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' REPLY BRIEF IN SUPPORT OF MOTION FOR REMAND WITHOUT VACATUR AND IN OPPOSITION TO PETITIONERS' CROSS-MOTION TO VACATE

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## $\underline{GLOSSARY}$

EPA United States Environmental Protection Agency

ESA Endangered Species Act

FIFRA Federal Insecticide Fungicide and Rodenticide

#### 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"), acknowledge that EPA failed to meet its obligation under the Endangered Species Act ("ESA") to make effects determinations prior to issuing the 2021 decision at issue. In that decision, EPA unconditionally amended Federal Insecticide Fungicide and Rodenticide ("FIFRA") registrations for two pesticide products containing streptomycin to allow new, time-limited uses on citrus crops for the management of debilitating bacterial diseases of citrus trees, Huanglongbing—also called citrus greening—and citrus canker. EPA has therefore sought voluntary remand to allow it to correct its error.

As EPA established in its motion, remand without vacatur is proper here and fully consistent with the criteria set forth in *Allied-Signal, Inc.* v. U.S. Nuclear Regulatory Commission, 988 F.2d 146, 150-51 (D.C. Cir. 1993), and with the D.C. Circuit's decision in Center for Biological Diversity v. EPA, 861 F.3d 174, 188 (D.C. Cir. 2017), in which the court granted remand without vacatur based on the same acknowledged error.

#### ARGUMENT

# I. Voluntary Remand Without Vacatur Is Warranted Under The *Allied-Signal* Two-Part Test.

"The 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 (quoting Int'l Union, United Mine Workers of Am. v. Fed. Mine Safety & Health Admin., 920 F.2d 960, 967 (D.C. Cir. 1990)). Both parts of the Allied-Signal test demonstrate that EPA's failure to make an effects determination is not so deficient as to warrant vacatur. Here, vacatur would render sale and distribution of streptomycin for the uses permitted in the 2021 amended registrations unlawful under FIFRA, thereby removing a pesticide of generally low risk from the market. Considering that risk, along with the clear, adverse economic and disruptive

<sup>&</sup>lt;sup>1</sup> Petitioners concede that the *Allied-Signal* test provides the appropriate framework for EPA's request for remand without vacatur. Pet'rs' Opp'n to EPA's Mot. for Remand Without Vacatur and Cross-Motion to Vacate ("Pet'rs' Resp.") at 14-15, ECF No. 45-1 (citing *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 532 (9th Cir. 2015), and *Allied-Signal*, 988 F.2d at 150-51).

consequences that would result from vacatur, remand without vacatur is proper.

A. Based on the record before the Court, the failure to make effects determinations is not so serious a deficiency that vacatur is compelled.

EPA has acknowledged that it did not make ESA effects determinations before approving new uses of existing pesticide products containing streptomycin, as required by the ESA. *See* Resp'ts' Mot. for Remand without Vacatur ("EPA Mot.") at 2, 11-13, ECF No. 42-1; EPA Mot. Appendix ("APP"), ECF No. 42-2, Matuszko Decl. ¶¶ 15, 18, 21-22 (APP120-22, APP127, APP128). This acknowledged error does not compel vacatur. EPA has proposed to undertake a Biological Evaluation in support of the required ESA effects determination to comply on remand. Matuszko Decl. ¶¶ 15, 18, 21-22 (APP120-22, APP127, APP128).

EPA has asked the Court to remand the registration approvals to allow EPA to make an effects determination and take any additional follow-up actions as appropriate. Remand is the preferred option "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).

Petitioners incorrectly assert that EPA contends that "it has already adequately considered effects to endangered species." Pet'rs' Resp. at 21. That is not so. Nor does EPA contend that the standards for FIFRA and the ESA are the same. *Id.* at 19. Rather, EPA contends that, as in *Center for Biological Diversity*, here EPA did not grant the amended registrations in complete disregard for streptomycin's environmental and ecological effects. EPA Mot. at 14-15. Because the decision to vacate requires an equitable balancing of the potential harm of leaving the amended registrations in place with the benefits for doing so, the analysis that EPA performed when granting the amended registrations is relevant to the Court's decision.<sup>2</sup> *See Ctr. for Biological Diversity*, 861 F.3d at 188. EPA's conclusion that streptomycin generally poses low

<sup>&</sup>lt;sup>2</sup> Petitioners therefore miss the mark when they argue that EPA cannot argue both that it "adequately considered effects to endangered species" and that it must also collect more data to perform such determinations. Pet'rs' Resp. at 20-21. As Petitioners themselves argue, EPA has a separate obligation under the ESA to weigh the impacts of its registration actions on listed species. *Id.* at 20. EPA is not arguing that its FIFRA assessment satisfies its ESA obligations, but rather that its FIFRA assessments have bearing on the Court's *Allied-Signal* analysis.

environmental and ecological risks informs the Court's analysis of the potential harm to leaving the amended registrations in place.

Here, under FIFRA, EPA concluded that streptomycin generally presents a low risk to non-target species. In that analysis, EPA evaluates risk to non-target species by integrating both toxicity and exposure to particular taxa, considering a wide range of studies and data. EPA Mot. at 15-16. The agency found no new ecological risks from the proposed new uses. See id. at 15 (citing APP3). Further, for most taxa—birds, mammals, fish, aquatic invertebrates—the available data suggested that the compound was "practically nontoxic." See id. at 15-16 (citing APP4-5, APP36, APP39). At the exposure levels contemplated by the new uses (which are lower than the exposure levels contemplated in streptomycin's registered uses on apples and pears), EPA found only a low risk of effects on non-listed species of terrestrial plants and vascular aquatic plants. See id. (citing APP4-5).

Petitioners argue that EPA's analysis is nonetheless insufficient because EPA identified that streptomycin may pose a chronic risk to mammals. Pet'rs' Resp. at 19; see also EPA Mot. at 16 n.4 (acknowledging EPA concluded potential risk to mammals from chronic exposure). But

Petitioners overstate that risk, which was limited to mammals that consume grasses, broadleaf forage, and insects, and which declined below the level of concern approximately three weeks after the last application of the registered products. APP34, APP41.

Next, Petitioners fault EPA for acknowledging that it "could not fully assess the risk posed to pollinators" before granting the amended registrations. Pet'rs' Resp. at 19-20. Petitioners misconstrue EPA's analysis here too. EPA reviewed the available data for pollinators, noting that no effects were reported in a bee contact study and that the compound is classified as "practically nontoxic" to honey bees on an acute exposure basis. APP36. But EPA caveated its analysis with a note that the "full suite of data" required under the agency's pollinator guidance available for streptomycin. APP41. EPAtherefore not were acknowledged that it analyzed the compound's effects on pollinators, albeit not to the extent called for under its more recent guidance, which is nonbinding.

Petitioners also argue that EPA's failure to conduct effects determinations is not an isolated event, suggesting that EPA acted in bad faith when approving the 2021 amended registrations. Pet'rs' Resp. at 18.

But an agency's acknowledgement of error *itself* is not evidence of bad faith—it is simply the basis for EPA's request for remand. See, e.g., SKF USA Inc. v. United States, 254 F.3d 1022, 1030 (Fed. Cir. 2001) (finding that the agency was not acting in bad faith by requesting voluntary remand due to its change in policy); Safer Chems., Healthy Fams. v. EPA, 791 F. App'x 653, 656-57 (9th Cir. 2019) (mem.) (granting a request by EPA for voluntary remand without vacatur after finding that the request was not frivolous or made in bad faith). EPA has a long history of working to harmonize its FIFRA registration actions with its ESA obligations. Matuszko ¶¶ 12-16 (APP118-26). Contrary to Petitioners' Decl. suggestion, EPA's ongoing programmatic efforts to improve the pesticide consultation process, its acknowledgment of the ESA defect in this case, and its prompt response to begin to address that error demonstrate its good-faith willingness to comply with the ESA.

Petitioners also argue that the timeline proposed by EPA to make effects determinations is insufficient given that ESA consultations may take years to complete. Pet'rs' Resp. at 20-21. That argument puts the cart before the horse. EPA must make an effects determination, 50 C.F.R. § 402.14(a), before beginning any consultation process. See Ctr. for

Biological Diversity, 861 F.3d at 178 (citing 50 C.F.R. § 402.14(a)-(b)). The argument is also contrary to Pollinator Stewardship Council, which inquires only as to whether it is possible for the agency to adopt the "same rule" on remand—here, that means whether EPA could make the same registration decisions under FIFRA after it complies with the ESA. 806 F.3d at 532.

EPA recognizes that it must make effects determinations for the amended registrations. However, the agency also believes that the environmental and ecological effects analysis performed under FIFRA demonstrates that EPA's error was not so serious as to warrant vacatur.

# B. Equitable considerations of disruptive consequences support leaving the amended registrations in place on remand.

As to the second part of the *Allied-Signal* test—the disruptive consequences from vacatur—vacating the amended registrations has the potential to disrupt citrus growers' management of two bacterial diseases, citrus greening and citrus canker. *See* EPA Mot. at 18 (citing APP14-15, APP21-32). Specifically, USDA has observed that the new use of streptomycin on citrus is beneficial to growers because streptomycin (1) suppresses citrus greening disease and (2) aids the management of

citrus canker disease by providing an alternative to copper-based treatments. See id. Although the approved new uses of streptomycin do not cure either disease, EPA concluded when reviewing these amended registrations that streptomycin provides real benefits to growers based on the data included in the application. APP24-25. Indeed, these streptomycin products are among the few tools citrus growers have to manage the diseases and to ameliorate their effects on citrus crops. See EPA Mot. at 18 (citing APP21-22, APP24-25, APP27-29, and Nesci Decl. ¶¶ 7-9, 20 (APP134-36, APP141)).

Petitioners contend that EPA can satisfy its burden only where vacatur itself would cause serious environmental harm. Pet'rs' Resp. at 16 (citing Pollinator Stewardship Council, 806 F.3d at 532). That's not correct. See Nat'l Family Farm Coal. v. EPA, 966 F.3d 893, 929 (9th Cir. 2020) (noting that consideration of "whether vacating a faulty rule could result in possible environmental harm" is one factor that courts weigh) (citation omitted). Indeed, Allied-Signal—the seminal case on remand without vacatur—held that economic consequences could be weighed in the balance of equities. 988 F.2d at 151. Likewise, in California Communities Against Toxics v. EPA, this Court concluded the economic

harms flowing from vacatur of a Clean Air Act rule would be "disastrous." 688 F.3d 989, 992-94 (9th Cir. 2012) (per curiam). Thus, the *Allied-Signal* analysis repeatedly endorsed by this Court allows for a broad balancing of the equities, including the economic consequences of vacatur. *See id*.

Next, Petitioners attempt to minimize streptomycin's benefits to citrus growers by claiming that the amended registrations are "[a]t most, . . . one of several options available to growers" to manage citrus greening and citrus canker diseases. Pet'rs' Resp. at 26. Not so. While there are some registered options available to mitigate the psyllid vector for citrus greening, vector control has been largely unsuccessful in stopping the spread of the disease. See APP15. When EPA granted these amended registrations, there was only one other registered pesticide product (containing another antibiotic—oxytetracycline) to control or suppress the disease itself. See APP15, APP23-24, APP25 (describing strategies for managing citrus greening as "almost non-existent"). Vacatur of the amended registrations would deprive growers of an important tool to manage this disease.

Similarly, before EPA granted the amended registrations, there were just two classes of products—those with copper-based compounds

and those with bio-pesticides—registered to manage citrus canker. APP26-27. Treatment of infected trees with streptomycin together with a low rate of copper demonstrated that treatment improved fruit yields, reduced cankers, and reduced fruit drop. APP28. Indeed, Petitioners do not contest that streptomycin aids management of citrus canker because it provides a different mode of action than copper-based registered alternatives. *See* EPA Mot. at 18 (citing APP25, APP28-29, and Nesci Decl. ¶ 9 (APP135-36)).

Petitioners next contend that the Court should give no weight to the fact that the amended registrations would aid in the management of antibiotic resistance when used in a management program with oxytetracycline because the registration for that antibiotic is allegedly unlawful too. Pet'rs' Resp. at 25. But that argument fails to see the forest for the trees. If the amended registrations are vacated, oxytetracycline will be the *only* ingredient registered to treat citrus greening. APP15. In those circumstances, no one could take advantage of the resistance management strategy contemplated by the applicant—alternating between streptomycin and oxytetracycline. *See* APP25. Consequently, Petitioners' request to vacate the amended registrations undermines

antibiotic resistance management practices, thereby potentially exacerbating the very same harm they seek to prevent.

In sum, equitable considerations of disruptive consequences support leaving the amended registrations in place on remand.

# II. Petitioners' FIFRA Claims Can Be Severed And Proceed To The Merits.

Petitioners argue that if the Court grants EPA's motion for remand without vacatur, then the Court should allow Petitioners' challenge to EPA's FIFRA analysis to proceed to the merits. Pet'rs' Resp. at 27-29. Depending on the outcomes of EPA's ESA analyses, EPA may take additional action under FIFRA if appropriate. For example, EPA can work with the registrant to make label changes. At that juncture, Petitioners may have rights to challenge those actions under FIFRA.

However, if the Court remands without vacatur but nonetheless wishes to reach the FIFRA issues now, EPA has no objection to severing and holding in abeyance the ESA claims while EPA performs the necessary ESA analysis, and proceeding to full briefing on the FIFRA claims alone. This path—addressing only one aspect of the challenged action and holding the other in abeyance—has ample precedent. See, e.g.,

Safer Chems., Healthy Fams., 791 F. App'x at 656-57; Cook Inletkeeper v. United States, 400 F. App'x 239, at \*2 (9th Cir. 2010) (similar).

#### **CONCLUSION**

EPA's motion for voluntary remand without vacatur should be granted.

Dated: March 17, 2022 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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