UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK et al., Petitioners, v. U.S. ENVIRONMENTAL PROTECTION AGENCY et al., Respondents.	No. 21-70719

PETITIONERS' REPLY IN SUPPORT OF CROSS-MOTION TO VACATE

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INTRODUCTION

As longstanding Circuit precedent makes clear, vacatur is the presumptive, and appropriate, remedy for EPA's conceded violation of the Endangered Species Act (ESA). EPA fails to justify its request for departure from this normal practice. Instead, the Agency misstates the appropriate test, conflates the two separate parts of the required analysis, and ignores the serious harms to the environment and human health posed by allowing—for years—continued spraying of millions of pounds of streptomycin while EPA conducts a new analysis. *See* Matuszko Decl. ¶ 25, ECF No. 42-2 (explaining that the new analysis will take at least four-and-a-half years). A straightforward application of this Court's precedent shows that vacatur of EPA's unconditional registration of streptomycin for use on citrus crops is warranted.

ARGUMENT

This case does not present one of the "limited circumstances" that warrant departure from the presumptive remedy of vacatur. *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015) (quoting *Cal.*

Cmties. Against Toxics v. EPA, 688 F.3d 989, 994 (9th Cir. 2012)); *Coal. to Protect Puget Sound Habitat v. U.S. Army Corps of Eng'rs*, 843 F. App'x 77, 80 (9th Cir. 2021). "[T]he seriousness of the agency's error[]" far outweighs any "disruptive consequences" that might flow from vacatur. *Pollinator Stewardship*, 806 F.3d at 532 (quoting *Cal Cmties.*, 688 F.3d at 992); *see also Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). Moreover, "leaving the EPA's registration . . . in place risks more potential environmental harm than vacating it." *Pollinator Stewardship*, 806 F.3d at 532. Accordingly, EPA has not met its burden to show that "equity demands" leaving streptomycin's registration in place, *id.* (quoting *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)), and the Court should vacate EPA's unlawful action.

I. EPA's ESA violation is a serious legal error

The first factor in determining whether departure from vacatur is warranted—the "seriousness of the agency's errors," *id.*—weighs heavily in favor of vacatur here. By its own admission, EPA "did not make ESA effects determinations before approving" use of streptomycin on citrus

groves, "as required by the ESA." EPA Resp. 3, ECF No. 48. The D.C. Circuit has held that EPA's failure to make an effects determination for another pesticide was a "serious[] . . . admitted error." Order 2, *Farmworker Ass'n of Fla. v. EPA*, No. 21-1079 (D.C. Cir. June 7, 2021). And EPA itself recently "recognize[d] the seriousness of not meeting its ESA obligations when registering products under FIFRA." Recording of Oral Argument at 16:05-16:22, *Ctr. for Biological Diversity v. EPA*, No. 15-1054 (D.C. Cir. Feb. 10, 2022), *available at* https://www.cadc.uscourts.gov/recordings/recordings2021.nsf/6328E1318AF8B0EE852587E50059E02B/$file/15-1054.mp3.

EPA argues that the analysis of whether it committed a serious legal violation of the ESA "requires an equitable balancing of the potential harm for leaving the amended registrations in place with the benefits for doing so," including consideration of the Agency's separate FIFRA assessment. EPA Resp. Br. 4. This argument conflates the two factors of what the Agency itself describes as "*Allied-Signal['s]* [t]wo-[p]art [t]est." *Id.* at 2. Balancing potential harms from granting or denying vacatur is relevant to

the *second* factor set out in *Allied-Signal*—that is, to the consideration of any "disruptive consequences" of vacatur. *Pollinator Stewardship*, 806 F.3d at 532. It has no bearing on the first factor—*i.e.*, "the seriousness of the agency's errors." *Id.*

Though EPA cites repeatedly to *Center for Biological Diversity v. EPA*, 861 F.3d 174, 188 (D.C. Cir. 2017), that case did not turn on the seriousness of the Agency's legal error. Instead, the court denied vacatur because it found that granting vacatur would cause disruptive environmental consequences that "would at least temporarily defeat the enhanced protection of the environmental values covered by the EPA rule at issue"—in other words, the court concluded that the *second Allied-Signal* factor weighed against vacatur in that case. 861 F.3d at 188 (cleaned up).

EPA's limited environmental analyses of streptomycin under FIFRA are relevant, if at all, only to the separate consideration of whether vacatur itself is likely to cause environmental harm. *See infra* pp. 8-10. They cannot

mitigate the seriousness of EPA's ESA violation.[1] Pet'rs' Cross-Mot. 19 (discussing *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005)). Where, as here, "an agency's action failed to follow Congress's clear mandate," there is a strong presumption of vacatur. *Cf. Cal. Wilderness Coal. v. Dep't of Energy*, 631 F.3d 1072, 1095 (9th Cir. 2011).

Misreading *Pollinator Stewardship Council*, EPA also contends that vacatur is inappropriate if the Agency "could make the same registration decisions under FIFRA after it complies with the ESA." EPA Resp. 8. But that case reinforces the appropriateness of vacatur here. There, the Court vacated a pesticide registration because EPA needed "to obtain further studies and data" regarding ecological effects, reasoning that once EPA had such information on remand, "a different result may be reached." *Pollinator Stewardship*, 806 F.3d at 532-33.

[1] EPA protests that its admission of error "is not evidence of bad faith," EPA Resp. 7, but bad faith is not at issue: Petitioners do not oppose voluntary remand. *See SKF USA Inc. v. United States*, 254 F.3d 1022, 1029-30 (Fed. Cir. 2001) (noting standard for denying an agency's request for remand, not vacatur). Instead, EPA's repeated past violations underscore the seriousness of the Agency's error and the inequity of granting its requested remedy. *See* Pet'rs' Cross-Mot. 18.

The same is true here. To comply with the ESA, EPA must first gather "significant data" and conduct a biological evaluation. Matuszko Decl. ¶ 24. The Agency has never done a biological evaluation for any antibiotic, and it "may encounter new or unexpected challenges in conducting its analyses and making effects determinations." *Id.* ¶ 24. "[T]he outcomes of EPA's ESA analyses" could change its FIFRA decisions, EPA Resp. 12, and may require ESA consultation, *see* Pet'rs' Cross-Mot. 21, ECF No. 45-1. This is not a case where the Agency can remedy a "technical" error by "offer[ing] better reasoning and adopt[ing] the same rule on remand." *Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 929 (9th Cir. 2020) (quotation marks omitted). Instead, EPA must perform a new and lengthy analysis, and that evaluation might well result in a different decision. That it will take EPA, at minimum, four-and-a-half years to complete this process, *see* Matuszko Decl. ¶ 25, underscores the seriousness of the Agency's violation. *See* Order, *Farmworker Ass'n of Fla.*, No. 21-1079, at 1 (describing "timely reconsideration" as "the central rationale for remand without vacatur").

EPA's unfounded "same rule" standard also ignores D.C. Circuit guidance on application of the first *Allied-Signal* factor where, as here, an agency has skipped a fundamental procedural step. In such cases, the question is "not whether the ultimate action could be justified, but whether the agency could, with further explanation, justify its decision to skip that procedural step." *Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs*, 985 F.3d 1032, 1052 (D.C. Cir. 2021).[2] EPA has nowhere argued—nor could it—that, on remand, it could justify skipping the ESA effects determination. Thus, it is irrelevant whether EPA might, in 2026 or thereafter, reissue the streptomycin registration.

The Agency's serious legal error favors vacatur.

[2] Because *Allied-Signal* is a D.C. Circuit decision, that court's decisions merit particular consideration in determining how to apply its factors. EPA has not disputed the applicability of this guidance, which Petitioners cited in their Cross-Motion. *See* Pet'rs' Cross-Mot. 15.

II. Environmental and public health risks from continued use of streptomycin during remand outweigh any disruptive consequences of vacatur

The second factor that guides this Court's analysis of whether to depart from the presumptive remedy of vacatur is "the disruptive consequences of an interim change that may itself be changed." *Pollinator Stewardship*, 806 F.3d at 532 (quoting *Cal. Cmties.*, 688 F.3d at 992). When an agency violates a statute enacted to prevent environmental harm, this factor considers "the extent to which either vacating or leaving the decision in place would risk environmental harm." *Nat'l Fam. Farm Coal. v. EPA*, 960 F.3d 1120, 1144-45 (9th Cir. 2020); *see also Ctr. for Biological Diversity*, 861 F.3d at 189 (determining vacatur of pesticide registration would cause more environmental harm than leaving it in place).

A. Harms to endangered species

Here, uncontested evidence indicates that maintaining the registration poses a credible risk to endangered species. The Agency's own assessment concluded that streptomycin exposure poses a risk to mammals. APP003. EPA's attempts to minimize this risk, arguing that it

applies only to *some* mammals, and only sometimes, EPA Resp. 5-6 (describing risk as "limited to mammals that consume grasses, broadleaf forage, and insects," and as lasting only "approximately three weeks" after each application), are unconvincing. Even accepting these statements as true, EPA authorized three applications per year, putting multiple endangered species at risk of harm from direct exposure to streptomycin for over a sixth of the year. *See* APP002. For example, the endangered Florida bonneted bat is an insect-eating mammal, 78 Fed. Reg. 61,004, 61,006 (Oct. 2, 2013), with a range including commercial citrus groves, *see* Bradley Decl., Ex. C, ECF No. 45-2. Chemical exposure and pesticides' impacts on the bats' prey are threats to the species. *See* 78 Fed. Reg. at 61,039. Similarly, the endangered San Joaquin kit fox's range overlaps with commercial citrus, *see* Bradley Decl., Ex. I, and it consumes insects and grasses, *see* EPA, *Endangered Species Facts: San Joaquin Kit Fox* 2 (Feb. 2010), https://www.epa.gov/sites/default/files/2013-08/documents/san-joaquin-kitfox.pdf. And endangered predators, including the Florida panther and ocelots, also have ranges that overlap with citrus, *see* Bradley Decl., Exs. B,

L, and rely on prey that may be harmed by streptomycin. At minimum, EPA's own limited assessments indicate that continued streptomycin use "may affect" these endangered species.[3] *Karuk Tribe v. U.S. Forest Serv.*, 681 F.3d 1006, 1027 (9th Cir. 2012) (en banc).

Furthermore, EPA has not claimed—and cannot reasonably claim—that *vacatur* would harm at-risk species, which is the relevant analysis for ESA harms. *See Idaho Farm Bureau*, 58 F.3d at 1405. Given the risks continued use of streptomycin poses to these and other imperiled species, EPA's argument—that the Court should nonetheless allow hundreds of thousands of pounds of streptomycin to be sprayed on citrus groves annually because doing so is "generally" low risk, EPA Resp. 4—flies in the face of "the ESA's policy of institutionalized caution." *Ctr. for Biological Diversity v. Zinke*, 900 F.3d 1053, 1073 (9th Cir. 2018) (quotation marks omitted).

[3] Similarly, EPA's insistence that streptomycin is practically nontoxic to honeybees "on an acute exposure basis," EPA Resp. 6, ignores the likelihood of harm from chronic exposures throughout the multi-year registration.

B. Harms to public health

The second factor requires consideration not only of the threat to endangered species, but also of the significant risks to human health posed by antibiotic resistance caused by continued streptomycin use. *See* Pet'rs' Cross-Mot. 24-25. EPA nowhere rebuts either the existence or the severity of these risks. Nor can it.

The authorized use of streptomycin as a pesticide far exceeds both its use in clinical medicine and existing agricultural uses. Graham Decl. ¶ 35, ECF No. 45-2. This use will select for antibiotic resistance, both among human pathogens in agricultural settings and among environmental bacteria with mobile genetic elements capable of transferring streptomycin resistance to bacteria of human health concern. *Id.* ¶¶ 34, 37. Antibiotic use in the agricultural sector can therefore affect human health and communities, *id.* ¶¶ 38-39, including by complicating treatment of human pathogens, *id.* ¶¶ 40-41. That risk is particularly pronounced for farmworkers in citrus groves. *Id.* ¶¶ 29-32.

The serious health risk of increasing antibiotic resistance stemming from continued use of streptomycin on citrus is both real and immediate. EPA nowhere denies this. Unable to refute that danger, the Agency pivots to its dubious contention that discontinuing use of streptomycin on citrus could increase the risk that bacteria develop resistance to a *different* antibiotic, oxytetracycline, that EPA has also registered for use on citrus. *See* EPA Resp. 11-12.

This is a red herring. First, the Agency relies on a conclusory assertion that alternating "different modes of action" is "generally" "considered a benefit" for managing resistance to plant pesticides. APP025. But EPA cites no evidence to support this bare assertion. *Cf. Ariz. Cattle Growers' Ass'n v. U.S. Fish & Wildlife Serv.*, 273 F.3d 1229, 1244 (9th Cir. 2001) (holding that agency action was arbitrary and capricious when based on "speculation . . . not supported by the record"). Further undermining EPA's reliance on this assertion, the Agency does not currently require citrus growers to alternate streptomycin and oxytetracycline. *See* Pet'rs' Cross-Mot. 25-26. Second, even accepting EPA's unsupported assumption,

the Agency focuses not on *health* risks, but rather on potential *economic* harm to growers, insofar as such resistance may reduce oxytetracycline's efficacy as a pesticide. *See* EPA Resp. 11 (citing APP025); APP025.

EPA's myopic focus on the purported economic benefit of cycling the two antibiotics also ignores associated public health risks. In addition to creating a risk of expanded antibiotic resistance to streptomycin itself, cycling streptomycin and oxytetracycline may actually contribute to "[m]ultiple drug resistance" because "oxytetracycline/streptomycin resistance is a common trait" on some mobile genetic elements of bacteria of human health concern. APP099; *see also* Graham Decl. ¶¶ 20, 34 (explaining multidrug resistance and mobile genetic elements). EPA's vague assertion on cycling's supposed benefits fails to justify using an antibiotic treadmill that compromises the efficacy of a medically important antibiotic to slow the declining efficacy of another antibiotic, especially where the combined use could worsen multiple drug resistance.

C. Potential economic disruptions

Petitioners do not, as EPA suggests, contend that potential economic disruption to citrus growers from discontinuing streptomycin's registration is irrelevant to this Court's analysis. *See* Pet'rs' Cross-Mot. 26-27; *contra* EPA Resp. 9. Rather, the vague and speculative economic consequences cited by EPA do not, under this Court's precedent, warrant departure from the default remedy of vacatur. Petitioners are unaware of any Ninth Circuit decision in which vacatur was denied on the grounds that economic impacts outweighed environmental considerations; EPA certainly has not cited any such case.

California Communities, cited by EPA, *see* EPA Resp. 9-10, is not to the contrary. Although this Court referenced "disastrous" economic harms as one reason not to vacate agency action in that case, it also found that vacatur could harm the environment by causing increased air pollution—"the very danger the Clean Air Act aims to prevent," 688 F.3d at 994. Thus, disruptive consequences to *both* the environment and the economy weighed against vacatur. *California Communities* is thus inapposite here,

where any "adverse impact[s] on growers," *Nat'l Fam. Farm Coal.*, 960 F.3d at 1145, are outweighed by the risks associated with leaving EPA's registration in place.

* * *

The balancing of equities is straightforward here: both of the *Allied-Signal* factors point toward the ordinary remedy of vacatur. EPA has not—and cannot—overcome this presumption.

III. In the alternative, the Court should adjudicate Petitioners' FIFRA claims and remand the ESA claim

The parties agree that this Court has authority to adjudicate Petitioners' FIFRA claims if it does not vacate streptomycin's registration. *See* EPA Resp. 12-13. If the Court declines the presumptive remedy of vacatur, it should remand the ESA claim and adjudicate the FIFRA claims. *See Cook Inletkeeper v. EPA*, 400 F. App'x 239, 242 (9th Cir. 2010) (granting EPA's motion for partial remand and retaining jurisdiction).

CONCLUSION

For these reasons, and those presented in Petitioners' cross-motion, the Court should vacate streptomycin's registration.

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Respectfully submitted,

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I hereby certify that the foregoing motion was served on all parties through this Court's electronic filing system.

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