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' OPPOSITION TO EPA'S MOTION FOR REMAND WITHOUT VACATUR AND CROSS-MOTION TO VACATE

TABLE OF CONTENTS

INTRODUCTION 1

BACKGROUND 3

I. Factual background 3

A. Antibiotic resistance poses serious risks to human health 3

B. EPA unlawfully approved use of a medically important antibiotic as a pesticide at an unprecedented scale 4

C. Petitioners challenged EPA's unlawful registration under both the ESA and FIFRA 10

II. Legal background 11

A. Endangered Species Act 11

B. Federal Insecticide, Fungicide, and Rodenticide Act 13

STANDARD OF REVIEW 14

ARGUMENT 16

I. EPA's admitted violation of the ESA is a serious legal error requiring vacatur 17

II. Risks to the environment and human health outweigh any disruptions to growers 23

III. In the alternative, the Court should permit Petitioners' FIFRA claims to proceed because remand without vacatur would effectively foreclose judicial review of these claims 27

CONCLUSION 29

CERTIFICATE OF COMPLIANCE 31

CERTIFICATE OF SERVICE 32

TABLE OF AUTHORITIES

Cases

All. for the Wild Rockies v. U.S. Forest Serv.,
907 F.3d 1105 (9th Cir. 2018).....16

Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n,
988 F.2d 146 (D.C. Cir. 1993) 15

Alsea Valley All. v. Dep't of Commerce,
358 F.3d 1181 (9th Cir. 2004).....14

Cal. Cmties. Against Toxics v. EPA,
688 F.3d 989 (9th Cir. 2012)..... 14, 23, 26-27

Ctr. for Biological Diversity v. EPA,
No. 15-1054 (D.C. Cir.) 18

Ctr. for Biological Diversity v. EPA,
861 F.3d 174 (D.C. Cir. 2017) 13, 16, 22

Ctr. for Biological Diversity v. EPA,
No. 20-73146 (9th Cir.).....18

Ctr. for Envt'l Health v. Regan,
No. 4:18-cv-03197-SBA (N.D. Cal. Jan. 4, 2022) 21

Ctr. for Food Safety v. EPA,
Nos. 19-72109, 19-72280 (9th Cir.) 18

Conner v. Burford,
848 F.2d 1441 (9th Cir. 1988).....13

Cottonwood Env't L. Ctr. v U.S. Forest Serv.,
789 F.3d 1075 (9th Cir. 2015).....11

Farmworker Ass'n of Fla. v. EPA,
No. 21-1079 (D.C. Cir. June 7, 2021) 22

Idaho Farm Bureau Fed'n v. Babbitt,
58 F.3d 1392 (9th Cir. 1995).....14, 23

In re NRDC,
956 F.3d 1134 (9th Cir. 2020).....29

Karuk Tribe v. U.S. Forest Serv.,
681 F.3d 1006 (9th Cir. 2012).....12, 13, 19

Nat'l Fam. Farm Coal. v. EPA,
960 F.3d 893 (9th Cir. 2020).....12, 15, 26

NRDC v. EPA,
No. 1:17-CV-02034 (D.D.C).....18

NRDC v. U.S. Food & Drug Admin.,
760 F.3d 151 (2d Cir. 2014).....3

Pollinator Stewardship Council v. EPA,
806 F.3d 520 (9th Cir. 2015).....14, 15, 16

Standing Rock Sioux Tribe v. U.S. Army Corps of Eng'rs,
985 F.3d 1032 (D.C. Cir. 2021) 15

Tenn. Valley Auth. v. Hill,
437 U.S. 153 (1978) 11, 17-18, 24

Wash. Toxics Coal. v. EPA,
413 F.3d 1024 (9th Cir. 2005).....11, 19, 23

W. Watersheds Project v. Kraayenbrink,
632 F.3d 472 (9th Cir. 2011).....11, 18

Statutes

7 U.S.C. § 136a(a) 13

7 U.S.C. § 136a(c)(5)(C) 11, 13

7 U.S.C. § 136a(c)(5)(D) 11, 13

7 U.S.C. § 136(bb) 11, 14

16 U.S.C. § 1536(a)(2) 12, 13

16 U.S.C. § 1536(b) 19

Regulations

40 C.F.R. § 152.112(b)-(c) 14

50 C.F.R. § 402.01(b) 21

50 C.F.R. § 402.13 12

50 C.F.R. § 402.14 12

50 C.F.R. § 402.14(a) 12, 21

Other Authorities

Centers for Disease Control and Prevention, *Antibiotic/Antimicrobial Resistance: Where Resistance Spreads: Water, Soil, & the Environment* 9

Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States* (2019) 4

EPA, *EPA EcoBox Tools by Exposure Pathways – Food Chains* 8

EPA, *Exploration of Methods for Characterizing Effects of Chemical Stressors to Aquatic Plants* (Nov. 1, 2010) 8

Federal Rule of Appellate Procedure 27(a)(3) 2

Ninth Circuit Rule 27-11(a)(3) 11

U.S. Food and Drug Administration, Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern, Guidance for Industry #152 (2003) 5, 9-10

World Health Organization, *Antibiotic Resistance* (July 31, 2020) 3-4

World Health Organization, Critically Important Antimicrobials for Human Medicine, 6th Revision (2018) 5

World Health Organization, *News: Stop using antibiotics in healthy animals to prevent the spread of antibiotic resistance* (Nov. 7, 2017) 9

INTRODUCTION

When the U.S. Environmental Protection Agency (EPA or "the Agency") issued an unconditional registration of streptomycin for use as a pesticide on citrus trees, it authorized the largest use ever of a medically important antibiotic in plant agriculture. The Agency admits it did so in violation of the Endangered Species Act (ESA). The Agency further confesses that it has *never* conducted an ESA analysis of *any* antibiotic authorized for use as a pesticide, and it will need years to do so here.

Though EPA asks this Court to leave the registration in effect while it undertakes the required ESA analysis, immediate vacatur of the registration is the presumptive remedy for this serious failure to fulfill a statutory duty. Petitioners agree this unlawful registration decision must be remanded. But this is not the rare case in which remand without vacatur is warranted, and EPA has not met its burden to prove otherwise. The admitted legal violation is egregious—as EPA has done repeatedly over the years, the Agency ignored Congress's unequivocal command by registering a pesticide without conducting any ESA review. And vacatur

will protect public health and the environment from the serious risks posed by the massive expansion in use of a medically important antibiotic.

At minimum, if the Court is inclined to grant EPA's request for remand without vacatur, Petitioners ask that briefing continue on their other claims. In addition to the ESA error EPA concedes, Petitioners seek review of several violations of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). EPA's requested relief would delay judicial review of Petitioners' FIFRA claims for many years; if EPA does not complete ESA compliance before the registration expires in 2028, it could entirely preclude such review. EPA's admitted violation of the ESA should not shield its FIFRA violations from this Court's oversight.

Pursuant to Rule 27(a)(3) of the Federal Rules of Appellate Procedure, Petitioners respectfully ask the Court to deny EPA's request that remand be without vacatur, and to instead vacate EPA's registration of streptomycin for use on citrus crops.

BACKGROUND

I. Factual background

A. Antibiotic resistance poses serious risks to human health

"For nearly seventy years, antibiotics have provided dramatic medical advances in the treatment of bacterial infections." *NRDC v. U.S. Food & Drug Admin.*, 760 F.3d 151, 152 (2d Cir. 2014). Antibiotics offer effective treatment of potentially fatal bacterial diseases, saving millions of lives since their first discovery. *See* Decl. of Jay Graham ¶ 13. They also deliver significant preventive benefits, particularly in high-risk settings. *See, e.g.*, *id.* ¶ 10.

For nearly as long as we have used antibiotics in human medicine, we have faced antibiotic resistance. *NRDC*, 760 F.3d at 152-53.

> Through repeated exposure to antibiotics, some strains of bacteria develop resistance or immunity . . . . Such resistance presents a serious threat to human health. Infections in humans caused by antibiotic-resistant bacteria result, on average, in longer hospital stays, worse side effects of treatment, and a greater likelihood of death.

Id. at 153. The World Health Organization ranks antibiotic resistance as "one of the biggest threats to global health, food security, and development

today." *Antibiotic Resistance*, World Health Organization (July 31, 2020), https://www.who.int/news-room/fact-sheets/detail/antibiotic-resistance. "More than 2.8 million antibiotic-resistant infections occur in the United States each year, and more than 35,000 people die as a result." Centers for Disease Control and Prevention (CDC), *Antibiotic Resistance Threats in the United States* vii (2019), https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.

B. EPA unlawfully approved use of a medically important antibiotic as a pesticide at an unprecedented scale

Streptomycin is an important antibiotic used to treat serious illnesses, including tuberculosis, plague, tularemia, and urinary tract infections. APP012.[1] It is often used in combination with other antibiotics because of the growing problem of resistant bacterial strains. *Id.*

[1] Petitioners cite documents in Petitioners' Appendix to Partial Opposition to EPA's Motion using the convention Pet.APP###; and cite documents in the Appendix to Respondents' Motion for Remand Without Vacatur using the convention APP###. These citations use the Bates page numbers found in the lower-right corner of each page.

Streptomycin is a member of the aminoglycoside class of antibiotics. *Id.* The Food and Drug Administration classifies aminoglycosides as "highly important" to human medicine, *see* U.S. Food and Drug Administration, Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern, Guidance for Industry #152, at 32 (2003), https://www.regulations.gov/document/EPA-HQ-OPP-2016-0067-0007 [hereinafter FDA Guidance #152]; and the World Health Organization ranks them as "high priority critically important antimicrobials," World Health Organization, Critically Important Antimicrobials for Human Medicine, 6th Revision 24 (2018).

Fruit and vegetable growers have previously used streptomycin on a smaller scale to treat bacterial diseases. *See* APP095-96. These uses have led to streptomycin resistance in several of the targeted environmental bacteria. *Id.* In recent decades, citrus growers have confronted two new diseases—citrus greening and citrus canker. APP014-15. Citrus greening disease (also known as Huanglongbing or HLB) has spread to almost all commercial citrus acres in Florida, significantly reducing crop yields.

APP023-24. Citrus canker disease is also widespread in Florida and has further reduced citrus yields. APP026.

To address these diseases, growers have tried a range of solutions. Primary control methods for citrus greening include removal of infected trees, planting uninfected seedlings, and controlling the pathogen-carrying insect. *See* Decl. of Kimberly Nesci ¶ 12. Citrus canker has typically been managed with copper-based pesticides. APP026. Some growers have also turned to antibiotics, including streptomycin. EPA has issued annual emergency authorizations to allow growers to use streptomycin in Florida since 2016 to help manage citrus greening disease; since 2018, these authorizations have extended to California. APP002.

However, streptomycin does not cure either citrus greening or citrus canker. APP015; APP076. Nor does it prevent the spread of either disease. *See* APP021-32, APP075 (citing no evidence of preventative effects and failing to respond to comment on lack of such effects). Instead, growers use it in hopes of reducing yield loss from infected trees, a use that requires multiple treatments on each tree each year. *See* APP015. Despite the

availability of streptomycin, citrus yields in Florida have continued to drop, with this year's orange crop expected to be the smallest in over 75 years. *See* EPA Mot. at 18-19 n.5, ECF No. 42-1.

On January 11, 2021, EPA issued an unconditional registration of streptomycin sulfate for use as a pesticide on citrus trees nationwide. *See* Decl. of Jan Matuszko ¶ 19. The unconditional registration authorizes the largest use ever of any medically important antibiotic in plant agriculture. EPA projects that growers will spray citrus plants with approximately 650,000 additional pounds of streptomycin per year in Florida alone, APP100—18 times the annual amount previously used across all plant agriculture, *id.*, and nearly 50 times the amount of *all* aminoglycosides used in human medicine each year, APP067-68. Airblast sprayers will disperse pressurized droplets of streptomycin into the air, blanketing 764,000 acres of citrus nationwide. APP011. The registration will last for seven years, expiring in January 2028. Matuszko Decl. ¶ 19.

In announcing its registration decision, EPA summarized its assessment of potential health and ecological risks associated with

streptomycin's use. EPA conceded then, as it does now, that its assessment "does not include a complete ESA analysis and effects determinations for specific listed species or their designated critical habitat." APP059. EPA now acknowledges that it has *never* conducted an effects determination for *any* antibiotic registered for use as a pesticide. Matuszko Decl. ¶ 18.

The limited analysis EPA did conduct found "potential risk to mammals on a chronic exposure basis," APP017; "incomplete" data on risks to pollinator species like bees, APP034; and potential risk to aquatic nonvascular plants, APP034.[2] EPA also acknowledged that using streptomycin as a pesticide creates a risk that bacteria, including those that cause disease in humans, could become resistant. APP009. This finding is

[2] "Nonvascular" plants lack certain tissues and fibers present in "vascular" plants. Aquatic plants "form the base of most aquatic food chains," *Exploration of Methods for Characterizing Effects of Chemical Stressors to Aquatic Plants* 5 (Nov. 1, 2010), https://www.epa.gov/sites/default/files/2015-08/documents/exploration_of_methods_for_characterizing_effects_of_chemical_stressors_to_aquatic_plants.pdf; many terrestrial animals also "derive all or most of their food from consumption of aquatic organisms," *EPA EcoBox Tools by Exposure Pathways – Food Chains*, https://www.epa.gov/ecobox/epa-ecobox-tools-exposure-pathways-food-chains (last visited Feb. 17, 2022).

consistent with recent data showing that antibiotic use in animal agriculture has increased antibiotic-resistant infections in humans. *See, e.g.*, *News: Stop using antibiotics in healthy animals to prevent the spread of antibiotic resistance*, World Health Organization (Nov. 7, 2017), https://www.who.int/news/item/07-11-2017-stop-using-antibiotics-in-healthy-animals-to-prevent-the-spread-of-antibiotic-resistance; *Antibiotic/Antimicrobial Resistance: Where Resistance Spreads: Water, Soil, & the Environment*, CDC, https://www.cdc.gov/drugresistance/environment.html (last visited Feb. 25, 2022). Resistant bacteria can spread from farms through air, water, and soil contact, or by insect and animal vectors. Graham Decl. ¶¶ 3, 15, 25, 27, 33. Agricultural workers, including those represented by Petitioners, are more likely than the general public to be exposed to antibiotic-resistant bacteria. *Id.* ¶ 29.

To analyze the potential for streptomycin's increased use to cause resistance, EPA repurposed a risk assessment framework developed by another federal agency to analyze antibiotic use in a materially different context: animal feed and veterinary medicine. *See* APP010; FDA Guidance

#152, at 2-3. That tool was designed to evaluate exposures caused by consumption of meat from animals treated with antibiotics, and "does not address the potential for resistance in human pathogens to develop from exposure of workers." APP012; *see* FDA Guidance #152, at 2-4. It also fails to consider exposures that occur through environmental pathways. Even with this incomplete assessment, EPA rated as "medium" the risk that streptomycin's unconditional registration poses to human health. APP012.

C. Petitioners challenged EPA's unlawful registration under both the ESA and FIFRA

On March 25, 2021, Petitioners filed a petition for review asking this Court to set aside EPA's unconditional registration of streptomycin. *See* Pet. for Review, ECF No. 1-4. Petitioners asserted "that EPA violated the Endangered Species Act by failing to consult with the U.S. Fish and Wildlife Service or the National Marine Fisheries Service," *id.* at 1-2—a charge EPA now concedes. Petitioners also asserted that EPA's action "violated the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA] because the Agency failed to ensure that the use of streptomycin would not cause unreasonable harm to human health or the environment." *Id*. at 1

(citing 7 U.S.C. §§ 136a(c)(5)(C), (D), 136(bb)). More than 10 months later, EPA moved for remand without vacatur. *See generally* EPA Mot., ECF No. 42-1. Pursuant to Ninth Circuit Rule 27-11(a)(3), EPA's motion stayed all merits briefing.

II. Legal background

A. Endangered Species Act

The ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978). The Act "affords endangered species the 'highest of priorities' in assessing risks and benefits." *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005) (quoting *Tenn. Valley Auth.*, 437 U.S. at 174), *abrogated on other grounds by Cottonwood Env't L. Ctr. v U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015). Its text "reveals a conscious decision by Congress to give endangered species priority over the 'primary missions' of federal agencies." *Tenn. Valley Auth.*, 437 U.S. at 185.

Section 7 is "[t]he heart of the ESA." *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 495 (9th Cir. 2011). It requires federal agencies to

"ensure that none of their activities, including the granting of licenses and permits, will jeopardize the continued existence of listed species or adversely modify a species' critical habitat." *Karuk Tribe v. U.S. Forest Serv.*, 681 F.3d 1006, 1020 (9th Cir. 2012). To accomplish this goal, the statute and its implementing regulations "delineate a process—known as Section 7 consultation—for determining the biological impacts of a proposed action." *Nat'l Fam. Farm Coal. v. EPA*, 960 F.3d 893, 922 (9th Cir. 2020); 16 U.S.C. § 1536(a)(2); 50 C.F.R. §§ 402.14, 402.13.

Under the first step of that process, EPA must "review its actions at the earliest possible time to determine whether any action *may affect* listed species or critical habitat." 50 C.F.R. § 402.14(a) (emphasis added). "May affect" is a low threshold; "*[a]ny possible effect*" is enough to trigger the next step in the consultation process. *Karuk Tribe*, 681 F.3d at 1027 (quotation marks omitted). At that step, the action agency must consult with expert agencies—the U.S. Fish and Wildlife Service or National Marine Fisheries Service (the "Services")—to "insure" that its action is "not likely to jeopardize the continued existence of any endangered species" or "result in

destruction or adverse modification" of a species' critical habitat. 16 U.S.C. § 1536(a)(2). In fulfilling its duties under section 7, EPA must "give the benefit of the doubt to the species." *Conner v. Burford*, 848 F.2d 1441, 1454 (9th Cir. 1988).

"[A]n agency may not duck its consultation requirement, whether based on limited resources, agency priorities, or otherwise." *Ctr. for Biological Diversity v. EPA*, 861 F.3d 174, 188 n.10 (D.C. Cir. 2017). It may skip consultation only if it concludes that its action will have "no effect" on any listed species or critical habitat. *Karuk Tribe*, 681 F.3d at 1027.

B. Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA requires EPA registration of pesticides before they can be sold or distributed. 7 U.S.C. § 136a(a). EPA will register a pesticide if, as relevant here, the pesticide "will perform its intended function without unreasonable adverse effects on the environment" and if "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." *Id.* § 136a(c)(5)(C), (D). "[U]nreasonable adverse effects on the environment"

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).

To issue a registration, EPA must conclude that it does not need any "additional data" to "make [a] determination[] of no unreasonable adverse effects." *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 528 (9th Cir. 2015) (quoting 40 C.F.R. § 152.112(b)-(c)).

STANDARD OF REVIEW

Remand with vacatur is the presumptive remedy for unlawful agency action. *See, e.g.*, *Alsea Valley All. v. Dep't of Commerce*, 358 F.3d 1181, 1185 (9th Cir. 2004). This Court grants remand without vacatur "only in 'limited circumstances,'" and "only 'when equity demands.'" *Pollinator Stewardship Council*, 806 F.3d at 532 (quoting *Cal. Cmties. Against Toxics v. EPA*, 688 F.3d 989, 994 (9th Cir. 2012); *Idaho Farm Bureau Fed'n v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995)). In considering a request for remand without vacatur, the Court weighs "the seriousness of the agency's errors"

against "the disruptive consequences" of vacatur. *Id.*; *accord Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993).

In evaluating the seriousness of an error, this Court "look[s] at whether the agency would likely be able to offer better reasoning or whether by complying with procedural rules, it could adopt the same rule on remand, or whether such fundamental flaws in the agency's decision make it unlikely that the same rule would be adopted on remand." *Nat'l Fam. Farm Coal.*, 960 F.3d at 1145 (quoting *Pollinator Stewardship*, 806 F.3d at 532). "When an agency bypasses a fundamental procedural step, the vacatur inquiry asks not whether the ultimate action could be justified, but whether the agency could, without 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).

When weighing "disruptive consequences" where an agency has violated an environmental protection law, the Court's analysis focuses on "the extent to which either vacating or leaving the decision in place would risk environmental harm." *Nat'l Fam. Farm Coal.*, 960 F.3d at 1144-45; *see*

also All. for the Wild Rockies v. U.S. Forest Serv., 907 F.3d 1105, 1121-22 (9th Cir. 2018). To overcome the presumption in favor of vacatur, the agency must show that vacatur itself would cause serious environmental harm. *See, e.g.*, *Pollinator Stewardship*, 806 F.3d at 532.

ARGUMENT

EPA's unlawful registration of streptomycin presents a paradigmatic case for vacatur. The Agency committed a serious legal error that goes to the heart of its analysis. EPA cannot simply provide a better explanation on remand; it must gather additional data and conduct a substantial new analysis—a process that it projects will take years to complete. And in the meantime, the vastly expanded use of an important antibiotic poses serious risks to human health and to endangered and threatened species.

EPA provides no compelling reason why this Court should depart from its usual practice of vacating invalid agency actions. EPA's contention that it did not commit serious error because it did not act "in total disregard" of streptomycin's environmental effects, EPA Mot. at 15 (quoting *Ctr. for Biological Diversity*, 861 F.3d at 188), relies on a misreading

of a single out-of-circuit case, confuses distinct statutory requirements, and ignores that EPA's own risk assessment noted the potential for streptomycin to harm both animal and plant species. Indeed, the registration poses serious risks of harm to species, farmworkers, and surrounding communities—the exact entities that the ESA and FIFRA seek to protect. Thus, both factors favor the presumptive remedy of vacatur.

I. EPA's admitted violation of the ESA is a serious legal error requiring vacatur

EPA now "concedes" to the Court what it stated outright at the time of registration: that it authorized the use of streptomycin on citrus groves without taking even the first step in the ESA consultation process. Matuszko Decl. ¶ 15; *see also* APP003 (admitting in EPA's Final Registration Decision that the assessment "does not contain effects determinations for any specific listed species or designated critical habitat"). Skipping a statutorily mandated process would be serious error in any circumstance. It is particularly so here, where the ESA's express purpose is to "institutionalize[] caution" and "give endangered species priority over the 'primary missions' of federal agencies." *Tenn. Valley Auth.*, 437 U.S. at 185,

194. EPA's choice to neglect entirely "the heart of the ESA," *W. Watersheds Project*, 632 F.3d at 495, merits vacatur.

EPA's failure to comply with the ESA here is not an isolated error. It is part of a sustained agency practice to disregard Congress's clear command. EPA's duty to make an effects determination—and to proceed with consultation, if warranted—is unequivocal. And yet, for years, EPA has routinely failed to consult before registering pesticides; when the Agency has inevitably been sued, it has admitted fault and sought to keep whatever pesticide it has approved on the market despite its failure to comply with the ESA. *See, e.g.*, *Ctr. for Food Safety v. EPA*, Nos. 19-72109, 19-72280 (9th Cir.) (sulfoxaflor); *NRDC v. EPA*, No. 1:17-CV-02034 (D.D.C) (imidacloprid); *Ctr. for Biological Diversity v. EPA*, No. 20-73146 (9th Cir.) (inpyrfluxam); *Ctr. for Biological Diversity v. EPA*, Nos. 15-1054, 15-1176, 15-1389, 15-1462, 16-1351 (D.C. Cir.). The Agency's repeated and unlawful practice of substituting its own policy preferences for Congress's directives calls for judicial intervention.

EPA's reliance on its separate FIFRA analysis to justify its decision to ignore the ESA is misplaced. *See, e.g.*, EPA Mot. at 14-15. The ESA and FIFRA serve different purposes and contain different standards. *Wash. Toxics*, 413 F.3d at 1032. Under the ESA, EPA must determine if an action "may affect" endangered or threatened species—a "low threshold." *Karuk Tribe*, 681 F.3d at 1027 (quotation mark omitted). If EPA concludes that a species or critical habitat may be affected, the Services may decide to impose binding conditions or alternatives to prevent jeopardy to listed species. 16 U.S.C. § 1536(b). "FIFRA does not require the same examination of environmental concerns," and EPA "cannot escape its obligation to comply with the ESA merely because it is bound to comply with another statute." *Wash. Toxics*, 413 F.3d at 1032.

EPA's existing FIFRA risk assessments only underscore its ESA violation. In those assessments, EPA concluded that streptomycin may pose a chronic exposure risk to mammals and an acute exposure risk to aquatic nonvascular plants that form the foundation of many food webs. APP017, APP034. The Agency further acknowledged that it could not fully

assess the risk posed to pollinators—including endangered and threatened pollinators—as data on pollinator toxicity was "incomplete." APP034. That EPA pushed forward in registering streptomycin without undertaking the requisite ESA analyses even in the face of these potential risks underscores the seriousness of its error.

Indeed, EPA's filing belies its implication that its FIFRA analyses approximate ESA compliance. To make an effects determination, EPA attests that it "need[s] to call in significant data" that "will take time to generate and . . . review." Matuszko Decl. ¶ 24. It must evaluate species ranges, critical habitat, and "off-site movement of [streptomycin]" to undertake "species-specific effects determinations" for "approximately 2600" federally listed species and critical habitats that may be exposed to streptomycin. *Id.* ¶ 16. Because the Agency has never completed these steps for any antibiotic, it "may encounter new or unexpected challenges in conducting its analyses and making effects determinations." *Id.* ¶ 24.

Taking these factors into account, EPA asserts that, at minimum, it will take until the fall of 2026 to complete the first step of consultation. *Id.*

¶ 25. If EPA finds that the registration of streptomycin for use on citrus meets the low threshold required for a "may affect" determination for *any* species, the ESA will require the Agency to conduct formal consultation with the Services. 50 C.F.R. §§ 402.14(a), 402.01(b). On its own, that formal consultation process often takes years. *See, e.g.*, Stip. Partial Settlement Agreement at 2-3, *Ctr. for Envt'l Health v. Regan*, Case No. 4:18-cv-03197-SBA (N.D. Cal. Jan. 4, 2022) (stating formal consultation process for pesticide ingredient began on January 18, 2017, and is expected to conclude by February 28, 2022), ECF No. 112. For streptomycin, formal consultation lasting much more than a year would extend past the registration's expiration.

EPA cannot argue both that it has already adequately considered effects to endangered species and that it will take the Agency another half decade to take the first step in considering such effects. The Agency's own expert confirms that the latter is true, and EPA's contrary argument does not survive scrutiny.

EPA's reliance on FIFRA risk assessments to excuse its ESA noncompliance also assumes that its FIFRA analysis was itself lawful. But Petitioners have challenged EPA for failing to ensure streptomycin use will not cause unreasonable harm to human health or the environment under FIFRA. Pet. for Review, ECF No. 1-4 at 1. EPA's flawed FIFRA analysis is no substitute for the required ESA analysis it failed to conduct.

EPA's invocation of the D.C. Circuit's decision to remand without vacatur in *Center for Biological Diversity*, 861 F. 3d 174 at 188, is also misplaced. There, the court declined to vacate a pesticide registration not because EPA conducted a risk assessment pursuant to FIFRA, but because the court was persuaded that vacating the registration would cause *more* harm to the environment than leaving it in effect. *Id.* at 189. The D.C. Circuit recently confirmed that, absent these unusual circumstances, failure to complete ESA consultation prior to registering a pesticide is a serious error that calls for vacatur. *See* Order at 1-2, *Farmworker Ass'n of Fla. v. EPA*, Case No. 21-1079 (D.C. Cir. June 7, 2021). The same holds true here, and this Court should vacate streptomycin's registration.

II. Risks to the environment and human health outweigh any disruptions to growers

Because leaving EPA's decision in place risks serious environmental and health harms, vacatur is warranted. In the context of environmental protection statutes, this Court has declined to vacate unlawful actions only when *vacatur itself* would result in greater environmental harm than leaving the action in place. *See, e.g.*, *Idaho Farm Bureau*, 58 F.3d at 1405-06; *Cal. Cmties. Against Toxics v. EPA*, 688 F.3d 989, 994 (9th Cir. 2012). The Court weighs potential harms to endangered species particularly heavily, given Congress's clear direction "that under the ESA, the balance of hardships always tilts sharply in favor of the endangered or threatened species." *Wash. Toxics*, 413 F.3d at 1035.

Here, use of streptomycin as a pesticide on citrus poses serious potential risks to endangered species, human health, and pollinators. Though EPA has not yet conducted an effects analysis, publicly available data show overlap between zones of citrus agriculture and endangered and threatened species' habitats, including those of endangered mammals like the Florida panther, the bonneted bat, the kit fox, and others. *See* Bradley

Decl. ¶¶ 5-6, 8-12, Exs. B-C, E-I. EPA's own conclusion that chronic exposure to streptomycin poses a risk to mammals suggests the registration could harm these species. By contrast, vacating the registration will avert potential harm to these or other protected species. Congress's goal of "institutionalized caution" when it comes to listed species heavily favors vacatur. *Tenn. Valley Auth.*, 437 U.S. at 194.

The human health risks of leaving EPA's registration in place further support vacatur. Antibiotic resistance is a major public health threat responsible for millions of deaths globally each year. Graham Decl. ¶ 13. Streptomycin is a medically important antibiotic used to treat infections such as tuberculosis and even plague. *Id.* ¶¶ 23-24. The registered use of streptomycin will accelerate the spread of antibiotic-resistant genes between bacterial species, putting farmworkers and nearby communities at risk. *Id.* ¶¶ 34, 37, 41. Although the human health impacts may not be instantly apparent, the application of streptomycin will immediately create pressure for resistance to develop. *Id.* ¶ 37. The registration and use of

streptomycin as a pesticide will worsen the public health risks from antibiotic resistance. *Id.* ¶¶ 49-50.[3]

EPA asserts that streptomycin use can help manage the development of resistance to another antibiotic, oxytetracycline, that the Agency registered as a pesticide in 2019. EPA Mot. at 19. In effect, EPA concedes that using medically important antibiotics as pesticides will hasten the development of resistant bacteria, and asks the Court to allow *this* antibiotic to be used as a pesticide to reduce harm being caused by its previous registration of *another* antibiotic for use as a pesticide. The Court should not risk the continued viability of one critical antibiotic because EPA has failed to ensure responsible use of another. Moreover, the purported benefit EPA touts is highly speculative, as growers are not

[3] Petitioners' members are injured by streptomycin's continued use on citrus. *See* Pet.APP27-140, 159-221. They include individuals who live near citrus groves and suffer from bacterial infections that may require treatment with streptomycin or are at increased risk of antibiotic-resistant infections, Pet.APP69-71, 74, 129-132, 160-166, 205-211, 218-220; who treat farmworkers at their medical clinics, Pet.APP47-53; and who photograph and observe endangered species found near citrus groves, Pet.APP88-106, 108-121, 136-38, 205-11. Vacatur of streptomycin's pesticide registration would remedy these injuries.

required to alternate the two pesticides. Pet.APP6-7. What is more certain is that the vastly expanded use of streptomycin *will* increase the likelihood that bacteria develop resistance to it. Graham Decl. ¶ 41.

Although EPA claims "important benefits" of streptomycin for citrus growers, EPA Mot. at 18, there is no evidence that streptomycin prevents the spread of either citrus greening or citrus canker disease. Nor can it cure either disease. At most, it is one of several options available to growers seeking to improve the yield from affected trees. Though streptomycin has been available to citrus growers in Florida since 2016, crop yields have continued to drop sharply.

Petitioners acknowledge the challenge that citrus greening and citrus canker pose for agricultural growers. But as evidence indicates, leaving streptomycin's registration in place would do little to ameliorate that challenge, while creating significant environmental and human health risks. As was true in *National Family Farm Coalition*, the potential for some "adverse impact[s] on growers," 960 F.3d at 1145, does not overcome the risks associated with leaving EPA's registration in place. *See id.*; *cf. Cal.*

Cmties., 688 F.3d at 993-94 (denying vacatur where it would cause both serious environmental harm and "economically disastrous" consequences to the power supply). Thus, the equities weigh heavily in favor of vacatur.

III. In the alternative, the Court should permit Petitioners' FIFRA claims to proceed because remand without vacatur would effectively foreclose judicial review of these claims

Should the Court decide to remand without vacatur, it should permit Petitioners' challenge to EPA's FIFRA analysis to proceed to judgment.

Petitioners have challenged not only EPA's admitted noncompliance with the ESA, but also its failure to comply with FIFRA's mandate to ensure that streptomycin use will not cause unreasonable harm to human health or the environment. Petition for Review, ECF No. 1-4 at 1. Petitioners maintain that EPA's registration of streptomycin violated FIFRA in at least three ways. First, EPA's assessment of the risk of antibiotic resistance fails to analyze adequately the potential spread of resistance through environmental pathways, and significantly underestimates the risk of farmworker exposures. *See supra* pp. 9-10. Second, EPA's assessment of the risk to pollinator species was based on

incomplete data that did not support an informed determination as to whether streptomycin will have unreasonable adverse effects on pollinators. Third, EPA's cost-benefit analysis overstated the benefits of streptomycin and failed to address evidence that streptomycin is not effective at treating citrus greening disease.

Unlike Petitioners' ESA claim, EPA has not expressed any intent to correct these alleged FIFRA errors on remand. Yet EPA's requested relief, which asks the Court to leave the registration in effect during the pendency of its requested remand, would preclude or severely delay judicial review of Petitioners' FIFRA claims. According to EPA, the first step of the ESA process will not be completed until the fall of 2026 at the earliest. Matuszko Decl. ¶ 25. If consultation with the Services is necessary, full compliance with the ESA will take even longer. Meanwhile, streptomycin's registration is set to expire in January of 2028—just over a year after the earliest date by which EPA projects it will make an effects determination.

Granting remand without vacatur in this situation would allow streptomycin to be applied in unprecedented quantities nationwide with

no judicial review of the adequacy of EPA's analysis. *See In re NRDC*, 956 F.3d 1134, 1139 (9th Cir. 2020) (seeking voluntary remand without then taking timely action "effectively postpone[es] judicial review"). The Court should not allow EPA to use its willful violation of the ESA to avoid judicial review of alleged violations of a separate federal statute. Instead, if the Court is inclined to grant EPA's request for remand without vacatur, equity warrants at minimum that litigation of Petitioners' FIFRA claims moves forward to a decision on the merits.

CONCLUSION

Remand with vacatur is the presumptive, and appropriate, remedy for EPA's serious violation of the ESA, and will protect both human health and the environment, including endangered species. Accordingly, Petitioners respectfully ask the Court to vacate EPA's registration of streptomycin sulfate for use on citrus crops, and to remand the matter to EPA with instructions to undertake a proper ESA analysis. In the alternative, should the Court deem remand without vacatur appropriate, Petitioners' FIFRA claims should proceed to judgment.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

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

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