No. 21-70719

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MIGRANT CLINICIANS NETWORK, et al.,
Petitioners,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al.,
Respondents.

On Petition for Review of Final Agency Action of the
United States Environmental Protection Agency

RESPONDENTS' MOTION FOR REMAND WITHOUT VACATUR

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GLOSSARY

EPA	United States Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide Fungicide and Rodenticide
Services	U.S. Fish and Wildlife Service, National Marine Fisheries Service, or both

INTRODUCTION

Respondents, the United States Environmental Protection Agency and Michael S. Regan in his official capacity as the Administrator of the EPA (collectively, "Respondents" or "EPA"), respectfully move for remand without vacatur. Petitioners challenge EPA's 2021 decision to unconditionally amend Federal Insecticide Fungicide and Rodenticide ("FIFRA") registrations for two existing pesticide products containing streptomycin to allow new, time-limited uses on citrus crops for the management of Huanglongbing—also called citrus greening, "the most destructive disease of citrus known"[1]—and citrus canker, another debilitating bacterial disease.[2] Petitioners allege that EPA violated the Endangered Species Act ("ESA") by failing to consult with the U.S. Fish and Wildlife Service, National Marine Fisheries Service, or both

[1] Gottwald, T.R. et al., *Inconsequential effect of nutritional treatments on huanglongbing control, fruit quality, bacterial titer and disease progress*, Crop Protection, June 2012, Vol. 36, pp. 73-82 (available at https://www.sciencedirect.com/science/article/abs/pii/S0261219412000063) (last visited Feb. 3, 2022).

[2] EPA amended the registrations for two products: (1) a technical use product, EAC Streptomycin Manufacturing Use Product (EPA Reg. #71185-4), and (2) an end-use product, Agri-Seed 50WP (EPA Reg. #80990-3). The active ingredient in both registrations is Streptomycin Sulfate. In this motion, EPA refers to this ingredient as streptomycin.

(collectively, the "Services") before it approved the registration amendments at issue and failed to ensure that the use of streptomycin would not cause unreasonable adverse effect on the environment. 7 U.S.C. §§ 136a(c)(5)(C), (D); *see also id.* § 136(bb).

EPA acknowledges that it did not make ESA effects determinations before approving the new uses of the existing pesticide products containing streptomycin. EPA therefore respectfully requests that this Court remand the challenged registration approvals to allow EPA to make those determinations and take any additional actions as appropriate. Vacatur of the registration amendments is not warranted, however, in light of EPA's consideration of the pesticide's new uses' effect on the environment and human health under FIFRA, and the harm to growers that will result from eliminating a useful tool for managing these two devastating citrus diseases. Petitioners oppose to the extent EPA's requested relief is without vacatur.

BACKGROUND

I. Statutory Framework For Pesticide Registrations

A. Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA generally precludes the distribution or sale of any pesticide unless it is "registered" by EPA. 7 U.S.C. § 136a(a). The registration

process begins through submission of a "statement," which includes, among other things, the name and complete "formula of the pesticide." *Id.* § 136a(c)(1). EPA then provides "a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern" and allows opportunity for comments. *Id.* § 136a(c)(4).

EPA issues a license, known as a "registration," for each specific pesticide product allowed to be marketed. *Id.* § 136a(a); *see also Nat'l Fam. Farm Coal. v. EPA*, 966 F.3d 893, 912 (9th Cir. 2020). "The terms and conditions on the license include exactly what product can be sold, the specific packaging it must be sold in, and labeling that contains instructions on proper use." *Nat'l Fam. Farm*, 966 F.3d at 912 (citing 7 U.S.C. § 136(p)). EPA "shall register a pesticide" if it determines that:

> (A) its composition is such as to warrant the proposed claims for it;
>
> (B) its labeling and other material required to be submitted comply with the requirements of [FIFRA];
>
> (C) it will perform its intended function without unreasonable adverse effects on the environment; and
>
> (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

7 U.S.C. § 136a(c)(5).

B. Endangered Species Act

Congress enacted the ESA "to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved," and "to provide a program for the conservation of such endangered species and threatened species." 16 U.S.C. § 1531(b). ESA section 7 directs each federal agency to ensure, in consultation with the Services, that "any action authorized, funded, or carried out by such agency . . . is not likely to jeopardize the continued existence of" any listed species or destroy or adversely modify designated critical habitat. *Id*. § 1536(a)(2).

If the agency proposing the relevant action (referred to as the action agency; here EPA) determines—based on the best information from the Services—that listed or proposed-to-be-listed species "may be present" in the area of the proposed action, the action agency may prepare a biological assessment to determine whether the identified species "is likely to be affected by such action." 16 U.S.C. § 1536(c)(1). If the action agency independently determines that the action will have "no effect" on listed species, the agency has no further obligations under the ESA. 50

C.F.R. §§ 402.14(a), (b). If, however, the agency determines that the action "may affect" listed species or critical habitat, the action agency must pursue either informal or formal consultation with one or both of the Services. *Id.* §§ 402.13-14. Or EPA may initiate consultation on a FIFRA action after making effects determinations pursuant to optional formal consultation procedures. *Id.* § 402.46.

II. Historical Context For EPA's Effects Determinations For FIFRA Registration Decisions

Because of the complexity of making effects determinations and completing consultations for pesticides, numerous pesticides have been approved and are available for use that have not undergone ESA review—namely, without EPA first undertaking effects determinations or, when appropriate, initiating consultation under the ESA. *See Wash. Toxics Coal. v. EPA*, 413 F.3d 1024 (9th Cir. 2005), *abrogation on other grounds recognized by Cottonwood Env't L. Ctr. v. U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015). In similar cases, EPA acknowledged that it has a duty to make effects determinations and, if required, consult under ESA section 7 before registering a pesticide containing a new active ingredient similar to this one. *See id.* at 1028. In recent years, EPA has worked with multiple agencies to establish scientifically valid

frameworks for assessing potential impacts to listed species and designated critical habitats from registration actions. *See* Declaration of Jan Matuszko ("Matuszko Decl.") ¶ 12 (APP118-19). EPA worked with these agencies to establish a process for pesticide consultation under the ESA. *Id.* ¶ 13 (APP119). Congress is aware of this dialogue and has requested that EPA report on consultation progress and streamline integration of ESA and FIFRA procedures. Agricultural Act of 2014, Pub. L. No. 113-79, 128 Stat. 649, 951 (2014) (Section 10013).

To this end, EPA began several "pilot" biological evaluations as a first step towards implementing recommendations provided by the National Academy of Science. *See* Matuszko Decl. ¶ 13 (APP119). Subsequently, EPA, the Department of the Interior, and the Department of Commerce signed a memorandum of agreement establishing an interagency working group—to include these and other federal agencies—tasked with providing recommendations to the agencies' leadership on improving the ESA consultation process for pesticides. *See id.* The Agriculture Improvement Act of 2018 ("2018 Farm Bill") (Pub. L. No. 115-334, 132 Stat 4490, 4915 (2018)) codified the interagency working group and the memorandum of agreement. Pursuant to section

10115 of the 2018 Farm Bill and FIFRA, 7 U.S.C. § 136a(c)(11), interagency working group reports were delivered to Congress in December 2019, June 2020, and June 2021. Matuszko Decl. ¶ 13 (APP119).

III. EPA's Decision To Grant Registration Amendments Approving Citrus Use For Two Existing Streptomycin Products

A. Historical use of streptomycin as an active ingredient in pesticides

Streptomycin is a broad-spectrum aminoglycoside antibiotic and fungicide derived from *Streptomyces griseus*, a bacteria commonly found in soil. *See* APP2, APP34, APP97. It has been used as a human and animal drug to treat bacterial infections for more than 40 years. APP2; APP10. Streptomycin has also been used commercially to control bacterial plant diseases since the 1950s. Declaration of Kimberly Nesci ("Nesci Decl.") ¶ 7 (APP134-35). It is an active ingredient in pesticide products registered for use on various crops, including apples, pears, celery, pepper, potatoes, tobacco, and tomatoes. APP2, APP23. It is also registered for use on ornamental house plants, such as chrysanthemum,

dieffenbachia, philodendron, and roses, and in home gardens.[3] *See, e.g.*, APP6.

More recently, EPA issued emergency exemptions under FIFRA Section 18 that allowed streptomycin's use on citrus crops in Florida and California. Nesci Decl. ¶ 7 (APP134-35). These emergency exemptions authorized the use of certain Streptomycin products as a foliar treatment (that is, applying it as liquid directly to leaves) to manage citrus greening and citrus canker diseases. APP23; *see also* Nesci Decl. ¶ 7 (APP134-35). These diseases have profound effects on infected citrus trees, such as premature leaf and fruit drop, changes to the size and shape of fruit, and tree decline leading to death. APP21-23; APP77. Indeed, since first detected in Florida in 2005, citrus greening has devastated the American citrus industry, causing the loss of about 100,000 acres of citrus, billions of dollars of lost revenue, and thousands of jobs. Nesci Decl. ¶ 8 (APP135); *see also* APP14-15, APP77.

[3] There are active registrations for products for all of these commercial and residential uses, though the products here are currently registered only for commercial use. *See, e.g.*, *AG Streptomycin (Reg. No. 66222-121)*, https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:8:::::P8_PUID,P8_RINUM:387915,66222-121 (last visited Feb. 3, 2022).

2. 2021 registration amendments at issue here

In 2015, Geo Logic Corporation and AgroSource, Inc. sought to amend the registrations of two existing products to add new uses of streptomycin on crop group 10-10, which includes citrus crops such as grapefruits, limes, and oranges. APP2; *see also* 40 C.F.R. § 180.41(c)(15) (identifying Crop Group 10-10). EPA published receipt of the applications in the *Federal Register* and received no comments. APP15-16. EPA then prepared a review of the benefits of the new use, *see* APP21-32, an environmental and ecological effects assessment, *see* APP33-41, and an assessment of streptomycin's potential to select for resistance in microbes of human health concern, APP94-102. Thereafter, EPA published its intent to grant the registration amendments, after which it received more than 40,000 comments, which EPA summarized and responded to. *See* APP16, APP42-70, APP71-82, APP83-93; APP103-113.

EPA granted the registration amendments on January 11, 2021, making streptomycin one of just two antibiotics registered for managing citrus greening and citrus canker diseases.

STANDARD OF REVIEW

Voluntary remand of a challenged agency action is proper where the agency seeks to reconsider its initial action. *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012). "Whether agency action should be vacated depends on how serious the agency's errors are 'and the disruptive consequences of an interim change that may itself be changed.'" *Id.* (quoting *Allied-Signal, Inc. v. U.S. Nuclear Regul. Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993)).

ARGUMENT

The Court should remand without vacatur the unconditional registration amendments challenged here. EPA satisfies the standard for voluntary remand without vacatur. The agency acknowledges that it did not make ESA effects determinations for the amendments, and that it must take further action to comply with the ESA on remand. But, as explained below, the equities weigh in favor of leaving the registration amendments in place during the remand period. EPA expressly considered the pesticide's effect on the environment and human health in issuing the amended registrations under FIFRA. Further, vacatur would be disruptive because it may harm growers by depriving them of an efficacious tool for managing two devastating citrus diseases.

I. EPA's Acknowledgment That It Did Not Make ESA Effects Determinations Supports Remand.

Agencies have inherent authority to reconsider past decisions and to revise, replace or repeal initial actions. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Voluntary remand is the preferred remedy for deficient agency decisions. As the D.C. Circuit has opined, "[a]dministrative reconsideration is a more expeditious and efficient means of achieving an adjustment of agency policy than is resort to the federal courts." *B.J. Alan Co. v. Interstate Com. Comm'n*, 897 F.2d 561, 562 n.1 (D.C. Cir. 1990) (citation omitted). That court explained that "[w]e commonly grant such [relief], preferring to allow agencies to cure their own mistakes rather than wasting the courts' and the parties' resources reviewing a record that both sides acknowledge to be incorrect or incomplete." *Ethyl Corp. v. Browner*, 989 F.2d 522, 524 (D.C. Cir. 1993).

In this case, EPA acknowledges that it has not made "effects determinations" for streptomycin or initiated consultation, if required, under the ESA. 16 U.S.C. § 1536(a)(2); Matuszko Decl. ¶ 15 (APP120-22). EPA recognizes that it must determine that streptomycin has "no effect" on ESA listed species or "may affect" those species. 50 C.F.R. § 402.14(a);

see Ctr. for Biological Diversity v. EPA, 861 F.3d 174, 188 (D.C. Cir. 2017); *see also* Matuszko Decl. ¶ 18 (APP127). If EPA reaches the latter determination, it must consult with one or both of the Services and obtain either biological opinions or concurrences in determinations that streptomycin is not likely to adversely affect listed species or critical habitats. *See* 50 C.F.R. §§ 402.13, 402.14, 402.46, Matuszko Decl. ¶ 10 (APP117). These "effects determinations" must be made by EPA in the first instance. 50 C.F.R. § 402.14(a).

On remand, EPA will undertake the necessary ESA-specific analysis for streptomycin, taking into account its existing obligations for other chemicals under settlement agreements and other public commitments to complete effects determinations and, where necessary, draft and final biological evaluations. *See* Matuszko Decl. ¶¶ 23-24 (APP128-30). EPA anticipates that it can complete the required determinations for streptomycin no sooner than the fall of 2026. *Id.* ¶ 25 (APP130). EPA will then initiate consultation with the Services, if necessary, at that time.

EPA's request for a remand is timely and made in good faith. EPA has acknowledged the ESA defect to Petitioners, and Petitioners' merits

brief has not been filed. Dkt. 40. Because the standard for voluntary remand is met, the registration amendments should be remanded to EPA. *See Cal. Cmtys.*, 688 F.3d at 992.

II. Vacatur Of The Registration Amendments Is Not Required During The Pendency Of The Remand.

This Court should leave in place the registration amendments while EPA satisfies its obligations under the ESA, and allow continued use of streptomycin on citrus crops during the remand.

To determine whether vacatur is warranted in a particular case, the Court undertakes an equitable analysis. "[T]he decision whether to vacate depends on the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Allied-Signal*, 988 F.2d at 150-51 (internal quotation omitted); *Cal. Cmtys.*, 688 F.3d at 992 (same). Also relevant to the analysis is whether "by complying with procedural rules, [the agency] could adopt the same rule on remand, or whether such fundamental flaws in the agency's decision make it unlikely that the same rule would be adopted on remand." *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015).

Though EPA did not make ESA "effects determinations" for streptomycin, the agency did consider the environmental and ecological effects of amending the registrations before granting the amended registrations. These analyses indicated that the risks presented by the use of streptomycin are generally low. Balanced against these risks is a real benefit to citrus growers: a method of managing devastating diseases that pose serious threats to the American citrus crop.

A. EPA considered the ecological effects of streptomycin's new use on citrus.

The facts here—the failure to comply with the ESA before registering a pesticide under FIFRA—are analogous to the facts in *Center for Biological Diversity*, 861 F.3d at 188-89, where the D.C. Circuit remanded a flawed FIFRA registration without vacatur. There, as here, EPA did not make effects determinations before issuing a registration for a pesticide under FIFRA. *Id.* The D.C. Circuit reasoned that "[n]otwithstanding the EPA's failure to make an effects determination and to engage in any required consultation, it did not register [the pesticide cyantraniliprole] in total disregard of the pesticide's potential deleterious effects" because it had assessed the ecological risks for cyantraniliprole as part of the registration process. *Id.* at 188. That

ecological risk assessment, while distinct from the statutorily required ESA analysis, was relevant to analyzing the seriousness of the failure to make effects determinations. *See id.*

So too here. EPA did not grant the registration amendments "in total disregard of the pesticide's potential deleterious effects" to species. *Id.* at 188. Rather, as required by FIFRA, EPA considered the ecological risks of streptomycin in relation to the new use on citrus, finding that the risks for the new use are much like those of other registered uses. *See id.* at 188-89; APP3. EPA analyzed streptomycin's environmental effects using exposure and toxicity data, particularly for mammals, birds, fish, invertebrates, and plants. APP4-5, APP33-41. It also conducted risk assessments to evaluate the risk to human health, APP5-7, and the potential development of resistance in human and plant pathogens, APP7-14.

After reviewing a variety of data, *see, e.g.*, APP2-3, APP36-41, EPA concluded that the environmental effects of a new use of streptomycin would be minimal. APP3-5. The data suggests streptomycin is "practically nontoxic" to birds, mammals, fish, and aquatic invertebrates

on an acute exposure basis.[4] APP4-5, APP36, APP39. It is classified as "practically nontoxic" to honey bees, though EPA recognizes that additional data are needed to more fully assess the products' effects on pollinators. APP4, APP36. Further, based on the available data, EPA concluded that, at the exposure levels contemplated by the new use, there is a low risk of effects on non-listed species of terrestrial plants. APP4. EPA determined that there is a low risk of effects on vascular aquatic plants. APP5. Only nonvascular aquatic plants were expected to be impacted. *Id.*

EPA also evaluated a variety of data to assess risks to human health, concluding there are "no risks of concern." *Id.* EPA concluded that available studies and "conclusions that can be drawn from the decades of use of streptomycin as a human antibiotic drug without significant incidents" were enough to assess the compound's risks. *Id.* EPA found no evidence that streptomycin was a carcinogen, *Id.*, no indication of neurotoxicity, APP6, no residual exposure concerns, *id.*, and no indication

[4] Notwithstanding these conclusions, EPA also noted that its risk assessment "indicate[d] the new uses result in a potential risk to mammals from chronic exposure . . . and risk to sensitive aquatic nonvascular plants . . . ." APP3.

of a dermal hazard, APP6-7. EPA also assessed the risks of the additional uses on citrus to human health, concluding (after reviewing a "database of studies") that "[t]here are no risks of concern." APP5.

Next, EPA evaluated the risk of development of resistance in human and plant pathogens and concluded there was an overall "medium" risk to human health associated with the new use. APP7-14, APP101. EPA also recognized the need to minimize the risks associated with the development of resistance in plant pathogens. APP13-14. Although the likelihood of resistance development in citrus greening and citrus canker is "not known," APP13, EPA determined that certain management strategies could slow the development of resistance in plant pathogens and prolong the useful life of streptomycin on agricultural products. APP14.

EPA also acted to reduce identified risks. The agency imposed labelling requirements to delay antibiotic, fungicide, and bactericide resistance. APP18-19. EPA also imposed terms on the registrations, imposing requirements for resistance management plans, monitoring, and annual sales reports. APP16-17. And it required mitigation

measures that address potential antibiotic resistance, applicator exposure, and spray drift. *See* APP14, APP19-20.

B. Streptomycin provides important benefits for citrus growers, especially in Florida.

EPA also evaluated the potential benefits provided by the new use of streptomycin on citrus. APP14-15; APP21-32. Streptomycin suppresses citrus greening disease and will aid resistance management of citrus canker because it provides a different mode of action than copper-based registered alternatives. APP25, APP28-29; *see also* Nesci Decl. ¶ 9 (APP135-36). Though the approved use of Streptomycin would not eliminate these diseases, the products improve tree health and vigor, thereby providing a useful tool to manage and ameliorate the diseases. APP21-22, APP24-25, APP27-29; *see also* Nesci Decl. ¶¶ 7-9, 20 (APP134-36, APP141). This is especially important in Florida, which has been affected the most by citrus greening disease.[5] APP25-26; *see also* Nesci Decl. ¶ 8 (APP135).

[5] In its application, the registrant noted that estimates of the citrus crop from 2016 to 2017 "put orange production at . . . the smallest crop Florida has produced in over 30 years." APP25. The decline of the Florida citrus industry continues today, with the most recent forecast predicting that "Florida is on pace to produce the smallest crop of oranges in more than 75 years." Associated Press, *Florida on Pace for Smallest Orange Crop in*

The new use of streptomycin on citrus is also an effective tool to manage antibiotic resistance. *See, e.g.*, APP13 ("general considerations for prudent agricultural use" include avoiding practices that rely on one chemical to control disease), APP25. EPA registered another antibiotic, oxytetracycline, for use on citrus in 2019. APP15, APP78. Because streptomycin and oxytetracycline have different modes of action, the registrations at issue can serve an important role in resistance management strategies. APP25. Streptomycin use on citrus therefore helps reduce the likelihood that plant pathogens would develop resistance to an individual pesticide.

CONCLUSION

For these reasons, this Court should remand without vacatur the decision to amend the registrations.

Dated: February 4, 2022

Respectfully submitted,

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Over 75 Years, Jan. 19, 2022, https://www.tampabay.com/news/business/2022/01/19/florida-on-pace-for-smallest-orange-crop-in-over-75-years/ (last visited Jan. 31, 2022).

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CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because this document contains 3,559 words.

2. This document complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook font.

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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.

/s/ *Robert M. Norway*
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