Case No. 21-70719

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, INC., AND UNITED STATES PUBLIC INTEREST RESEARCH GROUP,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND MICHAEL S. REGAN, in his official capacity as Administrator of the United States Environmental Protection Agency,

Respondents.

PETITION FOR REVIEW
of a final order of the U.S. Environmental Protection Agency

REPLY BRIEF OF PETITIONERS

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INTRODUCTION

EPA has authorized a vast new use of streptomycin—an antibiotic highly important for treating diseases like tuberculosis in people—as a plant pesticide. Despite the ongoing crisis of antibiotic resistance in human medicine, the Agency granted an unconditional registration for streptomycin's new uses on citrus ("the Registration") without adequate information about the risks and benefits. In doing so, EPA defied FIFRA and the ESA, and the Registration has put people, pollinators, and imperiled species at risk of unwarranted harm. To safeguard human health and the environment, Petitioners urge the Court to vacate the unlawful Registration.

ARGUMENT

I. EPA violated FIFRA by registering streptomycin's new uses without adequately assessing the risks and benefits

EPA erred in assessing both the potential risks the Registration poses to public health and the environment and the purported benefits of

streptomycin's new uses. *See* Pet'rs' Br. 35-66, ECF No. 54. EPA's opposition does not show otherwise.

The Registration violates FIFRA for three reasons. First, EPA undertook a deficient analysis of antibiotic-resistance risks. The Agency failed to assess significant risks that resistance will spread through environmental pathways and disregarded evidence that personal protective equipment (PPE) provisions on streptomycin's label will not protect farmworkers from antibiotic-resistant infections. Second, EPA approved streptomycin's new uses despite concededly incomplete data on risks to pollinators. Third, the Agency failed to ensure that substantial evidence supported the registrants' claims regarding streptomycin's efficacy. These violations go to the core of FIFRA's registration standard, and each independently supports vacatur.

A. The Agency's evaluation of antibiotic resistance ignores significant risks to human health

In its brief, EPA contends that it assessed streptomycin for various forms of toxicity and found "no risks of concern" to human health. EPA Br. 25-26, ECF No. 72 (quoting 1-ER-36 to -37). This argument is beside the

point. Whether the new uses of streptomycin are likely to harm people through *toxicity* is a distinct inquiry from whether they are likely to harm people by causing *antibiotic resistance*. EPA's failure to adequately assess the latter renders the Registration unlawful.

1. The record demonstrates that EPA never analyzed the risks of antibiotic resistance spreading "off field" through environmental pathways

EPA argues that it considered the potential for antibiotic resistance to spread beyond citrus groves through environmental pathways, but the record shows otherwise. The Agency's post hoc effort to string together out-of-context phrases as "analysis" does not substitute for an actual assessment of the risks posed by off-field environmental exposures to streptomycin and antibiotic-resistant bacteria. Because EPA failed to properly evaluate those risks, the Agency lacked substantial evidence to conclude that the Registration will not cause "unreasonable adverse effects" to human health. 7 U.S.C. §§ 136a(c)(5)(C), (D), 136(bb).

EPA analyzed the risks of using streptomycin as a pesticide in citrus groves based on FDA Guidance for Industry #152 (FDA Guidance #152), a

tool designed to assess the risks of antibiotic use in meat and dairy production. *See* 3-ER-285 to -286, 334 to -335. Rather than examining the risks posed by spraying antibiotics into the air, FDA Guidance #152 addresses the fundamentally distinct risks caused by eating food from farm animals that have been fed or injected with antibiotics. 3-ER-286, 335.

EPA itself admits that these uses are "dissimilar[]." 3-ER-286; *see also* 2-ER-187 to -188 ("FDA's Guidance [] #152 does not include any consideration of antibiotic use in an orchard."). So, too, are the exposures they cause. "[A]nimal drug use . . . has much less environmental exposure compared to agricultural sprays of antibiotics." 3-ER-290. Though EPA repeatedly states that it "adapted" FDA Guidance #152 to account for this difference, *e.g.*, 1-ER-42; 3-ER-273, 286, 291, the Agency nowhere explains what those adaptations were, or how they bridge the material differences between these vastly different exposures. EPA's exposure-assessment rating showed no signs of adaptation: it followed FDA Guidance #152's instruction to evaluate exposure risks by weighing the "amount of food

commodity being consumed" against the "level of food commodity contamination." 3-ER-290, 351.

Petitioners identified several types of exposures to airblasted streptomycin that FDA Guidance #152 does not address, including off-field exposures through environmental pathways—that is, exposures that will take place when either streptomycin or resistant bacteria spread beyond citrus groves and into neighboring communities and ecosystems through air, water, soil, or insects. *See* Pet'rs' Br. 40-44.[1] Though EPA asserts that it considered these exposures in its analysis, EPA Br. 33-34, the exposure assessment focused exclusively on foodborne exposures.

EPA purports that the reason it focused on foodborne exposures was because it concluded the risks from environmental pathways were not significant. EPA Br. 33-34. EPA summarizes this supposed conclusion by stringing together three phrases (from three different paragraphs in two separate documents) to argue that it (1) considered whether bacteria that

[1] Petitioners separately highlighted flaws in EPA's risk assessment for "in-field" exposures—that is, exposures experienced by farmworkers working in groves where streptomycin is sprayed. *See infra* Argument I.A.2.

are harmful to humans are found within citrus groves, (2) decided that, because there are relatively few human pathogens in agricultural fields, spraying antibiotics may have a "less direct impact on bacteria of human health concern" than using antibiotics in animal agriculture, and (3) determined that the largest risk to humans therefore comes from food-crop contamination. *See id.* at 33-34 (quoting 3-ER-290; 2-ER-182).

However, those three assertions appear together in only one place: EPA's brief. *Compare id.*, *with* 2-ER-182, *and* 3-ER-290. In the record itself, EPA's analysis focused narrowly on antibiotic-resistance risk from human exposure to foodborne bacteria. *See, e.g.*, 1-ER-43 ("The incidence of food borne illness is the way that exposure to bacteria of human health concern are identified . . . ."); 3-ER-274 to -275 ("The Agency's exposure estimate from consuming treated commodities yields a rating of 'medium' based on EPA's adaptation of FDA resistance assessment exposure table."), 3-ER-285 ("The release assessment considers the probability that resistant bacteria are present on food commodities . . . ."), 3-ER-285 ("The exposure

assessment considers the probability that humans would ingest or be exposed to bacteria from the treated food commodity.").[2]

Nothing in the record supports EPA's claim that it focused on foodborne exposures because it assessed all potential exposures and deemed those from food the most significant. Rather, the record makes clear that EPA evaluated only risks associated with foodborne exposures because those were the only risks that FDA Guidance #152 was *designed* to evaluate. 3-ER-335. EPA's newfound explanation that it considered other exposure routes and concluded that they would not be significant simply lacks support in the record. "[C]ourts may not accept appellate counsel's

[2] *See also* 1-ER-44, 45 (discussing "food borne incidents in citrus," "bacteria of human concern on citrus and citrus commodities," and "food safety hazards"); 2-ER-184 (stating that "the most likely microbes of human health concern are those associated with food poisoning incidents"), 2-ER-186 (discussing "food-borne bacteria"), 2-ER-186 (referring to "low incidence of food poisoning reported for citrus"); 3-ER-289 (describing "reports of foodborne illness from consumption of citrus products"), 3-ER-290 (analyzing "the amount of food commodity being consumed," "[t]he level of food commodity contamination for citrus," and "[t]he incidence of citrus being implicated in food poisoning").

post hoc rationalizations for agency action." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983).

Even if EPA *had* reasonably concluded that relatively few human pathogens would develop antibiotic resistance within citrus groves, *but see* Pet'rs' Br. 40, the Agency's exclusive focus on foodborne exposures to resistant bacteria was still unreasonable, for two reasons. First, EPA entirely failed to consider risks of off-field exposures to streptomycin that travels beyond the orchard through environmental pathways. *See id.* at 40-42. EPA acknowledged that off-field exposures may occur as wind carries streptomycin through the air into neighboring communities, or as rain carries streptomycin into nearby waterways. *See* 3-ER-314; *see also* 2-ER-210 to -211, 226, 234. Despite this recognition, EPA nowhere explained why these off-field exposures would not carry risks. Instead, counsel's post hoc argument, including the record documents they cite, focuses exclusively on in-grove exposures. *See* EPA Br. 33-34 (referring to exposures in "the plant agriculture environment," in "the general agricultural environment," and "in treated fields" (internal quotation marks omitted)).

Second, EPA's exclusive focus on foodborne illness also unreasonably failed to account for the potential spread of antibiotic resistance from off-field resistance transfer—that is, the potential that plant bacteria that develop antibiotic resistance within citrus groves will move off field through environmental pathways and share resistance genes with human pathogens, making those human pathogens resistant to streptomycin. *See* 2-ER-66 to -67 (explaining how different types of bacteria can share antibiotic-resistance genes, thus transferring resistance between unrelated bacteria populations). EPA knew both that streptomycin resistance is common among plant bacteria and that resistance genes can transfer between plant and human bacteria. *See* 2-ER-182. Petitioners also alerted EPA to the ease with which bacteria can move off field. *See* Pet'rs' Br. 43-44. Yet the Agency wholly ignored the potential for antibiotic resistance to spread through off-field resistance transfer.

EPA defends its failure to analyze this risk on the grounds—raised for the first time in its brief—that previous, significantly smaller uses of antibiotics as pesticides have not led to known instances of resistance

transfer. EPA Br. 37. However, this is not a reasonable basis for failing to consider that risk. The Agency's Registration authorizes a dramatic expansion of antibiotic use in plant agriculture; EPA estimates it will result in 18 times more streptomycin being sprayed on plants than ever before. 3-ER-290. That there is not definitive proof that plant bacteria have *already* transferred resistance genes to bacteria that cause human illness is not a reasonable basis for failing to consider the risk that streptomycin's significantly expanded use will result in resistance transfer. This is particularly true given that EPA does not look for evidence of resistance transfer off field, beyond the bounds of any required in-field monitoring. *See* 3-ER-276 (describing plan to "monitor for loss of field efficacy"), 3-ER-279 (calling for "plans to monitor soils and citrus").

EPA's argument that it has taken steps to mitigate the risks of antibiotic resistance, EPA Br. 35-36, is a red herring. EPA's mitigation measures are largely directed at the in-grove resistance risks that EPA identified. *See id.* at 28. They do not directly address off-field antibiotic resistance, that is, the risk that EPA failed to assess. Even the mitigation

measures that may incidentally reduce some off-field spread of streptomycin will not eliminate the spread of streptomycin resistance through environmental pathways, and therefore cannot relieve EPA of its duty to understand the risks that spread will cause and evaluate whether they are reasonable.

This Court reviews the analysis the Agency conducted during the registration process—not some alternative analysis that counsel present for the first time in briefing. *See NRDC v. EPA*, 31 F.4th 1203, 1206-07 (9th Cir. 2022). EPA's analysis must stand or fall based on the risk assessment it conducted *in the record*. Here, the record shows that EPA focused, expressly and exclusively, on the risks of exposure to antibiotic resistance in foodborne bacteria. Because EPA did not assess the risks of exposure to antibiotic resistance spread through air, water, soil, or insects, the Agency failed to adequately assess the risks to human health posed by the Registration.

2. EPA ignored evidence that actual PPE use will not adequately protect farmworkers from streptomycin-resistant infections

a. EPA disregarded evidence of widespread noncompliance with PPE label requirements

In its Final Registration Decision, EPA acknowledged that farmworkers risk acquiring streptomycin-resistant infections while "in treated fields or mixing, loading or applying antibiotics." 1-ER-44. Rather than evaluating this risk, however, EPA dismissed it based on the Agency's "belie[f]" that label provisions requiring use of PPE will provide farmworkers with sufficient protection. *Id.*; *see* EPA Br. 38-39. EPA's belief is not supported by substantial evidence.

The record reflects that label requirements do not translate into farmworkers' reality. EPA entirely ignored this reality when it relied on the mandatory nature of streptomycin's PPE label requirements as evidence that they will adequately protect farmworkers from antibiotic-resistant infections. *See, e.g.*, 2-ER-152 ("EPA is requiring, not assuming, that PPE be worn . . . ."); *see also* EPA Br. 38 ("Mandatory instructions on a pesticide product's labeling are not mere suggestions.").

Petitioners presented EPA with studies—uncontroverted by other record evidence—documenting widespread noncompliance with PPE requirements among pesticide-handling farmworkers, often through no fault of their own. *See* Pet'rs' Br. 46-47. EPA's failure to consider this evidence of "widespread and commonly recognized" noncompliance, 7 U.S.C. § 136a(c)(5)(D), undermines the Agency's conclusion that PPE label requirements will adequately protect farmworkers. *See* Pet'rs' Br. 45-51.

In its Response to Comments, EPA dismissed this evidence of widespread noncompliance because Petitioners had not submitted the underlying data on which the studies were based. *See* 2-ER-152. Faced with precedent from this Court rejecting that excuse, *see* Pet'rs' Br. 49 (citing *League of United Latin Am. Citizens v. Regan*, 996 F.3d 673, 699-700 (9th Cir. 2021)), EPA has since abandoned its original justification, *see* EPA Br. 40 (claiming that "EPA did not ignore Petitioners' surveys").[3]

[3] Notably, one of FIFRA's regulations provides that "additional data requirements *will* be imposed" if the data before the Agency are "not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment." 40 C.F.R. § 158.75 (emphasis

Instead, counsel for EPA now attempt—for the first time in EPA's brief—to dismiss these studies on the basis that the data are "general in nature" and do not provide "particular" evidence of noncompliance "with a label similar to the labels at issue here." *Id.* at 39-40. However, EPA never voiced this objection during the administrative proceedings, *see* 2-ER-152 (providing the Agency's actual response), and "courts may not accept appellate counsel's post hoc rationalizations for agency action." *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 50; *accord NRDC v. EPA*, 31 F.4th at 1210.

Even if the Court were to consider EPA's novel contention that the survey data were too general, it should reject that argument. In *National Family Farm Coalition v. EPA*, the Court held that EPA "entirely failed to acknowledge [a] risk[] . . . [that] it was statutorily required to consider" when the Agency ignored record evidence indicating "a risk of substantial

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added). Neither of the regulations that EPA cites, *see* EPA Br. 41, relieves the Agency of this duty. One regulation facilitates EPA's compliance with this duty by providing that the Agency may tailor data needs so as "to fully characterize" pesticide products. *See* 40 C.F.R. § 158.30(a). The other provides that EPA retains discretion on how to use data that the Agency has obtained. *See id.* § 158.1(b)(3).

non-compliance with the EPA-mandated label" for a pesticide. 960 F.3d 1120, 1139 (9th Cir. 2020). So too here. *See* Pet'rs' Br. 48-49.

EPA attempts to distinguish *National Family Farm Coalition* on the basis that the case involved specific "evidence of noncompliance with the label at issue" rather than "general" evidence of noncompliance with pesticide labels. EPA Br. 39-40. But that distinction was simply not at issue in the case. *See* 960 F.3d at 1139-42. There, as here, EPA failed to acknowledge a risk of label noncompliance, despite record evidence alerting the Agency to that risk. Nothing in the Court's analysis suggests that EPA must consider the risk of label noncompliance only in the face of definitive proof that it is already happening. Indeed, such a limitation would be illogical, as it would require evidence of noncompliance with a specific label in advance of registration—that is, before EPA has even approved the label.

Moreover, EPA's argument turns FIFRA's burden of proof on its head. It is not the *public's* burden to prove that streptomycin *will* pose unreasonable risks to farmworkers when used in accordance with

widespread practice. Rather, it is *EPA's* burden to ensure it has substantial evidence to conclude that streptomycin *will not* pose such risks. *See* 7 U.S.C. § 136a(c)(5)(D).

Here, EPA failed to meet that burden. The Agency unreasonably assumed perfect compliance with PPE label requirements notwithstanding Petitioners' submission of uncontroverted, real-world evidence that noncompliance with such requirements is widespread. EPA therefore lacked substantial evidence to conclude that PPE would adequately protect farmworkers from streptomycin-resistant infections.

b. EPA did not reasonably explain how even full compliance with PPE label requirements would adequately protect farmworkers

EPA does not deny that streptomycin's PPE label requirements apply only to farmworkers who are applying or otherwise handling streptomycin. *Compare* Pet'rs' Br. 51, *with* EPA Br. 42-43. Rather, EPA objects that "[n]o one adequately raised" the following concern during the registration process: that the PPE requirements do not protect farmworkers from streptomycin-resistant infections caused by exposures that occur

when farmworkers are not directly working with the pesticide and therefore not required to wear PPE. *See* EPA Br. 42-43. Those exposures include, for example, exposures from spray drift. They also include exposures that happen when farmworkers reenter treated fields: although EPA prohibits reentry within 12 hours of treatment, there is no reason to believe that streptomycin and antibiotic-resistant bacteria will be gone when farmworkers reenter treated fields after 12 hours. *See* Pet'rs' Br. 52.

Petitioners and others alerted EPA to these concerns during the public comment period. Commenters notified EPA that farmworkers are at risk of exposure even when not directly handling streptomycin. For example, farmworkers can be "exposed to pesticides as consumers and residents in areas where pesticides are applied" and streptomycin may "drift through the air into farmworker[s'] homes, schools, and playgrounds." 2-ER-216; *see also* 2-ER-233 to -234 (noting EPA's failure to ensure judicious antibiotic use and flagging that EPA "has allowed the second most drift-prone dissemination method of a pesticide"). Commenters also noted that EPA had provided no evidence that the

proposed PPE requirements for streptomycin "will actually work" to mitigate the "risks of antibiotic resistance resulting from workers handling streptomycin *or working in fields where it has been used*." Pet'rs' FER[4] 7, 12 (emphasis added).

Furthermore, EPA itself acknowledged that the presence of farmworkers "in treated fields" creates a risk that human pathogens will encounter streptomycin and develop resistance. 1-ER-44. The Agency investigated how long streptomycin persists in the environment and its conclusion indicated that significant quantities of the antibiotic will likely remain well past 12 hours after treatment. *See* 3-ER-288 (explaining, in a discussion on streptomycin resistance, that the most recent data show that it takes between 17 and 25 *days* for streptomycin residues in soil to decrease by half); *see also* 3-ER-369 (observing that some data indicate that it takes between 13 and 49 days for streptomycin residues in soil to decrease by half). The Agency thus had sufficient notice that farmworkers might come

[4] "FER" refers to Petitioners' Further Excerpts of Record, ECF No. 78.

in contact with streptomycin upon re-entering fields even 12 hours after treatment—and thereby risk acquiring streptomycin-resistant infections.

As this Court has explained, an "agency simply must have sufficient notice . . . to afford it the opportunity to rectify" alleged deficiencies. *Protect Our Cmtys. Found. v. LaCounte*, 939 F.3d 1029, 1037 (9th Cir. 2019) (internal quotation marks omitted). This Court "will consider any issue that was raised with sufficient clarity to allow the decision maker to understand and rule on the issue raised, whether the issue was considered sua sponte by the agency or was raised by someone other than the petitioning party." *Pac. Choice Seafood Co. v. Ross*, 976 F.3d 932, 942 (9th Cir. 2020) (internal quotation marks omitted). Here, the record reflects that EPA had sufficient notice that even full compliance with PPE label requirements—which apply only when farmworkers are spraying or otherwise handling streptomycin—may not adequately protect farmworkers.

On the merits, EPA makes no effort to argue that the PPE label requirements protect farmworkers off field. *See* EPA Br. 43. As for in-field exposures, EPA's post hoc argument that prohibiting entry into treated

fields for 12 hours "will reduce potential exposure leading to resistance in human pathogens, because human pathogens are a relatively minor component of the general agricultural environment," *id.*, is unconvincing. EPA's assertion is inconsistent with its repeated recognition in the record that the Agency is unsure how common human pathogens are in agricultural fields. *See* 2-ER-160, 161, 182, 184. And it ignores the risk that, even if human pathogens are uncommon in citrus groves, they will still be present in or on the bodies of farmworkers who enter fields containing streptomycin residues. In any event, EPA has identified no reasonable basis for concluding that "reduc[ing]" potential exposures, EPA Br. 43, will ensure that farmworkers do not face an unreasonable risk of developing antibiotic-resistant infections when—without PPE—they reenter treated fields where significant streptomycin residues are present. *See supra* p. 18 (noting record evidence that streptomycin residues will persist for many days).

Finally, EPA maintains that "streptomycin has been used in plant agriculture since the 1950s, with no such effects reported." EPA Br. 43.

However, EPA had previously approved only limited uses of streptomycin. *See* Pet'rs' Br. 19. The lack of adverse reports from these limited uses provides little assurance that the current Registration—which authorizes *an 18-fold increase* in streptomycin's use as a pesticide, *see id.* at 19-20—will not cause unreasonable adverse effects on farmworkers when they engage in activities that do not require PPE use. *Cf. supra* p. 10.

B. EPA's pollinator risk assessment is inadequate

EPA concedes that, "in several places" in the record, the Agency characterized the pollinator data for streptomycin as "incomplete" and "limited." EPA Br. 45 (quoting 1-ER-35; 3-ER-369, 376). In addition, EPA agrees that FIFRA prohibits unconditional registration of a pesticide unless the Agency concludes—based on data that it deems sufficient—that the pesticide will not cause unreasonable adverse effects. *See* EPA Br. 7-8, 44. By registering the new uses of streptomycin unconditionally based on admittedly incomplete pollinator data, EPA violated FIFRA. *See* Pet'rs' Br. 55-57.

There is nothing "unclear," EPA Br. 45, about EPA's characterization of the pollinator data. Although the Agency claims that it was referring to data it might need for the distinct process of reviewing existing registrations of streptomycin-containing pesticides, *see id.*, the record contradicts that explanation. EPA's ecological risk assessment, which describes the pollinator data as both "incomplete," 3-ER-369, and "limited," 3-ER-376, focuses specifically on the registration of streptomycin's proposed new uses on citrus, *see* 3-ER-368, and nowhere mentions the registration review for already-approved uses of streptomycin, *see* 3-ER-368 to -376. Likewise, EPA's Final Registration Decision states that "the pollinator data are incomplete" in a paragraph concerning the "new uses" of streptomycin. 1-ER-35.

Even if the Agency did mean to refer to the separate registration review process, however, the distinction falls flat. As EPA recognizes, the substantive standard for registration review is *the same* as that for unconditional registration. EPA Br. 7 (quoting 40 C.F.R. § 155.57); *see also* 40 C.F.R. § 155.40(a) ("Registration review is the periodic review of a

pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration."). If EPA was uncertain whether it had sufficient pollinator data for streptomycin's registration review, *see* EPA Br. 45, then it was necessarily also uncertain whether it had sufficient pollinator data to register the new uses of streptomycin.

FIFRA does not allow such uncertainty. EPA may grant an unconditional registration "only if" the Agency first "determines that no additional data are necessary" to decide whether a pesticide use will cause unreasonable adverse effects. 40 C.F.R. § 152.112(c) (citing 7 U.S.C. § 136a(c)(5)); *see Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 523 (9th Cir. 2015). "If the information required under [40 C.F.R. pt. 158] is 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." *Id.* § 158.75 (emphasis added). EPA misstates the law when it represents that the Agency "*may* decide that it needs to impose additional requirements" under this circumstance. EPA Br. 8 (emphasis

added). If EPA cannot conduct the requisite safety analysis, it *must* require more data—or deny unconditional registration.

EPA's reliance on its Pollinator Process Guidance is misplaced. *See* EPA Br. 8-10, 25, 46. EPA's brief makes much of the Guidance's suggestion that EPA may register certain new pesticide uses based on existing pollinator data and defer, until registration review, the collection of additional data needed to fully assess effects on pollinators. *See* EPA Br. 9-10, 46. This is another post hoc argument raised by litigating counsel, and should be rejected for that reason alone. *See Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 50. In the record, the Agency itself flagged the unavailability of "[a]dditional pollinator data" called for in the Pollinator Process Guidance. 1-ER-36; *see also id.* ("These additional studies examine potential toxicity to larval and adult honey bees from acute and chronic exposure."). Having done so, EPA could not—without explaining why it did not need those data to assess streptomycin's risks—reasonably conclude that streptomycin will not have unreasonable adverse effects on pollinators. *See* Pet'rs' Br. 59-60.

That said, EPA's post hoc argument also fails on the merits. "Unconditional registration necessarily requires sufficient data to evaluate the environmental risks." *Pollinator Stewardship Council*, 806 F.3d at 523. But unconditional registration is not the only pesticide registration option. FIFRA also allows EPA to amend a pesticide registration *conditionally* to add new uses "notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment." 7 U.S.C. § 136a(c)(7)(B).[5] EPA's Pollinator Process Guidance does not endorse granting *unconditional* registration when EPA lacks adequate data to assess whether a pesticide use will cause unreasonable harm to pollinators. *See* SER 140-65. Nor could the Guidance lawfully endorse such an approach; as discussed, FIFRA prohibits unconditional registration absent sufficient data

[5] If a pesticide applicant is unable to submit data required for unconditional registration because those data have not yet been generated, then EPA "may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this subchapter," that is, during registration review. 7 U.S.C. § 136a(c)(7)(B); *see id.* § 136a(g) (providing for registration review of existing pesticide registrations).

to evaluate whether a pesticide will cause unreasonable adverse effects. *See* Pet'rs' Br. 55-56.

EPA insists that it "*did* determine that the data were complete before granting the registration amendments." EPA Br. 44. But the Agency's repeated recognition that the pollinator data for streptomycin were "incomplete" and "limited," EPA Br. 45 (quoting 1-ER-35; 3-ER-369, 376), cannot be reconciled with the Agency's conclusion that "[t]he streptomycin database is . . . complete to assess risk to the environment." 1-ER-49. The "internal 'inconsistenc[y]'" between EPA's specific recognition that pollinator data were lacking and its general conclusion that it had complete data shows that the Registration is not backed by substantial evidence. *NRDC v. EPA*, 38 F.4th 34, 51 (9th Cir. 2022) (quoting *NRDC v. EPA*, 31 F.4th at 1210).

EPA's contention that "Petitioners are . . . seeking to compel EPA to make a scientific judgment that it has not yet made," EPA Br. 46, is misplaced. Petitioners simply seek to hold EPA to its statutory obligations. As a prerequisite for unconditional registration, Congress placed on EPA

the burden of determining that a pesticide will not cause unreasonable adverse effects, and the Agency cannot meet this burden absent adequate supporting data. *See* 7 U.S.C. § 136a(c)(5)(C), (D); *Pollinator Stewardship Council*, 806 F.3d at 523. Here, EPA lacked sufficient information to make the requisite safety determination and thus violated FIFRA when it unconditionally registered streptomycin's new uses based on "incomplete" and "limited" pollinator data. 1-ER-35; 3-ER-369, 376.

C. EPA fails to refute the flaws in its benefits analysis

EPA's brief not only fails to justify the Agency's inadequate assessment of the Registration's risks to public health and the environment; it also does little to address three significant deficiencies in the Agency's analysis of streptomycin's purported benefits. First, although EPA registered streptomycin to treat *and prevent* infection, 1-ER-48, the Agency concedes that the registrants submitted no data to support preventative benefits. EPA Br. 51-52. Second, EPA relied on a methodologically flawed study to support streptomycin's supposed treatment benefits for citrus canker disease. And third, the Agency ignored peer-reviewed research in

the record that concluded streptomycin was ineffective at treating citrus greening disease. These shortcomings render the Registration unlawful.

First, EPA authorized preventative use of streptomycin despite having *no evidence* of preventative benefits. Pet'rs' Br. 64-65. EPA concedes "the registrants did not submit any data to support a claim that streptomycin prevents infection." EPA Br. 51. Given the clear risks, *see* Pet'rs' Br. 21-27, and zero evidence of countervailing benefits, the preventative use cannot meet FIFRA's registration standard. *See* 7 U.S.C. § 136a(c)(5)(C), (D).

It is no comfort that the Agency "will work with the registrants to determine whether this claim [of preventative benefits] is supported by adequate data," or that EPA will "remove the claim from the labels if it is not so supported." EPA Br. 52.[6] Neither of these assurances satisfies EPA's

[6] The Agency's reference to FIFRA's misbranding provisions is perplexing. Those provisions make it unlawful to distribute or sell a "misbranded" pesticide, 7 U.S.C. § 136j(a)(1)(E)—that is, a pesticide with a label "bearing any statement . . . which is false or misleading," *id.* § 136(q)(1)(a). But if no data support registration of a pesticide use in the first instance, the lawful course of action is for EPA to deny registration—not to rely on post-registration actions to prevent that use.

obligation to evaluate a pesticide's benefits *before* registering its proposed new uses. *See Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 912-13 (9th Cir. 2020). Petitioners submitted comments explaining this lack of evidence for preventative benefits, but EPA authorized streptomycin for preventative use anyway. Pet'rs' Br. 65. The Agency cannot undo its mistake by representing in this litigation that it will now evaluate whether these benefits are supported.

Second, there is no factual dispute about the methodology for the citrus canker study, which evaluated streptomycin only when used in combination with copper—an already known treatment. *See* EPA Br. 48-50. As Petitioners argue, this study did not provide evidence that streptomycin is an effective treatment because it lacked a proper control group. *See* Pet'rs' Br. 62-63. EPA attempts to distract from that scientific error by asserting that the study tested streptomycin as it would be used in the field. EPA Br. 49. But EPA's argument fails to respond to the study's fundamental flaw: applying streptomycin alongside a substance known to treat citrus canker does not show that *streptomycin* treats the disease.

Similar reasoning would lead to absurd results. For instance, aspirin is a known treatment for headaches. If a registrant submitted a study claiming that aspirin, when combined with a sugar pill, *also* treats headaches, under EPA's logic that would be sufficient to show that *sugar pills* treat headaches. At best, the study that EPA endorsed here generated ambiguous findings about streptomycin, and EPA may not rely on ambiguous studies to support a FIFRA registration. *See Pollinator Stewardship Council*, 806 F.3d at 531.

Third, although EPA acknowledged the existence of a peer-reviewed study in the record that concluded streptomycin is ineffective at treating citrus greening disease, EPA Br. 50, it did not address that particular conclusion. Rather, EPA responded with an irrelevant point about *other* antibiotics analyzed in the study. *See* 2-ER-176. EPA never acknowledged, much less countered, the study's findings regarding streptomycin's ineffectiveness. *See id.*; Pet'rs' Br. 63-64. The Agency therefore failed to "examine the *relevant* data and articulate a satisfactory explanation for its action.'" *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43 (emphasis added).

Although EPA's counsel puts forward new arguments challenging the study's relevance, these arguments are without support in the record. *Compare* EPA Br. 50 (arguing study was "not definitively applicable to field conditions" and differentiating study's focus on treatment from EPA's focus on symptom-management), *with* 2-ER-176 (dismissing study on the basis that the Agency had not received applications to use any of the studied antibiotics as pesticides to combat citrus greening disease—but apparently overlooking the study's inclusion of streptomycin). The Court "may not accept appellate counsel's *post hoc* rationalizations for agency action." *Cal. Pub. Utils. Comm'n v. FERC*, 879 F.3d 966, 978 n.5 (9th Cir. 2018) (citation and internal quotation marks omitted).

EPA is unable to overcome these foundational errors. The finding that benefits outweigh risks is "the critical determination that the pesticide complies with FIFRA's safety standard." *NRDC*, 38 F.4th at 53. Here, EPA could not lawfully make this finding because it lacked substantial evidence to support the Registration's purported benefits.

II. EPA does not justify departure from the default remedy of vacatur

Vacatur is the presumptive remedy for unlawful agency action, and the appropriate remedy for EPA's violations here of FIFRA and the ESA.[7] *See* Pet'rs' Br. 32, 67. To determine whether to depart from this remedy, the Court (1) weighs the "seriousness of the agency's errors against the disruptive consequences" of vacatur; (2) considers the risk of "environmental harm" from "vacating or leaving the decision in place"; and (3) examines the likelihood an agency would adopt the "same" decision on remand. *NRDC*, 38 F.4th at 51-52 (citations omitted). EPA has not shown it is entitled to such a departure; indeed, it has not shown that any of these factors tilts in its favor.

A. EPA's serious legal errors outweigh any disruptive consequences from vacatur

EPA considers its conceded ESA violation a "significant concern," EPA Br. 59, and the D.C. Circuit recently vacated a pesticide registration based on a similar violation. *See* Pet'rs' Br. 70-71, 77; Order 1-2, *Farmworker*

[7] Because EPA concedes it violated the ESA, EPA Br. 55, remedy is the only disputed issue for Petitioners' ESA claim.

Ass'n of Fla. v. EPA, No. 21-1079 (D.C. Cir. June 7, 2021) (per curiam). Moreover, for remedy purposes, EPA has not contested the seriousness of the multiple legal errors in its FIFRA analysis, discussed above. *See* Pet'rs' Br. 68-70.

Instead, EPA argues that disruptive consequences from vacatur outweigh the seriousness of its errors. *See* EPA Br. 58-61. But the case EPA relies on to support its position, *Center for Biological Diversity v. EPA*, 861 F.3d 174 (D.C. Cir. 2017), is inapposite. There, the court determined that vacatur would itself pose the greater risk of environmental harm because growers would switch to a more harmful pesticide alternative that would "temporarily defeat the enhanced protection of the environmental values covered by the EPA rule at issue." *Id.* at 188 (cleaned up). Not so here, where EPA does not argue that vacatur will cause growers to revert to more environmentally harmful practices. *See* EPA Br. 58-61.

Furthermore, this Court has granted vacatur based on EPA's failures to acknowledge the risks posed by pesticide registration—failures that are materially similar to EPA's errors here—notwithstanding the potential for

"adverse impact[s] on growers." *Nat'l Fam. Farm Coal.*, 960 F.3d at 1145; Pet'rs' Br. 71-72. EPA has not carried its burden for this factor, particularly considering the serious questions about streptomycin's efficacy raised by EPA's flawed benefits analysis. *See supra* Argument I.C. This factor thus weighs strongly in favor of vacatur.

B. The potential for environmental harm from leaving the Registration in place outweighs any harm from vacatur

The second factor asks whether "leaving the EPA's registration . . . in place risks more potential environmental harm than vacating it." *Pollinator Stewardship Council*, 806 F.3d at 532. EPA identifies no environmental harms from vacatur, instead arguing that environmental harm from the Registration would be minimal. *See* EPA Br. 61-62. Even if that were true, some environmental harm is more than none.

EPA's attempt to minimize the risk of environmental harm from the Registration by referencing previous, smaller-scale authorizations, EPA Br. 62, ignores that the Registration authorizes a massive increase in the use of streptomycin, *see* Pet'rs' Br. 72. This unprecedented usage will pose unprecedented risks.

EPA's characterization of the risks as "very limited," EPA Br. 62, also cannot be squared with the risks described in the record—risks that the Agency identified notwithstanding its cursory, flawed assessment. Despite failing to analyze the full potential for antibiotic resistance, EPA concluded that there would be a "medium" risk of increased antibiotic resistance. *See* Pet'rs' Br. 23; EPA Br. 27. EPA also acknowledged potential risks to mammals, 1-ER-35, likely including endangered and threatened mammals with ranges that overlap with citrus groves, *see* 2-ER-90 to -121. Under the ESA, "the balance of hardships always tips sharply in favor" of these vulnerable species. *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1035 (9th Cir. 2005), *abrogated on other grounds as recognized in Cottonwood Env't L. Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015). Without vacatur, risks to these species would persist during the years it will take EPA to correct its ESA violation. *See* Pet'rs' Br. 74.

For these reasons, this factor too weighs in favor of vacatur.

C. EPA has not shown it is likely to adopt the same rule on remand

Finally, courts ask "whether the agency would *likely* be able to offer better reasoning or . . . whether such fundamental flaws in the agency's decision make it *unlikely* that the same rule would be adopted on remand." *Pollinator Stewardship Council*, 806 F.3d at 532 (emphases added). EPA's attempt to water down this factor to "whether it is *possible* for EPA to adopt" the authorized use of streptomycin on remand, EPA Br. 62 (emphasis added), is a misstatement of the law.

Vacatur is appropriate where "the 'fundamental flaws' in EPA's analysis are so substantial such that it is exceedingly 'unlikely that the same rule would be adopted on remand,'" *Nat'l Fam. Farm Coal.*, 960 F.3d at 1145 (citation omitted), or where EPA's need "to obtain further studies and data" on environmental effects means that "a different result may be reached" on remand. *Pollinator Stewardship Council*, 806 F.3d at 532-33.

Both are true here. There are fundamental flaws in EPA's analysis of both streptomycin's risks and benefits. *See supra* Argument I. In addition, there remain significant data gaps on the Registration's contribution to

antibiotic resistance, *see* Pet'rs' Br. 75-76; as well as data gaps, which EPA has admitted, on pollinators, *see* EPA Br. 46-47, streptomycin's benefits for preventative use, *see id.* at 51-52, and effects on endangered and threatened species, *see id.* at 56. Both of these considerations point this factor toward vacatur.

CONCLUSION

Based on the foregoing, Petitioners respectfully ask the Court to remand and vacate EPA's registration of streptomycin for use as a pesticide on citrus trees.

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Respectfully submitted,

s/ Hannah Connor
Hannah Connor
Center for Biological Diversity
1411 K Street NW, Suite 1300
Washington, DC 20005
Telephone: (202) 681-1676
hconnor@biologicaldiversity.org

Counsel for Petitioner Center for Biological Diversity

s/ Carrie Apfel
Carrie Apfel
Earthjustice
1001 G Street NW, Suite 1000
Washington, DC 20001
Telephone: (202) 667-4500
capfel@earthjustice.org

Dominique Burkhardt
Earthjustice
4500 Biscayne Boulevard Suite 201
Miami, FL 33137
Telephone: (305) 440-5432
dburkhardt@earthjustice.org

Counsel for Petitioners Migrant Clinicians Network, Beyond Pesticides, Environmental Confederation of Southwest Florida, Farmworker Association of Florida, and Farmworker Justice

s/ Margaret T. Hsieh
Margaret T. Hsieh
Natural Resources Defense Council
40 W. 20th Street
New York, NY 10011
Telephone: (212) 727-4652
mhsieh@nrdc.org

Sarah Fort
Natural Resources Defense Council
1152 15th Street NW, Suite 300
Washington, DC 20005
Telephone: (202) 513-6247
sfort@nrdc.org

Francis W. Sturges, Jr.
Natural Resources Defense Council
20 N. Wacker Drive, Suite 1600
Chicago, IL 60606
Telephone: (312) 847-6807
fsturges@nrdc.org

Counsel for Petitioners Natural Resources Defense Council and U.S. Public Interest Research Group

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of 9th Cir. R. 32-1(a) because it contains 6,442 words, excluding the parts of the brief exempted by 9th Cir. R. 32-1(c) and Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using 14-point Palatino Linotype font.

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s/ Margaret T. Hsieh
Margaret T. Hsieh
Counsel for Petitioners