Case Nos. 20-70787, 20-70801

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

RURAL COALITION, ORGANIZACIÓN EN CALIFORNIA DE LÍDERES CAMPESINAS, FARMWORKER ASSOCIATION OF FLORIDA, BEYOND PESTICIDES, AND CENTER FOR FOOD SAFETY,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents,

and

NATIONAL ASSOCIATION OF WHEAT GROWERS, *et al.*,

Respondent-Intervenors.

NATURAL RESOURCES DEFENSE COUNCIL, et al.,
Petitioners,
v.
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondent,
NATIONAL ASSOCIATION OF WHEAT GROWERS, et al.,
Respondent-Intervenors.

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

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PETITIONERS RURAL COALITION ET AL.'S OPENING BRIEF

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Petitioners Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, Beyond Pesticides, and Center for Food Safety certify that they have no parent corporations and that no publicly held corporation owns more than ten percent of the Petitioners.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Federal Cases

Page(s)

Federal Cases Cont'd

Page(s)

Federal Cases Cont'd

State Cases

Federal Statutes

Rules

Regulations

Page(s)

Regulations Cont'd

Other Authorities

Page(s)

Other Authorities Cont'd

Page(s)

Other Authorities Cont'd

Page(s)

Other Authorities Cont'd

GLOSSARY OF ACRONYMS AND TERMS

APA	Administrative Procedure Act
BE	Biological Evaluation
EPA	Environmental Protection Agency
ESA	Endangered Species Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FWS	Fish and Wildlife Service
IARC	International Agency for Research on Cancer
NMFS	National Marine Fisheries Service
ORD	Office of Research and Development
SAP	Scientific Advisory Panel
USDA	U.S. Department of Agriculture

INTRODUCTION

Glyphosate is the most widely-used pesticide[1] in the country, indeed, likely in human history. For decades, Intervenor Monsanto—maker of glyphosate-containing "Roundup" pesticides—assured customers that glyphosate was safe. But significant evidence emerged showing serious health effects, including world health experts agreeing that glyphosate is probably carcinogenic. Congress requires the Environmental Protection Agency (EPA) to reassess the safety of pesticides every fifteen years under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration review provisions. Given the exponential increase in glyphosate use since its last registration, careful analysis of glyphosate's safety to people who use it and the environment is long overdue. Rather than rigorously assess the registration based on current science, EPA rubber-stamped Monsanto's assurance of safety, contrary to its statutory duties.

Petitioners' members include the people who everyday work to bring food to America's tables. They are the frontline of exposure and

[1] Pesticides used to kill weeds are known as herbicides, a subset of the broader pesticide category.

possible health effects from glyphosate. EPA failed these essential workers by concluding there are no health risks without even assessing workers' exposure to glyphosate and its formulations. When absorbed through the skin, glyphosate enters the bloodstream to cause further harms, such as increasing cancer risk.

The purpose of Congress's command to review pesticide registrations every fifteen years is to ensure EPA uses the latest science and data to assess whether that pesticide still meets FIFRA's safety standard. Over time science advances, more data is collected, and latent harms are revealed. But here, EPA completely fails to fulfill FIFRA's command to use the most current information, or to even assess at all, various vital aspects of glyphosate's health and environmental impacts.

To ensure that glyphosate does not cause "unreasonable adverse effects" to people or the environment, EPA weighs the costs of a pesticide against its benefits. Here, EPA's cost-benefit analysis consists of a single sentence, where EPA completely fails to weigh the substantial costs of registration: among them, costs to farmers from the epidemic of glyphosate-resistant weeds and costs to wildlife exposed to spraying, especially crucial pollinators and iconic Monarchs.

EPA premises its conclusion that the registration would not have unreasonable adverse effects on three vague and ineffective label amendments, forms of mitigation against harm. Yet EPA fails to provide any evidence, let alone substantial evidence, in support of these measures' efficacy, to show how and why they would reduce the known risks below the FIFRA safety standard.

Finally, in addition to meeting the FIFRA safety standard, the Endangered Species Act (ESA) requires that EPA ensure its pesticide registrations will not jeopardize the continued existence of protected species. Agencies accomplish this through the Section 7 consultation process with the expert wildlife agencies, called by this Court the heart of the statute. The ESA's overarching directive is that agencies undertake this review at the earliest possible time. Here, EPA knows with certainty that glyphosate will likely adversely affect no less than 1,676 species of birds, mammals, fish, plants, amphibians, insects, and more. Yet EPA still issued this registration without undertaking the necessary consultation, in flagrant violation of the ESA.

EPA's fatally flawed decision should therefore be vacated.

JURISDICTIONAL STATEMENT

This petition presents for review the January 22, 2020 decision by EPA to issue the "interim" registration review decision for the pesticide glyphosate. Rural Coalition Excerpts of Record (RC_ER) Vol.1-RC_ER-0003-38 ("Glyphosate—Interim Registration Review Decision Case Number 0178").

EPA's "interim" registration is a final agency action subject to judicial review because (1) it marks the consummation of EPA's decisionmaking process on the human health and ecological risk assessments and mitigation measures, and (2) it determined rights or obligations from which legal consequences flow, namely allowing the continued registration of glyphosate and its hundreds of formulations. *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997); *United Farmworkers of America v. U.S. Envtl. Prot. Agency*, 2005 WL 7140333, *9 (W.D. Wash., Feb. 14, 2005).

This Court has jurisdiction under FIFRA, which provides for review in the courts of appeals of "any order issued by the [EPA]

Administrator following a public hearing." 7 U.S.C. § 136n(b).[2] EPA's January 22, 2020 decision is a final determination in EPA's review of the glyphosate registration, a process that began in 2009.[3] Petitioners timely filed. 20-70801, ECF 1-5; 7 U.S.C. § 136n(b), 40 C.F.R § 23.6.

ISSUES PRESENTED

1. Whether EPA violated FIFRA by authorizing the registration (1) without the data required to fully assess glyphosate's effects to farmworkers' and other users' health and the environment, (2) without weighing the true costs, and (3) without supporting its decision to register glyphosate with minimal label changes with substantial evidence; and

2. Whether EPA violated the ESA by failing to consult the expert wildlife agencies concerning glyphosate's effects on threatened and endangered species and their critical habitats, despite ample evidence and the agency's admissions that its approval decision "may affect" them.

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[2] *Ctr. for Biological Diversity v. Envtl. Prot. Agency,* 847 F.3d 1075, 1089-90 (9th Cir. 2017).

[3] Petitioners submitted comments to the agency in 2009, 2016, 2018, and 2019. 7-RC_ER-1416; 5-RC_ER-0876; 3-RC_ER-0473; 2-RC_ER-0067. Petitioners have standing. *Friends of Earth, Inc. v. Laidlaw Envtl. Serv. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000); *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977). The approval threatens to directly injure Petitioners' members' environmental, health, vocational, agricultural, recreational, aesthetic, and economic interests. *See* Addendum of Declarations, A106-209.

STATEMENT OF THE CASE

This case is about the most widely-used pesticide in the country: glyphosate, the active ingredient in hundreds of products, including Monsanto's Roundup brands. 1-RC_ER-0005-6.[4] EPA issued a registration decision for glyphosate early in 2020, allowing hundreds of millions of pounds of glyphosate to be sprayed on hundreds of millions of acres throughout the United States. 1-RC_ER-0011.

Glyphosate use has increased exponentially since the advent of Monsanto's genetically engineered "Roundup Ready" crops that resist glyphosate in the 1990s. Today, 280 million pounds of glyphosate are sprayed annually on 285 million acres of U.S. farmland.[5] For scale, that

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[4] The registration covers glyphosate acid (PC Code 417300) and its various salt forms (PC Codes 103601, 103604, 103605, 103607, 103608, and 103613). ER0003. Petitioners use glyphosate for simplicity.

[5] EPA recently updated these figures. *See* EPA, *Draft National Level Listed Species Biological Evaluation for Glyphosate*, 1-4, https://www.epa.gov/endangered-species/draft-national-level-listed-species-biological-evaluation-glyphosate#executive-summary (hereinafter "BE"). Petitioners request judicial notice of this and other extra-record information cited throughout this brief. Fed. R. of Evid. 201(c)(2); 201(b) (because this information is "not subject to reasonable dispute" and "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned," this Court can properly take notice). Government publications are frequently given judicial notice. *See, e.g.*, *Corrie v. Caterpillar*, 503 F.3d 974, 978 n.2 (9th Cir. 2007).

is nearly the size of three Californias. This is four times the amount of the second-leading conventional pesticide, atrazine. 4-RC_ER-0843. Over 21 million more pounds are sprayed by homeowners, on roadways, in forestry, and for other non-agricultural uses. BE at 1-4.

Despite Monsanto's assurance that glyphosate is safe, science emerged over the years showing that glyphosate may cause cancer. Currently in the courts are thousands of cases brought by over 100,000 plaintiffs alleging that their own or their loved ones' cancer developed after exposure to Monsanto's Roundup. This may only be the tip of the iceberg,[6] as more evidence emerges regarding the number of people whose risk of cancer was and is being increased by glyphosate exposure.

But even though EPA's registration review process began over a decade ago, in this decision EPA still fails to analyze glyphosate's health impacts to workers who are frequently exposed to glyphosate. This includes farmers and farmworkers like Petitioners' members, who

[6] While homeowners and groundskeepers brought early lawsuits, the vast majority of glyphosate users are farmers and farmworkers. *See* Patricia Cohen, *Roundup Maker to Pay $10 Billion to Settle Cancer Suits,* NY TIMES (June 24, 2020), https://www.nytimes.com/2020/06/24/business/roundup-settlement-lawsuits.html#:~:text=Bayer%20faced%20tens%20of%20thousands,set%20aside%20for%20future%20cases.

are on the frontlines of nearly every health and environmental crisis, from the COVID-19 pandemic to climate change, and are particularly at risk of health impacts from glyphosate spraying at work.

And despite those many decades and billions of pounds of glyphosate sprayed on farms, public lands, and homes, EPA registered glyphosate without consulting with the expert wildlife agencies to ensure glyphosate is not jeopardizing the continued existence of protected species. The monumental scale of this failure is now evident, because EPA recently made public a draft evaluation that finds *100%* of the 1,795 endangered and threatened species exposed to glyphosate may be affected.[7] And of those species, 93% will likely experience adverse effects, meaning they may be harmed, perhaps enough to jeopardize their very existence. Yet this evaluation and subsequent expert consultation is required before an agency action is taken, not after the fact.

I. BACKGROUND OF THE GLYPHOSATE REGISTRATION.

EPA first registered the plant-killing pesticide glyphosate in 1974. 2-RC_ER-0297. For two decades, glyphosate spraying in farming was

[7] *Supra* n.5.

limited because it kills crops and other desirable plants along with weeds. Thus, glyphosate could only be sprayed to kill weeds before crops like corn sprouted ("preemergence"), shortly before or after harvest, or between rows in orchards. 5-RC_ER-0924, 933.

However, following EPA's reregistration of glyphosate in 1993, 1-RC_ER-0006, Monsanto created a significant new expansion: spraying over the top of commodity crops that Monsanto genetically engineered to be resistant to glyphosate. Glyphosate resistance enabled what was previously impossible: these "Roundup Ready" crops are sprayed directly, post-emergence, one to three times throughout the growing season. 5-RC_ER-0933.

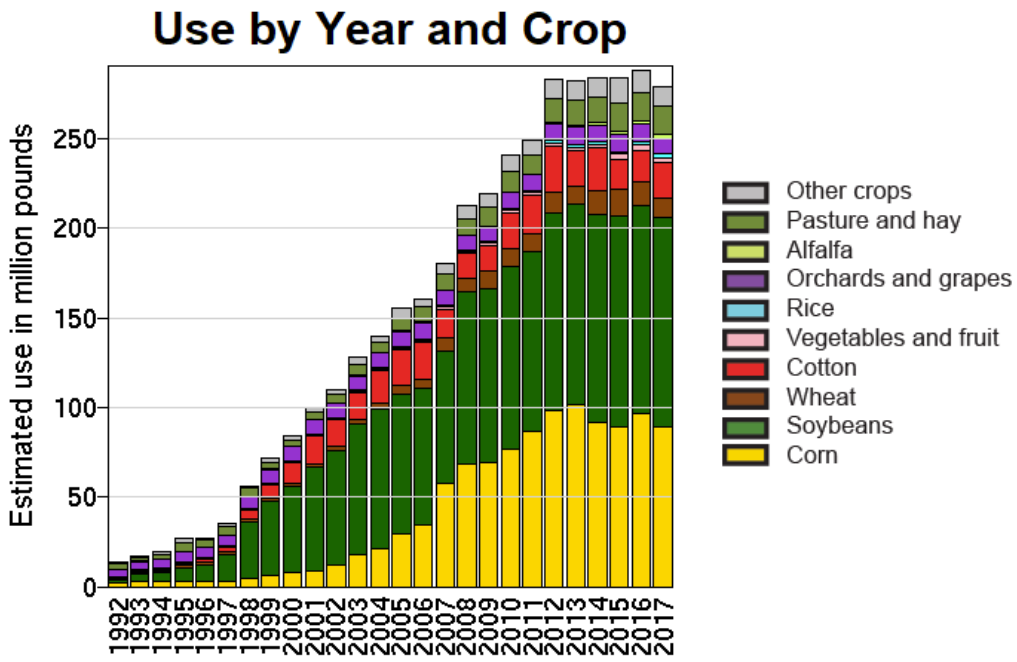
Near universal adoption of glyphosate-resistant soybeans, cotton, and corn since their introduction drove a massive increase in agricultural use of glyphosate, from less than 8 million pounds in 1990 to 280 million pounds today. 5-RC_ER-0928; 2-RC_ER-0267; 2-RC_ER-0074.[8] Home and other non-agricultural uses account for an additional 21-24 million pounds per year. 2-RC_ER-0282.[9] This U.S. Geological

[8] BE at 1-4.

[9] *Id.*

Survey graph shows the stark increase caused by introduction of genetically engineered, glyphosate-resistant crops:

Figure 1: Estimated Use of Glyphosate by Year and Crop (in million pounds).[10]



[10] USGS, *Pesticide National Synthesis Project—Estimated Annual Agricultural Pesticide Use Maps*, https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2017&map=GLYPHOSATE&hilo=L.

Health Impacts

Such intensive glyphosate use causes numerous harms. Regarding human health, EPA itself has found glyphosate to be a liver and kidney toxin, as well as a possible carcinogen. 3-RC_ER-0525; 2-RC_ER-0078-80; 3-RC_ER-0359-61; 2-RC_ER-0150-189; 6-RC_ER-1208-21; 11-RC_ER-2410-23. The World Health Organization's cancer experts classify glyphosate as "probably carcinogenic," and it is associated with increased risk of the cancer non-Hodgkin lymphoma in the pesticide's users. 5-RC_ER-1100-01; 3-RC_ER-336-58.

Currently, there are thousands of lawsuits against Monsanto/Bayer, by more than 100,000 plaintiffs alleging cancer from glyphosate exposure.[11] Monsanto has lost all three bellwether trials,[12] including one on appeal, *Monsanto Co. v. Hardeman*, No. 19-16636 (9th

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[11] U.S. Right to Know, *Monsanto Roundup & Dicabma Trial Tracker: Bayer backs away from plan to contain future Roundup cancer claims* (July 8, 2020), https://usrtk.org/monsanto-roundup-trial-tracker-index/#:~:text=More%20than%20100%2C000%20people%20in,covered%20up%20the%20cancer%20risks.

[12] *Johnson v. Monsanto Co.*, No. CGC-16-550128 (Cal. Super. Ct. 2018); *Hardeman v. Monsanto Co.*, No. C 16-00525-VC (N.D. Cal. 2019); *Pilliod v. Monsanto Co.*, No. RG17862702, JCCP No. 4953 (Cal. Super. Ct. 2019).

Cir.) (Oral Argument heard Oct. 23, 2020). These cases involve people who used glyphosate at home or at work, with each plaintiff later developing non-Hodgkin lymphoma. Following extensive jury trials, these plaintiffs were awarded over $2 billion in compensatory and punitive damages because glyphosate was a "substantial factor" in causing their cancers and Monsanto failed to warn that its glyphosate-based pesticides could cause cancer.

To settle the remaining non-Hodgkin lymphoma cases, Bayer has agreed to a massive $10 billion settlement, one of the largest settlements ever in U.S. civil litigation.[13] The settlement does not cover at least 30,000 claims from plaintiffs who did not join the settlement. Monsanto/Bayer has not agreed to include a warning about increased risk of cancer on any glyphosate product labels. *Id.*

[13] Patricia Cohen, *Roundup Maker to Pay $10 Billion to Settle Cancer Suits,* NY TIMES (June 24, 2020), https://www.nytimes.com/2020/06/24/business/roundup-settlement-lawsuits.html.

Environmental Impacts

Glyphosate is sprayed on 285 million acres of farmland annually (plus 21 million pounds on lawns, parks, schoolgrounds, forests, and roadways), with massive impacts to plants, animals, and their habitats. Glyphosate is ubiquitous in water bodies, the atmosphere, and in rainfall. 4-RC_ER-0812-21; 8-RC_ER-1669-97; 6-RC_ER-1382. Pollinators, frogs, and numerous other organisms are exposed, their habitats overlapping with spraying, drift, and runoff. 3-RC_ER-0504-5; 2-RC_ER-0100-101. Glyphosate formulations are extremely toxic to aquatic-stage amphibians, and are implicated as a factor in their world-wide decline. 2-RC_ER-0100-101. Glyphosate spraying may also reduce soil health by harming microbes that play critical roles in plant health and disease control, effects EPA did not assess. 7-RC_ER-1431-33. And rampant glyphosate drift has made it a leading culprit in damage to neighboring plants. 6-RC_ER-1355; 5-RC_ER-1049; 3-RC_ER-0557, 563; 9-RC_ER-2008-10, 2018-30; 8-RC_ER-1734.

Glyphosate is also a signficiant driver of the precipitous decline in Monarch butterflies, by nearly eliminating their host plant and food source, milkweed, from Midwestern crop fields. 6-RC_ER-1355; 5-

RC_ER-1049; 3-RC_ER-0555; 3-RC_ER-0483-85.[14] So much so that FWS recently determined that ESA listing and its associated protections for Monarchs is warranted. *Id.* The Monarchs' multigenerational migration path goes from Mexico through much of the Eastern half of the Continental U.S.:

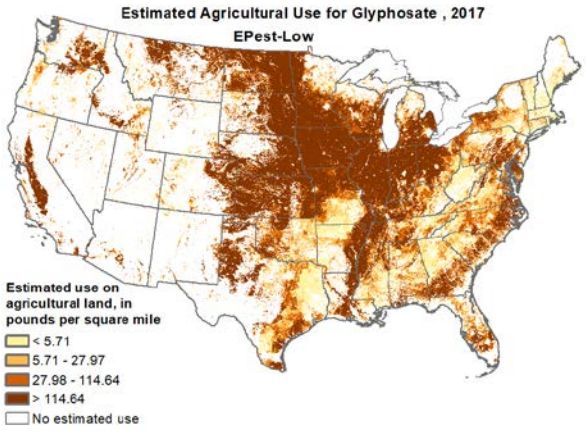
Figure 2: Monarchs Migratory Path[15]

[14] *See, e.g.*, FWS, Endangered and Threatened Wildlife and Plants; 90-Day Findings on Two Petitions, 79 Fed. Reg. 78775 (Dec. 31, 2014) (finding ESA protection for Monarchs "may be warranted" and initiating status review). On December 15, 2020 FWS announced that ESA protection for Monarchs is scientifically and legally warranted, but listing is precluded by other species at this time; listing for Monarchs is scheduled for 2024. FWS, *U.S. Fish and Wildlife Service Finds Endangered Species Listing for Monarch Butterfly Warranted but Precluded* (Dec. 15, 2020), https://fws.gov/news/ShowNews.cfm?ID=36817#:~:text=December%2015%2C%202020&text=After%20a%20thorough%20assessment%20of,on%20higher%2Dpriority%20listing%20actions.

[15] FWS, *Monarch Butterfly: Fall & Spring Migrations*, https://www.fws.gov/savethemonarch/pdfs/migration-map.pdf.

A map of glyphosate use shows the massive overlap with habitat:

Figure 3: Estimated Agricultural Use of Glyphosate in 2017 (in pounds per square mile).[16]



Superweeds

Exorbitant glyphosate use is also responsible for an epidemic of glyphosate-resistant "superweeds," which in just two decades have infested an astounding 120 million acres of cropland, causing severe harm to agriculture that agronomists have compared to the infamous boll weevil. 6-RC_ER-1354; 3-RC_ER-0509; 7-RC_ER-1447; 2-RC_ER-274. Just as excessive antibiotic use has fostered the evolution of

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[16] USGS, *Pesticide National Synthesis Project – Estimated Annual Agricultural Pesticide Use Maps*, https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2017&map=GLYPHOSATE&hilo=L&disp=Glyphosate.

resistant bacteria, over-reliance on glyphosate—at Monsanto's direction and encouragement—created this crisis. 7-RC_ER-1456. Superweeds create substantial costs to farmers to control them, including increased expenditures on additional pesticides and increased use of soil-eroding tillage. 2-RC_ER-0104. This increase in tillage comes with a price tag of $450 million in damages to water quality and climate effects. 2-RC_ER-0041.

Monsanto recently introduced a new generation of crops genetically engineered for resistance to another pesticide, dicamba, as a "solution" to the glyphodate-resistant weed epidemic. 7-RC_ER-1102; 6-RC_ER-1367. In a repetition of the glyphosate debacle, dramatically increased spraying of dicamba to kill glyphosate-resistant weeds is already triggering a predicted rise in weeds resistant to both pesticides. *Id.*

Still worse, massive use of dicamba, a volatile chemical extremely prone to drift, has caused unprecedented drift damage to millions of acres of crops across the country. *See, e.g., Nat'l Family Farm Coal. (NFFC) v. U.S. Envtl. Prot. Agency*, 960 F.3d 1120 (9th Cir. 2020) (collecting extensive evidence of economic, environmental, and social

harms from dicamba use on resistant crops to control glyphosate-resistant weeds, including millions of acres of reported dicamba damage to crops and gardens, and a rupture in the social fabric of farming communities). EPA has done virtually nothing to rein in this toxic treadmill of pesticide use and weed resistance caused by glyphosate, despite being warned it would occur at the outset of the registration review process. 6-RC_ER-1371.

II. GLYPHOSATE REGISTRATION REVIEW PROCESS AND DECISION.

The Food Quality Protection Act of 1996 and the Pesticide Registration Improvement Renewal Act of 2007 amended FIFRA, requiring EPA to review all registered pesticide every 15 years and determine whether the pesticide still meets the FIFRA standard for registration: that the pesticide not cause "unreasonable adverse effects on the environment." 7 U.S.C. § 136a(a), (g); 40 C.F.R. § 155.40(a); 7-RC_ER-1480; 1-RC_ER-0005.

A. Registration Review

Registration review enables EPA to reassess a pesticide in light of evolving science, improved ability to detect risks, policy changes, and importantly here, changes in pesticide usage practices that have

occurred since the pesticide's last review. 7-RC_ER-1480. EPA must ensure that each pesticide's registration "is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment." 40 C.F.R. § 155.40(a)(1). Accordingly, EPA may identify and solicit data that it does not have, but would be useful to its review. *Id.* § 155.50(b)-(c). Among other things, EPA must "assess any changes that may have occurred since the Agency's last registration decision in order to determine the significance of such changes and whether the pesticide still satisfies the FIFRA standard for registration." *Id.* § 155.53(a).

Registration review includes both the active ingredient and "all the products" containing it. *Id.* § 155.42(a). Here, that includes glyphosate and the 555 products containing glyphosate (like Roundup) that EPA identified. 2-RC_ER-0248. EPA also must assess the formulations' so-called "inert" ingredients, the different substances in a formulation that change how the pesticide product works. *Id.* § 155.53(a) (EPA must consider whether any new data is required for "an inert ingredient in the pesticide product...").

B. Glyphosate Registration Review

It has been nearly thirty years since EPA's last registration decision for glyphosate. 3-RC_ER-0516. In 2009, EPA began the glyphosate registration review process and anticipated it would take six years. 7-RC_ER-1485. Instead, it has taken nearly twice as long.

As part of its human health risk assessment, EPA says it evaluated the carcinogenic potential of glyphosate, concluding that glyphosate is "not likely to be carcinogenic to humans" in December 2017. 3-RC_ER-0499. This conclusion is at odds with EPA's own prior determination that glyphosate is a possible carcinogen, 11-RC_ER-2416, and with the World Heath Organization's International Agency for Research on Cancer's (IARC) 2015 determination that glyphosate is "probably carcinogenic to humans." 2-RC_ER-0217. IARC's conclusion is widely supported in the medical science community, as well as by the State of California, which listed glyphosate as a chemical known to cause cancer in July 2017. 3-RC_ER-0488. It also at odds with recent

court decisions that have found Monsanto's glyphosate-containing Roundup pesticides are a substantial factor in causing users' cancer.[17]

In February 2018, EPA opened its draft ecological and human health risk assessments to public comment. EPA received over 238,000 comments on the draft risk assessments. 2-RC_ER-0215. Astonishingly, EPA issued its public comment responses on the human health risk assessment *before the end of the comment period*, meaning the agency did not actually consider the comments submitted by Petitioner CFS or many thousands of others that filed their comments on the due date.[18] 83 Fed. Reg. 8476 (Feb. 27, 2018); 3-RC_ER-0498; 3_RC_ER-0473. Not surprisingly then, not one of the thousands of comments submitted on the drafts changed EPA's final risk assessments. 2-RC_ER-0215.

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[17] *See Johnson v. Monsanto Co.*, No. CGC-16-550128 (Cal. Super. Ct. 2018); *Hardeman v. Monsanto Co.*, No. C 16-00525-VC (N.D. Cal. 2019); *Pilliod v. Monsanto Co.*, No. RG17862702, JCCP No. 4953 (Cal. Super. Ct. 2019).

[18] *See* NRDC Opening Br. at 56-58, *filed concurrently*, Case No. 20-70787 (EPA failure to respond to Petitioner comments regarding human health was unlawful).

C. "Interim" Registration and EPA Health and Environmental Conclusions

EPA's so-called "interim" registration actually finalized its human health and environmental risks assessments, its cost-benefit analysis, and its so-called mitigation measures. It did so while admitting several crucial sets of information were incomplete, including human health data, impacts on pollinators (bees), and effects to threatened and endangered species.

In 2019, EPA issued a "proposed interim" registration decision for glyphosate, stating that no further human health data (like on cancer) were required. 2-RC_ER-0229, 0235. EPA acknowledged that information on endocrine disruption, pollinator impacts, and endangered species was missing, but stated that it was not making any findings associated with these three missing categories of information. 2-RC_ER-0250.

In 2020, EPA issued the final "interim" registration challenged here. 1-RC_ER-0003. EPA did not say when reviews of glyphosate's impacts on pollinators (including bees), threatened and endangered species, and endocrine disruption would be completed. 1- RC_ER-0014, 22.

Human Health and Environmental Conclusions

EPA's decision "finalize[d]" the agency's proposed draft ecological and human health risk assessments, even though EPA still lacked critical human health and environmental reviews and determinations. 1- RC_ER-0022. Despite the medical science community's consensus on its health risks, 5-RC_ER-0916, the agency's own prior analysis, and several court decisions finding glyphosate pesticides were a substantial factor in causing cancers, EPA nonetheless claims that it "did not identify *any* human health risks from exposure to glyphosate." 1-RC_ER-0017 (emphasis added). EPA reached this conclusion after determining that "no occupational handler or occupational post-application assessments were required" for "the most commonly used herbicide in the United States." 3-RC_ER-0525; 2-RC_ER-0267. Thus, EPA came to its "no health risks" conclusion without conducting *any assessment* of the potential health effects to those most heavily exposed to glyphosate, including farmworkers, farmers, and other workers. 9-RC_ER-2048.

EPA admits that "risks to terrestrial invertebrates at higher application rates are uncertain" and that it "believes that additional

data may be necessary to fully evaluate risks to bees." 1-RC_ER-0014, 19. Rather than acquire these data, EPA finalized this registration with an ineffective warning on glyphosate labels that it hopes will "alert users" of impacts to non-target organisms, including pollinators. 1-RC_ER-0019. Similarly, although EPA admits there are "risk[s] to listed species whose range and/or critical habitat co-occur with the use of glyphosate," rather than complying with its ESA duty to consult the expert wildlife agencies before taking action, EPA relies instead on the same ineffective label warning that it "expect[s]" will "reduce the extent of environmental exposure" to listed species. 1-RC_ER-0022.

Cost-Benefit Analysis

While admitting ecological risks to mammals, birds, and plants, and the costs to farmers from glyphosate-resistant weeds, EPA's cost-benefit assessment consists of a one-sentence conclusion that "the benefits outweigh the potential ecological risks when glyphosate is used according to label directions." 1-RC_ER-0017.

Label Amendments

EPA's "interim" registration also finalizes its mitigation measures, supposedly reducing the harm from continued glyphosate spraying.

First, EPA included "information and recommendations" to slow the spread of superweeds, consisting of two older, non-binding guidance documents, which are not specific to glyphosate. 1-RC_ER-0026 (providing link to guidances without requiring any statements be added to pesticide labels). Second, EPA added a "non-target organism advisory," to "alert users" that glyphosate "is toxic to plants," and instructs users to follow the label instructions. 1-RC_ER-0019-20, Third, EPA added steps to "manage off-target spray drift," including maximum wind speeds for spraying and minimum droplet sizes. 1-RC_ER-0017-18. EPA offers no information as to how any of these three "mitigation" measures will reduce the known risks to plants, birds, fish, amphibians, or aquatic invertebrates.

Despite the absence of crucial data on human health (including worker exposure), pollinators, and endangered species, EPA finalized the glyphosate "interim" registration and its label amendments. 1-RC_ER-0005-6. "Interim" registration is not part of FIFRA, but a creation of EPA in its regulations. 40 C.F.R. § 155.56. EPA uses "interim" registrations to finalize parts of a registration, like mitigation measures, or identify needed data, like through a Data Call-In pursuant

to FIFRA Section 3(c)(2)(B). *Id.* Here, EPA "finalized" its mitigation measures, and the health and ecological risk assessments, announcing that "[it] concluded its regulatory review of glyphosate."[19] Whether called "interim" or not, this was a final registration that had to comply with the FIFRA safety standard of causing no unreasonable adverse effects on the environment. 7 U.S.C. § 136a. And it is final agency action under *Bennett v. Spear*, 520 U.S. 154 (1997) and the ESA. 16 U.S.C. § 1536(a)(2).

III. PROCEDURAL HISTORY

EPA issued a proposed decision in March 2019. 2-RC_ER-211. Petitioners submitted timely comments. 2-RC_ER-67. In their comments, Petitioners raised numerous significant issues concerning EPA's human health and ecological risk assessments, ESA compliance, and cancer assessment. In January 2020, EPA issued the registration decision. 1-RC_ER-0003. This challenge followed. Another group of petitioners also filed suit, *see Nat. Res. Defense Council, et al. v. U.S. Envtl. Prot. Agency*, No. 20-70787, and the Court consolidated the cases.

[19] *EPA Finalizes Glyphosate Mitigation* (Jan. 30, 2020), https://www.epa.gov/pesticides/epa-finalizes-glyphosate-mitigation.

SUMMARY OF ARGUMENT

The Court should grant the petition for review and vacate the registration for at least four reasons. First, EPA's registration failed to protect workers, including Petitioners' farmworker and farmer members, because EPA lacks substantial evidence to support its conclusion that there are no "occupational risks of concern" from glyphosate exposure, in violation of FIFRA. Second, EPA failed to consider and assess the true costs—economic, social, and environmental—of glyphosate, also in violation of FIFRA. Third, EPA failed to assess and support with substantial evidence the efficacy of its label mitigation measures on which its decision is based. And fourth, EPA violated the ESA by taking action without first completing Section 7 consultation, despite its knowledge that thousands of species may be affected, the vast majority of which will likely be adversely affected, requiring formal consultation and opinions by the expert wildlife agencies.

For any or all of these reasons, the Court should vacate the registration.

STANDARDS OF REVIEW

The Court may sustain EPA's glyphosate registration under FIFRA only if EPA's order is "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). In reviewing for substantial evidence, the Court must consider the whole record and whether it "fairly detracts from its weight." *Universal Camera Corp. v. Nat'l Labor Relations Bd.,* 340 U.S. 474, 488 (1951). Judicial review must be "searching and careful, subjecting the agency's decision to close judicial scrutiny." *Containerfreight Corp. v. United States*, 752 F.2d 419, 422 (9th Cir. 1985) (internal citations and quotations omitted).

The substantial evidence standard "affords an agency *less* deference than the arbitrary and capricious standard." *Pollinator Stewardship Council v. U.S. Envtl. Prot. Agency*, 806 F.3d 520, 533 (N.R. Smith, J., concurring) (citing *Universal Camera Corp.,* 340 U.S. at 477; *Union Oil Co. of Cal. v. Fed. Power Comm'n,* 542 F.2d 1036, 1040-41 (9th Cir. 1976)) (emphasis added). Therefore, if EPA's decision is arbitrary and capricious, it cannot be supported by substantial evidence. To avoid being arbitrary and capricious, EPA "must examine the relevant data and articulate a satisfactory explanation for its action

including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal citations and quotations omitted).

Under either standard, the Court's "review must not rubber-stamp . . . administrative decisions that [the court deems] inconsistent with a statutory mandate or that frustrate the congressional policy underlying a statute." *Ocean Advocates v. U.S. Army Corps of Eng'rs*, 361 F.3d 1108, 1119 (9th Cir. 2004) (internal citations and quotations omitted). Any difference between these two standards is immaterial, however, because EPA's registration decision for glyphosate satisfies neither. If it finds EPA's actions violated FIFRA, this Court should set aside, or vacate, the registration. *Pollinator Stewardship,* 806 F.3d at 532-33.

EPA violated the ESA if its failure to consult the expert wildlife agencies in connection with its registration of glyphosate was arbitrary, capricious, an abuse of discretion, or otherwise not in compliance with law. 5 U.S.C. § 706(2)(A); *see Conner v. Burford*, 848 F.2d 1441, 1453 (9th Cir. 1988). The ESA requires that federal agencies consult the expert wildlife agencies before taking any action that "may affect" any protected species or critical habitat. 50 C.F.R. § 402.14(a); *see* 16 U.S.C.

§ 1536(a)(2). *Karuk Tribe of Cal. v. U.S. Forest Serv.*, 681 F.3d 1006, 1020-21 (9th Cir. 2012) (en banc).

ARGUMENT

I. EPA VIOLATED FIFRA.

A. EPA Failed to Protect Workers and Lacks Substantial Evidence For Conclusion That There Are No "Occupational Risks of Concern."

First, EPA abysmally failed to protect farmworkers and other users when it concluded that there are no "occupational risks of concern" from glyphosate spraying. 1-RC_ER-0011. People who work around, handle, and apply pesticides like glyphosate are the most highly exposed, and therefore most at risk of suffering the negative health effects from these toxins. 2-RC_ER-0309-10. They are the proverbial canaries in the coal mine: through skin contact and other exposure, they are at greater risk of harm, such as cancer, than people whose primary exposure is dietary. *Id.*; 3-RC_ER-0424, 431-32.

Yet from the outset of registration review in 2009, EPA concluded it would not conduct an occupational risk assessment, and maintained this position throughout the review process. 7-RC_ER-1504. In EPA's view, glyphosate is not hazardous and thus will not harm workers no

matter how much they take in via skin contact or other means, so there is no need to assess exposure in order to quantify risk.

But EPA failed to consider signficiant evidence to the contrary, as explained in Petitioners' and others' comments. 2-RC_ER-0089-97; 3-RC_0448-65. Even after the World Health Organization's IARC classified glyphosate as "probably carcinogenic to humans" in 2015,[20] based in part on elevated incidence of cancer in *glyphosate applicators*, EPA doubled down in 2017, reiterating that it would not undertake a "quantitative exposure risk assessment" for those most highly exposed to glyphosate. 3-RC_ER-0518.

Accordingly in its 2020 registration decision, EPA concluded that there are no health risks from glyphosate, despite evidence of carcinogenicity and its failure to quantify occupational exposure. And EPA completely failed to assess any formulations of glyphosate, the real world products that users spray, which are known to increase injury. This failings are reversible error; EPA did not have substantial

[20] The IARC Working Group included scientists from the EPA, the U.S. Institute of Environmental Health Sciences, and the California EPA. 4-RC_ER-0687-89.

evidence for its conclusion that there are no occupational risks from glyphosate.

1. EPA Failed to Assess Skin Absorption of Glyphosate, the Main Way Workers Are Exposed.

EPA itself has explained that "[skin] absorption [of pesticides] is a significant factor in occupational or residential exposure risk assessments since these exposures occur most frequently via the dermal route." 9-RC_ER-2048. And yet from glyphosate's initial registration in 1974 to the present day, EPA has apparently never collected *even a single dermal absorption study* to determine how much glyphosate users absorb into their systems via skin contact. 3-RC_ER-0518, 25, 27, 43; 9-RC_ER-2055-68ER.

Unbelieveably, EPA's refusal to assess absorption of glyphosate via skin contact is based on a 21-day dermal toxicity study conducted on 20 rabbits in 1982. 3-RC_ER-0525, 27, 43; 10-RC_ER-2121. There are at least three major problems with EPA's reliance on this stale, Monsanto-sponsored study.

First, the EPA guideline for this type of study cautions that such studies are "not capable of determining those effects that have a long latency period for development (e.g., carcinogenicity and life

shortening)."[21] It is unsurprising then that EPA further warns that "[e]xtrapolation from the results of this study to humans is valid *only to a limited degree*." *Id.* (emphasis added).

Whatever that "limited degree" is, EPA has far surpassed it, repeatedly pointing to this rabbit study decade after decade as its sole basis for not conducting a quantitative dermal exposure risk assessment for workers. 10-RC_ER-2121; 8-RC_ER-1715-16; 3-RC_ER-0525, 27, 43. Given that one of the hazards is cancer, and that this study was not capable of determining long-latency effects like those of cancer, EPA cannot rely on this study as substantial evidence for its conclusion that there are no occupational risks of concern. *Id.*

Second, the study is nearly 40 years old. The core point of registration review is to update "effects on human health" by using "current" science, to determine if the pesticide still meets FIFRA's safety standard. 40 C.F.R. § 155.40(a)(1). Indeed, Congress recognized the necessity in providing EPA with "sufficient authority to adjust pesticide evaluation and registration standards as scientific risk and

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[21] EPA, *Series 870 - Health Effects Test Guidelines*, 1 (Aug. 1998), https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances/series-870-health-effects-test-guidelines.

benefit assessment technologies and methodologies advance." H.R. Rep. No. 104-669(I), at 37 (1996). Thus, the registration review amendments to FIFRA "establish[ed] ongoing scientific look-back procedures" to enable EPA to integrate "the rapid development of science and the subsequent application of that knowledge in how it impacts human health and the environment" during registration review. *Id*. at 38. EPA's reliance on a 40-year-old rabbit study ignores this charge.

In other contexts, this Court has found agency reliance on outdated data is arbitrary and capricious. *Sierra Club v. U.S. Envtl. Prot. Agency*, 671 F.3d 955, 968 (9th Cir. 2012) (EPA approval of state implementation plan under Clean Air Act using old mobile source data, where newer data available, was arbitrary and capricious); *Lands Council v. Powell*, 379 F.3d 738, 748-49 (9th Cir. 2004) (data on habitat of trout "too outdated to carry the weight assigned to it" and rendered National Environmental Policy Act analysis inadequate); *see also Northern Plains Res. Council, Inc. v. Surface Transp. Bd.*, 668 F.3d 1067, 1086 (9th Cir. 2011) (similar).

The argument is even stronger here because, unlike in the National Environmental Policy Act context, EPA has broad authority to

require more data or studies as needed. 7 U.S.C. § 136a(c)(2)(B) (FIFRA gives EPA power to call in data from registrants); 40 C.F.R. § 155.40(c)(2) (EPA "will" require data via call in when it determines that new data or information are necessary for a pesticide's registration review). EPA has no administrative or resource-based excuse: it can and regularly does require the registrants to update studies.

For instance, here EPA should have required a "dermal penetration" study, for which EPA has specific test guidelines, to assess the critically important issue of how much glyphosate is taken up into a worker's system via dermal absorption of glyphosate. 9-RC_ER-2055-68. And there are many additional human health data needs. 2-RC_ER-0047-49; 2-RC_ER-0311-18. That Congress gave EPA this power underscores the need for EPA to use it rather than rely on stale data. 7 U.S.C. § 136a(c)(2)(B).

Finally, the rabbit study involved only the active ingredient (glyphosate) and not any of the hundreds of formulations of glyphosate, which contain numerous other ingredients that change how the pesticide works. 3-RC_ER-0542; 8-RC_ER-1730-33; 7-RC_ER-1392, 1399-1411. This flaw is explained further below. *Infra* 43.

This single study is nearly four decades old, assessed only the active ingredient and not the whole formulations, and cannot measure harms like cancer. Thus, EPA's reliance on it to claim no further data are needed does not comply with the FIFRA registration review requirements. There is no way EPA can know if glyphosate and its formulations continue to meet the FIFRA safety standard without updating its data. Because of EPA's failure to assess skin absorption of glyphosate, its conclusion that there are no occupational risks is not supported by substantial evidence.

2. EPA Ignored Increased Risk of Cancer to Workers from Glyphosate Exposure.

When workers are exposed to glyphosate, it can enter their bloodstream and cause harms, such as an increased risk of cancer. EPA's conclusion in the interim registration that there are no human health risks, and specifically no risk to people who work around glyphosate, is based in part on its erroneous conclusion that there is no risk of cancer from glyphosate. But given the significant evidence to the contrary, and dubious gaps in data, EPA's conclusion of no health risks is not supported by substantial evidence. *NFFC*, 960 F.3d at 1136-42 (EPA's failure to acknowledge some risks and understatement of other

risks demonstrated lack of substantial evidence for its registration of dicamba).

Scientists around the world, including many at EPA, regard glyphosate and its formulations as likely to be carcinogenic. Despite an earlier glyphosate classification as potentially carcinogenic, years of Monsanto interference and pressure led EPA's pesticide division to stick its head in the sand and accept Monsanto's erroneous conclusion to the contrary.[22] In this registration review, commenters pointed to ample evidence that glyphosate formulations cause cancer in farmers and other occupational users, but EPA failed to change or adequately explain its conclusion that there are no health risks to workers. Especially given that glyphosate is the most widely-used pesticide in the U.S., EPA cannot ignore this evidence under FIFRA.

In 2015, IARC determined that glyphosate is "probably carcinogenic to humans." 4-RC_ER-0797. This classification is just one

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[22] In 1985, EPA classified glyphosate as a Category C oncogene, 11-RC_ER-2416, equivalent to today's "suggestive evidence of carcinogenic potential," Proposed Guidelines for Carcinogen Risk Assessment, 49 Fed. Reg. 46294, 46297 (Nov. 23, 1984), and the National Research Council estimated its carcinogenic risk to consumers from dietary exposure. 11-RC_ER-2387; *see also* 3-RC_ER-567; 5-RC_ER-0896-98.

step below known carcinogens (e.g., tobacco smoking) and is widely supported by medical scientists, as well as the State of California. 4-RC_ER-0714; 5-RC_ER-0918; 3-RC_ER-0566. IARC's conclusion has been cited in multiple court cases where plaintiffs who were occupational users of glyphosate—and thus regularly exposed through skin contact—were awarded hundreds of millions of dollars after being diagnosed with cancer linked to that exposure. *See supra* 11-12.

IARC is not the only body to rebut Monsanto's claim. Also in 2015, EPA's *own* scientists at the Office of Research and Development (ORD) reviewed the EPA pesticide division's draft cancer analysis finding glyphosate not likely to be carcinogenic. They noted that EPA failed to properly analyze data, deviated from the EPA's own Cancer Guidelines[23] by dismissing rodent tumors in in glyphosate feeding trials, and agreed with IARC that epidemiology studies showed a "credible" association between glyphosate exposure and non-Hodgkin lymphoma in farmers. 5-RC_ER-0939; 4-RC_ER-0735. Based on EPA's Cancer Guidelines, ORD scientists within EPA concluded that

[23] EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (Mar. 2005), https://www.epa.gov/sites/production/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf.

glyphosate should be classified as either "likely to be carcinogenic" or "suggestive evidence" of carcinogenicity, and that occupational user—like farmer—cancer data *alone* ruled out the pesticide division's "not likely to be carcinogenic" conclusion. 5-RC_ER-0941, 5-RC_ER-0944.

Further, in 2016 EPA convened a Scientific Advisory Panel (SAP) to review its glyphosate cancer evaluation according to EPA's Cancer Guidelines. 4-RC_ER-0586. Like the ORD, this Panel found EPA flouted its Cancer Guidelines in assessing glyphosate, including by downplaying evidence of cancer in both animal and human epidemiology studies in ways that were "flawed," "highly imbalanced," "contrary to," and "at odds" with its Guidelines, all of which "further reduces the credibility of the assessment." 4-RC_ER-0594, 596, 621, 624-28, 651, 657; 5-RC_ER-0884-87.

Despite its own scientists and expert advisory panel warning EPA that it's conclusion was unsupported and failed to comply with its own Cancer Guidelines, EPA nevertheless maintained its "not likely to be carcinogenic" determination and conclusion therefore that there are no human health risks to workers in this registration. 2-RC_ER-0217; 1-RC_ER-0009, 11. But like EPA's registration of sulfoxaflor in *Pollinator*

Stewardship Council, EPA cannot deviate from its own guidelines for pesticide risk assessment. 806 F.3d at 531-32 (EPA set its own level of concern and some pesticide residue measurements triggered testing threshold; EPA's failure to require those tests before registering the pesticide was not supported by substantial evidence).

Other evidence further exposes EPA's failure to consider this key aspect of human health risks from glyphosate. In 2019, the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) published a "toxicological profile" of glyphosate, despite efforts by EPA's pesticide division and Monsanto to "kill" the report, which did delay it several years. 2-RC_ER-0049-0051; 2-RC_ER-0297-0318. This report found that the majority of epidemiological studies (which analyze the risk of illness in an exposed population) found glyphosate exposure increases the risk of non-Hodkin lymphoma. 2-RC_ER-0304-0307; *see also* 6-RC_ER-1235-45. Two subsequent meta-analyses confirmed that increased risk, one finding that more highly-exposed glyphosate users had a *41% elevated risk* of contracting non-Hodkin lymphoma. 3-RC_ER-0338-58; 2-RC_ER-0319-35.

EPA further failed to assess the cancer-causing potential of a contaminant found in glyphosate,[24] despite it being in a class of carcinogenic compounds. EPA's own testing policy requires carcinogenic testing if such contaminant levels exceed 1 part per million (ppm) in a pesticide product. 2-RC_ER-0092; 3-RC_ER-0505; *see also* 45 Fed. Reg. 42854 (June 25, 1980). Again, Petitioners raised this issue and EPA admitted that over 7% of glyphosate samples exceed the testing threshold, but dismissed the concern and collected no additional data. 2-RC_ER-0092; 3-RC_ER-0505. *Pollinator Stewardship Council*, 806 F.3d at 531-32.

Finally, as Petitioners commented to EPA, numerous studies that track glyphosate distribution in animal tissues demonstrate that it spreads to bone and bone marrow, one tissue where non-Hodgkin lymphoma begins. 2-RC_ER-0090-91; 11-RC_ER-2382; 8-RC_ER-1752-1759. Although these studies can "provide valuable insights into the likelihood of human cancer risk," and show how glyphosate may play a

[24] N-nitrosoglyphosate (or NNG), belonging to the N-nitrosamines.

role in triggering the cancer in farmers and farmworkers, EPA nowhere addresses this possibility in its risk assessment.[25]

EPA completely failed to analyze some aspects of glyphosate's cancer risk and understated others. EPA's failure to account for these gaps in data and evidence renders its conclusion of *no* risk to people who work around glyphosate arbitrary and capricious, and without substantial evidence. *See NFFC*, 960 F.3d at 1136-42; *State Farm*, 463 U.S. at 43 (agency action is arbitrary and capricious if EPA fails to consider an important aspect of the problem, or fails to articulate a satisfactory explanation for its action).

3. EPA Failed To Assess Health Threat From Glyphosate Formulations.

In the real world, pesticide products are not just the active ingredient, here "glyphosate technical." Rather, glyphosate formulations—like Roundup—are mixtures of glyphosate and various other ingredients that change the way the product works. 2-RC_ER-0077. By its plain language, FIFRA requires that EPA consider the whole pesticide and whether it will have unreasonable adverse impacts

[25] *Supra* n. 23 at 2-25.

when used in accordance with widespread and commonly recognized practice. 7 U.S.C. § 136a(c)(5)(D). FIFRA's definition of "pesticide" is "any substance or *mixture* of substances intended for preventing, destroying, repelling, or mitigating any pest," and plainly does not refer exclusively active ingredients. *Id.* § 136(u) (emphasis added). Thus, EPA's duty in registration review extends not just to the active ingredient *alone*, but also to *all* of the registered products containing glyphosate. *See also* 40 C.F.R. §§ 155.42(a), 155.53(a).[26]

Glyphosate formulations contain surfactants, confidential ingredients which can both: (1) cause skin and eye injuries in their own right, and (2) increase dermal absorption of glyphosate into the bloodstream. 2-RC_ER-0077-79, 85-91; 8-RC_ER-1730. But in registering glyphosate, EPA has apparently failed to assess *any* of the 555 glyphosate-containing formulations that contain surfactants that

[26] Petitioner Center for Food Safety (CFS) filed a petition with EPA to require safety testing of the whole pesticide formulations to capture impacts from surfactants and other "inert" ingredients, as well as tank mixes. EPA took public comment on the petition early in 2019 and has yet to respond. CFS, *Rulemaking Petition Seeking Revised Testing Requirements of Pesticides Prior to Registration* (July 10, 2017), EPA-HQ-OPP-2018-0262.

increase dermal absorption and, thus, enhance glyphosate's cancer-causing potential.

EPA's reason for not conducting a quantitative assessment of skin exposure for workers was based on a single rabbit study that only involved the active ingredient. 3-RC_ER-0542; *supra* 31-35. Thus, the effects documented in the 1982 rabbit study, 10-RC_ER-2121, cannot be extrapolated to the risks from exposure to the many different glyphosate *formulations*—like Roundup—that workers actually use and regularly come into contact with.

First, the skin toxicity of some glyphosate formulations is plainly shown by documented injuries to skin that include "blisters, rash, pruritis, skin irritation, hives, welts, sores, burning skin, and peeling skin." 7-RC_ER-1504-1506, 1527-1573. These injuries are among the most frequent category (30%) of reported glyphosate adverse effect incidents. *Id.* EPA also describes "severe dermal effects," including extensive chemical burns, from accidental exposure to glyphosate formulations containing surfactants, including one known as POEA (polyethoxylated tallow amines or MON 0818). 6-RC_ER-1253. POEA is severly irritating to skin and positively corrosive to eye tissue. 2-

RC_ER-0087. Petitioners' farmworker members have suffered skin damage from exposure to Roundup. *See, e.g.,* Cordero Decl. at A121-23.

Second, surfactants increase the amount of glyphosate that penetrates the skin and enters the bloodstream, which disseminates it throughout the body. Assessing skin absorption of glyphosate formulations is critical for understanding glyphosate's systemic toxicity, including potential adverse effects on other organs and diseases like cancer. 8-RC_ER-1824-25; 2-RC_ER-0123-0126.[27]

As explained by Monsanto scientists, surfactants enhance skin absorption of glyphosate by, for instance, removing protective lipids (e.g. oils) from the skin's surface; spreading out droplets of glyphosate solution on the skin; and via their skin irritation effects, which increase blood flow in blood vessels just beneath the epidermis. 9-RC_ER-2000. Because of compositional differences, Monsanto's scientists recommend that: "[i]deally, all of the different glyphosate formulations would have

[27] *See also Hardeman v. Monsanto*, Case No. 19-16636 (9th Cir.), Direct Testimony of Dr. Weisenberger (Hardeman ER521, 524) (explaining that "surfactants . . . help[ ] the glyphosate penetrate through the walls of the plants into the actual plant cells" and "when you get Roundup on your skin, just like the Roundup will penetrate the plant cells, it will penetrate the cells of the skin and it will get into the tissues and it will get into the lymph system and into the blood . . .").

to be tested for dermal uptake." *Id*. Indeed, a Monsanto-commissioned dermal absorption study found a huge difference in the glyphosate penetration rate of the two glyphosate formulations tested (though it was never submitted to EPA), underscoring the need for formulation-specific testing. 9-RC_ER-1957-92; 2-RC_ER-0125. Yet as noted above, after nearly half a century, EPA still does not have a single dermal absorption study in its toxicity database for even one glyphosate formulation, much less all of them. 3_RC_ER-0525.

Not only did EPA fail to assess how much more glyphosate might enter a person's body based on differences in the formulations, EPA also did not assess the carcinogenic potential of these formulations and their various surfactants. The evidence before EPA, however, shows that both glyphosate and its formulations trigger cancer-causing (genotoxic) changes in cells, such as mutations. 5_RC_ER-1100-01; 3-RC_ER-424-39; 7_RC_ER-1464-76; 4-RC_ER-0764-92.[28]

Indeed, EPA permits glyphosate formulations to contain (at levels up to 25%) surfactants like POEA, despite finding substantial risks to

[28] Notably, these tests for cellular changes were far more likely to give positive results when conducted by independent scientists rather than glyphosate registrants. 3-RC_ER-424-39.

occupational users, and despite lack of animal studies on their carcinogenicity, chronic toxicity, and endocrine disruption potential, among other data gaps, as pointed out by Petitioners. 2-RC_ER-0086-87; 7-RC_ER-1578; 74 Fed. Reg. 28616, 28623 (June 17, 2009). In contrast, European regulators banned use of POEA in glyphosate formulations based on evidence of its cancer-causing changes in cells and other harms, and lack of animal data on its carcinogenicity and other effects. 6-RC_ER-1229; 5-RC_ER-0926.

Even if it were true that glyphosate alone is "not likely to be carcinogenic"—it is not, *see supra* 35-41—this conclusion is largely irrelevant to workers exposed to glyphosate *formulations* like Roundup. As Monsanto's chief toxicologist warned colleagues: "you cannot say that Roundup is not a carcinogen … we have not done the necessary testing on the formulation to make that statement." 8-RC_ER-1760-61.

In summary with regard to human health risks, EPA did not assess a key routes of exposure (skin) to the people most exposed to glyphosate. It failed to assess the effects of these exposures, in part, because it denies the reality that glyphosate is probably carcinogenic. But EPA's conclusion that there are no "occupational risks of concern"

for glyphosate is not supported by substantial evidence. Accordingly, by registering glyphosate and its formulations without crucial health information—including on those formulations that *increase* the risk of harm—EPA has abdicated its duty to prevent unreasonable adverse effects to human health.

B. EPA Failed to Weigh the True Costs of Glyphosate.

Pesticides are biocides, meaning they are toxic substances intended to kill living things. As such, they come with significant risks or harms, or "costs" in FIFRA's rubric; costs that EPA is required by law to evaluate alongside any purported benefits, before granting registration. 7 U.S.C. § 136(bb) ("[U]nreasonable adverse effects on the environment" means "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.").

Here, there are significant costs to farmers and the environment from glyphosate drift and the plague of resistant weeds from glyphosate overuse, including the substantial increase in use of other toxic weed-killers in response. 4-RC_ER-0841; *NFFC*, 960 F.3d at 1120. And costs to the thousands of animal and plant species whose ranges and habitat

overlap with glyphosate spraying, including pollinators and Monarch butterflies. EPA must take these costs into consideration and assess them, because FIFRA does not allow it to register a pesticide with unreasonable adverse effects. That standard means EPA cannot blindly accept the purported benefits of glyphosate while ignoring the signficiant economic and environmental costs. But that is exactly what EPA did here.

1. EPA Failed to Weigh the Economic Costs of Glyphosate.

In evaluating whether a pesticide mets the FIFRA safety standard, EPA must take into account economic, social, and environmental costs and benefits of the use of any pesticide, as it is commonly used. 7 U.S.C. §§ 136(bb); 136a(c)(5)(D). Here EPA's cost-benefit "analysis" appears in a single sentence in its decision document and response to comments, concluding that the *ecological* costs are outweighed by the benefits. 1-RC_ER-0017; 2-RC_ER-0266-96. But EPA entirely failed to consider and assess the significant *economic* costs resulting from widespread glyphosate use. These costs include both glyphosate-resistant weeds and glyphosate drift damage.

First, the economic and social costs of the glyphosate-resistant weed epidemic are considerable and well-documented. EPA knows that pesticide-resistant weeds are "a widespread problem" that may "fundamentally change production practices in U.S. agriculture." 1-RC_ER-0019.

In fact, they already have. The U.S. Department of Agriculture (USDA) estimated over a decade ago that up to 25% of U.S. pest (weed and insect) control expenditures are attributable to managing pesticide resistance. 7-RC_ER-1437. EPA acknowledges that glyphosate applied to genetically-engineered (Roundup Ready) crops "has made glyphosate resistance the worst herbicide resistance problem." 2-RC_ER-0274.

Nonetheless, EPA nowhere assesses the extent, the explosive growth, or the astronomical costs of glyphosate-resistant weeds to farmers or U.S. agriculture. Glyphosate resistance first appeared in a Roundup Ready crop in 2001. 2-RC_ER-0291. Just five short years later, cotton agronomist Alan York described one such weed, glyphosate-resistant Palmer amaranth, as "potentially the worst threat [to cotton] since the boll weevil." 1-RC_ER-0019; 7-RC_ER-1447. The amount of agricultural land infested with glyphosate-resistant weeds

nearly *quadrupled* from 2010 to 2017, from 33 million to 120 million acres. 2-RC_ER-0104; 6-RC_ER-1354; 3-RC_ER-0509. In a 2017 survey of 4,000 growers, 73% reported glyphosate-resistant weeds in their fields. 2-RC_ER-0104; 3-RC_ER-0509.

Farmers incur substantial costs to control glyphosate-resistant weeds in the form of increased expenditures on additional toxic pesticides, while increased use of soil-eroding tillage is an environmental cost of resistance. 2-RC_ER-0104. In 2013, agronomists estimated that glyphosate-resistant weeds increased farmers' pesticide expenditures by six-fold in both Arkansas cotton (from $50-$75 to $370 per hectare) and Illinois soybeans ($25 to $160 per hectare). 2-RC_ER-0104; 6-RC_ER-1353. Georgia cotton growers saw their pesticide costs double by paying for additional pesticides to kill the rapidly spreading Palmer amaranth resistant to glyphosate. 2-RC_ER-0104; 6-RC_ER_1343. Even with these additional expenditures, for many farmers, it was insufficient to eradicate Palmer amaranth, so these farmers spent far more money on hand-weeding crews and for increased tillage operations. 2-RC_ER-0104-05; 6-RC_ER_1343.

Further, USDA found that glyphosate-resistant weeds reduced farmers' total returns by $67.29 per acre of planted corn, and a $22.53/acre loss for soybean farmers who reported declining effectiveness of glyphosate on weeds. 5-RC_ER-1085. Applied to the 120 million acres of farmland with glyphosate-resistant weeds, the costs borne by farmers amount to an enormous $5.4 billion.[29] Despite explicitly acknowledging these resistant weed costs elsewhere, EPA ignored all these costs when it concluded that glyphosate is "a relatively inexpensive herbicide in agricultural situations, with the cost of applications to most crops ranging from $1 to $13 per acre." 1-RC_ER-0016; 5-RC_ER-0858-59. EPA fails entirely to account for these substantial glyphosate-resistant weed costs.

Second, glyphosate has also caused extensive damage when it drifts or runs off of the fields to which it is applied and onto neighboring fields and crops. 5-RC_ER-1005-06; 6-RC_ER-1171-73. Glyphosate has ranked among the three top pesticides in drift episodes. 9-RC_ER-2008-10, 18-26; 8-RC_ER-1737. Organic farmers and conventional farmers

[29] Assuming corn and soybean fields are equally infested: (60 million x $67.29) + (60 million x $22.53).

who do not use pesticides often have to take measures to protect their crops from glyphosate drift, measures that cost time and money to implement. *See e.g.*, Shipman Decl. at A193-95; Walker Decl. at A205-208.

EPA's own spray drift analysis found that glyphosate spray drift causes plant damage exceeding its plant safety threshold many *hundreds* of feet from the edge of a sprayed field, depending on the application method and amount of glyphosate applied. 5-RC_ER-1036. While EPA recognized the "potential risk to terrestrial and aquatic plants from off-site spray drift" because glyphosate is an herbicide, it failed entirely to evaluate the economic costs that come from that drift. 1-RC_ER-0017.

Both glyphosate's drift costs and its weed resistance costs are analogous to the pesticide costs of dicamba, which this Court recently addressed in *National Family Farm Coalition v. EPA*, 960 F.3d 1120 (9th Cir. 2020). In *NFFC*, EPA registered dicamba pesticide products for the first time to be sprayed over the top of crops genetically engineered with dicamba resistance. That approval caused several growing seasons of substantial off-field drift, damaging millions of acres

of neighboring soybean crops as well as other crops, vegetables, and ornamental, fruit and other trees. *Id.* at 1127-29, 1136-38. The Court held that EPA's "substantially understated" this cost, pointing to record evidence. *Id.* at 1136-39. EPA's failure to consider, assess, and quantify the drift harm costs rendered the registration unsupported by substantial evidence. *Id.* at 1138-39 (holding that EPA "refused to quantify or estimate the amount of damage costs"). The Court therefore vacated the registration. *Id.* at 1144-45.

As explained above, ironically the purported benefit EPA gave for registering this damaging use of dicamba was to address the resistant weed crisis *costs* caused by the chief use of glyphosate, on glyphosate-resistant crops. EPA should have assessed these sigificant costs long before the dicamba case. But at a minimum it absolutely had to do so in this registration and its failure rendered its decision without substantial evidence, in violation of FIFRA.

2. EPA Failed to Weigh the Environmental Costs of Glyphosate.

FIFRA requires EPA to weigh environmental costs. 7 U.S.C. § 136(bb). Yet in its cost-benefit analysis for the latest glyphosate registration decision, EPA failed to evaluate the significant

environmental costs of glyphosate, despite its bald conclusion that the benefits outweigh the ecological costs. 1-RC_ER-0011-17; 2-RC_ER-0266-96. EPA quanitifed neither ecological costs nor purported benefits. *Id.*

EPA dismissed environmental costs, including to pollinators and Monarchs, from continued glyphosate spraying. Effects identified in EPA's ecological assessment include impairment of growth and reproduction of mammals, growth of birds and terrestrial-phase amphibians, and imperiling the survival of both of terrestrial and various aquatic plants. 5-RC_ER-0946. Yet EPA's registration decision dramatically downplays these serious impacts, strangely concluding that it "did not identify any potential risks of concern for fish, aquatic invertebrates, or aquatic-phase amphibians" and "low or limited risks of concern" for mammals and birds. 1-RC_ER-0014.

EPA admits that there may be direct impacts to honey bees and other pollinators from higher application rates, and indirect impacts via spray drift killing off wild plants that provide them with critical nectar sources and habitat. 1-RC_ER-0014, 19. And EPA admits that it does not even have the data necessary to evaluate these impacts. 1-RC_ER-

0014 ("additional data may be necessary to fully evaluate risks to bees" from glyphosate). But EPA ignores the major negative impact of glyphosate on Monarchs: its near-eradication of milkweed in Midwest corn and soybean fields. *Id*. at 12.

But both bee and Monarch populations have precipitously declined over the last twenty years, the same time period that glyphosate use has exponentially grown. Scientists know that the vastly increased agricultural use of glyphosate is a major factor in the nearly 90% decline in migratory Monarch butterfly populations; glyphosate is a particularly potent killer of common milkweed, a "critical food source" for Monarch butterflies, in agricultural fields throughout the butterfly's Midwest breeding grounds. 3-RC_ER-0483; 1-RC_ER-0014. Populations of pollinators, including honey bees, and other beneficial insects are in dangerous decline, and glyphosate is implicated. 2-RC_ER-0101-02, 0190-0210. Many of these insects depend on habitat near agricultural fields that is vulnerable to offsite movement of glyphosate in drift and run-off. 2-RC_ER-0102.

Instead of evaluating impacts to pollinators and other beneficial insects, EPA says it may call for additional data on honey bees.

1-RC_ER-0015. That does not amount to a consideration of the costs of continued glyphosate spraying and does not give EPA substantial evidence for its conclusion that glyphosate will not cause unreasonable adverse effects. *See Nat'l Family Farm Coal. v. U.S. Envtl. Prot. Agency,* 966 F.3d 893, 917 (9th Cir. 2020) (holding EPA's registration of the glyphosate-based pesticide Enlist Duo lacked substantial evidence because of failure to "consider[] how the destruction of milkweed on target fields would affect monarch butterflies.").

C. EPA Lacks Substantial Evidence For Conclusion That Label Will Prevent Harms.

Pesticide label use directions are a form of mitigation and EPA will most likely argue that it mitigated any environmental or economic costs with its label changes in this "interim" registration. However, just as with the rest of EPA's FIFRA determination, any such reliance on any mitigation measures must be supported by substantial evidence. That includes evidence that any mitigation measures will actually be *effective*—including that they can actually be followed—to ensure glyphosate spraying does not cause unreasonable adverse effects. That means the measures will work in the real world.

This Court in *NFFC* also explained this FIFRA requirement, when it comes to label mitigation. In that case, EPA had relied on a very complex list of use directions in the dicamba registration and "no unreasonable adverse effect" determination, but EPA had never analyzed how those measures would work in real world farming conditions, or if farmers could actually follow them. The record evidence showed the label was "difficult if not impossible" to follow. *NFFC,* 960 F.3d at 1124. Accordingly the Court held that EPA violated FIFRA by failing to acknowledge and consider the problems of users inability to follow the label instructions, despite the agency's heavy reliance on it as mitigation. *Id.* at 1139-40.

Here, EPA concluded that "the benefits outweigh the potential ecological risks when glyphosate is used according to label directions." 1-RC_ER-0017. Yet despite finding many risks of concern, EPA's label mitigation measures in its decision—which address pesticide resistance, non-target organisms, and spray drift—differ little from those on current glyphosate product labels. 1-RC_ER-0017-20.

Moreoever, at no point did EPA *actually assess the efficacy* of these mitigation measures on which it predicated its determination. Thus,

EPA lacks substantial evidence to support its conclusion that label directions will ensure that the alleged benefits of glyphosate outweigh the costs and that glyphosate meets the FIFRA safety standard.

First, EPA claims that "implementation of herbicide resistance measures" will help "slow the development and spread of herbicide resistant weeds." 1-RC_ER-0019. This is based on two pesticide registration notices (PRNs 2017-1 and 2017-2) that EPA incorporates into its registration decision. 1-RC_ER-0019, 26. Both notices are toothless "guidance" documents that suggest pesticide-resistance management language that pesticide registrants might choose to put on their product labels, but are entirely non-binding. 5-RC_ER-0871 ("pesticide applicants may assert that the guidance is not appropriate generally or not applicable a specific pesticide").

In any case, experience has taught that such label recommendations are wholly insufficient to actually slow the development and spread of glyphosate-resistant weeds. First, glyphosate product labels have for over 13 years listed very similar

"weed resistance management" measures,[30] but glyphosate-resistant weeds still dramatically spread over this time. *See supra* 15-16, 23. Second, the PRN recommendations reflect a pesticide-intensive approach to resistant weed management that serves the interest of chemical industry, fosters even more damaging weeds resistant to multiple pesticides, and is inferior to an integrated approach that lessens both pesticide use and resistance. 6-RC_ER-1365-75; 7-RC_ER-1435-41. EPA just assumed these *voluntary* measures would be sufficient to stop the weed resistance crisis. It did not support their efficacy with any evidence, let alone substantial evidence. *NFFC*, 960 F.3d at 1139.

Second, EPA added a "non-target organism advisory" to "alert users of potential impact to non-target organisms." 1-RC_ER-0019-20. This "advisory" states:

> This product is toxic to plants and may adversely impact the forage and habitat of non-target organisms, including pollinators, in areas adjacent to the treated site. Protect the forage and habitat of non-target organisms by following label directions intended to minimize spray drift.

[30] *See e.g.*, 2007 Roundup Pro label, Sections 5.1 & 5.2, at https://natseed.com/pdf/Roundup%20Pro%20Label.pdf.

1-RC_ER-0019. With this vague advisory to "[p]rotect the forarge and habitat of non-target organisms," EPA assumes that glyphosate applicators know which non-target organisms to look for and what their forage and habitat requirements are. EPA does not explain *how* users can follow this directive. And again, at no point does EPA assess whether users can actually *comply* with this advisory in real world farming conditions, and the effects to non-target organisms if those directions are not able to be followed. 9-RC_ER-1993-96. *NFFC*, 960 F.3d at 1139.

Moreover, the advisory only instructs users to comply with "label directions intended to minimize spray drift," something they are already required to do. And it only slightly differs from an existing advisory on some product labels.[31] It is entirely unclear how this "mitigation measure" will do *anything at all* to protect the thousands of wild species at risk of harm from glyphosate use.

Third, EPA claims that language added to the glyphosate label to manage spray drift "will reduce the extent of environmental exposure

[31] *See* 2007 Roundup Pro label, Section 7.1, at https://natseed.com/pdf/Roundup%20Pro%20Label.pdf.

and risk to non-target plants and animals." 1-RC_ER-0017. This language tells applicators the maximum wind speed and minimum droplet size for spraying glyphosate, and prohibits spraying during temperature inversions. *Id.* While EPA claims that the spray drift language "is intended to be mandatory, enforceable statements," *id.*, it provides no assessment of their efficacy or ability to be followed.

As stated above, glyphosate has ranked among the three top pesticides in spray drift episodes and EPA well knows that pesticide applications are often made when it is too windy. 9-RC_ER-1993-96. That is why it is critical that EPA assess the efficacy of the new spray drift mitigation. Instead, EPA only "assessed the potential impact on growers of the required spray drift management restrictions" and whether the restrictions would "substantially reduce the benefits of glyphosate to users." 1-RC_ER-0018. EPA's failure to assess the other side of the coin—the risks of non-compliance in real world conditions and the harm to that would occur—violated FIFRA. "Non-compliance with the restrictions, of course, will result in [glyphosate] damage" to non-target organisms, which "EPA entirely failed to acknowledge." *NFFC*, 960 F.3d at 1139.

In sum, the flaw in EPA's conclusion is that it assumes all of these mitigation measures are effective without any assessment of their efficacy. EPA's failure renders its decision without substantial evidence. *Pollinator Stewardship*, 806 F.3d at 532.

II. EPA VIOLATED THE ESA.

By issuing a glyphosate registration decision before completing ESA Section 7 consultation with expert wildlife agencies, EPA violated the ESA. EPA has indeed never completed a nationwide ESA consultation in the 46-year history of this pesticide, despite being the most widely-used in the country.

This violation is glaring: 1,795 species—100% of the species exposed and 100% of their critical habitats—may be affected, 1,676 of which will likely be adversely affected by EPA's own assessment. BE at 4-3. These include iconic birds like the whooping crane and endangered pollinators critical to our food sytem. And hundreds of plants, insects, and aquatic invertebrates, the abundance and diversity of which are crucial to intact ecosystems. For some of these species, their continued existence may be jeopardized by glyphosate spraying allowed by EPA's latest decision. These numbers are now publicly known, because EPA

has started its ESA duties, enough to know that formal consultation is required for 93% of exposed species, but is far from completion. *See infra* 70-71.

EPA knows that its registration action triggers the low "may affect" threshold requiring consultation, but went forward regardless. But before EPA can register glyphosate—including this final "interim" registration—it must consult with and obtain biological opinions from the FWS and NMFS ("Services"). The ESA's regulations require consultation at the "earliest possible time." 50 C.F.R. § 402.14(a). EPA started its registration review over a decade ago: whatever the earliest possible time to consult may be, that time has plainly passed.

Under EPA's latest decision, 306 million pounds of glyphosate will be sprayed, without any effective or enforceable mitigation, on over 285 million acres every year. To the detriment and possible extinction of thousands of protected species. The ESA, which prioritizes species' continued existence over the primary missions of agencies, does not allow such a result.

A. The Endangered Species Act and ESA Section 7 Consultation.

The ESA is "the most comprehensive legislation for the preservation of endangered species ever enacted by any nation." *Tenn. Valley Auth. v. Hill*, 437 U.S. 153, 180 (1978). Congress spoke "in the plainest of words, making it abundantly clear that the balance has been struck in favor of affording endangered species the highest of priorities, thereby adopting a policy which it described as 'institutionalized caution.'" *Id.* at 194.

Section 7(a)(2) is the "heart" of the ESA, and one of the statute's most important protections. *California ex rel. Lockyer v. U.S. Dept. of Agric.,* 575 F.3d 999, 1018 (9th Cir. 2009). It mandates that "[e]ach federal agency" "insure" its action—here, registration of glyphosate—is not likely to either jeopardize any species or adversely modify any designated "critical" habitat. 16 U.S.C. § 1536(a)(2).[32]

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[32] "Jeopardize" means taking an action that "reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution…." 50 C.F.R. § 402.02(d). Critical habitat means "the specific areas within the geographical area occupied by the species, at the time it is listed … on which are found those physical or biological features (I) essential to the conservation of

To do this, action agencies like EPA must consult the Services to determine if their actions may cause jeopardy, and if so, how to modify the action to avoid that result. 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14. This procedure must be rigorouly adhered to because it is the only way to ensure compliance with the ESA's substantive protections. *Thomas v. Peterson*, 753 F.2d 754, 764 (9th Cir. 1985).

Every federal agency, using the "best scientific and commercial information available," 16 U.S.C. § 1536(a)(2), must review its action "at the earliest possible time" to determine whether it "may affect" any listed species or designated critical habitat. 50 C.F.R. § 402.14(a).[33] The threshold for a "may affect" determination triggering the required ESA Section 7(a)(2) consultation process is very low. 51 Fed. Reg. 19,926, 19,949 (June 3, 1986) (codified at 50 C.F.R. pt. 402) ("Any possible effect, whether beneficial, benign, adverse, or an an undetermined

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the species and (II) which may require special management considerations or protection." 16 U.S.C. § 1532(5)(A).

[33] As the expert agencies, FWS and NMFS adopted joint regulations governing the Section 7(a)(2) consultation process.

character, triggers the formal consultation requirement.").[34] As this Court has explained, "actions that have *any chance of affecting listed species or critical habitat*—even if it is later determined that the actions are 'not likely' to do so—require at least some consultation under the ESA." *Karuk Tribe*, 681 F.3d at 1027 (emphasis added).

If the action "may affect" listed species or habitats, the agency *must* initiate and complete Section 7 consultation with FWS or NMFS before taking action. *Id.* It is "critical that ESA review occur early in the process to avoid piecemeal chipping away of habitat." *Conner*, 848 F.2d at 1453-55 (consultation required before sale of any leases, and biological opinion could not be put off until later stage of agency action); *Lane Cty. Audubon Soc. v. Jamison*, 958 F.2d 290, 294 (9th Cir. 1992) (agency must consult on initial actions that may affect listed species before implementing later actions).

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[34] *See also* FWS and NMFS, *Endangered Species Consultation Handbook*, xvi (1998) (defining "may affect" as "the appropriate conclusion when a proposed action may pose *any* effects on listed species or designated critical habitat") (emphasis in original); *id.* at 3-13, 4-26, https://www.fws.gov/ENDANGERED/esa-library/pdf/esa_section7_handbook.pdf.

ESA consultation may in some cases be informal, if the Service concurs in writing with a finding that that the action is "not likely to adversely affect" any listed species or critical habitat. 50 C.F.R. §§ 402.13(a); 402.14(b). Otherwise, formal consultation is required, which culminates with the Service's issuance of a biological opinion as to whether the action will likely jeopardize the continued existence of any species or adversely modify any critical habitat. *Id.* §§ 402.14(h)(3), (i); 402.02; 402.14(a). If there is a jeopardy finding for any species, the Service must include "reasonable and prudent alternatives," if any, to the action. *Id.* § 402.14(h)(2). A no-jeopardy biological opinion will include an incidental take statement for "take" of species that will not violate Section 7(a)(2) and any reasonable and prudent measures, along with the terms and conditions that implement them. *Id.* § 402.14(i). Thus, formal consultation is crucial to shaping the action to comply with the ESA and hence must be completed prior to the action happening.

B. EPA's "Interim" Registration is an "Agency Action" Under the ESA.

Under the ESA and its implementing regulations, EPA has a duty to consult with the Services prior to registering glyphosate, regardless of whether the agency calls it "interim" or anything else.

Respondents may attempt to argue that this decision is not a cognizable agency action triggering Section 7 duties. The ESA defines "agency action" as "any action authorized, funded, or carried out by [a federal] agency." 16 U.S.C. § 1536(a)(2). Congress intended "agency action" to have a broad definition in the ESA. *Karuk Tribe*, 681 F.3d at 1020. The Ninth Circuit established a two-part test for determining ESA "agency action" that triggers the duty to consult. EPA's glyphosate registration meets both parts.

First, the court asks whether a federal agency affirmatively authorized, funded, or carried out the underlying activity. *Id.* Pesticide registrations undoubtedly meet this standard. *Id.* (citing *Wash. Toxics Coal. v. U.S. Envtl. Prot. Agency*, 413 F.3d 1024, 1031-33 (9th Cir. 2005) (holding the ESA applies to FIFRA pesticide registrations). That EPA calls this registration "interim" makes no difference; it completed the health, ecological, and cost-benefit assessments and registered

glyphosate with the label "mitigation" measures. 1-RC_ER-0005, 17. *See Lane Cty. Audubon Soc'y*, 958 F.2d at 294 (interim management strategy designed to be implemented immediately constitutes agency action triggering consultation).

Second, the court determines whether the agency had some discretion to influence or change the activity for the benefit of a protected species. *Karuk Tribe*, 681 F.3d at 1024. EPA's decision to register a pesticide is discretionary because EPA can "influence a private activity [pesticide use] to benefit a listed species," *id.* at 1025, through label amendments, restricting the pesticides' uses, or not registering it. 40 C.F.R. § 155.40(a); 7 U.S.C. § 136a(a). EPA's glyphosate registration is plainly an cognizable agency action under the ESA, triggering Section 7 duties.

C. Because Glyphosate "May Affect" Listed Species, EPA Must Complete Consultation Before Registration.

Because EPA's "interim" registration of glyphosate is an agency action under the ESA that "may affect" thousands of listed species and hundreds of critical habitats, EPA must consult before registering

glyphosate.[35] Strict adherence to the ESA's procedural commands is required to guarantee compliance with its substantive provisions, which require that EPA ensure registering glyphosate (including all of its formulations) will not cause jeopardy to any protected species or habitat. EPA has abjectly failed to do that here.

First, there is absolutely no doubt that EPA's issuance of the registration "may affect" literally thousands of listed species and hundreds of critical habitats, because *EPA itself has already come to this conclusion*. In late November 2020, EPA released a draft "Biological Evaluation" (BE) assessing risks to listed species from labeled uses of glyphosate.[36] This is the "effects determination" that EPA, as action agency, must make before taking an action. 50 C.F.R. § 402.14(a). If

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[35] Based on FWS's announcement that Monarch butterflies are a candidate for listing, EPA should now also consider impacts to them in its ESA consultation. *See* FWS and NMFS, *Consultation Handbook* at 1-5, 3-7, *supra* n.31.

[36] EPA, BE, *supra* n.5. While this draft was released in November 2020, EPA clearly began work on this assessment earlier, overlapping with its January 2020 interim registration decision. For example, the draft BE considers listed species and designated critical habitats that were listed as of January 30, 2019, suggesting EPA started this assessment around that time. BE at 1-5.

EPA determines that its action "may affect" any listed species or critical habitat, it *must* consult with FWS and/or NMFS.

Not only did EPA find "may affect" for 100% of species it determined would be exposed to glyphosate—1,795 species—it went to the second step and found that 93% of those—1,676 species—*would likely be adversely affected*. BE at 4-3. A likely adverse effect call requires formal consultation, concluding with biological opinions. 50 C.F.R. §§ 402.02; 402.14(a); 402.14(h)(3), (i). Thus, EPA itself admits that there will likely be adverse effects to 75 mammals, 88 birds, 36 amphibians, 33 reptiles, 179 fish, 940 plants, 185 aquatic invertebrates, and 140 terrestrial invertebrates. And to 759 critical habitats. BE at 4-3. Given that glyphosate is an herbicide, it is not surprising that it is highly toxic to plants, with endangered plants making up a large portion of the species affected. BE at 4-11. Glyphosate's toxicity to plants also contributes to its toxic effects to listed species that rely on those plants for food and shelter. BE at 4-13.

Accordingly, formal consultation is required for all of these species and critical habitats *before* EPA moves forward with glyphosate registration. *Conner*, 848 F.2d at 1453-55; *Karuk Tribe*, 681 F.3d at

1020 ("Section 7 imposes on all agencies a duty to consult with either the Fish and Wildlife Service or the NOAA Fisheries Service *before* engaging in any discretionary action that may affect a listed species or critical habitat.") (emphasis added).

Second, EPA should have come to this conclusion years ago. EPA reregistered glyphosate in 1993 and started the review process in 2009. Now, after all this time, EPA finds that 100% of species and habitats exposed may be affected and "[n]o species or critical habitats met [the "no effect"] criteria for glyphosate" in the massive action area ("pesticide footprint based on all labeled uses ….and offsite transport due to spray drift"). BE at 4-4, 4-5.

Indeed, EPA admits that "[t]he number of and strength of [likely to adversely affect] determinations found for glyphosate is *expected* given the action area of the chemical and the toxicity profile." BE at 4-12 (emphasis added). In plain terms, it means that EPA knew this result was coming because it was self-evident: glyphosate has extremely widespread spraying and every species that overlaps with that spraying may be impacted, mostly adversely impacted.

The massive spraying footprint and the obvious overlap of spraying and the habitat of thousands of listed species should have triggered consultation. But twelve years into the glyphosate registration review process, EPA is just *now* taking the first step. Before registering glyphosate, EPA must first finish the formal consultation it should have started years ago.

Listed Species Examples

Some of the listed species likely to be adversely affected are the whooping crane, Indiana bat, and rusty-patched bumble bee, species important to Petitioners' members.[37]

The iconic whooping crane is among the world's most endangered animals. In 1954, there were as few as twenty-one whooping cranes left.[38] In the decades since, conservation efforts have led to only a limited recovery; there are now a few hundred in the wild,[39] about 4% of

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[37] *See* Crouch Decl. A125-132; Limberg Decl. A161-171; Shistar Decl. A196-201.

[38] *See* FWS, INTERNATIONAL RECOVERY PLAN: WHOOPING CRANE (GRUS AMERICANA) 1 (Mar. 2007), http://www.fws.gov/uploadedFiles/WHCR%20RP%20Final%207-21-2006.pdf.

[39] *Id*. at 13-14.

its historic numbers. Significant portions of the range of the two remaining whooping crane populations overlap with agricultural areas where there is extensive application of glyphosate.[40] EPA found the whooping crane is likely adversely affected by glyphosate. BE Appendix 4-1.

Indiana bats play a critical role in maintaining the balance of an ecosystem. A significant source of natural insect control, Indiana bats typically consume up to half their body weight in insects each night.[41] Their population has continued to decline despite conservation and recovery efforts; only half of those that existed when the species was listed as endangered remain.[42] FWS's Indiana bat recovery team specifically identified pesticide contamination of the bats' food supply as a reason for their continued decline.[43] Significant portions of the range of Indiana bat overlaps with with agricultural areas where there is

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[40] Compare *id*. at 4 with Figure 2.

[41] U.S. Fish & Wildlife Service, *Midwest Region Endangered Species: Indiana Bat (Myotis Sodalis)*, https://www.fws.gov/midwest/endangered/mammals/inba/inbafctsht.html.

[42] *Id*.

[43] *Id*.

extensive application of glyphosate, and EPA found the Indiana bat is likely adversely affected. BE Appendix 4-1.

The rusty-patched bumble bee was the first bumble bee listed in the continental U.S. under the ESA.[44] Before the mid- to late-1990s, the bumble bee was considered abundant across a broad geographic range that included the District of Columbia, 28 states, and two Canadian provinces.[45] Since 2000, however, it has been reported in only a few places in 13 states and one province and its current distribution is only 13% of its historical extent. *Id*. Pesticides are considered one of the leading threats that have contributed to the rapid decline in rusty patched bumble bee populations.[46] Unsurprisingly, EPA found the rusty-patched bumble bee is likely adversely affected by glyphosate. BE Appendix 4-1.

These species are just examples of the 1,676 species likely adversely affected by glyphosate use. Before approving any registration

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[44] FWS, *Rusty Patched Bumble Bee*, https://www.fws.gov/midwest/endangered/insects/rpbb/FAQsFinalListing.html#:~:text=These%20were%20the%20first%20bees,3.

[45] FWS, *Rusty patched bumble bee (Bombus affinis)*, https://ecos.fws.gov/ecp0/profile/speciesProfile.action?spcode=I0WI.

[46] *Supra* n.42 (FWS Rusty Patched Bumble Bee).

of glyphosate—including the so-called final "interim" registration—EPA needed to finish consultation to determine if any of these species are jeopardized with the Services. The FWS and NMFS have expertise on wildlife biology that EPA lacks, and that is why the ESA requires their expert opinions before an action is taken.

ESA Consultation Leads to Protective Measures

As explained above, if some species are jeopardized, the Services will provide EPA with reasonable and prudent alternatives to the registration, which could, for example, include prohibiting use in regions with these species. 50 C.F.R. § 402.14(h)(2). Even if *none* of the 1,676 species will be put in jeopardy, the Services still provide reasonable and prudent measures, along with the terms and conditions that implement them, to prevent any harm to species or habitats beyond what the Services find is incidental and will not cause jeopardy. *Id.* § 402.14(i). Given the sheer number of species and habitat impacted, it is beyond the pale that EPA would not have to modify the registration is some way to prevent harm and comply with the ESA.

EPA's "Advisory" Label Amendment Is Not ESA Compliance

Finally, instead of consulting, here EPA issued the "interim" registration with a new "advisory" label statement. 1-RC_ER-0019. Even if this "advisory" language can be followed, the command is simply to *follow the label directions*, which users are already bound to do. So this advisory changes nothing about how glyphosate will continue to be used, which as EPA admits is likely to adversely affected thousands of listed species. As explained above, EPA provides no evidence of the efficacy of this vague advisory language or whether glyphosate users can even identify the "forage and habitat of non-target organisms" that are supposed to be protected. *Supra* 23-24.

To comply with the ESA, mitigation measures must be the result of "specific and binding plans" and "reasonably certain to occur." *Nat'l Family Farm Coal.*, 966 F.3d at 923 (quoting *Defs. of Wildlife v. Zinke*, 856 F.3d 1248, 1258 (9th Cir. 2017) and *Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 524 F.3d 917, 936 n.17 (9th Cir. 2008)). EPA has not shown that this advisory language regarding harm to non-target plants instructing users to follow the label is specific, binding, or at all reasonably certain to occur.

Nor have the Services had a chance to weigh in, as required by the ESA. Instead of this ineffective "advisory" language, EPA needs to complete consultation and determine what changes must be made to *ensure* that no species or habitats are jeopardized. The ESA, its regulations, and the Ninth Circuit's own cases require EPA to finish assessing the impacts to listed species and tailor its action to avoid jeopardy, *before* issuing any registration. 50 C.F.R. §§ 402.14(a) (Agencies shall review actions "at the earliest possible time"); 402.14(c)(4) (even consultation on a segment of a larger action does "not relieve the Federal agency of the requirements for considering the effects of the action or actions as a whole."); *Conner*, 848 F.2d at 1454-55 (holding that agency could not put off biological opinion until later stage of oil and gas lease approvals, since it is "critical that ESA review occur *early in the process* to avoid piecemeal chipping away of habitat."); *Lane Cty. Audubon Soc.*, 958 F.2d at 294 (consultation required on interim strategy that may affect spotted owl before it could be implemented through individual timber sales); *Karuk Tribe*, 681 F.3d at 1020.

EPA has now spent over ten years reviewing glyphosate's registration but has not completed the ESA consultation it knows is required. Because EPA issued a registration without first completing consultation, EPA violated the ESA and the Court should vacate the registration.

III. THE COURT SHOULD VACATE THE REGISTRATION.

Because EPA violated FIFRA and ESA, the Court should set aside EPA's approval. Vacatur is the presumptive remedy for unlawful pesticide registrations. *All. for the Wild Rockies v. U.S. Forest Serv.*, 907 F.3d 1105, 1121-22 (9th Cir. 2018) ("presumption of vacatur," unless defendants meet burden to show otherwise); *Pollinator Stewardship*, 806 F.3d at 532 (remand without vacatur permitted only in "limited circumstances"); *Idaho Farm Bureau v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995) ("[o]rdinarily" vacatur applies unless "equity demands" otherwise).

This Court "weigh[s] the seriousness of the agency's errors against the disruptive consequences of an interim change that may itself be changed." *NFFC*, 960 F.3d at 1144 (quoting *Pollinator Stewardship*, 806 F.3d at 532). In these environmental circumstances, the only cognizable

disruptive consequences are those environmental harms that flow from vacatur. *Id.* at 1145; *Pollinator Stewardship*, 806 F.3d at 532; *see also All. for the Wild Rockies*, 907 F.3d at 1122 (vacatur "appropriate when leaving in place an agency action risks more environmental harm than vacating it").

Just like in recent pesticide cases *NFFC* and *Pollinator Stewardship Council*, EPA here substantially understated or entirely failed to acknowledge the health risks to glyphosate users, and the environmental risks to pollinators and other wild species, including thousands of ESA-protected species. EPA's errors are serious: human health and environmental risks are core considerations of FIFRA. Violating ESA's Section 7 goes to the "heart" of that statute. *Lockyer,* 575 F.3d at 1018. And while there may be disruptive economic consequences alleged, the environmentally-safer result is vacatur. *Pollinator Stewardship*, 806 F.3d at 532.

Vacatur here means that glyphosate use would be unlawful, including the individual glyphosate-based products, because they all rest on EPA's unlawful determination that glyphosate does not cause unreasonable adverse effects on the environment. *See* 7 U.S.C.

§§ 136a(c)(5)(C), (D); 136a(a). This is the correct result because continued use of glyphosate formulations comes with serious, unexplored risks to workers, including of cancer. Given the serious error here, precarious populations of endangered species and pollinators, and the signficiant but long-term health impacts, this Court should vacate EPA's unlawful glyphosate registration.

CONCLUSION

For the reasons stated above, Petitioners request the Court vacate the registration, and remand for further proceedings consistent with this Court's decision.

Respectfully submitted this 17th day of December, 2020.

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