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

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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
Supplemental Administrative Document	EPA's Preliminary Supplemental Consideration of Certain Issues in Support of its Interim Registration Review Decision for Paraquat (), Docket Number EPA-HQ-OPP-2011-0855 (Jan. 30, 2024), available at https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0318.

INTRODUCTION

In September 2021, Petitioners challenged an interim registration review decision by the Environmental Protection Agency (EPA) for the herbicide paraquat dichloride under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Thereafter, the Court granted EPA's motion to put the case into an abeyance to allow EPA additional time to consider the substantive issues raised in Petitioners' opening brief.

EPA has now determined that more information is necessary to evaluate aspects of paraquat relevant to its registration review decision. Accordingly, EPA respectfully requests that the Court grant this motion for voluntary remand so that EPA may withdraw the challenged decision. Withdrawal of the challenged decision is a more prudent use of limited agency resources than defending a decision that could change.

Intervenor Syngenta reserves its right to respond to the motion. Petitioners oppose this motion and intend to file a response.

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 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)). 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).

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. *Id.* § 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 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

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

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 identified various risk-mitigation measures that were necessary 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.

Petitioners sought judicial review of the Interim Decision and filed a brief challenging different aspects of the Interim Decision, including concerns related to EPA's assessment of human health risks. Pet. for Review, Dkt. Entry 1-4, Doc. No. 12237971; Pet'rs' Opening Br., Dkt. Entry 27-1, Doc. No. 12456190.

2. Abeyance and EPA's Intentions

In September 2022, the Court granted EPA's unopposed motion to hold the case in abeyance to allow the Agency to further consider issues raised by

[2] At this time, all product labels for which mitigation measures were required have been submitted by registrants, and EPA has approved those labels. Ex. 1, Declaration of Edward Messina ("Messina Decl.") ¶ 11.

Petitioners in relation to the Interim Decision. Order, Dkt. Entry 52, Doc. No. 12615122; Mot. Hold Case Abeyance, Dkt. Entry 51-1, Doc. No. 12593667. In its declaration supporting the abeyance motion, EPA stated its intention to publish preliminary administrative documents summarizing EPA's further consideration of those issues by January 2024 for public comment and then, after taking public comment into consideration, to finalize those administrative documents by January 17, 2025. Declaration of Michael Goodis, Dkt. Entry 51-2, Doc. No. 12593667. EPA also noted its intention to present next steps at that time, if additional mitigation was determined to be appropriate. *Id.*

During the abeyance, EPA has acted in accordance with its plan. In January 2024, EPA issued a preliminary administrative document further considering issues raised in Petitioners' brief, *see* EPA's Preliminary Supplemental Consideration of Certain Issues in Support of its Interim Registration Review Decision for Paraquat (Supplemental Administrative Document), Docket Number EPA-HQ-OPP-2011-0855 (Jan. 30, 2024),[3] and EPA subsequently took public comment on that document, Status Rpt., Dkt. Entry 61-1, Doc. No. 12906948; Messina Decl. ¶ 16. In the months since, EPA has been considering public comment and reviewing additional information that was submitted prior to the

[3] Available at https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0318.

release of the Supplemental Administrative Document. Status Rpt., Dkt. Entry 61-1, Doc. No. 12906948; Messina Decl. ¶ 16.[4]

One issue raised by Petitioners in their opening brief and on which EPA has been focused is paraquat's potential to volatilize. Messina Decl. ¶ 18. Volatilization occurs when the residues of an applied pesticide "change to a vapor or gaseous state due to chemical characteristics and then travel[] through the air from the application site to other offsite areas." Supplemental Administrative Document at 36. In the human health risk assessment for paraquat, which the Interim Decision finalized, EPA concluded that "no bystander post-application inhalation exposures would be expected from volatilization following applications of paraquat."[5] ER-431. Since taking that position, EPA has received new information about paraquat's vapor pressure submitted by a paraquat registrant, which creates a greater level of uncertainty about paraquat's potential to volatilize. Messina Decl. ¶¶ 16, 18-19. EPA now wishes to further investigate this issue. *Id.*

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[4] In November 2024, the Clerk administratively closed the petition. Order, Dkt Entry 62, Doc. No. 12913972.

[5] More specifically, the Draft Human Health Risk Assessment made this volatilization finding specific to applications of cotton in California based on the results of a 1987 California Air Resources Board study. ER-431. The Assessment acknowledged the uncertainties of the underlying data, stating that "[a]dditional air monitoring studies would be necessary to make a more definitive risk finding relating to paraquat volatilization exposures." *Id.*

Investigation of the volatilization issue could require a significant amount of time. *Id.* ¶ 19 (estimating at least four years). The typical process for obtaining such data is for EPA to issue a Data Call-In, in which EPA would require registrants to submit information concerning volatilization. *Id.* (citing 7 U.S.C. § 136a(c)(2)(B)). EPA first requires time to draft the Data Call-In. *Id.* Then, the Office of Management and Budget must review the Data Call-In. *Id.* Once approved, the Data Call-in will be published, and paraquat registrants will conduct the necessary study and submit the outcome to the Agency. *Id.* After receiving the registrants' submission, EPA would then require time to consider the study results and how they affect EPA's determinations concerning the potential of paraquat to volatilize and to cause potential non-bystander exposure. *Id.* Depending on the results, EPA may need to amend the human health risk assessment that underlies the current interim registration review decision, as well as to solicit additional public comment. *Id.*

Due to the need to revisit the volatilization issue, the underlying human health risk assessment and the Interim Decision which is based on that assessment could change. *Id.* ¶ 21. For judicial and governmental economy purposes, EPA

believes it is most efficient to withdraw the current Interim Decision while EPA further assesses the underlying science on which that decision was based.[6] *Id.*

Because EPA is seeking a remand to withdraw the Interim Decision, it does not intend to issue the final version of the Supplemental Administrative Document that was originally anticipated in EPA's abeyance plan. *Id.* ¶ 21. Since that document was intended to further consider issues raised in the Petitioners' Opening Brief challenging the Interim Decision, the withdrawal of that Interim Decision negates the need for that additional document. *Id.* Instead, EPA wishes to focus its limited resources on other administrative activities that will facilitate the completion of its registration review obligations. *Id.*

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.

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[6] Although EPA intends to withdraw the Interim Decision to further investigate the volatilization issue, other scientific findings underlying the Interim Decision remain the same, including that mitigation measures are necessary to address certain risks of paraquat use. Messina Decl. ¶ 20. These risks would need to be taken into consideration if any new paraquat labels or label amendments were submitted to EPA. *Id.*

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). "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).

ARGUMENT

Voluntary remand is appropriate here. EPA seeks a remand so that it may "reconsider its initial action[']s]" conclusion concerning the potential for paraquat to volatilize. *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (explaining that voluntary remand of a challenged agency action is proper when the agency seeks to reconsider its initial action (citing *SKF USA Inc. v. United States*, 254 F.3d 1022, 1029 (Fed. Cir. 2001)). Petitioners alleged that EPA failed to protect bystanders from inhalation exposures to indirect paraquat drift through the volatilization of deposited paraquat. Pet'rs' Opening Br., Dkt. Entry 27-1,

Doc. No. 12456190 at 44. EPA acknowledges that more information is needed to assess paraquat's potential to volatilize. Messina Decl. ¶¶ 18-19. For this reason, a remand is appropriate to further consider paraquat's potential to volatilize and whether paraquat continues to meet the FIFRA registration standard. *Id.* ¶ 20; *see also SKF USA Inc.*, 254 F.3d at 1029 (explaining that an agency may request a remand because it "wish[es] to consider further the governing statute, or the procedures that were followed").

On remand, EPA intends to withdraw the Interim Decision and will promptly do so once the Court rules on this motion. Messina Decl. ¶ 17. EPA plans to withdraw the Interim Decision within 60 days of the Court's issuance of the mandate granting the parties' motion for remand.[7] *Id.* Vacatur is not necessary, given EPA's stated intention to promptly withdraw the Interim Decision. *See id.*; Order, *Ctr. for Food Safety v. EPA*, No. 22-70118 (9th Cir. Apr. 21, 2023), Dkt. Entry 30, Doc. No. 12700331 (granting motion to remand to withdraw interim registration review decision for fungicide).

In sum, a voluntary remand is appropriate because it will allow EPA to withdraw the Interim Decision and thereby moot this case. EPA will then further

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[7] EPA has not unilaterally withdrawn the Interim Decision because EPA interprets section 16(b) of FIFRA to grant this Court "exclusive jurisdiction to affirm or set aside" the Interim Decision while a petition for review is pending. 7 U.S.C. § 136n(b).

consider paraquat's potential to volatilize and take further action as appropriate. Messina Decl. ¶¶ 17-22. Moreover, EPA's request for remand will not prejudice any of the parties; the parties will have the opportunity to challenge subsequent final agency action related to paraquat's registration or any agency failure to meet relevant statutory deadlines. Granting this request will also not create uncertainty for the public about what mitigation measures are necessary for paraquat use; the mitigation measures identified in the Interim Decision have been fully implemented by the registrants in the form of label amendments, and any new paraquat labels or label amendments submitted to EPA would need to account for paraquat risks regardless of Interim Decision withdrawal. *Id.* ¶ 20. Finally, granting this request will benefit the parties, as it will preserve party resources by obviating the need for additional briefing on the merits of Petitioners' claims.

CONCLUSION

For these reasons, the Court should grant EPA's motion and remand the Interim Decision to EPA.

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 2,447 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

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

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

DECLARATION OF EDWARD MESSINA IN SUPPORT OF EPA'S MOTION FOR REMAND

I. Background

A. Introduction

1. I, Edward Messina, 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 Director of the Office of Pesticide Programs (OPP), EPA. I have held this position since July 2021. Prior to becoming the Director of OPP, I served as the Acting Director of OPP from June 2020 to July 2021, the Deputy Office Director (Programs) of OPP from June 2019 to June 2020, and the Acting Deputy Officer Director (Programs) of OPP from March 2018 to June 2019. Prior to becoming Acting Deputy Officer Director (Programs) of OPP, I served in various positions within EPA since September 1996, including in the Office of Enforcement and Compliance Assurance and in the Office of Regional Counsel. I have a B.A. in Economics from Brandeis University and a J.D. and Master's in Environmental Law and Policy from Vermont Law School.

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

[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,

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.

5. The Environmental Fate and Effects Division (EFED) assesses the environmental fate and ecological risk of pesticides. 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. 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.

6. In my role as Director of OPP, among other duties, I am responsible for the management, coordination, and oversight of national pesticide programs under FIFRA and the Endangered Species Act (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 all regulatory activities associated with pesticides, including pesticide registrations,

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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.

amendments to registrations, and registration review cases. I also oversee the evaluation of listed species and their designated critical habitats to obtain compliance with the ESA for pesticide actions through coordination with other federal agencies. In addition, I am responsible for management and operational responsibilities across a full range of programmatic issues, 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 Remand. The purpose of this declaration is to describe EPA's identification of additional work that is needed in order to complete the registration review of paraquat and that supports the withdrawal of its Interim Registration Review Decision for paraquat.

B. Statutory and Regulatory Background

8. 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 was October 1, 2022. 7 U.S.C. § 136a(g)(1)(A)(iii)(I). The Consolidated Appropriations Act, 2023 extended that deadline until October 1, 2026. Pub. L. No. 117-328, § 711(a) (2022).

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 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. *Id.* § 155.58(a).

C. Paraquat Interim Registration Review Decision

11. 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 finalized the Agency's 2019 Draft Human Health Risk Assessment and 2019 Preliminary Ecological Risk Assessment for registration review for paraquat. [1-ER-9.][2] 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

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

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. Any change to the product labels would require submission of new label amendments and a determination by EPA that the new language complied with FIFRA. EPA's current analysis of the risks and benefits of paraquat does not support removing those mitigation measures or approving new labels without those same measures.

12. 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. As for the requested relief, Petitioners requested that the Court remand without vacating the Interim Decision to EPA with a deadline for a proposed revised registration review decision within one year of the Court's decision and finalizing that decision within two years.

II. Summary of EPA Activities During Abeyance Period

13. On November 22, 2022, EPA filed an unopposed motion with the Court seeking to hold the case in abeyance while it considered the substantive issues raised in the opening brief filed by Petitioners. EPA additionally stated its intention to

memorialize these considerations in a standalone document(s), take public comment, and after considering significant public comments, update and finalize the standalone document(s) by January 17, 2025. The Court granted this motion on December 20, 2022.

14. The substantive issues raised in the Petitioners' opening brief can be grouped into three different categories: human-health issues, benefits issues, and risk-benefit balancing issues.

15. Consistent with the intentions articulated in its November 2022 Motion to Hold Case in Abeyance and For Related Relief, on January 31, 2024, EPA issued its Preliminary Supplemental Consideration of Certain Issues in Support of its Interim Registration Review Decision for Paraquat ("Supplemental Document") further considering the three categories of issues raised by Petitioners. *See* EPA, Supplemental Document, https://www.regulations.gov/document/EPA-HQ-OPP-2011-0855-0318. The Supplemental Document was available for public comment until April 1, 2024. 89 Fed. Reg. 6521 (Feb. 1, 2024).

16. Throughout 2024, EPA has been working to consider all significant comments received during the public comment period, as well as review additional information that was submitted prior to the release of the Supplemental Document. That information consisted of studies and information relating to the potential health impacts of paraquat as well as a new vapor pressure study on paraquat submitted by Syngenta Crop Protection, LLC in January 2024. In addition, EPA intends to review and consider the recent report issued by the California Environmental Protection Agency Department of Pesticide Regulation, "Preliminary Report of the Potential Human Health Outcomes Resulting from Paraquat Exposure" in December 2024.

III. Planned Administrative Action for Voluntary Remand

17. As set forth in EPA's Motion for Remand, EPA is seeking a voluntary remand to withdraw the paraquat Interim Decision. For the reasons articulated below, the Interim Decision should be withdrawn as the Agency recognizes that additional action is necessary to resolve the volatilization data gaps. EPA intends to promptly withdraw the Interim Decision and anticipates withdrawing the Interim Decision within 60 days of the Court issuance of the mandate granting its motion for remand.

18. After reviewing the new vapor pressure study, EPA used this data to conduct a new volatilization screening-level assessment. The new volatilization analysis indicates greater uncertainty around the potential for paraquat to volatilize and exceed concentration levels of concern than was previously determined in the Interim Decision. Based on this new analysis and the conflicting data currently before the Agency, EPA believes that a field volatility study is necessary to resolve the uncertainty and determine potential inhalation risks to bystanders from the volatilization of paraquat. EPA intends to issue a data call-in to require the submission of additional data to allow EPA to assess the potential for bystander exposure risks from the volatilization of paraquat. The new vapor pressure study and the results of the volatilization analysis indicate that additional work needs to be done to estimate the potential inhalation risks to bystanders and determine if any mitigation is necessary.

19. The typical process for requiring data is for EPA to prepare a Data Call-In (DCI), in which EPA would require registrants to submit information concerning volatilization. *See* FIFRA section 3(c)(2)(B), 7 U.S.C. 136a(c)(2)(B). Before EPA issues the DCI to the relevant registrant(s), the Office of Management and Budget must review the DCI. Next, registrants conduct the study and submit the results and/or a final report of the results to the Agency. After the data is

submitted, EPA would need time to consider the data and how it affects EPA's determinations concerning the potential of paraquat to volatilize and any impact on potential non-bystander exposure. Depending on the results, EPA may need to amend its risk assessment and solicit further of public comment. This entire process can take several years, depending on the complexity of the study, the quickness of the OMB review and internal drafting of the DCI, as well as registrant timeliness in meeting the DCI deadlines and subsequent Agency review of the data submission. For the volatilization data at issue, EPA expects that the process would likely take at least four years.

20. Upon revisiting the issue of volatilization, the underlying human health risk assessment and the regulatory decision on which it is based could change. As a result, EPA would like to withdraw the current Interim Decision rather than expend resources defending a decision that could change. Additionally, as explained above, the mitigation measures identified in the Interim Decision have been fully implemented by the registrants in the form of label amendments. Even though EPA would be withdrawing the Interim Decision to further investigate the issue of volatilization, other underlying scientific findings concerning the risks and benefits of paraquat, including those that warranted the mitigation measures identified in the Interim Decision, remain the same and would need to be taken into consideration if any new paraquat labels or label amendments were submitted to EPA. Withdrawing the Interim Decision does not mean that the risk concerns that supported the mitigation measures in the first place no longer exist.

21. Because EPA is seeking a Motion for Remand to withdraw the Interim Decision, EPA does not intend to update the Supplemental Document as indicated in its November 2022 Motion to Hold Case in Abeyance and For Related Relief. Since that document was intended to further consider issues

raised in the Petitioners' Opening Brief challenging the Interim Decision, the withdrawal of that Interim Decision negates the need for that additional document. EPA wishes to focus its limited resources on other administrative activities that will facilitate completion of its registration review obligations. As part of that ongoing work, EPA intends to consider the best course of action for the release of its scientific analysis of the additional submissions received during this abeyance period.

IV. Conclusion

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

Digitally signed by EDWARD MESSINA
Date: 2025.01.17 11:37:02 -05'00'

_____, January 17, 2025

Edward Messina
Director
Office of Pesticide Programs
U.S. Environmental Protection Agency