No. 21-71287

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

CALIFORNIA RURAL LEGAL ASSISTANCE FOUNDATION; FARMWORKER ASSOCIATION OF FLORIDA, INC.; THE MICHAEL J. FOX FOUNDATION FOR PARKINSON'S RESEARCH; FARMWORKER JUSTICE; ALIANZA NACIONAL DE CAMPESINAS; PESTICIDE ACTION NETWORK NORTH AMERICA; CENTER FOR BIOLOGICAL DIVERSITY; TOXIC FREE NORTH CAROLINA,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY; MICHAEL REGAN, in his official capacity as Administrator of the United States Environmental Protection Agency,

Respondents,

and

SYNGENTA CROP PROTECTION, LLC

Intervenor-Respondent.

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

PETITIONERS' OPENING BRIEF

Dated: May 25, 2022 *Counsel Listed on the Following Page*

JONATHAN KALMUSS KATZ
KARTIK S. MADIRAJU
Earthjustice
48 Wall Street
19th Floor
New York, NY 10005
T: (212) 845-7376
jkalmusskatz@earthjustice.org
kmadiraju@earthjustice.org

PATTI A. GOLDMAN
Earthjustice
810 Third Avenue, Suite 610
Seattle, WA 98104
T: (206) 343-7340
pgoldman@earthjustice.org

GREGORY C. LOARIE
Earthjustice
50 California Street, Suite 500
San Francisco, CA 94111
T: (415) 217-2000
gloarie@earthjustice.org

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Petitioners California Rural Legal Assistance Foundation, Farmworker Association of Florida, Inc., The Michael J. Fox Foundation for Parkinson's Research, Farmworker Justice, Alianza Nacional de Campesinas, Pesticide Action Network North America, Center for Biological Diversity, and Toxic Free North Carolina state that they are non-profit organizations. None of the petitioners has a parent corporation and no publicly held corporation owns 10% or more of any petitioner organization's stock.

DATED: May 25, 2022

Respectfully submitted,

s/ Jonathan Kalmuss-Katz
Jonathan Kalmuss-Katz

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PRELIMINARY STATEMENT

Of all the chemicals used to kill weeds and to dry out crops for harvest, paraquat is one of the most dangerous to farmworkers and agricultural communities. A single sip can kill, yet millions of pounds are sprayed on U.S. cropland each year, causing Parkinson's disease, lung and kidney damage, and, when paraquat is ingested, death. More than 50 countries have banned paraquat because of those severe risks. The United States Environmental Protection Agency ("EPA") reauthorized the extensive use of paraquat despite them.

EPA's July 2021 interim registration review decision at issue in this case (the "Registration Decision"), which approves the use of paraquat for up to 15 additional years, is unsupported by the evidentiary record and contrary to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Under FIFRA, EPA cannot approve or maintain the registration of any pesticide—including herbicides like paraquat—unless it establishes the pesticide will not cause "unreasonable adverse effects" to human health and the environment. 7 U.S.C. § 136a(c)(5). When reviewing paraquat's registration, however, EPA repeatedly understated the extent of paraquat's adverse effects, and it failed to lawfully address the serious risks it did identify.

First, EPA misinterpreted the evidence and violated its own risk assessment practices to dismiss the connection between paraquat use and Parkinson's disease, a

devastating neurological condition with no known cure. EPA also failed to consider known exposures to people who live and work around the fields where paraquat is sprayed, further underestimating paraquat's risks. Despite those errors, EPA still found that paraquat will pose risks of concern to human health and the environment. In its Registration Decision, EPA allowed those risks to continue because it claimed they were outweighed by paraquat's benefits to growers. But EPA made that claim without ever considering the magnitude of paraquat's unaddressed risks or their costs to workers and agricultural communities, violating FIFRA's clear requirement to take such costs into account.

EPA's flawed risk assessment and one-sided weighing of paraquat's risks and benefits will leave people more likely to develop Parkinson's disease and suffer other serious harms, merely because of the jobs they hold or the places they live. Because paraquat's registration is unsupported by substantial evidence and does not satisfy FIFRA's registration requirements, Petitioners ask the Court to remand the Registration Decision so EPA can undertake the required analyses and afford workers and communities the protection FIFRA demands.

STATEMENT OF JURISDICTION

This Court has jurisdiction under FIFRA, which provides for review in the courts of appeals of "any order issued by the Administrator following a public hearing." 7 U.S.C. § 136n(b). This Registration Decision is an order issued by the

EPA Administrator, and this Court has ruled that a public comment process, as EPA held here, constitutes a "public hearing" within the meaning of FIFRA. *United Farm Workers of Am., AFL-CIO v. EPA*, 592 F.3d 1080, 1082-83 (9th Cir. 2010); 85 Fed. Reg. 67,536 (Oct. 23, 2020) (soliciting comment on proposed Registration Decision).

Petitioners may bring this challenge because each was "a party" to the proceedings before EPA, having submitted substantive written comments, and they are "adversely affected" by the Registration Decision. 7 U.S.C. § 136n(b); 2-ER-96–115; 2-ER-254–260; *see also* pp. 26–29 *infra* (describing Petitioners' harms). Venue is proper because several petitioners have places of business within this Circuit. *See, e.g.,* PA-013 (¶ 1); PA-021 (¶ 4). Petitioners timely filed their petition for review on September 24, 2021, within sixty days of entry of EPA's Registration Decision. *See* Pet. for Review at 2 (Dkt. No. 1-4). Per EPA regulations, that decision was entered for the purpose of judicial review on or after July 27, 2021, "the date that is two weeks after it is signed." 40 C.F.R. § 23.6; 1-ER-003 (signed July 13, 2021); *see Nat'l Fam. Farm Coal. v. EPA* ("*Family Farm II*"), 966 F.3d 893, 907–08 (9th Cir. 2020).

STATEMENT OF ISSUES

FIFRA requires a pesticide registration to be supported by "substantial evidence" that the pesticide "will not generally cause unreasonable adverse effects"

to human health or the environment. 7 U.S.C. §§ 136a(c)(5)(D), 136n(b). To make that finding, EPA must assess the pesticide's risks and determine whether any risks of concern are outweighed by the pesticide's benefits, "taking into account the economic, social, and environmental costs …" 7 U.S.C. § 136(bb). Does the Registration Decision violate those requirements where:

1. EPA dismissed risks of Parkinson's disease based on assertions that are unsupported by the studies that EPA relied upon and erroneously assumed that measures that fail to protect against paraquat's respiratory and dermal risks of concern will protect against Parkinson's disease?

2. EPA failed to assess the risks to bystanders who are directly exposed to paraquat spray that drifts from the application site and to people who inhale paraquat after it falls to the ground and then volatilizes or is resuspended as dust?

3. EPA skewed its analysis of paraquat's risks and benefits by conducting a one-sided assessment that measures paraquat's economic benefits to growers but does not measure the substantial costs to exposed workers, agricultural communities, and the environment, and fails to provide any explanation for EPA's conclusion that paraquat's benefits outweigh its risks?

STATUTORY AND REGULATORY BACKGROUND[1]

Congress enacted FIFRA to "protect human health and prevent environmental harm from pesticides." *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1032 (9th Cir. 2005). At its core, FIFRA prohibits the sale or distribution of a pesticide that has not been approved—or "registered"—by EPA. 7 U.S.C. § 136a(a).

Prior to registering or reregistering a pesticide, EPA must find that the pesticide "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). An "unreasonable adverse effect on the environment" is defined as "any unreasonable risk to [people] or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide." *Id.* § 136(bb). Therefore, once EPA identifies a risk associated with a pesticide, it must weigh that risk—and its associated economic, social, and environmental costs—against the pesticide's benefits, and may approve the pesticide's registration only if it "demonstrate[s] that the benefits outweigh that risk." *Env't Def. Fund v. EPA*, 548 F.2d 998, 1005 (D.C. Cir. 1976), *abrogated on other grounds by Dir., Off. of Workers' Comp. Programs, Dep't of Lab. v. Greenwich Collieries*, 512 U.S. 267 (1994); *see also* S. Rep. No. 92-970, S. Comm.

[1] Pursuant to Circuit Rule 28-2.7, Petitioners attach a separate addendum containing excerpts of pertinent statutes and regulations.

on Com., at 11 (1972) (expressing Congress' intent that "any adverse effect ought not to be tolerated unless there are overriding benefits from the use of a pesticide").

FIFRA requires EPA to review each pesticide registration at least once every 15 years to determine whether the pesticide still satisfies the FIFRA registration standard. 7 U.S.C. § 136a(g); *see also* 40 C.F.R. § 155.53(a). Registration review is designed to "ensure that pesticides do not remain registered once new data has shown them to be harmful to humans or the environment." *Family Farm II*, 966 F.3d at 918. During the registration review process, EPA must evaluate the latest information regarding a pesticide's effects on human health and the environment and determine whether the pesticide presents any "unreasonable adverse effects." 40 C.F.R. § 155.53(a); 7 U.S.C. § 136a(c)(5)(D).

The registration review process culminates with EPA's determination of "whether a pesticide meets, or does not meet, the standard for registration in FIFRA," including the absence of any unreasonable adverse effect. 40 C.F.R. § 155.57. This decision must "state [EPA's] proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings." *Id.* § 155.58(b)(1). If a pesticide does not meet FIFRA's registration standard, EPA can cancel the pesticide's registrations, *id.* § 155.40(a)(2), or impose additional mitigation measures to eliminate the pesticide's unreasonable adverse effects. *Id.* § 155.58(b)(2). Where, as here, EPA has completed parts of the registration review

process, EPA may issue an "interim registration review decision" that constitutes its decision on the completed parts of the process. *See id.* § 155.56.

STATEMENT OF THE CASE

A. Paraquat is Widely Used and Highly Toxic.

Paraquat—also known as paraquat dichloride—is one of the most widely used herbicides in the U.S. 1-ER-012. EPA initially registered paraquat for sale in 1964, and it has long been used in several different pesticide products, including the Gramoxone product line produced by Intervenor-Respondent Syngenta. 1-ER-7, 1-ER-18.

As a "non-selective" herbicide, paraquat is designed to kill all plants it contacts. 1-ER-6–7. In addition to killing weeds before, during, and after the growing season, paraquat is used as a desiccant to dry out and kill cotton and other crops before harvest. *Id*.

Those uses result in exposures to the pesticide handlers who mix, load, and apply paraquat; to the farmworkers who harvest crops, prune trees and vines, and conduct other work in the fields where paraquat is sprayed; and to the bystanders who live or work near those fields.[2] Each year, handlers spray more than eight million pounds of paraquat from low-flying airplanes and helicopters, tractor-pulled booms, and backpacks and other sprayers with hand-held wands. 1-ER-12.

[2] The term "workers," as used herein, encompasses both handlers and farmworkers.

The spraying of paraquat disperses droplets and particles that workers can breathe in and that can absorb into their skin, clothing and head coverings. *See* 3-ER-500–505. Those droplets and particles can also blow into surrounding areas, a process known as pesticide drift. 3-ER-500. Bystanders who live; work; or attend school, daycare, or church nearby can come into contact with pesticide drift while it is in the air or after it deposits on the ground. *Id.* People can also be exposed when they inhale, touch, or accidentally ingest deposited paraquat that volatilizes or is resuspended as dust. 3-ER-500–505; 2-ER-129.

Paraquat exposures cause severe harms. EPA has found that paraquat is associated with "lung inflammation, scarring, and compromised lung function," as well as "inflammation and necrosis of the kidneys," developmental delays, eye damage, and other serious health effects. 3-ER-407. A single exposure to paraquat can cause lasting respiratory harm, *id.*, and dermal contact "common[ly]" results in "incidents … severe enough to require skin grafts as a result of paraquat leaks, spills, and spraying." 3-ER-563. People exposed to paraquat have also reported shortness of breath, blurred vision, hypertension, and other injuries. 3-ER-553.

When ingested, paraquat is often deadly. *See* 3-ER-567; *see also* 3-ER-569–570 (describing deaths attributed to paraquat exposure, including a 15-month-old infant who accidentally sipped paraquat and two adults who inhaled paraquat drift from a neighboring farm). In 2016, after dozens of reported deaths from paraquat

poisoning, EPA imposed additional mitigation measures designed to prevent people from drinking and spilling paraquat and to prohibit paraquat application by non-certified applicators. 3-ER-559–560.[3] EPA continued to allow the use of paraquat, however, and people continued to suffer harm as a result. *See* 3-ER-556–557 (describing post-2016 paraquat exposure incidents).

Over the last 15 years, a substantial body of evidence has connected chronic, low-dose paraquat exposures to Parkinson's disease, a degenerative neurological condition that afflicts approximately one million people in the United States. 2-ER-254. Parkinson's disease is associated with a loss of neurons that produce dopamine, a chemical that coordinates movement in the body. *Id.* People with Parkinson's disease often experience stiffness and trembling, difficulty walking, and other symptoms that can worsen over time. There is currently no therapy to slow, stop, or reverse the progression of Parkinson's disease, and there is no cure. *Id*.

"A plethora of studies have shown that exposure to paraquat is correlated positively with [Parkinson's disease] in humans." 3-ER-551. Researchers from the National Institute of Health, analyzing data drawn from a survey of more than 50,000 pesticide applicators, found that people who applied paraquat were more

[3] As a "restricted use pesticide," paraquat can only be applied by certified pesticide applicators.

than twice as likely to develop Parkinson's disease as those who applied other pesticides. 3-ER-624; 2-ER-255. Many people experience even greater risks because genetic factors or preexisting conditions make them more susceptible to the effects of paraquat. *See* 3-ER-618 (reporting an 11-fold increase in Parkinson's disease among paraquat-exposed male workers who lack a gene involved in the metabolism of paraquat)[4]; 2-ER-160–162 (reporting a 3-fold increase in Parkinson's disease among paraquat-exposed workers with a prior head injury). A 2019 meta-analysis of more than a dozen human studies reported a "significant association between paraquat exposure and [Parkinson's disease]." 3-ER-548–549.

These findings are supported by animal studies showing "hallmarks" of Parkinson's disease, including impaired movement and conspicuous trembling, in mice exposed to paraquat. 2-ER-322.[5] Paraquat is so effective at producing such effects that it is often given to rats and mice to induce symptoms of Parkinson's disease in order to conduct medical research on the disease. 2-ER-255–256. Cellular, or "in vitro," studies have also shown that paraquat harms dopamine-

[4] The absence of this gene is "very common," affecting up to 50 percent of certain ethnic groups. 3-ER-619.

[5] Because non-human animals are not diagnosed with Parkinson's disease, animal studies examine the effects of paraquat by investigating the typical symptoms, or "hallmarks," of Parkinson's disease. 2-ER-321.

producing neurons, similar to the changes seen in Parkinson's disease patients. 2-ER-340–341.

More than 50 countries across the world, including China, Brazil, and members of the European Union ("EU"), have banned the use of paraquat because of its severe risks. 2-ER-256; *see also* PA-032 (¶ 8). While those countries were phasing out paraquat, its use in the United States soared, more than doubling between 2009 and 2016. 3-ER-543.

B. EPA's Registration Review Finds That Paraquat Presents Substantial Risks to Human Health.

EPA commenced the registration review process for paraquat in 2011. 1-ER-009. As part of that review, EPA prepared a new assessment of paraquat's risks to human health.

Risk is a function of the toxicity of a pesticide (i.e., its hazard) combined with how much exposure a person has to the pesticide.[6] Under its standard risk assessment process, EPA first identifies a pesticide's hazards by reviewing animal and human studies to determine the harms associated with the pesticide and the doses at which those effects occur. 3-ER-403–405, 3-ER-416-419. To assess human risk from those studies, EPA must apply "uncertainty factors" that account

[6] *See* EPA, Assessing Human Health Risk from Pesticides, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides (last updated March 31,2022).

for limitations in the risk assessment process, such as the "the uncertainty in extrapolating animal data to humans" and "the variation in sensitivity among the members of the human population." 3-ER-637. EPA then conducts an exposure assessment to calculate the levels at which people are exposed to the pesticide from food, drinking water, their work, and drift, and determines whether exposures at these levels pose risks of concern. *See* 3-ER-504–519.

i. EPA's hazard assessment omits Parkinson's disease.

In its hazard assessment, EPA confirmed the connection between paraquat and developmental harm, lung damage, respiratory harm, and dermal toxicity. 3-ER-416–419. For each of those hazards, EPA identified the highest dose at which animal test subjects did not experience an increase in the effect (also known as the No Observed Adverse Effect Level, or "NOAEL"), and used that dose as the starting point (or "Point of Departure") for its risk calculations. *Id.*

As part of its hazard assessment, EPA also identified uncertainty factors that are needed to assess human risks from the selected animal studies. For each of the foregoing hazards, EPA selected two uncertainty factors: a 10-fold "interspecies" uncertainty factor (to account for differences between test animals and people) and a 10-fold "intraspecies" uncertainty factor (to account for variations in susceptibility within the human population.) *Id.* These uncertainty factors are

needed to prevent the underestimation of human risk and to "[e]nsure that risk assessments are protective of human health." 3-ER-645.

EPA did not conduct that same analysis for Parkinson's disease, however. EPA did not select a NOAEL from the available Parkinson's disease studies or identify uncertainty factors that are needed to calculate human risk from those studies. Instead, EPA conducted a separate review of the studies connecting paraquat and Parkinson's disease and dismissed the evidence of that connection without adhering to its standard risk assessment process, as described below. *See pp.* 17–18 *infra*.

ii. EPA's exposure assessment omits known exposure pathways.

Next, in its exposure assessment, EPA estimated exposures to paraquat from food and drinking water, from different categories of worker activities, and from some, but not all, of the ways that bystanders come into contact with paraquat drift. 3-ER-500–508.

When estimating occupational exposures, EPA distinguished between paraquat handlers and the farmworkers who enter the fields after spraying to perform tasks like weeding, scouting, pruning, and harvesting. For handlers, EPA estimated dermal and inhalation exposures using different combinations of personal protective equipment (such as respirators and protective eyewear and gloves) and engineering controls (such as enclosed cockpits in planes, enclosed cabs in tractors,

and enclosed mixing and loading systems). 3-ER-504–511. For farmworkers in the fields where paraquat is sprayed, EPA estimated the length of time that paraquat residues remain on plants and crops that those workers come into contact with. 3-ER-511–519.

EPA also conducted a residential risk assessment that estimated risks to bystanders from exposures to the off-target movement, or drift, of the pesticide. 3-ER-500–503. When estimating such exposures, however, EPA considered contact to paraquat only after it deposited on the ground, also known as "indirect drift," but not "direct drift" through inhalation of or contact with paraquat when it is sprayed. 3-ER-500. EPA ignored direct drift because EPA's standard operating procedures assume that pesticide applications will comply with label and regulatory requirements designed to avoid applications that result in direct contact with paraquat drift. *Id.*; 3-ER-597–598. However, EPA's assessment of paraquat exposure incidents reports several instances of drift causing respiratory and other harm. 3-ER-554–555, 3-ER-558.

Moreover, when estimating "indirect" drift exposures, EPA considered exposures to bystanders who touch deposited paraquat and to children who then put their hands in their mouths, but not to people who inhale paraquat that volatilizes after it deposits or is resuspended as dust. 3-ER-500. When it commenced the registration review in 2011, EPA acknowledged that "residential

bystander inhalation exposures resulting from off-site transport (e.g., spray drift) may occur as a result of applications of paraquat dichloride." 3-ER-622. EPA developed a multi-factor Volatilization Screening Tool to determine whether additional analysis of bystander inhalation exposures is warranted. 3-ER-503. Paraquat failed the screen for all low- and medium-height crops, and EPA identified the need for a flux study to assess inhalation exposures. 3-ER-585; 3-ER-590. In its paraquat risk assessment, EPA claims that it used the screening tool to determine whether further data or analysis of bystander inhalation exposures were needed, but the risk assessment did not disclose the results of that screening analysis or explain why EPA failed to conduct the recommended study. *See* 3-ER-431. Nor did EPA assess exposures to people who inhale paraquat that is then resuspended as dust, despite "acknowledg[ing] the potential inhalation of dusts [that] are generated during post-application activities." 2-ER-129.

iii. Despite the gaps in its hazard and exposure assessments, EPA still finds that paraquat presents widespread health risks.

To calculate paraquat's risks for a given health effect and exposure scenario, EPA compares a Margin of Exposure (calculated by dividing the NOAEL for the effect by an estimated human exposure level) to a Level of Concern (calculated by multiplying applicable uncertainty factors). 3-ER-391–392; *see also* 3-ER-524. As this Court has previously described:

> Central to EPA's analysis of the risks posed by a pesticide is its calculation of the margin of exposure ("MOE"), which is used to determine whether exposure to a pesticide might cause an adverse effect. To discern whether a risk [of] concern exists, EPA first calculates a [level of concern] by multiplying a variety of uncertainty factors … After setting the [level of concern], the agency calculate[s] the … MOE under a number of scenarios … If … the MOE is less than or equal to [the level of concern] … there is a risk [of] concern …

Nat. Res. Def. Council v. EPA, 735 F.3d 873, 881–82 (9th Cir. 2013).[7]

Based on this analysis, EPA found that paraquat presents risks of concern to workers and bystanders. For handlers who mix, load, and apply paraquat, EPA found inhalation risks of concern from four of eight exposure scenarios and dermal risks of concern from six of eight scenarios, with some workers facing risks that are more than eight times worse than EPA's Level of Concern. 1-ER-015–016.[8] For applicators, inhalation risks are of concern for eight out of 21 exposure scenarios, even after assuming the use of engineering controls. 1-ER-016. EPA found that workers in the fields where paraquat is sprayed would face risks of

[7] While the risk assessment process described in *Natural Resources Defense Council v. EPA* is similar to the process employed in this case, EPA used varying terminology to describe certain steps in that process (i.e., referring to the combination of uncertainty factors as a "target margin of exposure" as opposed to a "level of concern"). The terminology in the excerpt above has been revised to match the terminology used in the paraquat human health risk assessment.

[8] The dermal risks identified by EPA were for "systemic toxicity," which encompasses not only harm to the skin but also harm to internal organs once paraquat is dermally absorbed and enters the blood stream. *See* 3-ER-407, 3-ER-418.

concern for up to 27 days following application, depending on the crop and use. 1-ER-017. EPA also found that children face risks of concern from "indirect" exposures to paraquat drift, extending up to 150 feet from the field edge. 1-ER-014.

C. EPA Fails to Undertake an Equivalent Assessment of Parkinson's Disease Risks.

Separate from its assessment of paraquat's other health effects, EPA prepared a literature review, which EPA describes as a "systematic review," of the studies examining the connection between paraquat and Parkinson's disease. 1-ER-2020. This review identified several "high-quality" epidemiological studies reporting an increased risk of Parkinson's disease among workers who used paraquat, 2-ER-297, 2-ER-304, as well as "well examined" and "compelling" animal data, 2-ER-379, and extensive cellular evidence supporting that connection. 2-ER-340–341.

EPA's consideration of those studies did not follow the process that EPA used for paraquat's other health effects. EPA did not identify a NOAEL or compare Parkinson's disease risks to a Level of Concern. Instead, EPA described the human, animal, and cellular evidence of the connection between Parkinson's disease and concluded that "the weight of evidence was insufficient to link paraquat exposure *from pesticidal use of US registered products* to [Parkinson's

disease] in humans." 2-ER-355 (emphasis added). While acknowledging that Parkinson's disease and "[Parkinson's disease]-like outcomes" were observed in several human and animal studies, EPA stated that such risks "are not likely to occur from label-directed use in the U.S." because human exposures to paraquat from such uses are expected to be lower than the "[dose] levels that elicited the neurodegenerative hallmarks of [Parkinson's disease] in laboratory animals." 2-ER-271, 2-ER-355. EPA deviated from its risk assessment practices, and from its assessment of paraquat's other effects, by comparing human exposure levels to animal test doses without applying any uncertainty factors, including the factor recommended "to account for the uncertainty involved in extrapolating from animal data to humans." 3-ER-644.

D. EPA Assesses Paraquat's Economic Benefits to Growers, but Not its Costs to Human Health and the Environment.

To determine whether paraquat's risks are "unreasonable," FIFRA requires EPA to weigh paraquat's "economic, social, and environmental costs and benefits." 7 U.S.C. § 136(bb); 1-ER-61. To calculate benefits, EPA prepared assessments that focused primarily on paraquat's economic value to growers of different crops ("Benefits Assessments"). 2-ER-164 (assessing benefits to soybean growers); 2-ER-130–132 (assessing benefits to cotton growers); 2-ER-218–220 (assessing benefits to peanut growers); 2-ER-191 (assessing benefits to growers of

other crops). EPA calculated those benefits based on how much growers would have to pay to replace paraquat with currently registered pesticide alternatives. 2-ER-173–174; 2-ER-235; 2-ER-141–144. While EPA identified alternatives for virtually all of paraquat's uses, it found that continued paraquat use would benefit growers because the alternatives were more expensive and certain crops would require multiple pesticides to replace paraquat's weed killing and harvest aid functions. 2-ER-173–174; 2-ER-235; 2-ER-141–144; *see also* 1-ER-29. Where EPA found that effective alternatives were unavailable, it estimated paraquat's benefits by calculating the costs of reduced crop yields. *See* 2-ER-237.

EPA did not conduct a comparable assessment of paraquat's human health and environmental costs. EPA did not estimate how many people will experience the lung damage, kidney harm, respiratory distress, or the other harms that are caused by paraquat exposure. *See* 3-ER-407–408. Nor did EPA calculate the costs associated with those harms, including medical bills, lost days of work, and premature deaths. In addition to paraquat's human health risks, EPA found that paraquat presents risk of concern to mammals, birds, bees, and non-target crops, but it did not measure the costs associated with those harms either. *See* 3-ER-546.

E. EPA's Registration Review Decision Leaves People Exposed to Serious Risks of Concern.

In September 2020, EPA proposed its interim registration review decision for paraquat. 2-ER-116. In that decision, EPA proposed additional mitigation measures to address some of the risks identified in its risk assessments. These measures include a ban on all aerial applications of paraquat aside from certain cotton uses; additional requirements of personal protective equipment ("PPE") and engineering controls to reduce farmworker exposures; and "no spray" buffers, droplet size restrictions, and other measures intended to limit bystander exposures to deposited paraquat drift. 2-ER-125–126. Even with those measures, however, EPA found that paraquat would present risks of concern to health and the environment. 2-ER-122–124; 3-ER-541, 3-ER-546.

Petitioners submitted comments on EPA's draft risk assessments and proposed registration review decision. Those comments explained that, among other flaws: (1) EPA understated the connection between paraquat and Parkinson's disease and failed to protect against Parkinson's disease risks, 2-ER-255–256; (2) EPA failed to account for or protect against workers and bystander exposures from paraquat drift, paraquat volatilization, and paraquat-contaminated dust, 2-ER-251–252, and (3) EPA did not lawfully weigh the costs and benefits of continued paraquat use. 2-ER-100–103.

In response to public comments, EPA did not strengthen, but rather weakened, its proposed mitigation measures. Based on the submission of new

dermal exposure data by the Agricultural Handler Exposure Task Force ("AHETF")—a coalition of 27 pesticide manufacturers[9]—EPA revised its prior risk calculations and eliminated its proposed ban on non-cotton aerial applications of paraquat. 1-ER-007–008. Instead, EPA chose to permit aerial spraying of up to 350 acres per crop over a 24-hour period, with no size limit for the spraying of cotton. 1-ER-030. EPA imposed additional measures to partially mitigate the effects of continued aerial applications, such as prohibiting the use of human flaggers and restricting such applications within 50-75 feet of residential homes, schools, playfields, and other places people gather. *Id.* EPA found that those measures would eliminate risks of concern to bystanders from dermal and incidental oral exposure to indirect paraquat drift, but it did not assess their impact on people who are directly exposed to paraquat drift or who inhale paraquat after the application has ended.

EPA acknowledged that that the mitigation in the final Registration Decision would not eliminate paraquat's risks of concern to workers and the environment. 1-ER-015–016; 1-ER-074–086. After accounting for mitigation measures, workers will still experience health risks that are up to four times worse than the Level of Concern. 1-ER-016. However, EPA concluded that those risks do not present any

[9] The AHETF was formed pursuant to FIFRA to jointly develop data for use in pesticide registrations. *See* 7 U.S.C. § 136a(c)(2)(B)(ii).

"unreasonable adverse effect" because it found that "any remaining potential worker and/or ecological risks are outweighed by the benefits associated with the use of paraquat." 1-ER-030.

Based on that conclusion, EPA issued the Registration Decision on July 13, 2021. The Registration Decision "finalizes" EPA's assessment of paraquat's human health and environmental risks as well as EPA's selection of mitigation measures based on those final assessments. 1-ER-006.[10]

STANDARD OF REVIEW

EPA's decision may be upheld under FIFRA only if it is "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). "Substantial evidence means more than a scintilla and is such [evidence] that a reasonable mind may accept it as adequate to support a conclusion." *Barber v. Widnall*, 78 F.3d 1419, 1423 (9th Cir. 1996) (citation omitted); *Nat. Res. Def. Council v. EPA*, 735 F.3d at 877. Because the Court must consider "the record as a whole," 7 U.S.C. § 136n(b), "[t]he substantiality of evidence must take into

[10] The decision is labeled "interim" because EPA continues to review certain of paraquat's impacts under other statutes: namely, the Endangered Species Act and the Federal Food Drug and Cosmetics Act ("FFDCA") Endocrine Disruptor Screening Program. 1-ER-006. EPA chose to issue the Registration Decision while those separate processes were ongoing "so that it can … move forward with" the paraquat determinations "that are complete." *Id.*

account whatever in the record fairly detracts from its weight." *Universal Camera Corp. v. Nat'l Labor Relations Bd.*, 340 U.S. 474, 488 (1951).

Judicial review under the substantial evidence standard is "searching and careful, subjecting the agency's decision to close judicial scrutiny." *Family Farm II*, 966 F.3d at 914 (citation omitted); *see also Mem'l, Inc. v. Harris*, 655 F.2d 905, 912 (9th Cir. 1980) ("Review under the substantial evidence standard is not to be superficial or cursory.") FIFRA's "substantial evidence" standard "[a]ffords an agency less deference than the arbitrary and capricious standard" generally applied under the Administrative Procedures Act. *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 533 (9th Cir. 2015) (Smith, J., concurring).

SUMMARY OF ARGUMENT

Before approving or renewing a pesticide's registration, EPA must show that the pesticide "will not" present any unreasonable adverse effects. 7 U.S.C. § 136a(c)(5). That standard requires EPA to assess the pesticide's risks to human health and the environment, taking into account hazards and exposures, and to weigh such risks and their associated costs against the pesticide's benefits. *See id.* § 136(bb). At every step of that process, EPA understated or disregarded paraquat's risks, resulting in an unsupported Registration Decision that leaves Petitioners' members and others exposed to serious lung, kidney, and neurological harm.

First, while extensive human and animal studies have linked paraquat exposure to Parkinson's disease, EPA improperly dismissed human Parkinson's disease risks by mischaracterizing the animal data. EPA stated that registered paraquat uses are unlikely to lead to Parkinson's disease because human exposure levels are lower than the doses associated with Parkinson's disease in test animals. But, contrary to EPA's longstanding practice and this Court's precedent, EPA failed to apply the uncertainty factors needed to assess human risks from animal data. This error understates human Parkinson's disease risks by a factor of at least 1,000 and renders EPA's dismissal of such risks unsupported by substantial evidence. EPA also erroneously claimed that, because paraquat allegedly causes respiratory and dermal harm at lower doses than Parkinson's disease, EPA's assessment of those other health effects will be "protective" of Parkinson's disease. But the Registration Decision does not eliminate risks of concern for either respiratory or dermal harm, and EPA's assessment of those effects does not cover the chronic exposures that are associated with Parkinson's disease, leaving no basis for EPA to conclude that measures that failed to prevent respiratory and dermal harm will protect against Parkinson's disease.

Second, EPA's risk assessment ignores several ways that people are exposed to paraquat, further underestimating paraquat's risks. EPA failed to assess risks to bystanders who are directly exposed to paraquat drift because paraquat's label and

EPA regulations prohibit the direct spraying of people, even though EPA has found this prohibition is insufficient to prevent harm from direct pesticide drift. Nor did EPA assess the inhalation of paraquat that deposits on the ground and then volatilizes or is resuspended as dust, even though paraquat failed EPA's volatilization screening analysis, triggering the need for further study. EPA never required that further study or measured exposures to paraquat-containing dust, leaving it without the information needed to assess and prevent paraquat's risks.

Third, EPA's weighing of paraquat's risks and benefits is contrary to FIFRA and wholly unsupported. EPA left workers exposed to risks of concern because it claimed those risks were outweighed by paraquat's benefits to growers, but EPA failed to conduct the risk-benefit balancing needed to support that claim. To assess paraquat's benefits, EPA emphasized paraquat's economic savings for growers without assessing the corresponding costs from lost exports to countries that have banned paraquat-treated crops. On the other side of the scale, EPA wholly failed to assess the magnitude of paraquat's risks and their costs to workers, agricultural communities, and the environment. Given this one-sided balancing, EPA could not "tak[e] into account the economic, social, and environmental costs and benefits" of continued paraquat use, as required by FIFRA. *Id.* EPA simply declared that paraquat's benefits outweigh its unaddressed risks, a conclusory assertion that is not, and cannot be, supported by substantial evidence.

ARGUMENT

I. Petitioners Are Harmed By The Registration Decision and Have Standing to Challenge It.

Petitioners include organizations of farmworkers who are exposed to paraquat's serious health risks; a foundation whose mission of eradicating Parkinson's disease is undermined by EPA's approval of continued paraquat use; and organizations dedicated to preventing the harms caused by pesticides like paraquat, including through trainings and educational programs that depend on complete and accurate EPA risk assessments. The Registration Decision's underestimation of paraquat's risks, and its failure to adequately regulate the risks that EPA did identify, harms Petitioners in numerous ways and gives them standing to seek the analyses and protections that FIFRA requires. *See Nat. Res. Def. Council v. EPA*, 735 F.3d at 878 (applying three-part standing test: (1) an "injury in fact" that is (2) "fairly traceable to the challenged action of the defendant" and that (3) "likely … will be redressed by a favorable decision.")

Petitioners Farmworker Association of Florida and Alianza Nacional de Campesinas ("Alianza") have farmworker members who will suffer the risks that EPA understated or left unaddressed in the Registration Decision. PA-006–007 (¶¶

6–9); PA-015 (¶ 9).[11] Those members work in the fields where paraquat is sprayed and in the neighboring fields where paraquat drifts, placing them at increased risk of lung and kidney disease, respiratory harm, and Parkinson's disease. PA-006–007 (¶¶ 6–9); PA-019 (¶¶ 9–10). They have no ability to control or avoid that risk, since they do not select the pesticides they are exposed to. PA-009–010 (¶ 14); PA-019 (¶ 11). They thus face a "credible threat" of paraquat exposure and harm due to EPA's violation of its statutory obligations to evaluate paraquat's risks and to prevent unreasonable adverse effects. *Nat. Res. Def. Council*, 735 F.3d at 878-79 (upholding standing because the "inability of NRDC's members to fully control their children's exposure to" nanosilver, a pesticide used in clothing, created a "credible threat" of exposure).

Petitioner Michael J. Fox Foundation for Parkinson's Research ("MJFF") is dedicated to the elimination of Parkinson's disease, a critical mission that is undermined by EPA's failure to acknowledge and address the established connection between paraquat use and Parkinson's disease. PA-030–031 (¶¶ 3–4). MJFF submitted letters and comments educating EPA about the extensive scientific evidence linking paraquat and Parkinson's disease. PA-034–035 (¶¶ 14–

[11] Alianza's members are farmworker organizations who themselves have individual farmworker members. PA-015 (¶ 9); *see also N.Y. State Club Ass'n, Inc. v. City of N.Y.,* 487 U.S. 1, 9-10 (1988) (upholding standing for a coalition of membership organizations based on harm to those organizations' respective members).

15). But EPA dismissed the evidence of Parkinson's disease risks and reauthorized the widespread use of paraquat, requiring MJFF to "expend[] … resources they would have spent on some other aspect of their organizational purpose"—such as medical research into a cure for Parkinson's disease or improved therapies for Parkinson's disease patients—to conduct advocacy and additional research related to the paraquat risks that EPA was required to, but did not, address. *Nat'l Council of La Raza v. Cegavske*, 800 F.3d 1032, 1040–41 (9th Cir. 2015) (citation omitted) (upholding standing based on harm from an organization's diversion of resources); PA-036–038 (¶¶ 21–24).

The Registration Decision also frustrates Petitioners' ability to protect people and the environment from harmful pesticides through training, advocacy and educational programs. Several Petitioners provide outreach to farmworkers who are exposed to pesticides, PA-011–012 (¶ 16), PA-022–023 (¶ 8); conduct trainings and community workshops on pesticide safety, PA-048–049 (¶¶ 7-8); and advocate for stronger state and federal protections from harmful pesticides. PA-041 (¶ 8); PA-047–48 (¶¶ 4–6); PA-052–053 (¶¶ 5–6). Those efforts require complete and accurate information about the risks that pesticides, including paraquat, pose to farmworkers, agricultural communities, and the environment. PA-048–049 (¶¶ 7–8); PA-023–024 (¶ 11). While FIFRA requires EPA to comprehensively assess paraquat's risks and to make those assessments available for public review, *see* 40

C.F.R. § 155.53, here EPA's human health risk assessment omitted key hazards and exposures, such as the risks associated with the inhalation of paraquat drift. *See* Point III *infra*. The Registration Decision harms Petitioners by depriving them of "information which must be publicly disclosed pursuant to a statute." *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 21 (1998).

Petitioners' harms are caused by the challenged Registration Decision and are redressable by the remand that Petitioners seek in this proceeding. *See Salmon River Concerned Citizens v. Robertson,* 32 F.3d 1346, 1355 (9th Cir. 1994) (plaintiffs established causation and redressability where agency's inadequate analysis could cause environmental and health consequences to be overlooked). Petitioners thus have standing.

II. EPA's Dismissal of Paraquat's Parkinson's Disease Risks is Unsupported By Substantial Evidence and Contrary to FIFRA.

Despite "high-quality" and "compelling" evidence linking paraquat exposures to Parkinson's disease, 2-ER-297, 2-ER-304, 2-ER-379, EPA concluded that Parkinson's disease was "not likely to occur from label-directed [paraquat] uses in the U.S." 2-ER-355. This conclusion is unsupported by substantial evidence for two reasons.

First, EPA dismisses Parkinson's disease risks based on a comparison of human exposure levels and animal doses, but without adhering to the process that EPA and this Court have found necessary to calculate human risk from animal

studies. Point II.A *infra*. Second, EPA claims that its analyses of paraquat's respiratory and dermal effects are "protective" of Parkinson's disease, even though neither of those analyses addressed chronic risks like Parkinson's disease and the Registration Decision allows serious risks of concern for respiratory and dermal harms to persist. Point II.B *infra*.

A. EPA's claim that registered paraquat uses are not likely to present Parkinson's disease risks misstates the evidence and violates accepted risk management practices.

EPA's dismissal of Parkinson's disease risks from registered paraquat uses "misinterpreted the relevant data," and is thus unsupported by substantial evidence. *Nat. Res. Def. Council v. U.S. Forest Service*, 421 F.3d 797, 807, 810 n.24 (9th Cir. 2005). EPA relied on animal studies to assess the likelihood of Parkinson's disease risks to workers and others, but it failed to conduct the assessment needed to determine human risks from animal data, and thus cited those studies for a conclusion they do not support.

EPA acknowledges that "the most comprehensive investigation of [Parkinson's Disease]-like hallmarks in a laboratory setting" reported "significant" Parkinson's disease symptoms in mice exposed to paraquat. 2-ER-322. In that study, mice exposed to 7.2 mg of paraquat/kg of body weight/day ("mg/kg/day") for four months experienced several hallmarks of Parkinson's disease, including motor impairment, trembling, and neurochemical changes. 2-ER-322–323 (citing Ren et.

al.). Other animal studies reported similar results. 2-ER-323. Because that dose is "between 2 and 4 orders of magnitude" higher than workers' estimated "worst-case" exposure levels, EPA concluded that "the neurodegenerative hallmarks of [Parkinson's disease] observed in laboratory animals" were "not likely" to present risks of concern to people. 2-ER-352, 2-ER-355. EPA relied on those "exposure considerations" to support its claim "the weight of evidence was insufficient to link paraquat exposure from pesticidal use of US registered products to PD in humans." 2-ER-355.

But the fact that mice develop Parkinson's disease symptoms at 7.2 mg/kg/day of paraquat does not mean that people exposed below that level will not experience such risk. To assess human risks from an animal study, EPA must apply its standard risk assessment process, including the use of uncertainty factors. *See, e.g.,* 3-ER-647 ("For almost 30 years, EPA, as well as others in the scientific and regulatory community, has routinely been using … uncertainty factors when relying on animal testing to assess the potential for human hazard …"). Here, EPA skipped that required step.

Uncertainty factors "are very important … to determining the safety of pesticide[s] … to humans," as they "often are the difference between the withdrawal of a pesticide from the market and its continued use." *Nat. Res. Def. Council v. EPA*, 658 F.3d 200, 209 (2d Cir. 2011). Both EPA and this Court have repeatedly

affirmed the need for uncertainty factors when assessing human risk based on animal data. *See* 3-ER-647; 3-ER-639; *see also NW. Coal. for Alternatives to Pesticides v. EPA* ("*NCAP*"), 544 F.3d 1043, 1046 n.1 (9th Cir. 2008) (describing EPA's use of an uncertainty factor when assessing human risks based on an animal study "to account for the possibility that people are more susceptible than animals studied in laboratory experiments); *see also Nat. Res. Def. Council v. EPA*, 735 F.3d at 881 ("To discern whether a risk concern exists, EPA … multipl[ies] a variety of uncertainty factors.").

Comparing animal doses to human exposure levels without the use of uncertainty factors is also inconsistent with EPA's analysis of paraquat's respiratory and dermal risks. According to EPA, "worst case" human exposures to paraquat are lower than the doses that EPA used to calculate respiratory and dermal harm from animal studies. *Compare* 2-ER-352 (describing "worst case" inhalation exposures of 0.00125 mg/kg/day and dermal exposures of 0.323 mg/kg/day) *with* 3-ER-417, 3-ER-420–421 (describing respiratory risks at 0.0026 mg/kg/day and dermal risks at 6 mg/kg/day in animal studies). Had EPA calculated those risks without uncertainty factors, it would have erroneously found that paraquat presents no risks of concern to workers or bystanders whatsoever. But EPA found extensive respiratory and dermal risks, because when calculating those risks EPA applied its accepted methodology and used two uncertainty factors—a

ten-fold "interspecies" uncertainty factor to account for differences between test animals and people and a ten-fold "intraspecies" uncertainty factor to account for variations in human responses to paraquat. 3-ER-418–419.

The same uncertainty factors, and others, are equally applicable to the assessment of Parkinson's disease risks. First, EPA considered the likelihood of human Parkinson's disease risks based on doses from animal studies, but it did not apply the 10-fold interspecies uncertainty factor. *See* 2-ER-352 .

Second, EPA failed to apply the 10-fold uncertainty factor needed "account for variations in susceptibility within the human population." 3-ER-639. While this factor is recommended even where EPA has not identified a particular cause for that variability, *id.*, here the Record contains evidence that certain groups of people are more susceptible to Parkinson's disease from paraquat exposures due to their genetic makeup or preexisting conditions. *See* 3-ER-618 (finding that a genetic trait significantly increased Parkinson's disease rates from occupational paraquat exposures).

Third, EPA guidance calls for an additional 10-fold uncertainty factor when calculating human risk based on the lowest dose at which effects were identified in animals (also known as the Lowest Observed Adverse Effects Level or "LOAEL"), as opposed to a dose that resulted in no adverse effects (the NOAEL). *See* 3-ER-644 (describing LOAEL-to-NOAEL uncertainty factor). All of the animal studies

that EPA used to compare to human exposure levels detected Parkinson's disease systems in animals exposed to at least 7.2 mg/kg/day, meaning 7.2 mg/kg/day is a LOAEL, not a NOAEL. 2-ER-317, 2-ER-322. But EPA did not apply the recommended LOAEL-to-NOAEL uncertainty factor either.

These departures from EPA's accepted practice significantly understate the risks that people face from their paraquat exposures. The interspecies, intraspecies, and LOAEL-to-NOAEL uncertainty factors alone increase the Parkinson's disease Level of Concern by 1,000 (10 x 10 x 10), or three orders of magnitude.[12] Given EPA's finding that occupational exposures to paraquat "are between 2 and 4 orders of magnitude below" the dose associated with Parkinson's disease in animal studies, an increase of three orders of magnitude would place the Level of Concern squarely within the range of human exposures. 2-ER-352. Because EPA "did not satisfy its own rule for determining when there is a risk concern," its assessment of Parkinson's disease risks is not supported by substantial evidence. *Nat. Res. Def. Council*, 735 F.3d at 881 (overturning pesticide registration approval where EPA failed to adhere to its policies for calculating risk).

[12] EPA's accepted risk assessment practices require the consideration of other uncertainty factors as well. For instance, Parkinson's disease is associated with chronic paraquat exposures, *see* 2-ER-346, and all of the animal studies cited by EPA were conducted over a shorter "subchronic" duration, *see* 2-ER-346, yet EPA never applied the uncertainty factor that EPA recommends for the estimation of chronic risks from a subchronic study. *See* 3-ER-642–643.

B. EPA's claim that its analyses of respiratory and dermal harm are protective of Parkinson's disease is unsupported by substantial evidence.

EPA also claims that because paraquat causes respiratory and dermal harm "at lower doses than those eliciting neurotoxicity in animal models," those health effects would "precede the [Parkinson's disease]-like neurotoxic effects reported in the literature" and EPA's analyses of those effects "are protective of" Parkinson's disease. 2-ER-355. This conclusion is unsupported for two reasons.

First, EPA's reliance on the protectiveness of its respiratory and dermal analyses assumes that the Registration Decision protects against respiratory and dermal harm. *Id.* But, as EPA has acknowledged, that is not the case.

Even after accounting for the mitigation required in the Registration Decision, EPA still found there would be respiratory "risks of concern" from the inhalation of paraquat. 1-ER-15–16; 1-ER-75–76. EPA also found risks of concern from dermal contact with paraquat, even with the use of gloves and other personal protective equipment. 1-ER-16. Since the Registration Decision does not prevent respiratory and dermal risks of concern, there is no basis to conclude that it would prevent Parkinson's disease either, even if Parkinson's disease occurred at higher exposure levels.[13] EPA's "conclusory allegations" that mitigation measures that

[13] To the extent EPA claims that paraquat's remaining respiratory and dermal risks are not "unreasonable" because they are outweighed by paraquat's benefits, that

failed to eliminate other harms will nonetheless prevent Parkinson's disease are not substantial evidence. *Nat. Res. Def. Council v. U.S. Env't Prot. Agency*, 857 F.3d 1030, 1038, 1042 (9th Cir. 2017) ; *see also Algonquin Gas Transmission Co. v. Fed. Energy Regul. Comm'n*, 948 F.2d 1305, 1313 (D.C. Cir. 1991) ("An agency's unsupported assertion does not amount to substantial evidence.").

Second, even if the Registration Decision had protected against respiratory and dermal risks of concern, that would not make it protective of chronic Parkinson's disease risks which occur over a different timeframe than the respiratory and dermal effects studied in the risk assessment. EPA analyses of health effects are duration specific; EPA guidance recommends conducting separate analyses for short-term, intermediate-term, and long-term exposures. *See* 3-ER-650; 2-ER-646 (acknowledging that "separate decisions may be necessary" for "different durations of exposure (e.g., acute, short-, intermediate-, long-term).") The respiratory and dermal analyses that EPA conducted in the paraquat risk assessment were for "short-term" (1-30 day) and "intermediate term" (1-6 month) inhalation and dermal exposures, occurring over the course of a single year. 3-ER-433. EPA did not assess "long-term"

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claim is also unsupported by substantial evidence. *See* pp. 56–58 *infra*. Moreover, EPA does not and cannot make that claim with respect to Parkinson's disease, which imposes distinct harms and costs that EPA made no attempt to consider. *See* p. 54 *infra*.

(or chronic) effects to workers and families who are repeatedly exposed to paraquat, year after year, over the course of their lifetimes.

However, the Record contains evidence that "low-level chronic exposure [to paraquat] significantly increases the risk of Parkinson's disease," such that exposure levels which may not be harmful during a single 6-month period can cause harm if experienced over a longer time span. 2-ER-254; *see also* 3-ER-634 ("Epidemiological studies suggest an increased risk for developing [Parkinson's disease] following chronic exposure to paraquat"); 2-ER-189 (explaining that "low-level, chronic [paraquat] exposure is reported to be associated with various health effects, including central nervous system toxicity …"). The people who mix, handle, and apply paraquat; who harvest crops in the fields where paraquat is applied; and who live next to those fields are exposed to paraquat over years, not months. An epidemiological study from Taiwan found that workers who used paraquat for at least 20 years were more than six times as likely as the general public to develop Parkinson's disease, a significantly higher rate than workers who used paraquat for less than 20 years. 3-ER-652 Therefore, even if respiratory and dermal harms are the "most sensitive" health effects over a six-month, intermediate-term duration, 2-ER-353, there is no evidence that would be the case compared to Parkinson's disease over a lifetime of repeated paraquat exposures.

EPA's claim that its respiratory and dermal analyses will protect against Parkinson's disease risks is unsupported by substantial evidence.

III. EPA Ignored Harmful Paraquat Exposures Without Substantial Evidence.

In addition to understating paraquat's hazards, EPA failed to assess several ways that bystanders and farmworkers are exposed to paraquat drift, further underestimating the pesticide's risks. EPA's failure to assess and protect against those excluded exposures is unsupported by substantial evidence.

First, EPA focused solely on indirect drift exposures to paraquat residues that have deposited on the ground, without accounting for and protecting against direct inhalation and dermal exposure to paraquat during the pesticide spraying. EPA ignored direct paraquat drift even though it has found that other label and regulatory requirements provide inadequate protection against harmful pesticide drift and that numerous people have been harmed by paraquat exposures from direct drift. Point III.A *infra*.

Second, when assessing indirect drift EPA considered only a fraction of potential exposures; namely, those associated with dermal contact or hand-to-mouth ingestion. EPA failed to account for the people who breathe paraquat that volatilizes after the spraying has ended, even though paraquat's failure of EPA's volatilization screening analysis was supposed to trigger further investigation.

Paraquat that does not volatilize can adhere to soil and be inhaled as dust, but EPA did not consider those exposures either. Point III.B *infra*.

A. EPA's failure to protect bystanders from direct paraquat drift is unsupported by substantial evidence.

EPA distinguishes between direct paraquat drift that contacts people directly during a pesticide application and indirect exposures to paraquat after the pesticide application. As to indirect drift, EPA found that bystanders face risks of concern, with children ages 1-2 facing the greatest risks, and EPA required labeling directions aimed at reducing the identified risks from dermal or hand-to-mouth exposures to spray drift after the application. 1-ER-14. Among other measures, the Registration Decision required the use of no-spray buffers of 50-75 feet when paraquat is aerially sprayed around schools, homes, parks, and other areas where people and children congregate. 1-ER-30, 1-ER-32 (also requiring additional spray drift management measures, such as droplet size, release height, and wind speed restrictions). However, EPA did not evaluate or impose any mitigation measures based on direct drift exposures, despite evidence that such exposures occur and cause harm.

EPA conducted a review of available human incident databases and found several paraquat incidents resulting from bystander exposures to direct paraquat drift, resulting in paraquat inhalation and subsequent respiratory harm. 3-ER-554–

555; 3-ER-558.[14] For example, a man experienced respiratory arrest while doing yardwork after an abutting vineyard was sprayed with paraquat. 3-ER-554. In another incident, a man, his wife, and daughter developed severe coughing and chest irritation when paraquat drifted from a farm across the street onto their property. 3-ER-555. In still another incident, "[a] worker at the fence of a vineyard felt mist on his face and noticed a metallic taste, which he attributed to an application about 40 feet away on the neighboring property." 3-ER-558.

Despite evidence of harm from direct exposure to drift, EPA failed to evaluate the risks from such exposures because it assumed that unspecified label requirements and regulations would prevent them. *See* 3-ER-500 (explaining that EPA evaluated paraquat drift based on "a premise of compliant applications which, by definition, should not result in direct exposures to individuals because of existing label language and other regulatory requirements intended to prevent them"); 3-ER-428 (same). This is the entirety of EPA's explanation for ignoring direct drift in its paraquat risk assessments, proposed Registration Decision, and final Registration Decision.

[14] Reported incidents capture only a fraction of poisoning incidents because, for example, workers fear retaliation, lack access to medical care, misdiagnoses, and spotty funding of the reporting systems. 80 Fed. Reg. 67,496, 67,498 (Nov. 2, 2015) (describing EPA's assumption that "just 10% of acute pesticide incidents are [r]eported").

EPA's standard spray drift risk assessment procedures, which it applied to paraquat, offer a similar explanation for why EPA ignores direct dermal and inhalation exposure to pesticide sprays. EPA states that it focuses its spray drift assessments only on applications that comply with label statements that prohibit sprays from contacting people directly through drift and assumes "no individual should be directly sprayed." 3-ER-597. Since 1992, EPA regulations known as the Worker Protection Standard have required that pesticide labels contain "do not contact" language, which in its current form states that "[t]he handler employer and the handler must ensure that no pesticide is applied so as to contact, directly or through drift, any worker or other person, other than an appropriately trained and equipped handler involved in the application." 40 C.F.R. § 170.505(a).

However, EPA has recognized that this prohibition has failed to protect people from the harms associated with direct pesticide drift. Its report on paraquat incidents documented this failure in numerous incidents of serious harm from direct paraquat drift. *See* p. 14 *supra.* And when EPA issued its spray drift methodology in 2014, it acknowledged that drift "can lead to exposures through direct contact with sprays," that "incidents due to spray drift occur," and that such incidents had caused "acute illnesses." 3-ER-595.

The very next year, EPA revised its Worker Protection Standard because it found that the "do not contact" provisions in labels like paraquat's had "proven

insufficient" and "additional protections are necessary" to reduce direct exposure during pesticide applications. 80 Fed. Reg. 67,496, 67,521-22 (Nov. 2, 2015). The revisions to the WPS—including a 25–100 foot Application Exclusion Zone ("AEZ") around application equipment where applications must be suspended if anyone other than an appropriately trained and equipped applicator is present—were intended "to avoid or mitigate approximately 44 to 73% of annual reported acute WPS-related pesticide incidents," meaning up to half of such incidents would not be avoided or mitigated. *Id.* at 67,499. In responding to comments arguing that the "do not contact" rule provides sufficient protection, EPA stated:

> EPA disagrees with the assertion that the "do not contact" requirements, along with the other protections on pesticide labels, are by themselves sufficient to protect workers and bystanders from being directly contacted by pesticides that are applied. First, many commenters cited incidents where people were directly exposed to pesticide applications, even if there was disagreement about how regularly these types of incidents happen.

Id. at 67,521.

In a challenge to a 2020 rule that weakened the AEZ requirements, a District Court enjoined the rule from going into effect, rejecting EPA's argument that the "do not contact" requirements rendered additional drift protections "redundant." *Rural & Migrant Ministry v. EPA*, 510 F. Supp. 3d 138, 159–60 (S.D.N.Y. 2020). The court held that EPA had not provided a reasoned explanation for disregarding its prior finding that the "do not contact"

requirements, without more specific criteria, "were not sufficient to protect individuals off of the agricultural establishment from the danger of pesticide drift." *Id.* at 159–60.[15]

EPA also established the uniform requirements set out in the Worker Protection Standard as a floor to be supplemented by product-specific requirements based on the risks identified during registration and registration review process. 80 Fed. Reg. at 67,500, 67,501. Applicators must comply with more restrictive pesticide-specific requirements, including any that apply during pesticide applications. *See, e.g.*, 40 C.F.R. § 170.505(d) (requirements for soil fumigant applications). As EPA explained when it revised the Worker Protection Standard in 2015:

> There is no one solution that can prevent all drift incidents and it will take a comprehensive approach, including additional regulatory requirements, . . . to further reduce the number of people who are directly exposed to pesticide spray/applications.

80 Fed. Reg. at 67,521.

[15] To the extent EPA is relying on the AEZ, the rule was weakened after EPA issued its risk assessments and Proposed Interim Decision for Paraquat, but before the Registration Decision. The weaker rule, which never went into effect, would limit the AEZ to the agricultural establishment and make the AEZ only 25 feet for groundboom applications. 85 Fed. Reg. 68,760, 68,771 (Oct. 20, 2020). Vaguely referencing regulatory requirements, even as they are changing, fails to provide substantial evidence that whatever requirements that will be in place over the next 15 years will be effective or sufficient to prevent direct drift exposures.

EPA has not explained how it will discern what additional mitigation measures are required for direct paraquat drift if it never assesses those exposures or their associated risks. It assumed paraquat applications would comply with the "do not contact" prohibition, even in the face of its findings that the "do not contact" label language affords insufficient protection and the extensive evidence of serious harm to people from direct paraquat drift. EPA's failure to assess and protect people from direct paraquat drift rests on an unsubstantiated and incorrect assumption, and therefore is unsupported by substantial evidence. *Nat. Res. Defense Council*, 857 F.3d at 1038–40 (where EPA cites no evidence to support its underlying assumption, its decision is unsupported by substantial evidence).

B. EPA's failure to protect bystanders from inhalation exposures to indirect paraquat drift is unsupported by substantial evidence.

EPA also failed to protect bystanders from inhalation exposures to indirect paraquat drift, both through the volatilization of deposited paraquat and the resuspension of paraquat-contaminated dust.

At the outset of paraquat's registration review, EPA indicated that it was "refining the methods used to complete residential exposure assessments" and "the potential need for a bystander inhalation risk assessment will be examined during registration review." 3-ER-622. EPA subsequently developed a volatilization screening tool to determine whether further analysis of bystander post-application exposures to indirect drift is required for pesticides going through registration

review. 3-ER-431; 3-ER-503. The tool has three steps: (1) a range of factors are considered to predict pesticide flux; (2) air concentrations of the pesticide are modeled at different distances from a treated field; and (3) bystander inhalation risks are estimated based on chemical-specific toxicology data and the results of EPA's modeling. 3-ER-573–574; 3-ER-578–581.[16]

Applying this tool, EPA conducted a screening analysis of the 427 conventional pesticides going through registration review. Paraquat was among the 68 pesticides that failed the screen. 3-ER-582; 3-ER-585. Despite paraquat's low vapor pressure, air concentrations of concern for inhalation exposures were exceeded for fields of all sizes for low- and medium-growing crops (up to 18 feet high), which include soybeans, berries, and tomatoes. 3-ER-585; *see also* 3-ER-579 (explaining that EPA uses cole crops to represent low-growing crops of three feet or less and row crops to represent medium growing crops of 6-18 feet). Concentrations of concern persist at 298-3,052 meters from the field for cole crops and at 180-3,250 meters from the field for row crops. 3-ER-590. For the pesticides that failed the screen, EPA indicated whether they needed additional studies. EPA found that paraquat "needs a flux study based on screen." 3-ER-592.

[16] EPA developed the screening tool based on recommendations of its Scientific Advisory Panel, which disfavored relying solely on a pesticide's vapor pressure to predict volatilization because pesticide ingredients may be diluted with water or other additives like surfactants that can increase or decrease vapor pressure. 3-ER-627.

Inexplicably, EPA's risk assessments never reveal that paraquat failed the volatilization screen and that a flux study is needed to investigate bystander inhalation exposures to indirect paraquat drift. EPA stated that it would use the results of the screening analysis to determine when flux studies or other studies should be required for the pesticide. 3-ER-573; 3-ER-583 (failing the screen is a trigger for further investigation and studies). Yet EPA failed to require the necessary flux study and conducted no further investigation of bystander inhalation exposures, as the screening analysis calls for. Nor did EPA explain this failure, even though EPA found that paraquat inhalation exposures can cause severe damage to the lungs and respiratory system of pesticide applicators even when PPE and engineering controls like closed cabs are used. 1-ER-16. In contrast, bystanders and farmworkers who are exposed to volatilized paraquat are far less likely to wear PPE.[17]

When, as here, EPA establishes a process for identifying concerns and fails to adhere to that process, its action is unsupported by substantial evidence. *See Nat. Res. Defense Council*, 735 F.3d at 883–84 (9th Cir. 2017) (decision lacks substantial evidence where EPA did not follow its rule for when a risk of concern is triggered). As in *Pollinator Stewardship Council v. EPA*, when EPA identifies the need for

[17] EPA's risk assessments refer to paraquat air monitoring conducted in 1987, which reported no detections above the detection limit. EPA noted that the data are old and from a single geographic location and that additional air monitoring would be necessary to make a definitive risk finding relating to paraquat volatilization exposures. 3-ER-431.

additional studies, but approves a registration without obtaining the studies, its registration decision is unsupported by substantial evidence. 806 F.3d at 530–32.

EPA also failed to protect bystanders by ignoring inhalation exposures due to resuspension of paraquat-contaminated dust. When deposited paraquat does not volatilize, it can bind to soil that is then resuspended and inhaled as dust. 3-ER-424, 3-ER-446 (identifying "resuspension of dusts" as a "potential source[] of post-application inhalation exposure to individuals performing post-application activities in previously treated fields"). Farmworkers and bystanders breathe paraquat-containing dust in the fields and surrounding communities, and farmworkers carry it home with them on their clothing and bodies. 2-ER-251–252. When responding to comments on the human health risk assessment, EPA "acknowledge[d] the potential inhalation of dusts [that] are generated during post-application activities in previously treated fields." 2-ER-129; *see also* 3-ER-556 (describing harm to a farmworker who "mowed the field" that had been previously treated with paraquat and "breathed in the dust from the sprayed product").

Yet, here too, EPA did not assess the risks associated with the inhalation of paraquat-containing dust, and thus failed to protect bystanders and workers from the harms caused by such inhalation. In response to comments noting this oversight, EPA asserts that "the assessment of the inhalation exposures from the occupational handling of paraquat products is protective of any potential inhalation

exposure from dusts," because handlers' inhalation of paraquat droplets during mixing, loading and application is expected to exceed their inhalation of paraquat-containing dust. 2-ER-129. But EPA did not assess bystanders' direct inhalation of either paraquat droplets or paraquat-containing dust, and it did not calculate the risks to bystanders and field workers who lack the respirators and other PPE that paraquat handlers are required to wear. Nor did EPA consider the risks to people who inhale both paraquat droplets and paraquat dust, and thus experience greater overall risks than EPA calculated in its risk evaluation.

EPA failed to assess and protect against the harm to bystanders from inhalation exposures, whether during the pesticide spraying or afterward. While the Record contains evidence that direct pesticide drift presents an ongoing threat to bystanders; that paraquat failed EPA's volatilization screen and required further investigation of its volatilization exposures; and that paraquat can also adhere to soils that are resuspended as dust, EPA ignored those exposure pathways and left bystanders exposed to serious risks. EPA's failure to consider and protect against the foregoing drift exposures is unsupported by substantial evidence.

IV. EPA's Balancing of Paraquat's Risks and Benefits is Unsupported by Substantial Evidence and Contrary to TSCA.

Despite underestimating paraquat's hazards and exposures, EPA still found that paraquat will present risks of concern to human health and the environment. *See* pp. 21–22 *supra*. To determine whether those risks constitute an "unreasonable

adverse effect," EPA must "tak[e] into account the economic, social, and environmental costs and benefits" of continued paraquat use. 7 U.S.C. § 136(bb). EPA cannot approve the registration of a pesticide that presents risks of concern unless it accounts for the costs associated with those risks and either eliminates the risks of concern or "demonstrate[s] that the benefits" of continued paraquat use "outweigh the risks." *Env't Def. Fund*, 548 F.2d at 1005 (citation omitted).

EPA violated those requirements in two ways. First, despite acknowledging that the Registration Decision will not eliminate paraquat's risks of concern, EPA failed to consider the extent of those unaddressed risks or their "economic, social and environmental costs." 7 U.S.C. § 136(bb). Instead, EPA approved harmful uses of paraquat based on a one-sided assessment of the pesticide's economic benefits to growers, without accounting for its harms to workers, agricultural communities, and the environment. Second, without an objective balancing of risks and benefits, EPA's claim that paraquat's benefits outweigh its unaddressed health and environmental risks is wholly conclusory and unsupported by substantial evidence.

A. EPA failed to conduct the required balancing of paraquat's risks and benefits.

EPA's determination that paraquat presents risks of concern to human health and the environment triggered the need for "a careful balancing of risks and benefits." *Chem. Specialties Mfrs. Ass'n v. EPA*, 484 F. Supp. 513, 515 (D.D.C. 1980); *Nat'l Fam. Farm Coal. v. EPA* ("*Family Farm I*"), 960 F.3d 1120, 1133

(9th Cir. 2020). To conduct that balancing, EPA must consider the extent of paraquat's risks, as well as their associated "economic, social and environmental costs," so it can weigh them against paraquat's benefits. 7 U.S.C. § 136(bb). Congress intended this balancing to be comprehensive, "tak[ing] every relevant factor that the Administration can conceive into account":

> The question [EPA] must decide is 'Is it better for [people] and the environment to register this pesticide, or is it better that this pesticide be banned?' [EPA] must consider hazards to farmworkers, hazards to birds and animals and children yet unborn. [EPA] must consider the need for food and clothing and forest products, forest and grassland cover to keep the rain where it falls, prevent floods, provide clear water … All these factors [EPA] must consider, giving each its due. No one should be given undue consideration, no one should be singled out for special mention …

S. Rep. No. 92-838, S. Comm. on Agric. and Forestry, at 10 (1972).

Here, EPA conducted a one-sided assessment of paraquat's benefits to growers with no comparable assessment of paraquat's costs to human health and the environment, leaving EPA unable to conduct FIFRA's required balancing of risks and benefits or to determine, much less prevent, paraquat's unreasonable adverse effects.

i. EPA's one-sided assessment of paraquat's benefits to growers violates FIFRA.

During the registration review process, EPA prepared four distinct assessments of paraquat's benefits, covering growers of cotton, soybeans, peanuts, and other crops. *See* pp. 18-19 *supra*. Those assessments were fine-grained,

estimating the economic benefits of paraquat relative to other, alternative pesticides down to the cent per acre, along with the impacts of various mitigation measures on growers' revenues. *See, e.g.,* 2-ER-141–144 (cotton benefits assessment); 2-ER-173–174 (soybean benefits assessment); 2-ER-235 (peanut benefits assessment). EPA separately calculated benefits to growers of different crop varieties and in different locations, distinguishing between "upland cotton" and "pima cotton," 2-ER-141–144, and between soybeans grown in Kansas and Missouri. 2-ER-167, 2-ER-174.

However, EPA never assessed the offsetting costs from lost or reduced agricultural exports to countries that have banned the import of food containing paraquat residues. Because the Registration Decision permits paraquat residues to remain on all crops, U.S. growers can no longer sell foods grown using paraquat to countries like Thailand, which has prohibited the import of any food containing paraquat to protect public health. *See* 2-ER-100–101; 1-ER-089–093 (establishing tolerances for paraquat residues on food). Thailand previously purchased more than $524 million of U.S. soybeans and $162 million of U.S. wheat per year, along with other crops that contain paraquat residues. 2-ER-101. The United States Department of Agriculture has estimated that lost exports of crops treated with paraquat and another pesticide restricted by Thailand (chlorpyrifos) could cost the U.S. economy

$0.9-1.1 billion per year. *Id.*[18] The European Union also imposes more stringent limits on paraquat residues than are required by the Registration Decision, further limiting U.S. agricultural exports. 2-ER-102. All of this information was presented to EPA during the public comment period on the proposed Registration Decision, yet EPA did not measure or "tak[e] into account" those costs, as required by FIFRA. 7 U.S.C. § 136(bb). By relying on paraquat's economic benefits to growers without considering those countervailing costs, EPA impermissibly "tip[ped] the scales" in support of paraquat's benefits. *Sierra Club v. Sigler*, 695 F.2d 957, 975, 979 (5th Cir. 1983) (overturning agency's assessment of project's costs and benefits under National Environmental Policy Act where agency "cite[d] possible benefits in order to promote a project … yet avoid[ed] citation of accompanying costs …").

ii. EPA failure to assess paraquat's costs to human health and the environment violates FIFRA.

On the other side of the scale, EPA conducted no comparable assessment of the magnitude of paraquat's risks and their costs to human health and the environment. Without that cost information, EPA had nothing to weigh against paraquat's alleged benefits. EPA admits that such costs exist; it found that paraquat is associated with reduced lung function, kidney damage, respiratory distress, and other serious harms. *See* 3-ER-407. Even after accounting for the mitigation

[18] Since that USDA analysis, EPA has prohibited all food uses of chlorpyrifos, meaning only paraquat is currently contributing to those estimated trade losses.

required by the Registration Decision, EPA still found that workers will experience health risks that far exceed EPA's level of concern. *See* 1-ER-015–016 (finding that workers will continue to face respiratory risks up to four times worse and dermal risks up to five time worse than the level of concern). EPA also allowed farmworkers to reenter fields where paraquat had been sprayed after seven days, despite finding that risks of concern could last for nearly four weeks. 1-ER-017.

When assessing paraquat's environmental risks, EPA found risks of concern to mammals, birds, bees, algae, and non-target plants, including developmental risks to mammals that are up to 609 times worse than EPA's Level of Concern. 3-ER-541 (finding a risk quotient of 609 based on chronic harm to mammals' prenatal growth). EPA claims that the mitigation in its Registration Decision would "reduce[]" those risks of concern, without any assessment of the risks that remain. *See* 1-ER-045.

The identification of a risk of concern is merely a finding that a risk exists, not a measurement of its extent or costs. EPA did not estimate how many people would suffer harm to their lungs, kidneys, throats, and other organs because of their continued exposure to paraquat. 1-ER-030 (stating that paraquat's benefits would outweigh "any" unaddressed risks to human health and the environment, without measuring those risks). Nor did EPA consider the increased medical bills and costs to the health care system, reduced wages from lost days of work, and other economic and non-economic costs associated with those risks, leaving only the benefits to

growers quantified. As the Ninth Circuit held in connection with a different set of unassessed costs, "[w]ithout any investigation of those [costs] … EPA could not do even a rough and ready balancing" of paraquat's risks and benefits. *Love v. Thomas*, 858 F.2d 1347, 1361–62 (9th Cir. 1988); *see also Family Farm I.*, 960 F.3d at 1138 (holding that EPA's failure "to quantify or estimate the amount of damage caused by … application of dicamba herbicides" rendered EPA's registration decision unsupported by substantial evidence).

EPA also "entirely failed to acknowledge other costs" associated with its Registration Decision, and thus could not factor them into its weighing of risks and benefits. *Id.* at 1144. For instance, because EPA dismissed the risks of Parkinson's disease without undertaking the assessment required by FIFRA, *see* Point II *supra*, EPA attributed no costs to one of paraquat's most damaging effects. During the public comment period, EPA heard from the friends, spouses, children, and grandchildren of people with Parkinson's disease, and who have seen that disease steadily erode their loved ones' ability to perform everyday tasks. *See* 2-ER-260–265. The Record also contains evidence that Parkinson's disease costs individuals, families, and the United States government more than $52 billion per year, from the treatment and care of people with the disease to lost wages and productivity and other associated costs. *See* 2-ER-257. Even a small increase in Parkinson's disease

incidence can impose substantial public health and economic costs, which EPA must consider when weighing paraquat's risks and benefits.

Additionally, while EPA purported to reduce exposures to certain workers by requiring the use of respirators, double-layered clothing, and other PPE, those requirements subjected workers to increased heat-related risks without any consideration of the associated costs. Because they work long days, outdoors, during the hottest months of the year, pesticide handlers and farmworkers already face increased risks of heat stroke and dehydration. 2-ER-251. The Registration Decision exacerbates those harms by requiring handlers to work in respirators and other PPE, as well as by requiring the use of closed cabs without any requirement of air conditioning to ensure adequate ventilation and heat management within those cabs. *Id. See also* 1-ER-016; 1-ER-033; *see also* 1-ER-074–086 (measuring paraquat's risks with PPE and enclosed cabs). EPA's reliance on PPE and engineering controls to reduce paraquat exposures thus imposes "economic…and environmental costs," including health care costs associated with the treatment of heat-related injuries and lost wages from missed days of work. 7 U.S.C. § 136(bb). EPA failed to measure or account for those costs, as well.

EPA's "fail[ure] to perform a proper analysis of the risks and resulting costs" of continued paraquat use violates FIFRA. *Family Farm I*, 960 F.3d at 1144. Without measuring the extent and costs of paraquat's risks to workers,

communities and the environment, EPA could not "tak[e] into account" paraquat's "economic, social, and environmental costs." 7 U.S.C. § 136(bb). And without taking those costs into account, EPA could not conduct the balancing required by FIFRA or "demonstrate[s] that the benefits" of paraquat "outweigh the risks." *Env't Def. Fund*, 548 F.2d at 1005.

This Court has consistently rejected agency decisions, taken under FIFRA and other statutes, where the agency "put a thumb on the scale" of its risk-benefit balancing, in either direction. *Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin*., 538 F.3d 1172, 1198 (9th Cir. 2008) (remanding fuel economy rules where the National Highway Traffic Safety Administration measured industry compliance costs but failed to measure benefits associated with reduced greenhouse gas emissions). In *National Family Farm Coalition*, the Court vacated the registration for another herbicide, dicamba, because EPA "entirely failed to acknowledge" certain costs to agricultural communities and failed to "quantify or estimate the amount of damage" caused by the herbicide. 960 F.3d at 1138, 1142. In *Love v. Thomas*, the Court vacated an order suspending the registration of an herbicide because EPA failed to assess the economic impacts of the suspension on growers in the Pacific Northwest. 858 F.2d at 1361–62. Here, EPA not only overstated paraquat's economic benefits, but it never measured the extent of paraquat's unaddressed toll on farmworkers and communities and its associated

environmental, social, and economic costs. EPA therefore did not, and could not, conduct the balancing required by FIFRA.

B. EPA's finding that paraquat's benefits outweigh its human health and environmental risks is unsupported by substantial evidence.

Despite its failure to measure the costs associated with paraquat's unaddressed risks, EPA still asserted that those risks are outweighed by paraquat's benefits, and thus concluded that paraquat does not present any unreasonable adverse effects. 1-ER-045. This conclusion—the foundational underpinning of EPA's Registration Decision—is unexplained and unsupported.

To approve paraquat's continued registration, EPA must not only find that paraquat will not present any "unreasonable adverse effects," taking into account environmental, economic and social costs and benefits, 7 U.S.C. §§ 136a(c)(5), 136(bb), but it must also "describe the basis for such … findings." 40 C.F.R. § 155.58(b)(1); *see also Env't Def. Fund*, 548 F.2d at 1012 ("Once the Administrator has found that a risk inheres in the use of a pesticide, [EPA] has an obligation to *explain how* the benefits of continued use outweigh that risk.") (emphasis added). Here, EPA provided no such explanation.

EPA's comparison of paraquat's risks and benefits amounts to a single, conclusory sentence: "*Any* potential risks of concern that aren't fully mitigated by the measures discussed herein, are outweighed by the benefits associated with the

use of paraquat." 1-ER-045 (emphasis added). But EPA never says how it compared paraquat's risks and benefits or came to the conclusion that "any potential" risks to human health and the environment are outweighed by paraquat's benefits. *Id.* Nor does the Record contain the analysis required to support that claim.

Instead, EPA simply declares that paraquat's benefits are "important" and that its unaddressed costs to public health and the environment, whatever they may be, are not worth addressing. 1-ER-28–29. If that were sufficient to approve a pesticide's registration, then FIFRA's registration standard would be effectively meaningless. But EPA's "unsupported assertion" that paraquat's benefits outweigh its risks "does not amount to substantial evidence." *Algonquin Gas Transmission Co*, 948 F.2d at 1313. FIFRA demands "a careful balancing of risks and benefits," *Chem. Specialties Mfrs. Ass'n*, 484 F. Supp. at 515, supported by "a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Pollinators Stewardship Council*, 806 F.3d at 534 (Smith, J. concurring) (citing *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983)); *see also NCAP*, 544 F.3d at 1052 (EPA must "provide enough information to demonstrate a rational connection between the factors that the EPA examined and the conclusions it reached"). Because the Record neither reflects that "careful balancing" nor contains that required explanation,

EPA's conclusion that paraquat's benefits to growers outweigh its risks to workers, communities, and the environment is unsupported by substantial evidence.

V. The Registration Decision Should be Remanded With a Deadline for Action Upon Remand.

For all the foregoing reasons, the Registration Decision should be remanded to EPA. 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. While those mitigation measures are insufficient to address paraquat's risks to human health and the environment, vacating them would result in increased exposures and greater risks during the remand period. Remand without vacatur is appropriate where, as here, vacating the challenged decision would exacerbate the harm that the remand seeks to address. *See, e.g., Cal. Cmties. Against Toxics v. EPA*, 688 F.3d 989, 994 (9th Cir.2012) (remanding without vacatur because vacatur could increase air pollution, undermining the goals of the Clean Air Act).

Given the severe risks associated with paraquat, Petitioners request that the Court exercise its "authority to impose a deadline for the remand proceedings" and establish deadlines for the proposal and finalization of a revised Registration Decision. *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 937 (9th Cir. 2008). EPA's deadline for completing the paraquat registration review process is October 1, 2022. 7 U.S.C. § 136a(g)(1)(A)(iii). To adhere as closely to

that deadline as possible, if the Court remands the Registration Decision to EPA it should require EPA to propose a revised registration review decision within one year of the Court's decision and to finalize its revised decision rule within two years.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request the Court remand the Registration Decision, without vacatur and with a clear deadline for further action, along with any other relief that the Court deems just and proper.

Respectfully submitted May 25, 2022.

s/ Jonathan Kalmuss-Katz
Jonathan Kalmuss-Katz
Kartik S. Madiraju
Earthjustice
48 Wall Street, 19th Floor
New York, NY 10005
T: (212) 845-7376
jkalmusskatz@earthjustice.org

Patti A. Goldman
Earthjustice
810 Third Avenue, Suite 610
Seattle, WA 98104
T: (206) 343-7340
pgoldman@earthjustice.org

Gregory C. Loarie
Earthjustice
50 California Street, Suite 500
San Francisco, CA 94111
T: (415) 217-2000
gloarie@earthjustice.org

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 13,456 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word and 14-point Times New Roman font.

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/s/Jonathan Kalmuss-Katz
Jonathan Kalmuss-Katz
Earthjustice
48 Wall Street, 15th Floor
New York, NY 10005
T: 212.823.4989
jkalmusskatz@earthjustice.org

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on May 25, 2022.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: May 25, 2022

/s/Jonathan Kalmuss-Katz
Jonathan Kalmuss-Katz
Earthjustice
48 Wall Street, 15th Floor
New York, NY 10005
T: 212.823.4989
jkalmusskatz@earthjustice.org