the agency expect us to excuse its failure to follow the law?" But unlike Catiline, the EPA escapes any serious consequence. The answer to the court's question, apparently, is "at least until the completion of the proceedings on remand."

To its credit, the court acknowledges the bad incentives created by remand without vacatur. To mitigate those incentives, the court imposes a time limit on the agency, mandating that it complete its review within 180 days. That is an understandable response to the agency's procrastination, but it creates a different set of problems. A court generally "may not, after determining that additional evidence is requisite for adequate review, proceed by dictating to the agency the methods, procedures, and time dimension of the needed inquiry." *Vermont Yankee Nuclear Power Corp. v. NRDC, Inc.*, 435 U.S. 519, 544–45 (1978) (quoting *FPC v. Transcontinental Gas Pipe Line Corp.*, 423 U.S. 326, 333 (1976)); *see also Center for Biological Diversity v. EPA*, 861 F.3d 174, 189 n.12 (D.C. Cir. 2017) (rejecting the plaintiffs' "request to establish a deadline for the EPA to conduct its ESA consultation" because "'[t]he function of the reviewing court ends when an error of law is laid bare. At that point the matter once more goes to the [agency] for reconsideration.'" (quoting *FPC v. Idaho Power Co.*, 344 U.S. 17, 20 (1952)) (second alteration in original)). Rather than assume for ourselves the responsibility for micromanaging the agency's schedule, I

would simply vacate its unlawful action and let it determine how, and at what pace, to proceed.