No. 21-71287

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CALIFORNIA RURAL LEGAL
ASSISTANCE FOUNDATION, *et al.*,
Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,
Respondents

and

SYNGENTA CROP PROTECTION, LLC,
Intervenor-Respondent.

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

MOTION FOR VOLUNTARY REMAND WITHOUT VACATUR

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GLOSSARY

CAA	Clean Air Act
EPA	Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
Interim Decision	EPA's Interim Registration Review Decision for paraquat
Paraquat	Paraquat dichloride

INTRODUCTION

Petitioners challenge the U.S. Environmental Protection Agency's (EPA) discretionary issuance of an interim registration review decision for the herbicide paraquat dichloride (Interim Decision) under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Interim Decision finalized certain portions of EPA's analysis of paraquat dichloride's risks and benefits. It also determined that certain mitigation measures were necessary in order for paraquat to meet the FIFRA standard for registration. In this Petition for Review, Petitioners California Rural Legal Assistance Foundation *et al.* (the Foundation) allege that various aspects of the Interim Decision are unsupported by substantial evidence. Pet. for Review, Dkt. Entry 1-4, Doc. No. 12237971; Pet'rs' Opening Br., Dkt. Entry 27-1, Doc. No. 12456190 at 23–25.

In light of the arguments raised by the Foundation, EPA now seeks voluntary remand of the Interim Decision. On remand, EPA will reconsider various aspects of its discretionary Interim Decision as challenged by the Foundation. For example, EPA wishes to reconsider the Interim Decision's volatilization analysis, risk-benefit balancing, and assessment of costs. Granting this motion will conserve the Court's and the parties' resources, as it will allow EPA to address the above-described issues without the need for further briefing, oral argument, or a Court decision.

If the Court grants EPA's motion to remand, the Court should decline the Foundation's request for deadlines for administrative action. *See* Pet'rs' Opening Br. 59. Deadlines are not an appropriate remedy for the Foundation's claims, which are brought against an interim determination that EPA was under no obligation to issue in the first place. Not only would deadlines be improper, they would unnecessarily entangle the Court in the Agency's administrative processes.

Consistent with the Foundation's requested relief, EPA requests that the remand be granted without vacatur. Vacatur of the Interim Decision would be unduly disruptive; it could lead to confusion about whether the risk mitigation measures that the Agency has required to reduce human health risks are still necessary while the Agency reconsiders aspects of the Interim Decision.

The Intervenor-Respondent—the registrant Syngenta— does not oppose remand without vacatur, but reserves the right to file a response. The Foundation takes no position at this time and reserves the right to file a response after reviewing the motion.

BACKGROUND

A. Legal Background

1. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

FIFRA generally precludes the distribution or sale of any pesticide unless it is "registered" by EPA. 7 U.S.C. § 136a(a). EPA issues a license, referred to as a "registration," for each specific pesticide product allowed to be marketed. *Id.*; *see also Nat'l Family 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 Family Farm*, 966 F.3d at 912 (citing 7 U.S.C. § 136(p)). It is unlawful to use a pesticide "in a manner inconsistent with its labeling." 7 U.S.C. § 136j(a)(2)(G).

FIFRA directs that EPA "shall register a pesticide" if the Agency 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 this subchapter;
>
> (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). FIFRA defines "unreasonable adverse effects on the environment" as "(1) 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, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21." 7 U.S.C. § 136(bb).

EPA must periodically review pesticide registrations. *See* 7 U.S.C. § 136a(g); 40 C.F.R. §§ 155.40-.58. The purpose of registration review is to evaluate registered pesticides "to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration." 40 C.F.R. § 155.40(a). In conducting this review, EPA examines all available data, as well as determines what other data might be necessary to fully evaluate the risks and benefits of the registered pesticide, and determines whether new assessments are necessary. *Id.* § 155.53. Prior to issuing a final decision, EPA releases any draft risk assessments and its proposed decision for public comment. *See* 40 C.F.R. §§ 155.53(c), 155.58(a). After considering any comments, EPA issues a registration review decision. *Id.* § 155.58(c).

EPA need not conduct the entirety of the registration review at once, but rather has discretion to make an "interim registration review decision" when it deems appropriate. 40 C.F.R. § 155.56. "Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review." *Id.* But EPA may also proceed to a final registration review decision without ever issuing an interim decision.

B. Procedural History

1. The Paraquat Interim Decision

Paraquat dichloride (paraquat) is a fast-acting, non-selective herbicide used in an array of agricultural and other settings. ER-006–07.[1] Registered for use since 1964, paraquat is one of the most commonly used herbicides in the United States. ER-007.

In July 2021, EPA issued its interim registration review decision for paraquat (the Interim Decision) under 40 C.F.R. § 155.56. ER-009–10. EPA issued the Interim Decision to "(1) move forward with aspects of the registration

[1] Citations to ER-__ are to the Foundation's excerpts of record, submitted with their opening brief. Pet'rs' Excerpts of R., Dkt. Entry 28, Doc. No. 12456197.

review that are complete and (2) implement interim risk mitigation." ER-006. Among other things, the Interim Decision finalized certain draft registration review risk assessments, including the human health risk assessment and the preliminary ecological risk assessment. ER-009.

The Interim Decision also briefly summarized EPA's conclusions (as of the date of signature) as to the benefits and risks associated with paraquat. EPA concluded that paraquat offered substantial benefits as an effective, inexpensive, versatile, and widely used method of weed control. ER-027–29. As for the risks, EPA determined that paraquat presented potential risks of concern to occupational handlers, workers, and bystanders in certain scenarios, as well as potential ecological risks to certain non-target plants and animals. ER-013–27, ER-029. The Interim Decision imposed various risk-mitigation measures to reduce those risks.[2] ER-029–43. Ultimately, EPA concluded that, with the mitigation measures, "any remaining potential worker and/or ecological risks are outweighed by the benefits associated with the use of paraquat." ER-30, ER-044–45.

The Foundation petitioned for review of the Interim Decision. Pet. for Review, Dkt. Entry 1-4, Doc. No. 12237971. The Foundation has challenged the

[2] At this time, all product labels for which mitigation measures were required have been submitted by registrants, and EPA has approved those labels. Goodis Decl. ¶ 15.

Interim Decision on FIFRA grounds only. Pet'rs' Opening Br., Dkt. Entry 27-1, Doc. No. 12456190 at 23–25.[3]

STANDARDS OF REVIEW

"A reviewing court has inherent power to remand a matter to the administrative agency." *Loma Linda Univ. v. Schweiker*, 705 F.2d 1123, 1127 (9th Cir. 1983). "[I]t is generally accepted that in the absence of a specific statutory limitation, an administrative agency has the inherent authority to reconsider its decisions." *Macktal v. Chao*, 286 F.3d 822, 825–26 (5th Cir. 2002); *Trujillo v. Gen. Elec. Co.*, 621 F.2d 1084, 1086 (10th Cir. 1980) (noting that "the power to decide in the first instance carries with it the power to reconsider").

While the reviewing court has discretion over whether to remand, voluntary remand is appropriate where the request is reasonable and timely. *Macktal*, 286 F.3d at 826. "[I]f the agency's concern is substantial and legitimate, a remand is usually appropriate." *Citizens Against the Pellissippi Parkway Extension, Inc. v. Mineta*, 375 F.3d 412, 417 (6th Cir. 2004).

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[3] After the Foundation filed its brief, the Ninth Circuit issued a decision remanding EPA's interim registration review decision for the pesticide glyphosate. *Nat. Res. Def. Council v. U.S. Env't Prot. Agency*, 38 F.4th 34, 62 (9th Cir. 2022) (granting EPA's motion to remand the ecological portion of the interim decision without vacatur, vacating the human health portion of the interim decision).

"Generally, courts only refuse voluntarily requested remand when the agency's request is frivolous or made in bad faith." *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (citation omitted). This authority includes the right to seek voluntary remand of a challenged agency decision, without confessing error. *SKF USA Inc. v. United States*, 254 F.3d 1022, 1029 (Fed. Cir. 2001).

"Administrative 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. ICC*, 897 F.2d 561, 562 n.1 (D.C. Cir. 1990) (quoting *Commonwealth of Pennsylvania v. ICC*, 590 F.2d 1187, 1194 (D.C. Cir. 1978)). As the D.C. Circuit has stated, "[w]e commonly grant such motions, 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); *see also Anchor Line Ltd. v. Fed. Maritime Comm'n*, 299 F.2d 124, 125 (D.C. Cir. 1962) ("[W]hen an agency seeks to reconsider its action, it should move the court to remand or to hold the case in abeyance pending reconsideration by the agency.").

ARGUMENT

I. Remand Is Appropriate to Allow EPA to Reconsider Issues Raised by the Foundation.

EPA satisfies the standard for voluntary remand because it wishes to reconsider issues raised by the Foundation. In litigation, courts have recognized that an "agency may take one of five positions," including to "request a remand (without confessing error) in order to reconsider its previous position."[4] *SKF USA Inc.*, 254 F.3d at 1028–29; *see also Cal. Cmtys.*, 688 F.3d at 992 (same and citing *SKF*, 254 F.3d at 1029); Charles H. Koch Jr., *Administrative Law & Practice* § 8:31, at 187 (3d ed. 2010). The agency may "wish[] to consider further the governing statute, or the procedures that were followed," or it may have "doubts about the correctness of its decision or that decision's relationship to the agency's other policies." *SKF USA Inc.*, 254 F.3d at 1029. "[I]f the agency's concern is substantial and legitimate, a remand is usually appropriate." *Id.*; *see also Limnia, Inc. v. U.S. Dep't of Energy*, 857 F.3d 379, 387 (D.C. Cir. 2017) (observing that an

[4] An agency may also "seek a remand because of intervening events outside of the agency's control, for example, a new legal decision or the passage of new legislation." *SKF USA Inc.*, 254 F.3d at 1028. When an agency seeks a remand on such grounds, "remand to the agency is required, absent the most unusual circumstances verging on bad faith." *Id.* at 1029–30. Voluntary remand would also give EPA the opportunity to consider the ramifications, if any, of this Court's glyphosate opinion for EPA's analysis of paraquat. *See supra* n.3; *Nat. Res. Def. Council*, 38 F.4th 34.

agency does not need to "confess error or impropriety in order to obtain a voluntary remand" so long as it has "profess[ed] [an] intention to reconsider, re-review, or modify the original agency decision that is the subject of the legal challenge").

Here, EPA confesses no error in its Interim Decision analysis, but a voluntary remand is nonetheless appropriate because EPA wishes to reconsider various aspects of its discretionary Interim Decision as challenged by the Foundation. For example, EPA wishes to further consider the Interim Decision's risk-benefit balancing and its assessment of costs. Ex. 1, Declaration of Michael Goodis (Goodis Decl.) ¶ 18. EPA acknowledges that the Interim Decision's discussion of these issues could have been more robust. *Id.* EPA also wishes to reconsider its analysis of the potential for volatilization—which occurs when an applied pesticide volatilizes and moves through the air. *Id.* ¶ 17. There is evidence in the record that paraquat may be likely to volatilize, ER-585, and EPA wishes to consider this issue further. *Id.* ¶ 17.

In addition to addressing the above-mentioned issues, EPA will consider the remaining substantive issues raised by the Foundation's brief. *Id.* ¶ 19. EPA will determine whether any further reconsideration or supplementation of the Interim Decision in relation to those issues is warranted. *Id.*

A. EPA Has Established Specific Plans for Administrative Action on Remand.

During remand, EPA intends to draft and issue documents summarizing EPA's reconsideration of the Interim Decision's volatilization analysis, risk-benefit balancing, and assessment of costs, as well as any other issue requiring reconsideration or supplementation. *Id.* ¶ 20. Those documents are likely to take the form of an addendum to the human health risk assessment, an addendum to the benefits assessment, and/or another stand-alone clarification statement. *Id.* EPA intends to issue those documents within one year of this Court's order granting EPA's motion for a voluntary remand. *Id.*

Upon issuance, EPA will release the documents for public comment. *Id.* ¶ 20. After considering substantive comment, EPA will determine the next steps for concluding paraquat's registration review. *Id.* ¶ 21. These next steps may include an affirmation of previous conclusion(s), revisions to the human health risk assessment, developing a revised proposed registration review decision, and/or initiating work to finalize registration review for paraquat. *Id.*

B. Voluntary Remand Would Promote Judicial Economy.

Remand of EPA's Interim Decision will serve the interests of judicial economy by possibly mooting or significantly narrowing the issues that the Foundation has raised in this litigation. Granting this motion promotes efficiency

because remand is the ultimate outcome that the Foundation seeks in this litigation. *See* Pet'rs' Opening Br. 59 ("[T]he Registration Decision should be remanded to EPA."). Put differently, even if the Foundation prevailed in its challenge to EPA's Interim Decision, there would still need to be further administrative proceedings. EPA is simply proposing to move forward with remand now, rather than wasting judicial and governmental resources litigating over an earlier decision, portions of which EPA is agreeing to administratively reconsider. Denying EPA's motion for voluntary remand would merely compel EPA to devote limited resources to this litigation, as opposed to completing the ongoing review process.

II. The Court Should Decline the Foundation's Request that the Court Impose Deadlines for EPA's Administrative Processes on Remand.

In their opening brief, the Foundation requests that the Court set deadlines for EPA's administrative processes on remand. Pet'rs' Opening Br. 59–60. The Foundation may repeat that request in their response to this motion. The Court should decline the Foundation's request.

A. A Deadline Is an Improper Remedy for the Foundation's Claims.

The only issue presented in the Foundation's Petition for Review is whether EPA's Interim Decision is supported by substantial evidence. *See* Pet'rs' Opening Br. 2. If the Court were to adjudicate the merits and answer no, then the proper

remedy would be remand. *See Fed. Power Comm'n v. Idaho Power Co.*, 344 U.S. 17, 20 (1952) ("[T]he function of the reviewing court ends when an error of law is laid bare. At that point the matter once more goes to the [agency] for reconsideration.").

Imposing a deadline on top of remand, however, goes too far. For one thing, deadlines remedy *delayed* actions, not unsupported ones. And the Foundation in this Petition under 7 U.S.C. § 136n does not contest alleged unreasonable delay. Indeed, EPA is under no statutory obligation to issue an interim decision in the first place. By requesting the Court impose a deadline, the Foundation is improperly requesting the sort of timing relief that successful mandamus petitioners and unreasonable-delay litigants might get—but without actually raising any mandamus or unreasonable delay claim and then meeting the stringent requirements applying to such claims. *See, e.g.*, *In re Pesticide Action Network N. Am.*, 798 F.3d 809, 813 (9th Cir. 2015) (explaining that a writ of mandamus is "an extraordinary remedy justified only in 'exceptional circumstances'" (citations and internal quotation marks omitted)); 5 U.S.C. § 706(1).

Moreover, courts override an agency's discretion to set its own timetables only "in those rare instances when an agency's delay is egregious." *In re Pesticide Action Network N. Am.*, 798 F.3d at 813; *see also Vt. Yankee Nuclear Power Corp.*

v. NRDC, 435 U.S. 519, 544-45 (1978) (absent "substantial justification," courts may not dictate remand's "time dimension.").

That is not this case. There was nothing egregious about EPA's timing of the 2021 Interim Decision. The Interim Decision—like all interim registration review decisions—was discretionary; EPA was under no obligation to issue it at all, let alone by a specific date. *See* 40 C.F.R. § 155.56 (providing that EPA "may issue, when it determines it to be appropriate" an interim registration review decision.) That EPA exercised discretion to issue an Interim Decision reflects that EPA has been working in good faith to complete its registration review analyses for paraquat. *See* Goodis Decl. ¶¶ 14–15.

The Foundation's brief observes that EPA is required to complete registration review by October 1, 2022. *See* 7 U.S.C. § 136a(g)(1)(A)(iii)(I). While true, this case is not about EPA's *final* registration review decision for paraquat. Any challenge to that decision or its timing is not presently before the Court. This action relates solely to EPA's discretionary Interim Decision.

B. The Court Should Decline the Foundation's Request to Superintend EPA's Administrative Processes on Remand.

Not only would a deadline be improper, it would unnecessarily entangle the Court in the Agency's administrative processes. *See In re Barr Lab'ys, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("The agency is in a unique—and authoritative—

position to view its projects as a whole, estimate the prospects for each, and allocate its resources in the optimal way.").

As described *supra* at Argument § I.A, the Agency has set forth specific plans for its administrative processes on remand. Ultimately, however, the appropriate next steps in the registration review process are dependent upon EPA's future analyses, as well as the anticipated public comments it receives on those analyses. Goodis Decl. ¶ 21. The next steps may include an affirmation of previous conclusion(s), revisions to the human health risk assessment, developing a revised proposed registration review decision, and/or initiating work to finalize registration review for paraquat. *Id.*

As EPA undertakes its next steps in the registration review process, it will take into account its available resources and existing obligations for the hundreds of other pesticides undergoing registration review. *See id.* ¶¶ 11–14. The Court should decline the Foundation's invitation to set the Agency's priorities. *See also Sierra Club v. Thomas*, 828 F.2d 783, 797 (D.C. Cir. 1987) (noting that courts are generally "ill-suited to review the order in which an agency conducts its business" and are "hesitant to upset an agency's priorities by ordering it to expedite one specific action, and thus to give it precedence over others") (citations omitted).

In sum, the Court should decline the Foundation's request to set deadlines for EPA's administrative action on remand because such a remedy would be inappropriate and would unnecessarily entangle the Court in the Agency's administrative processes.

III. Consistent with the Foundation's Request, the Court Should Not Vacate the Interim Decision.

This Court should grant remand without vacatur, leaving in place the Interim Decision while EPA further considers aspects of the Interim Decision. The Foundation agrees that remand without vacatur is appropriate. *See* Pet'rs' Opening Br. 59 ("Petitioners seek remand without vacatur so the mitigation measures in the Registration Decision remain in place while EPA revises its paraquat analyses and issues a new registration decision.").

To determine whether vacatur is appropriate, the Court undertakes an equitable analysis. "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, Inc. v. U.S. Nuclear Regul. Comm'n,* 988 F.2d 146, 150–51 (D.C. Cir. 1993) (internal quotations marks and citation omitted); *Cal. Cmtys.*, 688 F.3d at 992 (same). Also relevant to the analysis is whether EPA "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).

Here, the equities weigh in favor of remand without vacatur. EPA does not confess any error regarding the Interim Decision, and EPA could reach the same ultimate conclusion on remand. Furthermore, vacatur of the Interim Decision would be unduly disruptive. The Interim Decision required registrants to adopt measures necessary to mitigate certain human health and ecological risks of concern. ER-029. The mitigation measures include, *inter alia*, limits to aerial applications, the prohibition of the use of human flaggers, the requirement that applicators use closed cabs and respirators, the prohibition of the use of mechanically pressurized handguns and backpack sprayers, the requirement of restricted entry intervals, the use of a "non-target organism advisory," and herbicide resistance management. ER-030. Registrants have already submitted labels including the new mitigation requirements and EPA has already approved those labels. Goodis Decl. ¶ 22. Vacatur of the Interim Decision could create confusion concerning whether those mitigation measures continue to be necessary for paraquat products. *Id.* Accordingly, the Court should remand the Interim Decision without vacatur.

CONCLUSION

For the foregoing reasons, the Court should grant EPA's motion and remand the Interim Decision without vacatur.

Respectfully submitted,

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1-22037

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 3,612 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 Times New Roman font.

/s/ *Elliot Higgins*
Elliot Higgins

Counsel for Respondents

CERTIFICATE OF SERVICE

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

/s/ *Elliot Higgins*
Elliot Higgins

Counsel for Respondents

Exhibit 1

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION, et al., *Petitioners*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, et al., *Respondents*, SYNGENTA CROP PROTECTION, LLC, *Intervenor-Respondent*.	)	No. 21-71287

DECLARATION OF MICHAEL GOODIS IN SUPPORT OF EPA'S MOTION FOR VOLUNTARY REMAND WITHOUT VACATUR

I. Background

A. Introduction

1. I, Michael Goodis, declare under penalty of perjury that the following statements are true and correct to the best of my knowledge and belief and that they are based upon my personal knowledge, information contained in the records of the United States Environmental Protection Agency (EPA), and/or information supplied to me by EPA employees under my supervision and in other EPA offices. *See* 28 U.S.C. § 1746.

2. I am the Deputy Director of Programs for the Office of Pesticide Programs (OPP), EPA. I have held this position since March 2022. Prior to becoming the Deputy Director of Programs for OPP, I served as the Acting Deputy Director of Programs for OPP from July 2020 to March 2022. Prior to becoming Acting Deputy Director of Programs for OPP, I served in various positions within OPP since March 1997, including the Director of the Registration Division and the Associate Director of the Pesticide Re-evaluation Division. I have a B.S. in Geological Engineering from the South Dakota School of Mines and Technology and a M.S. from The Johns Hopkins University in Technical Management.

3. OPP is the office within EPA that regulates the distribution, sale, and use of pesticides in the United States under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Part of OPP's responsibility includes implementing the periodic "registration review" of pesticides as required by section 3(g) of FIFRA, 7 U.S.C. § 136a(g). EPA's essential responsibility under registration review is to review each registered pesticide at least every 15 years to determine whether it continues to meet the FIFRA standard for registration.

4. Several divisions within OPP are involved in registration review. The Pesticide Re-Evaluation Division (PRD) is the lead division overseeing the registration review of conventional pesticides[1] that are currently registered under FIFRA, including paraquat. PRD develops EPA's regulatory position as to whether such pesticides continue to meet the FIFRA standard for registration. PRD's work is supported by the work of three other divisions. The Environmental Fate and Effects Division (EFED) assesses the environmental fate and ecological risk of pesticides. In this context, "environmental fate" is the life cycle of a chemical (such as a pesticide) after its release into the environment. Part of this responsibility includes evaluating potential effects to species listed as threatened or endangered (listed species) and/or their designated critical habitats under the Endangered Species Act (ESA). If OPP determines that an action "may affect" listed species or designated critical habitat in its Biological Evaluations, OPP would then initiate consultation with the National Marine Fisheries Service (NMFS) and/or the U.S. Fish and Wildlife Service (FWS) (collectively, the Services) under the Services' ESA implementing regulations.[2] See 50 C.F.R. § 402.14.

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[1] Conventional pesticides are all active ingredients other than biological pesticides (*i.e.*, certain types of pesticides derived from natural materials such as animals, plants, bacteria, and minerals) and antimicrobial pesticides (*i.e.*, pesticides intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms or provide certain protections against bacteria, viruses, fungi, protozoa, algae, or slime). Conventional pesticides are generally synthetic chemicals that prevent, mitigate, destroy, or repel any pest or that act as plant growth regulators, desiccants, defoliants, or nitrogen stabilizers.

[2] EPA may consult with one or both of the Services, depending on the listed species. Congress has divided responsibility for implementing the ESA between the U.S. Secretary of the Interior, who is generally

5. The Health Effects Division (HED) is responsible for reviewing and validating data on properties and effects of pesticides, as well as, characterizing and assessing exposure and risks to humans. The Biological and Economic Analysis Division (BEAD) provides pesticide use-related information, information on agronomic practices, and economic analyses in support of pesticide regulatory activities, including ESA evaluations. BEAD develops information about how much and the way pesticides are used to help EPA evaluate potential exposures, the need for various pesticides, and the potential agronomic and economic impacts of regulatory options. In addition to registration review, EFED, HED, and BEAD provide support for pesticide registrations, amendments to registrations, and other pesticide regulatory activities, including ESA compliance for many of these actions.

6. In my role as Deputy Director of Programs for OPP, among other duties, I am responsible for assisting the Office Director of OPP with the management, coordination, and oversight of national pesticide programs under FIFRA and the ESA, as well as the Federal Food Drug and Cosmetic Act (FFDCA), the amendments to FIFRA and FFDCA by the Food Quality Protection Act (FQPA) of 1996, and the Pesticide Registration Improvement Act (PRIA). I am responsible for assisting the Office Director of OPP with all regulatory activities associated with pesticides, including pesticide registrations, amendments to registrations, and registration review cases. In addition, I am responsible for

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responsible for terrestrial species and inland fishes, and the U.S. Secretary of Commerce, who is generally responsible for marine species and anadromous fish species. 16 U.S.C. §§ 1532(15), 1533(a)(2). The Secretary of the Interior and the Secretary of Commerce have delegated their ESA responsibilities to FWS and NMFS, respectively. 50 C.F.R. § 402.01(b).

assisting the Office Director of OPP with the management and operational responsibilities across a full range of programmatic issues, including providing program policy guidance and oversight over OPP's appropriated budget, resources, personnel, and the implementation of agency policies.

7. This declaration is filed in support of EPA's Motion for Voluntary Remand without Vacatur. The purpose of this declaration is to describe EPA's ongoing work related to paraquat in registration review, including the work that EPA is doing program-wide to better meet its obligations under EPA's current workload and staffing levels, and the steps required for EPA to complete the registration review decision.

B. Statutory and Regulatory Background

8. **FIFRA.** FIFRA, 7 U.S.C. §§ 136–136y, governs the sale, distribution, and use of pesticides. Its principal purpose is to protect human health and the environment from unreasonable adverse effects associated with pesticides. FIFRA generally prohibits the distribution and sale of a pesticide product unless it is "registered" by EPA. *See* 7 U.S.C. § 136a(a). EPA issues a registration to a particular registrant for a particular formula, packaging, and labeling. That registration provides rights only to the registrant.

9. Pesticide registrations are periodically reviewed as part of the registration review program under FIFRA section 3(g), 7 U.S.C. § 136a(g). For pesticides like paraquat that were registered before 2007, the statutory deadline for completing the initial registration review is October 1, 2022. 7 U.S.C. § 136a(g)(1)(A)(iii)(I).

10. EPA regulations set forth the procedures for registration review. *See* 40 C.F.R. part 155. They provide that a "registration review decision" is EPA's determination

whether a pesticide meets, or does not meet, the standard for registration in FIFRA. *Id.* § 155.57. The regulations also allow EPA to issue, when it determines it to be appropriate, an "interim registration review decision" before completing a registration review. *Id.* § 155.56. Among other things, a registration review decision or interim registration review decision contains EPA's findings with respect to the FIFRA registration standard and identifies risk mitigation measures and other remedies as needed. *Id.* § 155.58(b). EPA must propose and take public comment on a registration review decision or interim registration review decision before finalizing it. *Id.* § 155.58(a).

11. **EPA Workload**. Paraquat is one of 726 registration review cases, which cover 1,100 pesticide active ingredients and which FIFRA requires EPA to complete initial registration review by October 1, 2022.[3] Of those 726, PRD—with the support of EFED, HED, and BEAD, as described in paragraph 4—has responsibility for overseeing registration review for 461 cases for conventional pesticides, including paraquat.

12. Each registration review case, including ESA compliance, for a conventional pesticide requires an estimated 8.5 full-time equivalents (FTEs), or workers.

13. EPA estimates that since 2005, the number of pesticide actions, including new registrations, before the Agency has ranged from 10,000 to 20,000 per year. However, since 2005, OPP has experienced an approximately 30 percent decline in staffing levels, to the current total of approximately 600 FTEs. These FTEs carry out all regulatory activities

[3] A registration review case may be composed of one or more active ingredients and includes all of the pesticide products containing those active ingredients. Pesticides are grouped into a case when they are closely related or similar in toxicity. *See* 40 C.F.R. § 155.42(a).

associated with all pesticides, including pesticide registrations, amendments to registrations, and registration review cases, as well as ESA compliance for many of these actions. In addition to the statutory deadline for registration review cases, many of these other actions have their own statutory deadlines. *See generally* 7 U.S.C. § 136w-8.

14. In light of this significant workload and these resource constraints, EPA has issued interim registration review decisions for many pesticides, including paraquat, in order to move forward with aspects of the registration review that are complete and implement interim risk mitigation measures before completing registration review, which is a time-consuming process that includes ESA compliance. Of the 461 conventional pesticides in the initial round of registration review, EPA has issued more than 280 interim registration review decisions and more than 80 final registration review decisions, completed more than 400 proposed interim registration review decisions, conducted more than 450 human health and ecological draft risk assessments (excluding endangered species assessments), imposed risk mitigation measures for nearly 70 percent of pesticides for which EPA issued an interim or final registration review decision, and cancelled some or all uses of more than 80 pesticides.

C. Paraquat Interim Registration Review Decision

15. In August 2021, EPA published its Interim Registration Review Decision for paraquat (Interim Decision) under FIFRA section 3(g), 7 U.S.C. § 136a(g); 40 C.F.R. § 155.56. It explained that EPA issued the Interim Decision so that it could move forward with aspects of paraquat's registration review that were complete and implement interim risk mitigation measures, and it acknowledged that EPA had other work left to do. Among other things, the Interim

Decision summarized the Agency's 2019 Draft Human Health Risk Assessment and 2019 Preliminary Ecological Risk Assessment for registration review for paraquat. [1-ER-27.][4] It determined that certain interim risk mitigation measures were necessary to mitigate potential human health and ecological risks, including label amendments restricting paraquat applications, requiring residential area drift buffers, prohibiting human flaggers, imposing engineering controls and personal protective equipment requirements, adding a "non-target organism advisory" and an herbicide resistance management statement, among others. [1-ER-29-30]. The Interim Decision included instructions for registrants to submit product label amendments with the specified mitigation measures. [1-ER-46.] It also identified certain components of EPA's analysis that would be completed in EPA's final registration review decision. [1-ER-45.] At this time, all product labels for which mitigation measures were required have been submitted, and EPA has approved those labels.

16. On September 23, 2021, the Petitioners filed a Petition for Review challenging the Interim Decision. The Petitioners' brief, filed on May 25, 2022, focused on human health-related concerns and questions about the Agency's risk-benefit balancing discussion. In particular, the Petitioners challenged the Agency's assessment of Parkinson's risk, analysis of exposure to paraquat from volatilization, and analysis of costs and benefits associated with paraquat usage. Petitioners did not raise issues concerning the Agency's analysis of environmental or ecological impacts or impacts to endangered species. As for the requested relief, Petitioners requested that the Court remand without vacating the Interim Decision to EPA with a deadline for

[4] Citations to ER-__ are to the Petitioners' excerpts of record, submitted with their opening brief.

proposed a revised registration review decision within one year of the Court's decision and finalizing that decision within two years. Although the Petitioners noted the FIFRA registration review deadline of October 1, 2022, the deadlines they requested would extend beyond that date.

II. Planned Administrative Action for Voluntary Remand.

17. As set forth in EPA's Motion for Voluntary Remand without Vacatur, EPA is seeking a voluntary remand of the paraquat Interim Decision in order to reconsider aspects of the Interim Decision in light of arguments raised in the Petitioners' opening brief. For example, EPA wishes to reconsider its analysis of the potential for volatilization—which occurs when an applied pesticide volatilizes and moves through the air. In 2014, EPA developed a volatilization screening tool to assess the potential inhalation bystander risks resulting from volatilization of conventional pesticides. [ER-573–74.] EPA used the tool to assess paraquat, concluding that paraquat may be likely to volatilize. [ER-585.] In the Draft Human Health Risk Assessment, the Agency investigated volatilization further by finding and describing a study that concluded that no bystander post-application inhalation exposures to paraquat would be expected from volatilization following applications of paraquat to cotton in California. [ER-431.] The Agency wishes to further analyze volatilization on remand.

18. EPA also wishes to further consider, in light of arguments raised in the Petitioners' brief, the Interim Decision's risk-benefit balancing and its assessment of costs. EPA acknowledges that the Interim Decision's discussion of these issues could have been more robust.

19. While EPA addresses the above-mentioned issues, EPA will also further consider all substantive issues raised by Petitioners. EPA will determine whether any further

reconsideration or supplementation of the Interim Decision in relation to these issues is warranted.

20. During remand, EPA intends to draft and issue documents summarizing EPA's reconsideration of the Interim Decision's volatilization analysis, risk-benefit balancing, and assessment of costs, as well as any other issue requiring reconsideration or supplementation. Those documents are likely to take the form of an addendum to a risk assessment, benefits assessment, and/or another stand-alone clarification statement. EPA intends to issue those documents within one year of this Court's order granting EPA's motion for a voluntary remand. After releasing those documents, EPA intends to provide an opportunity for public comment. A typical public comment period might be 60 days or more depending on the complexity of the issue and if any additional time is requested.

21. Following the opportunity for public comment on the supplemental documents, EPA will consider substantive comments and determine next steps for registration review. Given the unknown nature of the specific documents to be issued, as well as the anticipated comments on those documents, it is difficult to predict exactly what those next steps might be or how long they would take to complete. Additional analyses could be necessary to address public comments; new issues could be raised that were not previously considered. The next steps may include affirmation of previous conclusion(s), revisions to the human health risk assessment, developing a revised proposed registration review decision, and/or initiating work to finalize registration review for paraquat.

III. Vacatur of the Interim Decision Would Be Disruptive.

22. Vacatur of the Interim Decision would be disruptive. The Interim Decision required registrants to adopt measures

necessary to mitigate certain human health and ecological risks of concern. [ER-029.] The mitigation measures include, *inter alia*, limits to aerial applications, the prohibition of the use of human flaggers, the requirement that applicators use closed cabs and respirators, the prohibition of the use of mechanically pressurized handguns and backpack sprayers, the requirement of restricted entry intervals, the use of a "non-target organism advisory," and herbicide resistance management. [ER-030.] Registrants have already submitted labels including the new mitigation requirements and EPA has already approved those labels. Vacatur of the Interim Decision could create confusion concerning whether those mitigation measures continue to be necessary for paraquat products.

IV. Conclusion

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

MICHAEL GOODIS Digitally signed by MICHAEL GOODIS Date: 2022.09.23 16:21:07 -04'00'

_____, September 23, 2022

Michael Goodis
Deputy Director of Programs
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