# IN THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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

## **STATUS REPORT**

Respondent United States Environmental Protection Agency, et al., (EPA) files this status report pursuant to the Court's April 28, 2025 order holding this petition in abeyance. Dkt. No. 74. This Court directed EPA to file written status reports within 90 days of the Court's April 28, 2025 order and every 90 days thereafter. Id. This is the first such status report.

EPA states as follows:

- 1. In September 2021, Petitioners challenged an interim registration review decision by EPA for the herbicide paraquat dichloride under the Federal Insecticide, Fungicide, and Rodenticide Act. Dkt. 1. Thereafter, the Court granted EPA's motion to put the case into an abeyance to allow EPA time to further consider the substantive issues raised in Petitioners' opening brief. Dkt. 52. During this initial abeyance period, EPA obtained new information that created greater uncertainty about paraquat's potential to volatilize. Dkt. 71. Accordingly, EPA supported Intervenor Syngenta's motion to put the case into a second abeyance while EPA further considers the volatilization issue. *Id.* The Court granted the motion and held this case in abeyance. Dkt. 74.
- 2. As described in EPA's attached declaration, EPA has determined that a field volatility study is necessary to further assess paraquat's potential for volatilization. Ex. 1, Declaration of Edward Messina ("Messina Decl.") ¶ 14. A field volatility study will help EPA

<sup>&</sup>lt;sup>1</sup> 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." Dkt. 63 at 7 (internal quotation marks and brackets removed).

to determine the potential inhalation risks of paraquat for people who are not involved in the pesticide application process. *See id*.

- 3. EPA intends to obtain this study via a Data Call-In, *id*. ¶ 16, in which EPA requires registrants to submit additional data or information, *see* 7 U.S.C. § 136a(c)(2)(B). Before EPA may issue a Data Call-In to paraquat registrants, the Office of Management and Budget must review and approve the Data Call-In. 44 U.S.C. § 3507(a).
- 4. Currently, EPA is preparing this Data Call-In notice and expects to transmit it to the Office of Management and Budget for review and approval by fall 2025. Messina Decl. ¶ 17. EPA then expects to issue the Data Call-In to registrants by early 2026. *Id*.

Respectfully submitted,

ADAM R.F. GUSTAFSON
Acting Assistant Attorney General

Is/ Elliot Higgins
ELLIOT HIGGINS
Trial Attorney
U.S. Department of Justice
Environment and Natural Resource

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Division

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Environmental Defense Section P.O. Box 7611 Washington, D.C. 20044 (202) 598-0240 elliot.higgins@usdoj.gov

Attorney for Respondents U.S. Environmental Protection Agency et al.

#### CERTIFICATE OF COMPLIANCE

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

<u>/s/ Elliot Higgins</u> Elliot Higgins

Counsel for Respondents

## CERTIFICATE OF SERVICE

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

<u>/s/ Elliot Higgins</u> Elliot Higgins

Counsel for Respondents

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| SYNGENTA CROP PROTECTION, LLC,                        | )<br>)       |
| Respondent-Intervenor.                                | )<br>)       |

# DECLARATION OF EDWARD MESSINA IN SUPPORT OF EPA'S STATUS REPORT

### 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

<sup>&</sup>lt;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. 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, 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.
- 6. This declaration is filed in support of EPA's Current Status Report. The purpose of this declaration is to describe the present status of EPA's further consideration of issues related to the EPA action at issue in this petition—the Interim Registration Review decision for paraquat (Interim Decision).

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.

### B. Statutory and Regulatory Background

- 7. 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.
- 8. 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).
- 9. 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).

10. In accordance with FIFRA Section 3(c)(2)(B), EPA is required to issue a Data Call-In (DCI) when it determines that additional data are required to "maintain in effect" an existing pesticide registration. 7 U.S.C. § 136a(c)(2)(B)(i). Before EPA issues a DCI to the relevant registrant(s), the Office of Management and Budget must review and approve the DCI. See 44 U.S.C. § 3507. After the DCI is issued, the registrant must, within ninety days, provide evidence to EPA that they are "taking appropriate steps to secure the additional data." *Id.* § 136a(c)(2)(B)(ii). Additionally, if a registrant fails to take appropriate steps to secure the data within the time required by EPA, then EPA may issue a notice of intent to suspend such registrant's registration. *Id.* § 136a(c)(2)(B)(iv).

### C. Paraquat Interim Registration Review Decision

11. In August 2021, EPA published its Interim Registration Review Decision for paraguat (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 paraguat's registration review that were complete and implement interim risk mitigation measures. 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 paraguat. [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

 $<sup>^{\</sup>rm 2}$  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.

12. On September 23, 2021, the California Rural Legal Assistance Foundation, et al. (Petitioners) filed a Petition for Review challenging the Interim Decision. The Petitioners' brief, filed on May 25, 2022, focused on human healthrelated concerns and questions about the Agency's riskbenefit balancing discussion. In particular, the Petitioners challenged the Agency's assessment of Parkinson's risk, analysis of exposure to paraguat from volatilization, and analysis of costs and benefits associated with paraguat 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. Status of EPA Activities During Present Abeyance Period

- 13. On February 10, 2025, one of the registrants of Paraquat, Syngenta, filed a motion to hold the case in abeyance while EPA further investigates paraquat's capacity to volatilize. On March 17, 2025, EPA filed a reply in support of this motion and on April 28, 2025, the Court granted the motion.
- 14. By way of background, EPA has determined that a vapor pressure study submitted by Syngenta in 2024 increases the uncertainty around the potential for paraquat to volatilize

and exceed concentration levels of concern than was previously determined in the Interim Decision. In order to resolve this uncertainty and determine potential inhalation risks to bystanders from the volatilization of paraquat, EPA has determined that a field volatility study is necessary. A field volatility study specific to paraquat applications can directly inform the inhalation bystander analysis by providing flux measurements that take into account field application and meteorological conditions such as temperature, rainfall, humidity, wind speeds, soil characteristics, application rate, application timing, crop target, product formulation, application type, and equipment that can influence flux and therefore the air concentration of pesticide residues.

- 15. There are several other studies, in addition to the field volatility study, which may be used to refine EPA's volatilization assessment such as studies on the physiochemical properties of paraquat.
- 16. EPA is currently considering which data, in addition to the field volatility study, to request from Syngenta, and all other technical registrants, in a forthcoming DCI.
- 17. EPA is in the final stages of preparing this DCI request and expects to transmit it to OMB for review and approval by fall 2025. Once the DCI has been approved by OMB, EPA will then issue the DCI to the paraquat registrants. EPA expects to issue the DCI by early 2026.

## III. 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: 2025.07.25
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Digitally signed by EDWARD MESSINA Date: 2025.07.25

**Edward Messina** 

Director

Office of Pesticide Programs

U.S. Environmental Protection Agency