FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK; BEYOND PESTICIDES; CENTER FOR BIOLOGICAL DIVERSITY; ENVIRONMENTAL CONFEDERATION OF SOUTHWEST FLORIDA; FARMWORKER ASSOCIATION OF FLORIDA; FARMWORKER JUSTICE; NATURAL RESOURCES DEFENSE COUNCIL; UNITED STATES PUBLIC INTEREST RESEARCH GROUP, *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY; MICHAEL REGAN, in his official capacity as Administrator of the United States Environmental Protection Agency, *Respondents*.	No. 21-70719 OPINION

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

Argued and Submitted January 23, 2023
San Francisco, California

Filed December 13, 2023

Before: Ronald M. Gould, Johnnie B. Rawlinson, and Daniel A. Bress, Circuit Judges.

Opinion by Judge Bress

SUMMARY*

Federal Insecticide, Fungicide, and Rodenticide Act / Endangered Species Act

The panel granted in part and denied in part a petition for review of the Environmental Protection Agency's amended pesticide registrations of streptomycin sulfate for use in combating citrus diseases, vacated the EPA's amended registrations, and remanded to the agency to comply with its statutory obligations.

Before a pesticide can be distributed and sold in the United States, the EPA must satisfy the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Endangered Species Act (ESA). On

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

January 11, 2021, the EPA issued a Final Registration Decision, which unconditionally amended the registration of streptomycin for use on citrus crop group 10-10.

Petitioners argued that substantial evidence did not support the EPA's determination, as required by FIFRA, that registration of streptomycin for use on citrus would not cause "unreasonable adverse effects on the environment." *See* 7 U.S.C. § 136a(c)(5)(C), (D).

The panel held that substantial evidence supported the EPA's assessment of the risk that the registration of streptomycin, which is used as a human antibiotic drug, would lead to antibiotic resistance. However, the EPA's assessment of the risk that the registration poses to pollinators (bees) was incomplete—or, at the very least, inadequately explained. Further, although substantial evidence supported the EPA's determination that streptomycin was effective at treating Huanglongbing disease and citrus canker, the EPA failed to provide a sufficient explanation for the registration labels' suggestion that streptomycin could be used to *prevent* either disease. Accordingly, the panel granted the petition for review as to the pollinator and disease prevention issues so that the EPA could provide either additional support or a more cogent explanation of why the current record was adequate to support the registration, or both.

The EPA conceded that its amended registrations failed to comply with the ESA but argued that the equities weighed against vacatur. Given the seriousness of the EPA's failure to comply with the ESA, as well as its failure to fully comply with FIFRA, the panel held that remand without vacatur would not be an appropriate remedy. Accordingly, the panel vacated the EPA's amended registration of streptomycin for

use on citrus group 10-10, and remanded so that the agency could address the defects in its FIFRA analysis and conduct an ESA effects determination.

COUNSEL

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OPINION

BRESS, Circuit Judge:

We consider a petition for review of the Environmental Protection Agency's amended pesticide registrations of streptomycin sulfate for use in combating citrus diseases. The EPA concedes that its amended registrations failed to comply with the Endangered Species Act (ESA). We also conclude that some aspects of the EPA's registration decision contravene the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). We grant the petition for review in part, vacate the EPA's amended registrations, and remand to the agency so that it can comply with its statutory obligations. Although we do not vacate EPA's amended registrations lightly, the EPA's statutory violations coupled with its own concessions make this the required course.

I

A

Before a pesticide can be distributed and sold in the United States, the EPA must satisfy the requirements of FIFRA and the ESA. *See, e.g.*, *Ctr. for Food Safety v. Regan*, 56 F.4th 648, 652–53 (9th Cir. 2022).

FIFRA "is a comprehensive regulatory scheme" governing "the use, sale, and labeling of pesticides." *Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1204 (9th Cir. 2002). Under this scheme, manufacturers are required to "register a pesticide with the EPA before introducing it into the market." *Id*. The registration, once granted, "functions as a license setting forth the conditions under which the pesticide may be sold, distributed, and used." *Nat'l Res. Def.*

Council v. EPA, 38 F.4th 34, 40 (9th Cir. 2022); *see also* 7 U.S.C. § 136a(a).

Under FIFRA, the EPA may not register a pesticide (or, as here, amend an existing pesticide registration) unless the pesticide, "when used in accordance with widespread and commonly recognized practice," will perform its intended function without causing "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C), (D); 40 C.F.R. § 152.44. FIFRA defines "unreasonable adverse effects on the environment" 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). When the EPA grants an unconditional registration, as it did here, it must "review[] all relevant data in [its] possession n" and "determine[] that no additional data are necessary to make the determinations required by FIFRA." 40 C.F.R. § 152.112(b)–(c); *see also* 7 U.S.C. § 136a(c)(5); *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 523 (9th Cir. 2015) ("Unconditional registration necessarily requires sufficient data to evaluate the environmental risks.").

Once the EPA grants a pesticide registration, the pesticide must undergo a broader registration review at least every 15 years "to determine whether the pesticide continues to meet the statutory standard for registration under FIFRA section 3(c)(5)"—i.e., that it will not "generally cause unreasonable adverse effects on the environment." Pesticides; Procedural Regulations for Registration Review, 65 Fed. Reg. 24586, 24587 (EPA 2000) (to be codified at 40 C.F.R. pt. 152); *see also* 7 U.S.C. § 136a(g)(1)(A)(i). If the EPA determines upon review that the pesticide no longer satisfies this standard, it can cancel the registration or take other appropriate action. 7 U.S.C. § 136d(b).

In addition to FIFRA, the EPA's pesticide registration decisions must also comply with the ESA. *See Ctr. for Food Safety*, 56 F.4th at 657. The ESA requires federal agencies to ensure "that any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of any endangered species or threatened species" or damage its habitat. 16 U.S.C. § 1536(a)(2). Thus, "at the earliest possible time," the EPA must determine whether its proposed pesticide registration decisions "may affect listed species or critical habitat." 50 C.F.R. § 402.14(a). This process is generally called an "effects determination." *Ctr. for Food Safety*, 56 F.4th at 657.

Should the EPA determine that a pesticide registration will have no effect, "further action is unnecessary." *Id*. (citing 50 C.F.R. § 402.14(b)(1)). But if the EPA determines that a pesticide registration "may affect" an endangered species or critical habitat, it then must consult the appropriate wildlife agency to analyze the potential impacts of the proposed action. 50 C.F.R. §§ 402.14(a), 402.40; *see also Ctr. for Food Safety*, 56 F.4th at 657; *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 178 (D.C. Cir. 2017). The consulted agency must then provide a written statement setting forth its opinion. 16 U.S.C. § 1536(b)(3). "The threshold for triggering" this consultation requirement is "relatively low." *California ex rel. Lockyer v. U.S. Dep't of Agric.*, 575 F.3d 999, 1018 (9th Cir. 2009).

B

Streptomycin sulfate (streptomycin) is an antibiotic that has been used in agriculture, animal husbandry, and human medicine for several decades. It has been used commercially to control bacterial plant diseases in the United States since the 1950s. Streptomycin has been approved for use on,

among other things, apples, pears, beans, peppers, celery, and tomatoes, as well as in residential ornamental gardens.

Streptomycin is also considered "highly important" in human and veterinary medicine. The Food and Drug Administration (FDA) has approved streptomycin for use on humans and animals to treat various ailments, ranging from urinary tract infections to tuberculosis to plague. For several decades, streptomycin has been used as a human antibiotic drug "without significant incidents" raising concerns for human health. More recently, though, clinical use of streptomycin has diminished due to the development of resistance in many human pathogenic species and its higher toxicity relative to other antibiotics. For these reasons, streptomycin is typically prescribed as a "second line agent" in combination with other antibiotics.

In 2015, pesticide manufacturers proposed another use for streptomycin: the management of Huanglongbing disease and citrus canker in oranges and other citrus crops. Huanglongbing or "HLB," also known as "citrus greening," is an incurable and often fatal plant disease spread by the Asian citrus psyllid, an invasive insect. Since it was first detected in the United States in 2005, HLB has devastated domestic citrus production. In Florida, which contains most of the citrus crop in the United States, HLB affects over 90% of citrus acres, and the disease has led to a 42% reduction in citrus acreage in the state. Researchers have estimated that HLB cost Florida citrus growers $4.5 billion in lost revenues and led to the loss of 8,000 jobs. HLB has also affected citrus operations in Texas and California.

American citrus groves have also suffered from citrus canker disease. Citrus canker is caused by the bacterium *Xanthomonus citri* subsp. *Citri (Xcc)*, and is spread by wind,

rain, irrigation, and human contact. Despite citrus growers' considerable eradication efforts, the U.S. Department of Agriculture (USDA) determined in 2006 that citrus canker had spread in Florida citrus groves to such a degree that eradication was not possible. The consequences for growers have been severe. Between 2004 and 2016, it is claimed that citrus canker reduced citrus acreage in Florida by 30%. Together, citrus greening and citrus canker have seriously harmed citrus crops, affecting fruit size, health, and numbers, and leading to premature tree death.

Citrus growers historically struggled to find effective treatment methods for citrus greening and citrus canker. There is currently only one registered pesticide that targets the specific bacteria that causes HLB disease. And although there are other pesticides designed to manage infestations from the insects that spread HLB, they have not proven successful at preventing HLB transmission. Citrus canker, meanwhile, has been managed using copper-based pesticides, but these can be harmful to citrus fruits when applied frequently. As these two citrus diseases continued to spread, pesticide manufacturers and citrus farmers sought alternative treatment methods.

C

In November 2015, Geo Logic Corporation and AgroSource Inc. submitted applications to the EPA to amend the pesticide registrations of streptomycin for use on citrus crop group 10-10, which consists of lemons, limes, oranges, and grapefruits, as well as other less common citrus fruits, such as the pummelo. *See* 40 C.F.R. § 180.41. While these applications were pending, the EPA granted several emergency exemptions for use of streptomycin on citrus in California and Florida. *See* 7 U.S.C. § 136p; 40 C.F.R.

§ 166.2. In December 2018, the EPA submitted for public comment its proposed decision to grant the amended registrations. After receiving over 4,700 unique substantive comments, the EPA addressed concerns raised by stakeholders, but it did not alter its proposed decision.

On January 11, 2021, the EPA issued a Final Registration Decision, which unconditionally amended the registration of streptomycin for use on citrus crop group 10-10. The registration amendments—set for a 7-year term—will expire automatically in January 2028, thus "allow[ing] for an additional reevaluation of the resistance risk" for the expanded use of the antibiotic. The EPA's decision also required the manufacturers to submit yearly reports describing the implementation of plans to monitor soil and citrus for incidents of antibiotic resistance.

In amending the streptomycin registration, the EPA attempted to comply with FIFRA. But it admits it did not comply with the ESA. Indeed, the EPA acknowledged that in the thousands of pesticide registrations it has approved in the past decades under FIFRA, it has met its ESA obligations for less than 5% of those actions. The EPA attributes this "multifold" failure to the high volume of pesticide applications, "the unusual complexity" of ESA pesticide reviews, and the proliferation of lawsuits challenging pesticide products. *See also In re Ctr. for Biological Diversity*, 53 F.4th 665, 668 (D.C. Cir. 2022) (describing the EPA's "fraught relationship with the ESA"). To right the ship, the EPA has promulgated a workplan to "improve the efficiency and timeliness of the ESA-FIFRA process." Still, the EPA faces a considerable backlog of other ESA effects determinations (some court-ordered) which it represents it must complete before it can perform an effects determination for streptomycin. Even under the new workplan, the EPA

does not anticipate being able to complete the effects determination for streptomycin any sooner than fall 2026.

In March 2021, petitioners—a consortium of environmental advocacy groups and other public interest organizations (including those representing agricultural workers)—filed a petition for review asking us to set aside EPA's amended registrations of streptomycin for use on citrus. In February 2022, the EPA filed a motion to remand to the agency without vacatur of the pesticide registrations. The EPA acknowledged that it had violated the ESA by failing to make an ESA effects determination before approving the new uses of streptomycin, but argued that the equities weighed against vacatur. Petitioners cross-moved for remand with vacatur. A motions panel of this court denied both motions without prejudice and set a briefing schedule.

II

We have jurisdiction to review the EPA's registration decision under 7 U.S.C. § 136n(b). *See Nat'l Fam. Farm Coal. v. EPA*, 960 F.3d 1120, 1131 (9th Cir. 2020). Petitioners have Article III standing based on their organizational purposes and because their members would have standing to sue in their individual capacities. *See, e.g.*, *Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 908–910 (9th Cir. 2020) (holding that environmental groups satisfied Article III standing requirements for FIFRA and ESA challenges to EPA pesticide registrations); *Nat'l Res. Def. Council*, 38 F.4th at 54–55 (same).

We review the EPA's compliance with FIFRA for "substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b); *Nat'l Fam. Farm Coal.*, 966 F.3d at 914. Under this deferential standard, we will affirm

the EPA's decision when there is "'such relevant evidence as a reasonable mind might accept as adequate to support a conclusion' even if it is possible to draw two inconsistent conclusions from the evidence." *Nat. Res. Def. Council v. EPA*, 857 F.3d 1030, 1036 (9th Cir. 2017) (quoting *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013)). As for the ESA, that statute "does not specify a standard of review," so "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." *Nat'l Fam. Farm Coal.*, 966 F.3d at 923. Although an agency decision may be upheld even if it is of "less than ideal clarity," it does not pass muster if the agency's path cannot "reasonably be discerned." *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974).

Because the EPA concedes that it failed to comply with the ESA, we will address the ESA only in the context of determining the appropriate remedy. Before we do that, however, we address whether EPA complied with FIFRA.

III

As FIFRA requires, the EPA determined that registration of streptomycin for use on citrus would not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(C), (D). Petitioners argue that this determination was not supported by substantial evidence. Specifically, they contend that the EPA (1) did not fully assess the risk that the streptomycin registration would lead to antibiotic resistance, posing a threat to human health; (2) failed to evaluate the risk that the registration poses to pollinators (bees); and (3) credited streptomycin with providing benefits absent evidentiary support.

We agree with the EPA on Point 1, with petitioners on Point 2, and with a little from both sides on Point 3. We conclude that substantial evidence supports the EPA's assessment of the risk of antibiotic resistance and deny the petition of review as to this issue. The EPA's assessment of the amended registrations' risk to pollinators, however, is incomplete—or, at the very least, inadequately explained. We also conclude that although substantial evidence supports the EPA's determination that streptomycin is effective at *treating* HLB disease and citrus canker, the EPA failed to provide a sufficient explanation for the registration labels' suggestion that streptomycin can be used to *prevent* either disease.

We therefore grant the petition for review as to the pollinator and disease prevention issues so that the EPA can provide either additional support or a more cogent explanation of why the current record is adequate to support the registration, or both. In the sections that follow, we explain our reasoning as to each of petitioners' three challenges under FIFRA.

A

In its Final Registration Decision, the EPA concluded that streptomycin is not toxic to humans—unsurprisingly so, considering that streptomycin has long been prescribed for use in humans as an antibiotic drug. Petitioners do not dispute this conclusion. Rather, their marquee argument is that the widespread use of streptomycin on citrus crops will increase antibiotic resistance, thereby undermining the effectiveness of streptomycin and other antibiotics in the same class.

The EPA did specifically evaluate the risk of antibiotic resistance as part of the registration process and concluded

that the risk was not unreasonable. But petitioners argue that the EPA's analysis was defective in failing to account fully for all the potential vectors by which antibiotic resistance could spread. We conclude, however, that substantial evidence supports the EPA's assessment of the risk of antibiotic resistance. EPA sufficiently evaluated this risk and put in place measures to mitigate it.

To evaluate the risk of antibiotic resistance, EPA adapted the analytical approach from FDA Guidance for Industry #152. *See* U.S. Food & Drug Admin., Guidance For Industry #152: Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern (2003). The FDA uses this framework to assess "the effect of the transmission of foodborne bacteria of human health concern through the consumption of animal derived food products." FDA Guidance for Industry #152 assesses the risk of antibiotic resistance by evaluating the probability of resistance developing in the target organism (here, citrus fruit), the exposure of antibiotic resistant bacteria to humans through consumption of treated food products, and the importance of the antibiotic to human health. Applying a modified version of this risk analysis methodology, the EPA determined that the risk of adverse human health effects from streptomycin resistance resulting from its use on citrus was "medium."

Petitioners argue that FDA Guidance for Industry #152, as adapted by EPA, does not fully account for the risks posed by the amended registration because it was designed to evaluate the spread of resistance through farm animals fed or injected with antibiotics, which, petitioners allege, has a lower risk profile than spraying the antibiotic on crops. According to petitioners, agricultural use of streptomycin is more likely to expose the antibiotic to human pathogens

through either direct contact with farm workers or indirect exposure through air, soil, or groundwater. Because the risk of antibiotic resistance increases with exposure of the antibiotic to human pathogens, petitioners maintain that the EPA underestimated the risk of antibiotic resistance by applying a framework that did not sufficiently account for significant vectors of exposure.

The record shows, however, that the EPA adequately accounted for the various pathways by which antibiotic resistance might spread following streptomycin's application to citrus groves. And the agency sufficiently explained why the risk of increased resistance was not unreasonable based on defined mitigation measures.

First, the EPA explicitly recognized that the "agricultural use [of streptomycin] has a much greater environmental exposure due to the application by air blast or other spray technologies," and it took into account that the registration would likely lead to an 18-fold increase in the use of streptomycin in agriculture. Though this increase in use is not without risk from an antibiotic resistance standpoint, the EPA explained that overall exposure of the antibiotic to the environment is only one piece of the puzzle. For human bacteria to develop resistance to streptomycin, they must first be exposed to it. When antibiotics are used on livestock meant for human consumption, there is likely a more direct effect on potential antibiotic resistance in human pathogens because bacteria of human health concern are often present in the treated animals.

In plant agriculture, however, the EPA explained that the risk of exposing human bacteria to streptomycin is lower because "human pathogens are a relatively minor component of the general agricultural environment." Indeed, the EPA

emphasized that "there is no data that antibiotic use in agriculture leads to the presence of antibiotic resistance in bacteria of human health concern," and that "[a]t the present time, there is little evidence for or against the presence of microbes of human health concern in the plant agricultural environment." Under these circumstances, and in combination with the mitigation measures that we discuss below, the EPA could reasonably rely on the fact that after many decades of using streptomycin in agricultural applications, there is no indication it has led to antibiotic resistance that poses a concern to human health.

Petitioners argue that the EPA's focus on human bacteria within the agricultural environment ignores the potential that, through the "air blasting" of streptomycin onto citrus groves, humans (and human pathogens) may be exposed to streptomycin through drinking water, "off-field" spray drift, and contact with workers' boots, clothes, and tools. But the EPA adequately addressed these vectors of contamination. *See Nat'l Fam. Farm Coal.*, 966 F.3d at 922 (holding that EPA's registration decisions were "supported by substantial evidence because the record evidence was of the type that 'a reasonable mind might accept as adequate'" (quoting *Nat. Res. Def. Council*, 857 F.3d at 1036)).

As part of its decision-making process, the EPA consulted with the Center for Disease Control (CDC), FDA, and USDA on how to protect the public from streptomycin residues on food or in water. Based on these discussions, EPA developed several mitigation requirements to reduce off-field exposure to streptomycin. These requirements are not merely pro forma. Pesticide registrants are obligated to educate growers on mitigating antibiotic resistance and to monitor soil and citrus fruit for any incidence of resistance. The EPA's registration label also requires applicators to

spray the streptomycin pesticide directly into the orchard canopy and to "turn off outward pointing nozzles at row ends" "to help reduce off-target drift." The EPA's registration further prohibits using the product through "any type of irrigation system" or through "aerial application."

The record thus demonstrates that the EPA considered the risk of antibiotic resistance spreading through environmental pathways, and that it took steps to mitigate it. Petitioners' theory that these measures are insufficient lacks factual support. *See Ctr. for Cmty. Action & Env't Just. v. FAA*, 61 F.4th 633, 640 (9th Cir. 2023) ("[T]he burden is on petitioners to demonstrate that the [agency's] ultimate conclusions are unreasonable." (quoting *City of Olmsted Falls v. FAA*, 292 F.3d 261, 271 (D.C. Cir. 2002))).

Second, substantial evidence supports the EPA's determination that human bacteria exposure to streptomycin can be reduced through mandatory use of personal protective equipment (PPE) by agricultural workers. As part of its Final Registration Decision, the EPA instituted requirements for PPE. At a minimum, workers applying streptomycin—who cannot reenter treated areas at all for 12 hours—must wear protective eyewear, coveralls, chemical-resistant headgear and gloves, socks and shoes, and an approved respirator. According to the EPA, this PPE use "will reduce the contribution of occupational exposure to the overall risk estimations."

Petitioners are not satisfied that these PPE requirements will mitigate the development of antibiotic resistance in human pathogens. Because FIFRA requires the EPA to evaluate risks posed by a pesticide "when used in accordance with widespread and commonly recognized practice," 7 U.S.C. § 136a(c)(5)(D), petitioners argue that the agency

must account for "real-world" (i.e., non-compliant) PPE use by workers handling streptomycin. According to petitioners, the fact that PPE is costly and cumbersome will discourage full compliance among workers. Petitioners also argue that the PPE requirements, even when followed, do not go far enough because they only apply when workers are actively spraying the pesticide and not when they reenter previously sprayed groves.

The EPA acknowledged that it did not account for non-compliance with PPE requirements in its risk assessment. It emphasized, however, that the PPE requirements were not mere suggestions. Pesticide labels are legally enforceable and carry the statement: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." *Cf.* 7 U.S.C. § 136j(a)(2)(G). Petitioners correctly note that, in certain circumstances, the EPA must account for non-compliance with pesticide labels in conducting its risk assessments. *See Nat'l Fam. Farm Coal.*, 960 F.3d at 1139–41. They rely in particular on *National Family Farm Coalition*, in which we held that the EPA erred in failing to account for regulatory non-compliance because there was "substantial evidence that even conscientious applicators had not been able consistently to adhere to the label requirements," which in that instance were "complex and onerous." *Id*. at 1140.

Here, there is no evidence that it is "difficult or impossible to comply with" the labels' PPE requirements, *id*. at 1141, which include such standard measures as wearing gloves, coveralls, and respirators. Petitioners cite surveys indicating that non-compliance with PPE requirements is common. But these surveys are not specific to the PPE requirements for streptomycin or citrus growers, nor do they involve use labels akin to the one here. Petitioners have not

demonstrated material flaws in the EPA's determination that mandatory PPE use will reduce direct contact between streptomycin and human bacteria.[1]

In sum, in its risk assessment, the EPA acknowledged that resistance to antibiotic pesticides "can be spread by resistant species in or on food, the skin of workers, or indirectly through the environment or clothing." For the reasons we have explained, we conclude that the EPA's antibiotic resistance assessment was based on "reasonable inferences," and that petitioners have presented us with insufficient reason to "question the agency's well-considered conclusions." *Protect Our Communities Found. v. Jewell*, 825 F.3d 571, 583–84 (9th Cir. 2016). To the extent petitioners disagree with the EPA on the merits of its scientific analysis, "[m]ere differences in opinion . . . are not sufficient grounds for rejecting the analysis of agency experts." *Ctr. for Biological Diversity v. Bureau of Land Mgmt.*, 833 F.3d 1136, 1148 (9th Cir. 2016).

B

We turn next to petitioners' argument that EPA failed to evaluate the risk that streptomycin will pose to pollinators—e.g., bees. FIFRA's implementing regulations set forth requirements for how the EPA must evaluate the effect of any pesticide registration on pollinators. *See* 40 C.F.R.

[1] Petitioners argue that the registration labels' requirement that agricultural workers not reenter sprayed groves for 12 hours does not reduce the risk of exposure, especially if workers are not wearing PPE. This argument was not raised before the agency during the notice and comment period and is therefore forfeited. *See Exxon Mobil Corp. v. EPA*, 217 F.3d 1246, 1249 (9th Cir. 2000). Regardless, for the reasons discussed above, we conclude that the EPA adequately addressed the risk of streptomycin exposure through human and environmental pathways.

§ 158.630(d). We have previously recognized that bees in particular are "essential to pollinate important crops" but "in recent years have been dying at alarming rates." *Pollinator Stewardship Council*, 806 F.3d at 532 (vacating pesticide registration due to "the absence of sufficient data documenting the risk to bees" and noting the "precariousness of bee populations"). As the EPA has said in its own internal pollinator guidance, "[t]he scientific community is in general agreement that a multitude of factors contribute to potential adverse impacts on bees, including . . . pesticides."

Under FIFRA, the EPA may approve a registration only if it has "reviewed all relevant data in [its] possession" and "has determined that *no additional data are necessary*" to assess whether the pesticide will perform its intended function without "unreasonable adverse effects on the environment." 40 C.F.R. § 152.112(b)–(c) (emphasis added); 7 U.S.C. § 136a(c)(5). In addition to these general requirements, EPA regulations require applicants to provide specific data on the pesticide's effects on pollinators. 40 C.F.R. § 158.630(d). For any pesticide registration or registration amendment, EPA requires at a minimum that applicants submit a honeybee acute contact toxicity study, though other studies may be conditionally required. *Id*. Furthermore, under the EPA's current internal guidance, additional studies can be required to "identify whether potential risks to bees exist." *Pollinator Stewardship Council*, 806 F.3d at 524.

Under its internal guidelines, if the EPA identifies any concerns based on these studies, it will further evaluate the likelihood and extent of the potential exposure to bees, focusing on "whether the registered uses involve bee-attractive crops," whether the pesticide would be applied "when bees may be present," and whether "measures can be

identified to mitigate exposure." The EPA's own guidance makes clear that when the required data "are not available to evaluate potential exposure and effects to bees, it may be difficult to develop suitable mitigation measures for some [pesticides]." In such cases where the studies specifically required by the regulations are "not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed." 40 C.F.R. § 158.75.

In this case, and as part of its FIFRA analysis, the EPA was thus required to analyze whether the amended registration of streptomycin would have an unreasonable adverse effect on pollinators. Based on our review of the record, we conclude that the EPA's evaluation of streptomycin's effects on bees does not pass muster. The EPA's own statements indicate that it lacked "sufficient data to evaluate the environmental risks" of streptomycin registration for use on citrus. *Pollinator Stewardship Council*, 806 F.3d at 523. Further, the EPA's statements on this issue point in different directions, and its path thus cannot be reasonably discerned. *See, e.g.*, *Crickon v. Thomas*, 579 F.3d 978, 982 (9th Cir. 2009) (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins.*, 463 U.S. 29, 43 (1983)).

Here, there is no dispute that the EPA received and reviewed the pollinator acute toxicity data required by 40 C.F.R. § 158.630(d). That honeybee contact study reported "no effects." The EPA in its Final Registration Decision therefore classified streptomycin as "'practically nontoxic' to honey bees on an acute exposure basis." And overall, the EPA considered the streptomycin database "to be complete to assess risk to the environment and human health, when using the Agency's standard processes."

But the EPA also stated in its Final Registration Decision that its "pollinator data are incomplete" and that "[a]dditional pollinator data, in accordance with the recent pollinator guidance . . . [,] are not available for streptomycin at this time." Moreover, the EPA conceded elsewhere that it based its risk assessment on "limited pollinator data" since "the full suite of data now being required for pollinators is not available for streptomycin." These statements suggest that the EPA has not, in fact, concluded that "no additional data are necessary to make the determinations required by FIFRA." 40 C.F.R. § 152.112(c).

On this point, the EPA in its Answering Brief concedes that some of the language in the Final Registration Decision is "admittedly unclear." That is an understatement. On its face, the Final Registration Decision confusingly states both that the streptomycin database is "complete" (and thus sufficient to conduct a pollinator risk assessment) yet that its "pollinator data are incomplete." These statements stand in apparent opposition to each other. The EPA nevertheless argues that these Janus-like pronouncements are reconcilable: in its view, the Final Registration Decision's statement that "pollinator data are incomplete" refers to data the EPA might require as part of its ongoing registration review process for all streptomycin products and uses, but for the purposes of the amended registration at issue here, the pollinator data are "complete."

We recognize that, as part of the broader registration review process, the EPA may evaluate additional data to ensure that a pesticide registration "reflect[s] advances in the science of hazard characterization or exposure assessment." Procedural Regulations for Registration Review, 65 Fed. Reg. at 24588; *see also* 7 U.S.C. § 136a(g)(2). Here, however, the Final Registration Decision does not limit its

statement that "pollinator data are incomplete" to only the data required for registration review. As petitioners note, the statement comes from a section discussing the risk of the registration for citrus group 10-10. Absent a better explanation (or any explanation) in the Final Registration Decision, we must take the Final Registration Decision at its word: the pollinator data are "incomplete" with respect to this amended registration. The EPA's FIFRA analysis was therefore deficient, for "[w]ithout sufficient data, the EPA has no real idea whether [streptomycin] will cause unreasonable adverse effects on bees." *Pollinator Stewardship Council*, 806 F.3d at 532.

But even if we were to brush aside this confusion and assume that the EPA never intended to suggest that the pollinator data was incomplete for the purposes of this amended registration, the EPA fails to explain why the specific data it has identified as necessary for registration review is not also necessary here. Under FIFRA, the EPA cannot unconditionally approve or amend a registration until it has "reviewed all relevant data" and "determined that no additional data are necessary." 40 C.F.R. § 152.112(b)–(c); *see also Nat'l Fam. Farm Coal.*, 966 F.3d at 912. EPA regulations also provide that "[r]egistration review is the periodic review of a pesticide's registration to ensure that each pesticide registration *continues to satisfy* the FIFRA standard for registration." 40 C.F.R. § 155.40(a) (emphasis added).

Here, the Final Registration Decision explained that "[a]dditional pollinator data" from studies that would "examine potential toxicity to larval and adult honey bees" could be "necessary to help make a final registration review decision for streptomycin." In its guidelines for assessing pollinator risk, the EPA explains that these studies "are

necessary to more fully evaluate the potential exposure and effects to bees for various pesticide use patterns," and that without these additional data, "risk assessors may not be able to fully determine the potential for exposure and effects to bees." But in its final decision approving the amended registration of streptomycin, the EPA admitted that such "[a]dditional pollinator data, in accordance with the recent pollinator guidance . . . are not available for streptomycin at this time."

The EPA argues that, although its own internal guidelines emphasize the general importance of these additional pollinator studies, the guidelines do not require any additional data for this registration because it involved an "existing pesticide" with a "new outdoor use." In such cases, the guidelines recommend that the EPA conduct its review "with existing data," with additional data to "be called in under registration review criteria." But the EPA's claimed compliance with its own internal non-binding guidelines does not absolve it of its obligation to provide a "reasoned explanation" for its decision. *Ass'n of Irritated Residents v. EPA*, 10 F.4th 937, 945 (9th Cir. 2021) (quoting *Judulang v. Holder*, 565 U.S. 42, 45 (2011)). Because the EPA never explained how it complied with its internal guidelines in its registration decision, or how compliance with the guidelines would be sufficient for present purposes, the EPA cannot rely on these guidelines to justify its conclusion that no additional pollinator data was necessary. After all, "judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'" *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) (quoting *Michigan v. EPA*, 576 U.S. 743, 758 (2015)).

As it stands, the EPA has not explained how additional data that it has deemed essential for assessing the risk of streptomycin on registration review are not also necessary to conclude, under this amended registration, that streptomycin poses no unreasonable risks to pollinators. *See Nat. Res. Def. Council*, 38 F.4th at 46 (granting petition for review when agency's conclusion was "in tension with parts of [its] own analysis and with the guidelines it purports to follow"). And even if the EPA's conflicting statements are reconcilable, we are not permitted to make a "best guess as to what reasoning truly motivated" the agency's decision. *Williams Gas Processing-Gulf Coast Co., L.P. v. FERC*, 475 F.3d 319, 329 (D.C. Cir. 2006); *see also State Farm*, 463 U.S. at 43 ("We may not supply a reasoned basis for the agency's action that the agency itself has not given." (quotation omitted)).

For these reasons, we grant the petition for review with respect to this issue so that the agency can either solicit the additional pollinator data necessary to evaluate whether use of streptomycin on citrus poses any unreasonable adverse effects to bees, or else sufficiently explain why no further data are needed at this time.

C

We now turn to petitioners' final argument under FIFRA. FIFRA requires the EPA to determine whether registration of a pesticide would pose any "unreasonable adverse effects on the environment," "taking into account the economic, social, and environmental costs *and benefits* of the use of any pesticide." 7 U.S.C. § 136(bb) (emphasis added). Though the EPA's Final Registration Decision described how streptomycin would benefit citrus growers struggling with HLB disease and citrus canker, petitioners

argue that the EPA's benefits assessment was not supported by substantial evidence. We agree with the petitioners in part.

As previously discussed, HLB disease and citrus canker have devastated citrus crops, resulting in substantial reductions in the overall citrus acreage in the United States. Citrus growers currently have few options for mitigating damage from either disease. The EPA concluded, based on evidence from expert reports and scientific studies, that applying streptomycin to citrus trees infected with HLB disease increased tree height and fruit load and reduced branch dieback and fruit drop. It further found that, when used alongside existing copper treatments, streptomycin reduces the incidence of citrus canker and associated defoliation and fruit drop. Studies indicate that using streptomycin to treat citrus canker can also reduce the amount of copper spray that needs to be applied, which ultimately results in healthier trees because copper itself has adverse effects.

Petitioners contend the EPA's benefits assessment was not supported by substantial evidence, for three reasons:

First, petitioners argue that the studies finding streptomycin to be an effective treatment for citrus canker were flawed because they lacked a proper control group. We disagree. The EPA's conclusion that streptomycin is an effective treatment for citrus canker is reasonable, notwithstanding the fact that the studies it relied upon compared trees treated with streptomycin and a "low rate of copper" to "untreated" trees, without using a streptomycin-only or copper-only control group. Petitioners view the lack of a single-chemical control group as significant because they believe it means the EPA could not discern which

chemical—streptomycin or copper—was producing the observed benefits. But the lack of a control group that tested streptomycin or copper on their own does not undermine the EPA's registration decision because EPA expects streptomycin to be used in a mixture with other currently registered products, including copper.

When copper is used alone, it typically requires several sprays throughout the season. Because copper is phytotoxic (poisonous to plants), heavy spraying can cause blemishing on the fruit and ultimately lead to the development of copper resistance in bacteria. Data submitted by the applicants indicate, however, that streptomycin combined with copper reduces the number of copper sprays needed to improve yields. The absence of a streptomycin or copper-only control therefore does not detract from the EPA's conclusion that streptomycin is a beneficial treatment for citrus canker.

Second, petitioners contend that the EPA ignored scientific evidence in the record suggesting that streptomycin is ineffective at treating HLB disease. Specifically, they allege that the agency failed adequately to address a single study (the "Zhang study") that the Center for Biological Diversity (CBD) cited with limited elaboration in a footnote to a public comment that CBD submitted during the notice and comment period. The Zhang study evaluated 31 antibiotics for effectiveness in managing HLB disease. It found that streptomycin, along with several other antibiotics, was "not effective in eliminating or suppressing" the HLB-causing bacteria. In its response to comments, the EPA briefly addressed the study, noting that it was conducted on "newly grafted citrus scion on root stock under laboratory conditions." The EPA did not comment more broadly on the study's claim regarding the supposed ineffectiveness of streptomycin.

Though the EPA is obligated to "respond to comments received on the notice of application," 40 C.F.R. § 152.102, it is expected to focus its consideration and response on "significant comments." *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 96 (2015). This does not necessarily include every minute point, however obliquely raised. *Cf. Altera Corp. & Subsidiaries v. Comm'r of Internal Revenue*, 926 F.3d 1061, 1081 (9th Cir. 2019) ("[A]n agency need only respond to . . . comments . . . which raise relevant points and which, if adopted, would require a change in the agency's proposed rule." (quotations omitted)); *Covad Commc'ns Co. v. FCC*, 450 F.3d 528, 550 (D.C. Cir. 2006) (explaining that the agency "need not address every comment, but it must respond in a reasoned manner to those that raise significant problems." (quoting *Reytblatt v. Nuclear Regul. Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997))). Since the Zhang study was raised in a footnote, with minimal elaboration, the EPA's brief response to that study was commensurate. The EPA did not ignore the study, but instead explained that the study was based on laboratory conditions. This was a sufficient response.

Third, petitioners argue that the EPA registered streptomycin for "use[] to treat or *prevent* infection" without providing any evidence in support of streptomycin's preventative capacity. At the outset, we question whether petitioners have correctly characterized the Final Registration Decision. Taken in context, it is not clear that the EPA is, in fact, recommending that streptomycin be used to "prevent" infection in the full sense of that term. Rather, in the final decision EPA is cautioning applicators that to "delay antibiotic . . . resistance," "[t]his product should be used to treat or prevent infection that are proven or strongly suspected to be caused by the indicated target bacteria." In

context, "prevent infection" could simply mean "prevent the further spread of infection" or its harmful effects.

But the EPA does not make these arguments and instead appears to concur in petitioners' reading of the relevant language. Indeed, the EPA in its Answering Brief "agrees that the registrants did not submit any data to support a claim that streptomycin prevents infection," but argues it committed no error since it did not *itself* consider disease prevention as a benefit of streptomycin during its review process. The EPA suggests that it would need to determine if streptomycin prevented HLB or citrus canker only if a manufacturer made such a claim on its registration label. But the EPA does not cite any authority for the proposition that it could include an unsupported use in a registration decision and then police the issue on a back-end review of pesticide labels.

Thus, to the extent that the Final Registration Decision determined that streptomycin can be used to prevent infection, we grant the petition for review so that the EPA can provide a more coherent and detailed explanation of whether it understands disease prevention to be a benefit of streptomycin, and, if so, to provide sufficient support for that conclusion. We note, however, that our determination here does not materially undermine the EPA's bottom-line conclusion about the benefits that streptomycin will otherwise provide in treating trees infected with citrus greening and citrus canker.

IV

At this point in our analysis, we have now concluded that the EPA did not fully comply with FIFRA because it (1) failed to include additional data in its pollinator risk assessment or explain why such data was not necessary and

(2) suggested that streptomycin could be used to prevent disease without providing evidentiary support for such a claim.

We have not discussed the Endangered Species Act in any measure because there is little to say: the EPA admits it failed to abide by that statute. We have previously found "troubling" the "EPA's apparent habit of ignoring ESA's effect determination and consultation requirements" in its pesticide registration decisions. *Ctr. for Food Safety*, 56 F.4th at 658. And we have explained that the EPA may not avoid compliance with the ESA merely because of its own internal regulatory priorities. *See id.* It is Congress that required the EPA to comply with the ESA when making pesticide registration decisions, and it is our duty to enforce Congress's command. *Id.* at 658–59.

This brings us to the question of the appropriate remedy given the EPA's several statutory violations. Specifically, we must determine whether to vacate the registration amendments or remand to the agency to address the above errors while leaving the registrations in place (so-called "remand without vacatur"). The traditional remedy for erroneous administrative decisions is vacatur, but we will "leave invalid agency action in place 'when equity demands' that we do so.'" *Id.* at 663 (quoting *Pollinator Stewardship Council*, 806 F.3d at 532).

To determine whether an agency's action should remain in effect on remand, we apply a two-factor balancing test: "We weigh the seriousness of the agency's errors against 'the disruptive consequences of an interim change that may itself be changed.'" *Id*. (quoting *Cal. Cmties. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012)). When weighing the seriousness of the agency's errors, we look to whether

the agency could, "by complying with procedural rules, . . . adopt the same rule on remand," and whether "vacating [the] faulty rule could result in possible environmental harm." *Pollinator Stewardship Council*, 806 F.3d at 532.

In balancing these equitable considerations, we are not working off a blank slate. In *Center for Food Safety*, decided in late 2022, we held that remand without vacatur was appropriate even though there, as here, the EPA failed to comply with FIFRA in some respects and failed entirely to conduct an ESA effects determination for a pesticide registration. 56 F.4th at 663–64. Though we expressed "serious concern that EPA has continued to flout the ESA, we ultimately conclude[d] that EPA could maintain the same registration decision once it makes an effects determination and engages in any required consultation." *Id*. at 664. We thus "reluctantly remand[ed] without vacatur" of the pesticide registration. *Id*. at 668. And we did so in part "because a vacatur would likely harm the environment more and disrupt the agricultural industry," facts that we characterized as "unique." *Id.* at 668 & n.15. However, based on our concern that the EPA on remand would not, as required by the ESA, make its effects determination "at the earliest possible time," we directed the EPA to "act immediately" and "to address the[] deficiencies" in its FIFRA analysis and abide by its ESA obligations "within 180 days of the mandate being issued." *Id.* at 657, 669.

As in *Center for Food Safety*, the EPA contends that the balance of equities in this case favors remand without vacatur. The EPA attempts to downplay the seriousness of its wholesale failure to comply with the ESA by arguing that its FIFRA analysis was sufficient to demonstrate that streptomycin use on citrus is unlikely to threaten any endangered species or its habitat. The EPA thus maintains

that it would, after complying with the ESA, still be able to "adopt the same rule on remand." *Pollinator Stewardship Council*, 806 F.3d at 532. The EPA also argues that vacatur would have considerable disruptive consequences for citrus growers who have few alternatives for managing HLB and citrus canker.

We are sympathetic to the EPA's equitable concerns and to the plight of citrus growers, whose products contribute to our food supply. But under our decision in *Center for Food Safety*, a blank check remand without vacatur would not be an appropriate remedy in this case. Given the seriousness of the EPA's failure to comply with its congressionally mandated ESA obligations, *Ctr. For Food Safety*, 56 F.4th at 657, as well as its failure to comply fully with FIFRA, any remand without vacatur would at least require as a condition a mandatory timetable for compliance similar to the 180-day deadline that we imposed in *Center for Food Safety*. *See id.* at 669. The EPA has not explained how the equities here would justify a more lenient remand than we ordered in *Center for Food Safety*.

But we do not need to decide whether to impose any timing requirement here. When asked at oral argument whether it would prefer a time-limited remand to outright vacatur of the amended pesticide registration, counsel for EPA explained that the agency would request the latter. The reason: the EPA knows it cannot complete an ESA effects determination for streptomycin until at least the fall of 2026. In other words, the EPA does not want a court-ordered deadline that it recognizes it cannot meet.

Although the EPA's assertion that it cannot complete an ESA effects determination until the fall of 2026 is itself troubling, we appreciate the agency's candor in alerting us

that a time-limited remand without vacatur would not be a sensible remedy. Between our governing law and the EPA's concessions, we thus have no choice other than to vacate the EPA's amended registration of streptomycin. The EPA has provided no argument as to why we should be willing to allow a longer timeframe to complete the ESA analysis (and revised FIFRA analysis) when we only permitted the EPA 180 days in *Center for Food Safety*. And since the EPA has acknowledged that any deadline sooner than the fall of 2026 would be unworkable, the tighter leash that we imposed for remand without vacatur in *Center for Food Safety* is simply not available in this case.

We therefore vacate the EPA's amended registrations of streptomycin for use on citrus group 10-10 and remand to the agency so that it can address the above-noted defects in its FIFRA analysis and conduct an ESA effects determination.

PETITION FOR REVIEW GRANTED IN PART AND DENIED IN PART; VACATED AND REMANDED.