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
Office of Pesticide Programs
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