

IN THE UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

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| CALIFORNIA RURAL LEGAL                 | ) |              |
| ASSISTANCE FOUNDATION, <i>et al.</i> , | ) |              |
|                                        | ) |              |
| Petitioners,                           | ) |              |
|                                        | ) |              |
| v.                                     | ) | No. 21-71287 |
|                                        | ) |              |
| U.S. ENVIRONMENTAL PROTECTION          | ) |              |
| AGENCY, <i>et al.</i> ,                | ) |              |
|                                        | ) |              |
| 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<sup>1</sup> that are currently registered under

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<sup>1</sup>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.]<sup>2</sup> 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

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<sup>2</sup> 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.

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\_\_\_\_\_, January 17, 2025

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