

**Case Nos. 20-70787, 20-70801**

**UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

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NATURAL RESOURCES DEFENSE COUNCIL, et al.,  
*Petitioners,*

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,  
*Respondent,*

NATIONAL ASSOCIATION OF WHEAT GROWERS, et al.,  
*Respondent-Intervenors.*

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RURAL COALITION, et al.,  
*Petitioners,*

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,  
*Respondent,*

NATIONAL ASSOCIATION OF WHEAT GROWERS, et al.,  
*Respondent-Intervenors.*

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

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**BRIEF OF PETITIONERS NATURAL RESOURCES DEFENSE  
COUNCIL, ET AL.**

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Dated: December 17, 2020

## **CORPORATE DISCLOSURE STATEMENT**

Petitioners Natural Resources Defense Council, Inc. (NRDC) and Pesticide Action Network North America (PANNA) are non-profit corporations with no parent corporation and no outstanding stock shares or other securities in the hands of the public. NRDC and PANNA do not have any parent, subsidiary, or affiliate that has issued stock shares or other securities to the public. No publicly held corporation owns any stock in NRDC or PANNA.

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## INTRODUCTION

Glyphosate, a noxious chemical first approved in the 1970s to kill a broad range of plants, NRDC\_ER-7, 11, is the most heavily used weed-killer in the nation, NRDC\_ER-112.<sup>1</sup> Each year, over 300 million pounds of glyphosate—commonly sold under the name Roundup, *see, e.g.*, NRDC\_ER-50—are applied across massive swaths of agricultural land, in forests, parks, and along roadways, and by homeowners in their lawns and gardens. NRDC\_ER-11–12.

Indiscriminate use of glyphosate has caused widespread harm to people and the environment. Glyphosate use has eradicated milkweed from enormous agricultural areas, a primary factor in bringing the iconic monarch butterfly, which relies on milkweed, to the brink of population collapse. NRDC\_ER-89–90 (collecting studies). It has resulted in the evolution of glyphosate-resistant “super weeds,” forcing farmers to resort to increasingly costly and ecologically harmful forms of weed control. *See, e.g.*, NRDC\_ER-166, 214. Further still, human

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<sup>1</sup> NRDC\_ER refers to Petitioners NRDC and PANNA’s Excerpts of Record filed with this brief.

exposure to glyphosate is linked to serious health harms, such as kidney and liver damage, and an increased risk of cancer. NRDC\_ER-79–80.

EPA regulates the use and sale of pesticides under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). 7 U.S.C. § 136 *et seq.* Through the “registration review” process, EPA is required to carefully re-assess the environmental and human health risks of each pesticide on the market every 15 years, and weigh the costs and benefits of its use, to make sure it still satisfies the applicable legal standard. 7 U.S.C. § 136(g); *id.* § 136(bb). Use of glyphosate in the United States has skyrocketed since EPA last comprehensively reviewed its safety, in the early 1990s, and decades of new research confirms that the weed-killer threatens human health and degrades the environment. Despite these changed circumstances, EPA recently approved the continued, widespread use of glyphosate nationwide, in a decision marked by missing information, untested and unsupported assumptions, and major procedural violations.

Petitioners NRDC and PANNA filed this lawsuit to challenge EPA’s glyphosate approval decision. The decision is unlawful because EPA: (1) ignored environmental and economic costs imposed by the use

of glyphosate; (2) failed to offer any reasoned explanation of how it balanced the pesticide's costs and benefits before re-approving it; (3) relied on the unsubstantiated assumption that untested mitigation measures would reduce recognized risks caused by glyphosate to tolerable levels; and (4) unlawfully ignored public comments on important issues central to EPA's safety determination. The decision should therefore be vacated and remanded, and glyphosate product registrations should be vacated.

### **STATEMENT OF JURISDICTION**

This Court has jurisdiction under FIFRA, which provides for review in the courts of appeal "as to the validity of any order issued by the Administrator following a public hearing." 7 U.S.C. § 136n(b). "[A]ny person who will be adversely affected by such order and who had been a party to the proceedings" may obtain judicial review under this provision. *Id.*

Petitioners challenge EPA's decision titled "Glyphosate Interim Registration Review Decision" (the decision). The decision is an order "following a public hearing" because it "arises from a notice-and-comment period." *Nat'l Family Farm Coal. v. EPA*, 960 F.3d 1120, 1132

(9th Cir. 2020) (hereinafter *Family Farm I*); *United Farm Workers of Am., AFL-CIO v. EPA*, 592 F.3d 1080, 1083 (9th Cir. 2010).

Petitioners were “part[ies] to the proceedings” because both NRDC and PANNA timely submitted comments opposing the proposed interim decision. NRDC\_ER-62–67, 74–99. And they are “adversely affected” by EPA’s interim decision on glyphosate, as discussed in the standing section below, *infra* Argument Part IV.

Additionally, venue is proper because both NRDC and PANNA have “a place of business” in the Ninth Circuit. 7 U.S.C. § 136n(b); Trujillo Decl. ¶ 3 (ADD3); Reeves Decl. ¶ 7 (ADD44).<sup>2</sup> And the petition is timely because it was filed on March 20, 2020, NRDC\_ER-237–238, “within 60 days after the entry of [the] order” on February 5, 2020. 7 U.S.C. § 136n(b); 40 C.F.R. § 23.6.

## STATUTORY AND REGULATORY FRAMEWORK

### I. The FIFRA safety standard

Congress enacted FIFRA to “protect human health and prevent environmental harm from pesticides.” *Wash. Toxics Coal. v. EPA*, 413

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<sup>2</sup> “ADD” refers to the Addendum of Declarations in Support of Standing at the close of this brief.



F.3d 1024, 1032 (9th Cir. 2005). Pesticides must be registered by EPA before they are sold or used. 7 U.S.C. § 136a(a). A registration operates as a “product-specific license” for pesticides. *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010). EPA must evaluate each pesticide to determine that the product “will not generally cause unreasonable adverse effects on the environment.”

7 U.S.C. § 136a(c)(5)(D). Congress defined unreasonable adverse effects on the environment to include “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.” *Id.* § 136(bb).

This Court and others have long found that this safety standard requires EPA to conduct a careful balancing of the costs and benefits of pesticide use. *Family Farm I*, 960 F.3d at 1142 (“FIFRA requires the EPA to consider” economic, social, and environmental costs “as part of a cost-benefit analysis.”); *Wash. Toxics Coal.*, 413 F.3d at 1032 (describing the required “cost-benefit analysis of the pesticides”), *abrogated on other grounds by Cottonwood Env. Law Center v. U.S. Forest Serv.*, 789 F.3d 1075 (9th Cir. 2015); *Chem. Specialties Mfrs. Ass’n v. EPA*, 484 F. Supp.

513, 515 (D.D.C. 1980) (FIFRA “requires a careful balancing of risks and benefits before allowing the use of pesticides”). This careful cost-benefit assessment is at the heart of pesticide registration procedures, including registration review.

## **II. Registration review**

During registration review, EPA must re-evaluate existing pesticide registrations at least every 15 years. 7 U.S.C. § 136a(g). Through this process, EPA must comprehensively review the latest information regarding a pesticide’s threats to human health, environmental harms, and other effects and determine whether it continues to satisfy the FIFRA safety standard. *See* 40 C.F.R. § 155.53(a). At the close of this appraisal, EPA issues its registration review decision, which constitutes “the Agency’s determination whether a pesticide meets, or does not meet” the safety standard. *Id.* § 155.57.

Registration review “serves as a backstop to ensure that pesticides do not remain registered once new data has shown them to be harmful to humans or the environment.” *Nat’l Family Farm Coal. v. EPA*, 966 F.3d 893, 918 (9th Cir. 2020) (hereinafter *Family Farm II*); *see also* H.R. Rep. 104-669 at 38 (1996), *reprinted in* 1996 U.S.C.C.A.N. 1208, 1212-

13 (explaining that registration review is designed to account for the “rapid development of science” and evolving understanding of a pesticide’s “impacts [on] human health and the environment”). EPA first registered glyphosate in the 1970s and did not comprehensively re-assess it until the early 1990s, through a process called pesticide re-registration. *See generally* 7 U.S.C. § 136a-1 (describing the re-registration process for pesticides first registered before November 1984).<sup>3</sup> Nearly 30 years have passed since that last review, and much has changed, including an explosion in the amount of glyphosate used nationwide, the emergence of a serious glyphosate weed-resistance problem, and reams of new scientific knowledge about the harms glyphosate can cause both to the environment and human health.

If, during registration review, EPA finds that a pesticide does not satisfy the safety standard, EPA must either initiate cancellation proceedings to rescind the pesticide’s registration, *see* 40 C.F.R. § 155.40(a), or identify mitigation measures necessary to reduce risk to

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<sup>3</sup> Re-registration was a one-time pesticide re-evaluation process established by Congress that is now complete. Subsequent FIFRA amendments created registration review.

acceptable levels, *id.* § 155.58(b)(2) (EPA “will . . . [i]dentify proposed risk mitigation measures or other remedies as needed” in its registration review decision). Mitigation measures might include changes to how and how much of a pesticide can be applied, “buffer zones” that prohibit pesticide application near sensitive areas, a prohibition on using the pesticide on certain crops or commodities, or any number of other measures. Such mitigation measures, once finalized, are enforceable changes to a pesticide’s registration. *See, e.g.*, NRDC\_ER-18 (revised label language is “enforceable”). At bottom, any mitigation must accomplish the purpose of the registration review process: to “ensure” that a pesticide’s registration satisfies the safety standard. 40 C.F.R. § 155.40(a).

EPA’s regulations also permit the agency to issue an “interim registration review decision.” *Id.* § 155.56. The same procedures and standards govern both interim registration review decisions and registration review decisions. *Id.* §§ 155.56, 155.58. In an interim decision, EPA may finalize parts of the registration review decision and “require new risk mitigation measures.” *Id.* § 155.56. Petitioners challenge EPA’s interim registration review decision for glyphosate,

which announced EPA's determination that glyphosate satisfies the safety standard and finalized certain (inadequate) mitigation measures.

### **ISSUES PRESENTED**

Did EPA violate FIFRA by ignoring known costs of glyphosate use, and by failing to explain why it believes the benefits of glyphosate use outweigh the costs?

Did EPA violate FIFRA by relying on unfounded assumptions that untested risk mitigation measures would reduce the risks of glyphosate use enough to meet the safety standard in the law?

Did EPA violate its own regulations and the Administrative Procedure Act by failing to consider and respond to significant public comments on and alternatives to its proposed decision?

### **STATUTORY AND REGULATORY AUTHORITIES**

All relevant statutory and regulatory authorities are included in the Addendum to this brief, *supra* pp. ADD55.

## STATEMENT OF THE CASE

### I. Factual history

#### A. Use of glyphosate started small but has since skyrocketed

Roundup, the most well-known name-brand formulation of glyphosate, was first registered by EPA and sold commercially by the company Monsanto in 1974. NRDC\_ER-102, 182. Initially, use “was limited because glyphosate could only be sprayed where land managers wanted to kill all vegetation.” NRDC\_ER-182.

As of 1990, glyphosate use remained moderate and was estimated at 12.7 million pounds annually. NRDC\_ER-186. In 1996, so-called “Roundup Ready” crops were approved for planting in the United States. NRDC\_ER-182. These crops were genetically engineered to resist the toxicity of glyphosate. Farmers could now apply glyphosate products indiscriminately to crops, without killing the crops themselves. As a result, glyphosate’s use skyrocketed. NRDC\_ER-186.

The approval of Roundup Ready crops marked a sea change in glyphosate’s use; it is now the most widely used herbicide in the United States. NRDC\_ER-112. “Approximately 281 million pounds of glyphosate was applied to 298 million acres *annually* in agricultural

settings” between 2012 to 2016. NRDC\_ER-12, 112 (emphasis added).

On average, that is 15 times more than was applied annually when

EPA last reviewed glyphosate’s registration, in the 1990s. *See* EPA,

Reregistration Eligibility Decision (RED): Glyphosate at 1 (1993)

(reporting 18.7 million pounds of glyphosate applied annually),

available at <https://bit.ly/33aBT9m>.<sup>4</sup> The geographic scope of application

is enormous: 298 million acres is equivalent to treating every single

acre of land in California, Texas, Maine, and Delaware combined.<sup>5</sup>

Today, glyphosate is used on field crops (such as soybean, corn, and

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<sup>4</sup> Petitioners request judicial notice of this and other extra-record information cited in this brief. A court “must take judicial notice if a party requests it and the court is supplied with the necessary information.” Fed. R. Evid. 201(c)(2). The Court may appropriately take judicial notice of this EPA document because it is “not subject to reasonable dispute” and “can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b)(2). This Court has routinely taken judicial notice of government publications such as those at issue here. *See, e.g., Corrie v. Caterpillar, Inc.*, 503 F.3d 974, 978 n.2 (9th Cir. 2007). Moreover, Circuit Rule 28-2.8 provides that record citations are not required for “undisputed facts offered only for general background.”

<sup>5</sup> *See* U.S. General Accounting Office, GAO/RCED-96-40, Land Ownership: Information on the Acreage, Management, and Use of Federal and Other Lands at 20-21 (1996), available at <https://bit.ly/3a8Dpx8> (reporting total land area of 101.6 million, 171 million, 21.5 million, and 1.5 million acres for California, Texas, Maine, and Delaware, respectively); Fed. R. Evid. 201(b)(2).

cotton), citrus fruits (grapefruits, oranges, lemons), tree nuts (almonds, walnuts, pistachios), and for other agricultural purposes. NRDC\_ER-11–12. Between 2012 and 2016, glyphosate was applied to 92 percent of soybeans, 89 percent of cotton, and 80 percent of corn grown in the United States. NRDC\_ER-124.

Another “24 million pounds of glyphosate are applied to non-agricultural sites annually, on average.” NRDC\_ER-12. Most non-agricultural use is in the homeowner market and for turf, forestry, and roadways. NRDC\_ER-12. Where there are plants to be killed, there is glyphosate.

**B. Rampant glyphosate use carries substantial economic costs and threatens severe environmental and health harms**

Since EPA’s last comprehensive review of glyphosate nearly 30 years ago, research increasingly has demonstrated the grave implications of glyphosate’s widespread use. This includes the proliferation of glyphosate-resistant weeds, serious harms to human health, and ubiquitous direct and indirect harm to the environment.



1. *Weed resistance threatens agriculture, imposes economic losses, and causes environmental harm*

Over-reliance on glyphosate has resulted in the evolution and proliferation of glyphosate-resistant weeds. NRDC\_ER-119. Weed resistance to glyphosate “has been widely reported and confirmed in 17 different weed species in the United States.” NRDC\_ER-113. For example, glyphosate-resistant Palmer amaranth spreads explosively through fields, “can easily exceed six feet in height, and has an extremely sturdy stalk that can be from 6-8 inches wide at its base,” which can damage harvesting equipment. NRDC\_ER-213.

Weed resistance is a major problem. Glyphosate-resistant weeds impose substantial costs on farmers, NRDC\_ER-166–67, “including increased expenditures on additional herbicides and increased use of soil-eroding tillage.” NRDC\_ER-71–72.<sup>6</sup> EPA notes that “growers are

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<sup>6</sup> Tillage is a form of mechanical weed control in which a grower disturbs the soil surface to kill existing weeds and prevent emergence of seedlings. This practice increases runoff and other soil loss and reduces sequestration of carbon in the soil. Conservation tillage practices reduce these ill effects by reducing soil disturbance. *See* Roger Claassen et al., *Tillage Intensity and Conservation Cropping in the United States*, USDA Economic Research Service, Economic Information Bulletin No. 197, at 1-2 (Sept. 2018), available at <https://bit.ly/3mr42zT>; Fed. R. Evid. 201(b)(2).

facing severe economic impacts from herbicide-resistant weeds.”

NRDC\_ER-166. Weed resistance takes an environmental toll, too. The battle against glyphosate-resistant weeds has caused “damages to water quality and climate effects” conservatively estimated at \$450 million, by forcing farmers to reduce use of conservation tillage practices.

NRDC\_ER-97. The prevalence of resistant weeds also causes farmers to use still more pesticides, increasing environmental contamination with toxic chemicals. NRDC\_ER-71, 98.

## 2. *Glyphosate threatens human health*

Studies of human exposure link glyphosate-based products to an elevated risk of adverse health effects in people, including kidney and liver damage, respiratory harms, birth defects, pre-term deliveries, miscarriages, and neural tube defects. NRDC\_ER-79–82. People exposed to glyphosate-based herbicides (also referred to as GBH) also have a greater risk of developing non-Hodgkin lymphoma cancers. NRDC\_ER-79–80.

In March 2015, the International Agency for Research on Cancer, a subdivision of the World Health Organization (WHO), classified glyphosate as “probably carcinogenic to humans,” NRDC\_ER-178, based

on a report by a committee of nationally-recognized experts that conducted a comprehensive evaluation of evidence from epidemiology, animal studies, and other information. EPA itself has resisted reaching that conclusion. Instead, EPA maintains that “glyphosate is not likely to be carcinogenic to humans.” NRDC\_ER-13, 157.

3. *Glyphosate causes environmental degradation*

Glyphosate use poses serious, extensive risks to the environment, including harmful effects on soil ecosystems, insect pollinators, and a variety of other wildlife. The widespread use of glyphosate is especially problematic for the imperiled monarch butterfly. Each spring, the Eastern North American population of monarch butterflies embarks on a multigenerational migration that begins in the forests of central Mexico. See U.S. Forest Service, *Monarch Butterfly Migration and Overwintering*, <https://bit.ly/3oDndrH> (last visited Dec. 14, 2020); 9th Cir. R. 28-2.8. The monarchs fly north across the United States, reproducing along the way. Because the migration occurs over multiple generations and milkweed is the only plant the monarch caterpillars can feed on, the monarch butterflies need to find milkweed across their entire migratory pathway. U.S. Fish and Wildlife Service, *The Monarch*

*Super Generation and Their Phenomenal Migration,*

<https://bit.ly/3oDndrH> (last visited Dec. 14, 2020); 9th Cir. R. 28-2.8.

Monarch experts have found that glyphosate is a major cause of monarch decline because it decimates milkweed in agricultural fields along the monarch migratory path. *See* NRDC\_ER-88–91 (collecting studies). There was a 64 percent loss of milkweed in the Midwest between 1999 and 2012, and researchers estimate that this has corresponded with an 88 percent decrease in monarch production. NRDC\_ER-90. The overwintering population in Mexico has dropped from a high of approximately one billion butterflies in 1997 to a low of approximately 33.5 million butterflies. NRDC\_ER-90–91. Scientists warn that the iconic monarch migration is at risk of vanishing. NRDC\_ER-91.

Research also shows that glyphosate use may negatively impact soil health by disrupting microbial communities, earthworms, and fungi. NRDC\_ER-150–152. These organisms play a crucial role in recycling soil nutrients and combatting soil-borne crop diseases, both of which are important for sustainable crop yield. *Id.*

Finally, EPA itself has identified risks to numerous categories of organisms, like mammals, birds, terrestrial and aquatic plants, NRDC\_ER-188, and some threatened and endangered fish, amphibians, and aquatic invertebrates, NRDC\_ER-190. Glyphosate's widespread use presents risks to plants and wildlife across the nation.

## II. Procedural history

EPA's most recent comprehensive safety assessment for all registered uses of glyphosate was in 1993, during the re-registration process. *See generally* EPA, Reregistration Eligibility Decision (RED): Glyphosate (1993), available at <https://bit.ly/33aBT9m>. Congress amended FIFRA in 2007 to require a comprehensive re-evaluation of the safety of all registered pesticides every 15 years; the first deadline for that review was established as October 1, 2022. *See* 7 U.S.C. § 136a(g); Pesticide Registration Improvement Renewal Act, Pub. L. 110-94, 121 Stat. 1000 (2007).<sup>7</sup> As discussed above, this process is called registration review.

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<sup>7</sup> Congress initially enacted a voluntary version of registration review in 1996, *see* Food Quality Protection Act, Pub. L. 104-170, 110 Stat. 1489 (1996), but first mandated the process in the 2007 amendments.

EPA began the registration review process for glyphosate in 2009. *See* NRDC\_ER-232. The process for glyphosate consisted of three main components: draft human health and ecological risk assessments, a proposed interim registration review decision, and a final interim registration review decision.

**A. EPA’s draft human health and ecological risk assessments for glyphosate identified pervasive human exposure and environmental risk**

EPA prepared a draft human health risk assessment for glyphosate on December 12, 2017, and solicited public comment on it. A human health risk assessment is the analysis conducted by EPA to “evaluate hazard and exposure data and conduct dietary, occupational, residential, and aggregate exposure assessments, as needed, to estimate the risk to human health that will result from all registered uses for glyphosate.” NRDC\_ER-154. The draft risk assessment notes that adults and children are exposed to glyphosate in food, in tap water, through the air, and through contact with the skin. NRDC\_ER-156. EPA stated that “the human health risk assessment supports continuation of the current registered glyphosate uses.” NRDC\_ER-155.

EPA published a preliminary ecological risk assessment for glyphosate on September 8, 2015, and solicited comment on that analysis too. The purpose of the ecological risk assessment is to assess the effects of glyphosate use on all wildlife and plants in the environment, referred to by EPA as “non-target organisms.” NRDC\_ER-187. In this assessment, EPA concluded that glyphosate poses potential risks of concern to mammals and birds. NRDC\_ER-188. EPA also found that glyphosate poses potential risks to terrestrial and aquatic plants, primarily from pesticide spray drift, NRDC\_ER-188, and to some endangered fish, amphibians, and aquatic invertebrates. *See* NRDC\_ER-190 (In one scenario, “[risk quotients] slightly exceeded the acute endangered species [level of concern] for freshwater fish, aquatic-phase amphibians, and estuarine/marine invertebrates . . .”).

Pesticide spray drift is “the movement of pesticide dust or droplets through the air at the time of application or soon after, to any site other than the area intended.” EPA, Introduction to Pesticide Drift, <https://bit.ly/3gzoxsP> (last visited Dec. 10, 2020). EPA performed a glyphosate spray drift assessment for milkweed to determine “the necessary distances off-field required to be below toxicity thresholds” at

various permitted spray rates. NRDC\_ER-197. That analysis showed that milkweed plants could still be harmed by glyphosate as far as 157 feet away from the treated field for ground application, and 620 feet for aerial application (or more than two football fields away). NRDC\_ER-197.

**B. EPA’s Proposed Interim Registration Review Decision recommended nominal mitigation to redress acknowledged risks from glyphosate use**

In April 2019, EPA issued its “Proposed Interim Registration Review Decision” for glyphosate, which proposed to “move forward with aspects of the registration review case that are complete” and approve its continued registration. NRDC\_ER-101, 105. Despite finding widespread environmental harm, including increasing glyphosate weed resistance and risks to birds, mammals, plants, and other taxa from glyphosate use, EPA proposed only minimal mitigation. Namely, the agency proposed certain restrictions on how the pesticide should be applied to decrease spray drift, a written notice on the pesticide label to alert users that glyphosate has the potential to impact “non-target organisms,” and another notice on the label to inform applicators about risks of herbicide resistance. NRDC\_ER-105–108. EPA did not propose



as mitigation any type of pesticide buffer zone to protect off-field milkweed or other plants or animals.

**C. Public comments identified significant flaws in EPA’s proposed decision and suggested alternative approaches and mitigation measures**

EPA solicited public comments on its proposed interim registration review decision in 2019. NRDC\_ER-8. Petitioners NRDC and PANNA, along with many others, submitted critical comments. NRDC\_ER-62–99. In all, EPA received “roughly 283,300 comments,” including “[o]ver 12,000 unique submissions,” and “approximately 120 unique substantive comments.” NRDC\_ER-8.

NRDC’s comments identified shortcomings in EPA’s proposed decision. Among other issues, NRDC cited evidence showing the harm to monarch butterflies caused by glyphosate’s decimation of milkweed both inside and outside of agricultural fields. NRDC\_ER-94–95. NRDC proposed alternative measures to mitigate the harms to monarchs, including mandating the use of buffer zones, planting strips of milkweed and other pollinator-friendly plants, and requiring the use of agricultural methods that reduce the need for intensive pesticide use. NRDC\_ER-94–96. NRDC also identified information missing from

EPA’s human health risk assessment, NRDC\_ER-80–81, and noted the proposed decision’s failure to take into account the enormous economic and environmental costs of glyphosate-resistant weeds, *see* NRDC\_ER-97–98. Petitioner PANNA submitted comments and studies showing, among other impacts, how glyphosate harms soil health, which can undermine crop health. NRDC\_ER-64–65.

EPA responded to the “approximately 120 unique substantive comments,” including those submitted by NRDC and PANNA, in a little over three pages. NRDC\_ER-8–11. EPA also issued two other brief documents that responded to comments in summary form. *See generally* NRDC\_ER-40–46, 49–61. EPA did not respond to Petitioners’ comments regarding harm to monarchs from decimation of on-field milkweed, gaps in the human health risk assessment, EPA’s inadequate cost-benefit analysis, or harms to soil health.

**D. EPA published the final Interim Registration Review Decision without any changes to its proposal**

On January 22, 2020, EPA issued the final “Interim Registration Review Decision” for glyphosate. EPA’s press release announced that “EPA has concluded its regulatory review of glyphosate” and “Finalize[d] Glyphosate Mitigation.” EPA, *EPA Finalizes Glyphosate*

*Mitigation* (Jan. 30, 2020), <https://bit.ly/3oLs4Hn> (last visited Dec. 10, 2020). The decision finalized the human health and environmental risk assessments without any changes in response to public comments.

NRDC\_ER-7–8. According to the decision, “EPA thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not identify any risks of concern.”

NRDC\_ER-12. And EPA concluded that there are “[n]o additional human health data needs” for registration review. NRDC\_ER-15. The decision also finalized the earlier ecological risk assessment, confirming potential risks to birds, mammals, terrestrial and aquatic plants, and endangered fish, amphibians, and aquatic invertebrates. NRDC\_ER-15, 190.

In the final decision, EPA summarized various asserted benefits of glyphosate: It kills a wide variety of weeds, it is relatively inexpensive, and it is widely used in agriculture and for non-agricultural purposes.

NRDC\_ER-16–17. EPA also explained that glyphosate is useful to control weeds in orchards and specialty crops, it can be used to control weeds in aquatic systems, and it is “versatile” and “can be applied with many different types of application equipment.” NRDC\_ER-17.

Based on these risks and purported benefits, EPA finalized the limited mitigation measures set out in the proposed decision. First are modest steps intended to “manage” off-field spray drift. NRDC\_ER-18–19. These include restrictions on aerial application of glyphosate when wind-speeds exceed 10 miles per hour and a ban on aerial application when they exceed 15 miles per hour. NRDC\_ER-19. EPA also prescribed maximum “release heights” (heights from which glyphosate may be sprayed) and minimum droplet sizes (specifically, when glyphosate is used alone, medium or coarser droplet size must be used).

NRDC\_ER-19.

Second, EPA required that labels on glyphosate products include “information and recommendations” for combatting glyphosate-resistant weeds. NRDC\_ER-20. The recommendations EPA identified are not new or specific to glyphosate; they come from guidance documents EPA first published in 2017, *see* NRDC\_ER-20, 27, which include suggestions and “example label statements” for herbicide resistance generally, *see* NRDC\_ER-168–71. EPA does not specify which label statements are required to be added to glyphosate products, but instead provides a link to its older guidance documents. NRDC\_ER-27.

Neither guidance document requires changes to the ways in which glyphosate is used.

Third, EPA has required labels to include a “non-target organism advisory,” which will advise users that glyphosate, an herbicide, is toxic to plants, and that users should follow the instructions on the label. NRDC\_ER-20–21. EPA does not explain how or whether the advisory is expected to reduce harm to “non-target organisms,” including terrestrial and aquatic plants, birds and mammals, and certain categories of fish, amphibians, and aquatic invertebrates, all of which EPA found to be at risk from glyphosate use.

EPA did not explain or cite evidence to show that its chosen mitigation measures will reduce the identified risks of harm. EPA did not explain why alternative mitigation measures—including those proposed by Petitioners—were rejected, or whether they were considered at all.

Finally, after briefly summarizing glyphosate’s risks and benefits, EPA’s final decision states in a single sentence that “the benefits outweigh the potential ecological risks when glyphosate is used

according to label directions.” NRDC\_ER-18. Accordingly, the final decision approves glyphosate for continued use.

The decision thus finalized EPA’s environmental and human health risk analyses, its cost-benefit analysis, and its mitigation measures. At the same time, EPA identified three discrete, pending tasks it intends to complete in a later decision, before closing its registration review: (1) its determination of the effects of glyphosate on threatened and endangered species and any needed consultation under the Endangered Species Act, 16 U.S.C. § 1536; (2) an assessment of glyphosate’s possible hormonal effects in people, as required by the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 346a(p); and (3) resolution of a petition filed by business and environmental groups under the FFDCA, which seeks to ban glyphosate on oats when used to kill and dry the crop just before harvesting. NRDC\_ER-6–7.

On March 20, 2020, Petitioners challenged EPA’s decision in this Court. *See* NRDC\_ER-237–38. Another group of petitioners also filed suit on March 20, *see Rural Coal. et al. v. U.S. EPA*, No. 20-70801, and the cases were consolidated on April 29.

## STANDARD OF REVIEW

### I. FIFRA requires that EPA's decision be supported by substantial evidence

EPA's decision may be upheld under FIFRA only if it is "supported by substantial evidence when considered on the record as a whole." 7 U.S.C. § 136n(b). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion," *Family Farm I*, 960 F.3d at 1132–33 (quoting *Nat. Res. Def. Council v. EPA*, 857 F.3d 1030, 1036 (9th Cir. 2017)); it requires "more than a mere scintilla" of evidence. *Nat. Res. Def. Council v. EPA*, 735 F.3d 873, 877 (9th Cir. 2013).

Courts applying the substantial evidence standard require an agency to "identify relevant factual evidence, to explain the logic and the policies underlying any legislative choice, to state candidly any assumptions on which it relies, and to present its reasons for rejecting significant contrary evidence and argument." *N. Am.'s Bldg. Trades Union v. OSHA*, 878 F.3d 271, 282 (D.C. Cir. 2017) (quoting *United Steelworkers v. Marshall*, 647 F.2d 1189, 1207 (D.C. Cir. 1980)); see also, e.g., *Am. Iron & Steel Inst. v. OSHA*, 939 F.2d 975, 982 (D.C. Cir. 1991) (explaining that substantial evidence standard requires "a

reasoned explanation for [] policy assumptions and conclusions” (quotations and citations omitted)).

Agency action that is arbitrary and capricious under the Administrative Procedure Act (APA), 5 U.S.C. § 706, is also unsupported by substantial evidence. *See Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 533 (9th Cir. 2015) (N.R. Smith, J., concurring) (Substantial evidence standard “affords an agency less deference than the arbitrary and capricious standard . . . .”); *Nat’l Oilseed Producers Ass’n v. OSHA*, 769 F.3d 1173, 1178 (D.C. Cir. 2014) (“[T]he substantial evidence standard demands more stringent review . . . than would the APA’s arbitrary and capricious standard.”). EPA must minimally, therefore, “provide enough information to demonstrate a rational connection between the factors that the EPA examined and the conclusions it reached.” *Nw. Coal. for Alternatives to Pesticides v. EPA*, 544 F.3d 1043, 1052–53 (9th Cir. 2008) [hereinafter *NCAP*] (citing *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). EPA’s decision “must be upheld, if at all, on the basis articulated by the agency itself.” *State Farm*, 463 U.S. at 50.



## II. EPA's decision must be set aside if it is arbitrary, capricious, or contrary to law

Under the APA, courts “set aside agency action, findings, and conclusions’ if [they] find them to be ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law’; or ‘in excess of statutory jurisdiction, authority, or limitations, or short of statutory right’; or ‘without observance of procedure required by law.’” *Am. Min. Cong. v. EPA*, 965 F.2d 759, 763 (9th Cir. 1992) (quoting 5 U.S.C § 706). A court must “determine whether EPA has considered the relevant factors and articulated a rational connection between the facts found and the choice made.” *Id.* (quoting *Rybachek v. EPA*, 904 F.2d 1276, 1284 (9th Cir. 1990)).

### SUMMARY OF ARGUMENT

EPA's decision to re-approve widespread use of glyphosate is fatally flawed in four ways. First, EPA failed to consider major environmental and economic costs of glyphosate use. When deciding whether a pesticide may be registered under FIFRA, EPA must “tak[e] into account” the economic, environmental, and social costs of the use of that pesticide. 7 U.S.C. § 136(bb). The decision, however, ignored economic and environmental costs of glyphosate-resistant weeds,

economic and environmental costs of harm to soil health caused by glyphosate, and environmental costs of decimation of milkweed in agricultural fields. All of these costs were presented to EPA in public comments. Because EPA “entirely failed” to consider these costs, EPA’s decision is unsupported by substantial evidence and arbitrary. *Family Farm I*, 960 F.3d at 1139.

Second, EPA failed to provide any explanation as to how it weighed the purported benefits and risks of glyphosate use to determine that the benefits outweighed the risks. FIFRA requires that EPA balance the benefits and costs of a pesticide before approving its continued use. *E.g.*, *Chem. Specialties Mfrs. Ass’n*, 484 F. Supp. at 515. In conducting this balancing, EPA is required to “articulate . . . a ‘rational connection between the facts found and the choice made.’” *State Farm*, 463 U.S. at 43 (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). At a minimum, EPA must conduct a reasoned balancing of the costs and benefits and explain how it reached the conclusion that benefits outweigh the costs. But here, EPA identified numerous, substantial costs of glyphosate use and concluded in a single sentence that glyphosate’s purported benefits “outweigh”

those costs. NRDC\_ER-18. This conclusory justification fails to provide the rational connection required.

Third, EPA's approval of glyphosate rests on the unsubstantiated assumption that paltry, untested, and unproven mitigation measures will, in fact, reduce the acknowledged risks of environmental harm. The agency provided no evidence that the mitigation it imposed—consisting of some application instructions intended to lessen spray drift, and various label advisories—will ensure that glyphosate satisfies the safety standard. EPA's blind optimism is not the "substantial evidence" required by FIFRA. 7 U.S.C. § 136n(b). Nor did EPA explain why it rejected other, more protective mitigation measures recommended by Petitioners and others in public comments. EPA's reliance on limited mitigation to re-approve glyphosate is thus unlawful under both FIFRA and the APA.

Finally, EPA's scant response to public comments violates the agency's regulations and basic principles of administrative law, both of which require EPA to respond to significant comments on its proposed decision. EPA's final decision is therefore arbitrary and capricious and without observance of procedure required by law. 5 U.S.C. § 706(2)(A),

(D); 40 C.F.R. § 155.58(c). EPA failed to consider and respond to significant comments regarding (1) harm to monarch butterflies, (2) impaired soil health, (3) significant data gaps in EPA's assessment of glyphosate's health effects, which undermines EPA's conclusion that glyphosate exposure is safe for people, and (4) the economic and environmental costs of rampant glyphosate weed resistance. These comments identified harmful effects of glyphosate and proposed reasonable alternatives to EPA's proposed decision, and EPA may not simply ignore them. *See Action on Smoking & Health v. C.A.B.*, 699 F.2d 1209, 1219 (D.C. Cir. 1983), *amended by* 713 F.2d 795 (D.C. Cir. 1983).

EPA styles its decision as “interim,” but it is final and effective, and judicial review is proper now. Because EPA's re-approval decision violates core requirements of FIFRA and the APA, the Court should vacate the decision and thereby vacate EPA's registrations of glyphosate products.

## ARGUMENT

### **I. EPA ignored relevant costs and failed to explain why benefits outweighed identified costs**

Congress directed EPA to consider the economic, social, and environmental costs and benefits of pesticide registration during registration review. 7 U.S.C. §§ 136(bb), 136a(g). EPA's finding that glyphosate's benefits outweigh its costs is unlawful for two reasons. First, EPA entirely failed to consider relevant economic and environmental costs of glyphosate use. Second, EPA failed to explain or support its conclusion that the benefits of glyphosate use outweigh the costs that it did identify.

#### **A. EPA failed to consider relevant costs of glyphosate use**

When conducting registration review, EPA must take into account the economic, environmental, and social costs and benefits of a pesticide's use. 7 U.S.C. §§ 136(bb), 136a(g). The use of glyphosate imposes substantial costs that EPA ignored. EPA's decision is therefore unsupported by substantial evidence and arbitrary.

First, glyphosate use has caused an epidemic of glyphosate-resistant weeds, which increases financial costs for farmers

who must combat those weeds. NRDC\_ER-71–73, 97–98. Weed resistance also imposes an environmental cost, through the impaired water quality and harmful climate impacts caused by tillage and other efforts necessary to fight these super weeds. NRDC\_ER-97–98 (estimating the cost of these environmental harms at nearly half a billion dollars). To combat resistant weeds, farmers resort to still more pesticides, exacerbating environmental costs. NRDC\_ER-71, 98.

In its decision, EPA did not take into account the economic and environmental costs of glyphosate resistance. Instead, in response to comments that raised this issue, EPA stated simply: “Whenever a [sic] herbicide is used, there is a potential for that use to contribute to the evolution of herbicide resistance.” NRDC\_ER-46. Acknowledging that herbicides in general may cause herbicide resistance is not the same as accounting for the costs of glyphosate-resistant weeds. Record evidence submitted by Petitioners shows that glyphosate contributes uniquely to weed resistance and imposes enormous costs on farmers and society. NRDC\_ER-71–72, 97–98. EPA ignored those costs in its decision.

Second, glyphosate harms microbial communities in soil, with serious financial and ecological implications for crop health.

NRDC\_ER-150–52, 180–81, 199–201. Poorer quality soil can exacerbate plant diseases that devastate certain crops, reduce nutrients available for plants, and decrease crop yield. *Id.* This too imposes both economic and environmental costs.

EPA nodded to this issue in an earlier response to comments, but again refused to assess the evidence, let alone account for the costs in its registration decision. Instead, EPA admitted: “Potential effects to soil microbes/ communities is not currently assessed in [EPA’s] ecological risk assessments.” NRDC\_ER-149. In other words, EPA declined to account for these costs.

Third, glyphosate imposes an environmental cost by killing milkweed within agricultural fields, throughout the vast acreage where glyphosate is sprayed. NRDC\_ER-89–95. That contributes significantly to monarch butterfly decline. EPA looked at the off-site impacts of glyphosate that result from spray drift, but completely failed to account for the environmental costs of glyphosate use *within* agricultural fields. NRDC\_ER-15, 18, 20 (discussing off-field spray drift and failing to acknowledge ecological impacts within the application area in agricultural fields). In other words, EPA failed to account for the

environmental costs of milkweed loss in the nearly 300 million acres of land intentionally sprayed with glyphosate. NRDC\_ER-12.

Fourth, EPA neglected to consider the possibility that glyphosate use might impose any economic costs at all. Instead, EPA evaluated glyphosate's environmental risks (or some of them), but made no mention of potential economic costs. NRDC\_ER-18, 105. EPA's analysis assumes that glyphosate provides only economic benefits, and no costs. *Id.*

These are glaring omissions. EPA's glyphosate registration review decision is unsupported by substantial evidence because the agency "entirely failed to acknowledge" the environmental and economic costs above, which it was "statutorily required to consider." *Family Farm I*, 960 F.3d at 1139. EPA's decision is arbitrary and capricious under the APA for the same reason. *Cigar Ass'n of Am. v. U.S. Food & Drug Admin.*, 964 F.3d 56, 61 (D.C. Cir. 2020) (where agency must "tak[e] into account" certain factors, it must "reach[] an 'express and considered conclusion' pursuant to the statutory mandate," and the failure to do so is arbitrary (quoting *Time Warner Entm't Co. v. FCC*, 56 F.3d 151, 175 (D.C. Cir. 1995))). EPA's failure to account for *any* economic costs is



alone fatal to the agency’s approval decision. *See Pub. Citizen v. Fed. Motor Carrier Safety Admin.*, 374 F.3d 1209, 1216 (D.C. Cir. 2004) (“[T]he complete absence of any discussion’ of a statutorily mandated factor ‘leaves us with no alternative but to conclude that . . . [the] agency’s reasoning [is] arbitrary and capricious.’” (alterations omitted) (quoting *United Mine Workers v. Dole*, 870 F.2d 662, 673 (D.C. Cir.1989))). Even if it is difficult to quantify the costs precisely, EPA may not lawfully assume those costs are zero. *See Ctr. for Biological Diversity v. NHTSA*, 538 F.3d 1172, 1198–1200 (9th Cir. 2008). And EPA cannot properly balance a pesticide’s economic costs and benefits if it completely ignores many of the costs.

This Court recently vacated a different pesticide registration for the same reason: EPA failed to consider certain costs of use. *See Family Farm I*, 960 F.3d at 1144–45. There, the Court reviewed EPA’s registration of dicamba, another herbicide. *Id.* at 1126. The Court found that EPA failed to consider both economic and social costs. *Id.* at 1144. The Court thus concluded that “substantial evidence [did] not support” EPA’s decision because it “entirely failed to acknowledge” these costs. *Id.* at 1144, 1145. The same is true here.

In another recent decision, the Ninth Circuit remanded EPA's registration of a pesticide called Enlist Duo, which contains both glyphosate and the weed-killer 2,4-D. *Family Farm II*, 966 F.3d at 904, 905. There, the Court held EPA's registration decision lacked substantial evidence because of EPA's admitted failure to "consider[] how the destruction of milkweed on *target fields* would affect monarch butterflies." *Id.* at 917. EPA repeated the exact same mistake in the glyphosate decision challenged here, and the decision is unlawful for the same reason.

In sum, EPA failed to analyze significant economic and environmental costs of glyphosate use, as required by FIFRA, despite available evidence presented in public comments. EPA's determination that the benefits of glyphosate use outweigh its costs is, therefore, unsupported by substantial evidence and arbitrary.

**B. EPA failed to explain why the benefits of glyphosate use outweigh the costs**

In addition to ignoring major costs of glyphosate use, EPA failed to meaningfully compare the costs and risks it does acknowledge to purported benefits and explain how that cost-benefit analysis supports its registration review decision. It is axiomatic that an "agency 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.” *State Farm*, 463 U.S. at 43 (emphasis added) (quotations and citation omitted); *see also NCAP*, 544 F.3d at 1052 (EPA must “provide enough information to demonstrate a rational connection between the factors that the EPA examined and the conclusions it reached”). EPA’s conclusory cost-benefit balancing fails to demonstrate a rational connection between the facts and its determination that glyphosate satisfies the FIFRA safety standard. It is, therefore, arbitrary and capricious and unsupported by substantial evidence.

The FIFRA safety standard requires EPA to balance costs and benefits before permitting continued use of a pesticide. *See* 7 U.S.C. §§ 136(bb), 136a(c)(5)(C)–(D); 40 C.F.R. § 155.40(a); *Wash. Toxics Coal.*, 413 F.3d at 1032; *Chem. Specialties Mfrs. Ass’n*, 484 F. Supp. at 515. If EPA identifies a risk, it “has an obligation to explain how the benefits of continued use outweigh that risk.” *Env’t Def. Fund v. EPA*, 548 F.2d 998, 1012 (D.C. Cir. 1976), *abrogated on other grounds by Dep’t of Labor v. Greenwich Collieries*, 512 U.S. 267 (1994).

EPA has failed to support its glyphosate registration review decision with the requisite analysis. EPA acknowledges enormous ecological risks of glyphosate approval but concludes without meaningful explanation that these risks—which constitute environmental costs within the meaning of the statute—are outweighed by glyphosate’s benefits. In other words, the agency “shunted aside significant questions with merely conclusory statements,” rendering its decision arbitrary. *Ctr. for Biological Diversity*, 538 F.3d at 1223 (citation omitted).

To start with, EPA identified “potential ecological risk to mammals and birds” at the “application area or areas near the application area.” NRDC\_ER-18. That innocuous-seeming statement expresses a deceptively large environmental threat. Birds and mammals each comprise an entire biological class. The application area is nearly 300 million agricultural acres annually, plus the additional acreage treated by another 24 million pounds of glyphosate for residential and non-agricultural uses. NRDC\_ER-12. Thus, glyphosate’s agricultural “application area” alone amounts to about one-eighth of the entire country. U.S. Gen. Accounting Office, GAO/RCED-96-40, Land

Ownership: Information on the Acreage, Management, and Use of Federal and Other Lands 20–22 (1996) (total land area of United States is 2.34 billion acres). EPA’s own analysis, therefore, shows that glyphosate presents potential risks to wildlife across huge swaths of the country.<sup>8</sup>

EPA also found that glyphosate use presents a potential risk to both terrestrial and aquatic plants from off-site spray drift. NRDC\_ER-18. And in other documents, EPA acknowledged risk of harm to honey bees and other pollinators, caused by loss of forage and habitat, NRDC\_ER-148–149, and certain categories of fish, amphibians, and aquatic invertebrates, *see* NRDC\_ER-190.

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<sup>8</sup> EPA’s ecological risk assessment elaborates on the broad scope of risks of concern. *E.g.*, NRDC\_ER-190 (“[Risk quotients] slightly exceeded the acute endangered species [level of concern] for freshwater fish, aquatic-phase amphibians, and estuarine/marine invertebrates.”); NRDC\_ER-191 (finding an “exceedance of the acute avian listed [level of concern] for all use rates” and that “[s]ingle application rates of >2.2 and .5 lbs formulation/A results in acute non-listed and listed [level of concern] exceedances”); NRDC\_ER-192 (finding [level of concern] exceedances for large, medium, and small mammals); NRDC\_ER-194 (glyphosate “affect[s]” “vegetative vigor”); NRDC\_ER-196 (finding “potential for adverse effects to terrestrial plants” and “potential indirect effects . . . to other taxa that rely on terrestrial plants as a resource for food and/or habitat”); NRDC\_ER-197 (finding off-field effects on common milkweed, on which monarch butterfly larvae rely).

EPA’s decision document then provides a brief, qualitative summary of glyphosate’s putative benefits—namely, that it is generally inexpensive, versatile, and widely used. NRDC\_ER-18. But instead of explaining *why* these benefits justify the risks and costs identified, EPA summarily concludes that “the benefits outweigh the potential ecological risks when glyphosate is used according to label directions.” *Id.*

This single sentence represents the entirety of EPA’s balancing of costs and benefits. EPA does not explain why it thinks the benefits outweigh the costs. EPA does not attempt to quantify the benefits and costs, or even offer a qualitative comparison of the two. EPA fails to articulate how the costs and benefits it considered informed its determination at all. Without a reasoned explanation of its cost-benefit analysis, EPA’s decision cannot stand. *Pub. Citizen, Inc. v. Mineta*, 340 F.3d 39, 58 (2d Cir. 2003) (vacating and remanding a regulation where the record failed to “explain *why* the costs saved were worth the benefits sacrificed” (emphasis added)); *Env’t Def. Fund*, 548 F.2d at 1012 (EPA must explain why benefits of pesticide use outweigh the risks).

## II. The decision depends on EPA's unfounded assumption that mitigation will reduce risks and costs

The purpose of registration review is to “make sure that” glyphosate “continue[s] to meet the statutory standard of no unreasonable adverse effects.” NRDC\_ER-6; *see* 40 C.F.R. § 155.40(a). Here, EPA determined that current, registered uses of glyphosate pose numerous environmental risks, but that with additional mitigation, those uses satisfy the safety standard. *See* NRDC\_ER-7 (describing “mitigation measures that were proposed to address risks of concern”); NRDC\_ER-18 (concluding that glyphosate’s benefits outweigh its risks “when . . . used according to label directions” and requiring additional labeling); NRDC\_ER-23 (stating that “changes to the affected registrations and their labeling are *needed*” (emphasis added)). Namely, EPA’s approval of glyphosate is predicated on three mitigation measures presumed to reduce environmental risks: restrictions to reduce spray drift, a non-target organism advisory, and the addition to product labels of “information and recommendations” for reducing glyphosate-resistant super weeds. NRDC\_ER-18–21, 27. EPA failed, however, to provide any evidence, let alone substantial evidence, that these mitigation measures will reduce risk such that continued

glyphosate use satisfies the safety standard. The decision is, therefore, arbitrary and unsupported by substantial evidence.

When EPA's registration decision is predicated on measures intended to reduce risk, the agency must support its reliance on those measures with substantial evidence. *See Pollinator Stewardship Council*, 806 F.3d at 528–30 (“No additional studies were submitted to evaluate the mitigation measures the EPA added in its unconditional registration. We cannot conclude that the unconditional registration is supported by the record as a whole.”); *Aqua Slide ‘N’ Dive Corp. v. Consumer Prod. Safety Comm’n*, 569 F.2d 831, 835, 844 (5th Cir. 1978) (Commission’s balancing of risks was unsupported by substantial evidence because determination relied on unsubstantiated theory of mitigation); *cf. Family Farm I*, 960 F.3d at 1142 (registration vacated in part because EPA failed to consider evidence that proposed mitigation, on which registration was conditioned, would be ineffective).

In *Pollinator Stewardship Council*, this Court rejected EPA's attempt to register a different pesticide based on unsubstantiated mitigation. 806 F.3d at 528–30. There, EPA proposed granting only



conditional<sup>9</sup>—as opposed to unconditional— registration for the pesticide sulfoxaflor because EPA lacked data on pollinator impacts and could not determine that the registration of sulfoxaflor satisfied the safety standard. *Id.* at 526. Months later, EPA announced its decision to *unconditionally* register sulfoxaflor, determining that its use, in accordance with various mitigation measures, would not cause unreasonable adverse effects on the environment. *Id.* at 527.

This Court found the decision to be unsupported by substantial evidence because EPA offered no evidence that the mitigation it imposed would protect against unreasonable adverse effects on the environment. *Id.* at 530 (“EPA was lacking sufficient data on the impact of sulfoxaflor generally even at the reduced application rate of 0.09 pounds of active ingredient per acre.”). EPA repeats the same mistake here: The Agency has failed to provide any evidence that its mitigation

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<sup>9</sup> Under certain circumstances, EPA may “conditionally” register a pesticide product. 7 U.S.C. § 136a(c)(7). To do so, EPA must determine, in part, that the pesticide “would not significantly increase the risk of any unreasonable adverse effect on the environment.” *Id.* § 136a(c)(7)(A)–(B).

measures bring glyphosate use into compliance with the FIFRA safety standard.

**A. EPA presents no evidence that its spray drift mitigation adequately reduces risk**

The decision explains that glyphosate spray drift is a significant source of risk to non-target plants, including milkweed, a “critical food source” for the monarch butterfly. NRDC\_ER-15 (noting impacts to milkweed); NRDC\_ER-18 (summarizing “potential risk to terrestrial and aquatic plants from off-site spray drift”). To address this risk, EPA required label language to reduce spray drift, including restrictions on application of the pesticide during high wind-speeds, maximum release heights, and minimum spray droplet sizes. *See supra* p. 24.

There is no evidence that the required measures will effectively reduce risk. In fact, when a glyphosate registrant analyzed “appropriate practices” to protect threatened and endangered non-target plants from drift, it recommended mitigation different than that imposed by EPA.

NRDC\_ER-234–35.<sup>10</sup> Namely, it recommended “separation

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<sup>10</sup> Though initially designated as “Protected Information” subject to the protective order entered by this Court, ECF No. 41, 37-2, NRDC, PANNA, and Respondents later agreed to de-designate this document, ECF No. 50, pursuant to Paragraph 6.c. of the protective order.

distance[s] . . . between the application area and any habitat” for aerial application. NRDC\_ER-235. And although the registrant’s study did not recommend mitigation for ground application at “rates up to 3.5 lb a.e./acre,” *id.*, EPA’s decision approves maximum application rates that exceed this level for nearly all uses. NRDC\_ER-31–35. EPA’s mitigation, therefore, finds no support in this industry recommendation.

EPA’s only analysis of its chosen mitigation does not show that it will effectively reduce risk; instead, EPA focuses on ensuring that mitigation will not affect current usage levels. As for maximum release heights, “EPA does not anticipate that these releases [sic] heights will impact the use of glyphosate because applications at these heights are standard practice.” NRDC\_ER-136. Similarly, EPA explains that glyphosate is frequently tank-mixed with other herbicides, *id.*, a condition that significantly eases the droplet-size restrictions imposed by EPA, NRDC\_ER-19. Finally, the wind-speed restrictions “should provide *more flexibility to applicators*” because most labels currently restrict application of glyphosate at *lower* wind-speeds. NRDC\_ER-137 (emphasis added). Despite claiming that its mitigation will “reduce the

extent of exposure and risk” to plants and wildlife, NRDC\_ER-18, EPA’s minimal analysis did not explain this conclusion at all.

**B. EPA presents no evidence that its non-target organism advisory reduces the risk of environmental harm**

EPA identified potential risks to a wide variety of plants and wildlife that would prevent it from finding that glyphosate satisfied the safety standard. NRDC\_ER-18 (finding “potential ecological risk to mammals and birds” and “potential risk to terrestrial and aquatic plants from off-site spray drift,” and requiring mitigation of spray drift); *see* NRDC\_ER-23 (“changes to the affected registrations and their labeling are *needed*” (emphasis added)). For example, EPA found that risks of glyphosate use exceeded the agency’s level of concern—a threshold used to identify problematic risks—for certain categories of fish, amphibians, and aquatic invertebrates. *See* NRDC\_ER-190 (risks exceeded acute endangered species level of concern). Further still, the agency found that glyphosate use presented risks to birds at “all use rates” for one product, NRDC\_ER-191, as well as to mammals of all sizes, NRDC\_ER-193. And—predictably—use of the herbicide presents risks for plants and any species that rely on those plants. NRDC\_ER-

196 (highlighting “potential indirect effects . . . to other taxa that rely on terrestrial plants”).

There is no evidence that advisory statements on warning labels effectively reduce risk, let alone the threat of widespread environmental harm acknowledged here. EPA’s decision requires the following label language:

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.

NRDC\_ER-20–21. This language vaguely identifies broad, ecosystem-wide threats and directs a user to other statements on the label. But EPA is relying on these two sentences to reduce harm to mammals, birds, plants, pollinators, and other species on hundreds of millions of acres nationwide. EPA does not explain how or whether this language will reduce risk at all, much less provide any evidence that it will reduce identified risks to acceptable levels.

**C. EPA presents no evidence that its herbicide resistance label language effectively or adequately reduces risk**

EPA states that the “development and spread of herbicide-resistant weeds in agriculture is a widespread problem that has the potential to fundamentally change production practices in U.S. agriculture.” NRDC\_ER-20. To address this threat, the agency is “requiring the implementation of herbicide resistance measures” that are “[c]onsistent with” previously-issued guidance. *Id.* To the extent EPA believes this step mitigates adverse effects stemming from proliferation of weed resistance, that assumption is unsupported.

To start with, it is unclear what specific language EPA intends to require on glyphosate labels to deal with weed resistance. Instead of identifying the required label language, the agency merely provides a link to guidance documents on EPA’s website. NRDC\_ER-27. That does not advise registrants what specific language they need to include on glyphosate product labels, or explain which measures will adequately reduce risk. Moreover, the referenced guidance was issued in 2017, meaning that applicators have had access to these recommendations for three years already. EPA does not provide any information about

whether the language has mitigated the proliferation of glyphosate-resistant super weeds since then, and, if not, why it would be expected to do so now.

But most importantly, although EPA’s guidance provides “Example Label Statements,” *none* of them require applicators to change herbicide application practices. NRDC\_ER-168–69. None are tailored to glyphosate-resistant weeds. *Id.*; *see also* NRDC\_ER-170–71. And neither this guidance nor the administrative record contains evidence that these informational materials will reduce the substantial risks and costs associated with glyphosate-resistant weeds.

Similarly, “PRN 2017-1,” a guidance document mentioned only in the Appendix to EPA’s decision, NRDC\_ER-27, does not contain any enforceable requirements for preventing weed resistance. Instead, it provides a list of recommendations which “may not be appropriate or pertinent for every product label.” NRDC\_ER-162. EPA’s decision does not specify which of these label statements apply—if any—nor does the agency explain how or whether these statements will reduce the costs of glyphosate-resistant weeds. NRDC\_ER-20 (requiring registrants to

provide applicators with “information and recommendations” about herbicide resistance).

EPA’s assumption that any of its mitigation will work is unsubstantiated. The decision is therefore unsupported by substantial evidence.

### **III. EPA failed to consider and respond to significant public comments and proposed alternatives**

EPA’s regulations require the agency to consider and respond to significant public comments submitted on proposed interim registration review decisions. Despite this duty, the agency failed to address several of Petitioners’ significant comments and proposed alternatives. EPA’s failure to consider and respond to significant comments is “arbitrary, capricious . . . or otherwise not in accordance with law” and “without observance of procedure required by law.” 5 U.S.C. § 706(2)(A), (D).

Under EPA’s regulations, the agency must publish a proposed interim registration decision, provide a public comment period of at least 60 days, and issue a decision with “an explanation of any changes to the proposed decision and the Agency’s response to significant comments.” 40 C.F.R. § 155.58(a), (c). In cases reviewing the sufficiency of notice-and-comment rulemaking under the APA, courts have



interpreted “significant comments” to mean “those which raise relevant points and which, if adopted, would require a change in the agency’s proposed rule.” *Am. Min. Cong.*, 965 F.2d at 771.

EPA’s response “must address, with some precision, the major comments received and . . . reflect reasoned consideration of competing objectives and alternatives.” *Action on Smoking & Health*, 699 F.2d at 1216. It must also explain how resolution of significant problems raised in comments led to the final rule. *Id.* Where a relevant proposal or alternative “receive[s] no attention whatsoever[,] [s]uch treatment plainly disregards the agency’s obligation to respond to the major comments received in rulemaking.” *Id.* at 1219.

There are at least four significant, substantive comments Petitioners made that EPA has ignored or “disposed of without reasons.” *Id.* Each shows that the “decision was not based on a consideration of the relevant factors.” *Am. Min. Cong.*, 965 F.2d at 771. The decision should be remanded to EPA so that the agency can consider these important comments and provide a reasoned response. *E.g.*, *Action on Smoking & Health*, 699 F.2d at 1219; *Am. Coll. of Emergency Physicians v. Price*, 264 F. Supp. 3d 89, 94–95 (D.D.C. 2017).

**A. EPA failed to adequately consider and respond to comments about monarch butterflies**

Petitioner NRDC made several significant comments and proposals related to harm to monarch butterflies that EPA ignored. There is broad scientific consensus that “the loss of milkweed due to the widespread use of glyphosate is responsible for the decline in the monarch population.” NRDC\_ER-90. NRDC’s comments explain that EPA’s proposed spray drift mitigation fails to adequately protect monarchs in two ways. First, the mitigation is insufficient to address the impact of glyphosate on milkweed *outside* of agricultural fields, because the agency is not requiring any pesticide buffer zone. This despite the results of the agency’s own spray drift assessment showing that buffer distances of 118–620 feet for aerial application, and 33–157 feet for ground application, are needed to protect milkweed outside of fields. NRDC\_ER-94, 104. Second, the spray drift measures do nothing to mitigate harm from the decimation of milkweed *within* agricultural fields, an issue the agency completely ignored. NRDC\_ER-94–95. As noted above, the Ninth Circuit recently remanded EPA’s registration of Enlist Duo, a pesticide containing glyphosate, for precisely this reason: the agency failed to “consider[] how the destruction of milkweed on

*target fields* would affect monarch butterflies.” *Family Farm II*, 966 F.3d at 917.

NRDC’s comments also provided information about proposed alternatives to mitigate harm to monarchs. This included research demonstrating the benefits of planting strips of native prairie plants—like milkweed—within fields, both to mitigate the risk to monarchs and improve soil quality. NRDC\_ER-95–96. NRDC also suggested buffer zones based on EPA’s spray drift analysis. NRDC\_ER-94.

In its decision and various “response to comments” documents, EPA ignored NRDC’s comments on the need to consider harm to milkweed within agricultural fields, and NRDC’s proposals to require pesticide buffer zones and prairie strips as mitigation. EPA simply declares that “[m]onarch butterfly conservation is an important issue” and that EPA’s mitigation measures—adopted without change from the agency’s proposal—“are expected to reduce exposure to pollinators, including monarchs.” NRDC\_ER-45. But the primary point of NRDC’s comments is not that monarchs will be harmed by direct exposure to glyphosate, but that milkweed will be destroyed by glyphosate, causing harm to monarchs.

Harm to monarchs through destruction of habitat is an adverse environmental effect, and NRDC raised issues with EPA's analysis that cannot simply be ignored. The proposals raised by NRDC, if adopted, would require changes to the agency's decision. *See Am. Min. Cong.*, 965 F.2d at 771. The agency unlawfully ignored these significant comments and proposals.

**B. EPA failed to consider and respond to comments about soil health**

EPA refused to respond to and consider comments highlighting significant ecological harm to soil health resulting from glyphosate use. Petitioner PANNA raised the issue in comments on EPA's preliminary ecological risk assessment, explaining and citing research showing that glyphosate reduces soil health by harming soil bacteria, earthworms, and fungi. NRDC\_ER-150-52.

PANNA, along with others, again submitted comments on the proposed decision raising the threat of harm to soil health. NRDC\_ER-64-65. Those comments included citations to studies showing that glyphosate-based herbicides significantly decrease the activity of earthworms, which play a crucial role in soil health. *Id.* The comments also presented studies that demonstrate many other ways that

glyphosate harms soil health, including by inhibiting mycorrhizal fungi—fungi that have an important, symbiotic relationship with plant root systems—diminishing nutrient cycling, and disrupting microbial ecology in the soil surrounding plant roots. *Id.*

Despite being presented with these comments and studies on soil health, EPA finalized its ecological risk assessment without change, and the decision and contemporaneous response to comments make no mention of soil health as a consideration. EPA’s only mention of comments on soil health is in the agency’s earlier response to comments on the draft ecological risk assessment, which admits that “[p]otential effects to soil microbes/communities is not currently assessed in [the] ecological risk assessments.” NRDC\_ER-149. The potential for widespread harm to soil biology on the hundreds of millions of acres where glyphosate is applied is an adverse effect on the environment, *see* 7 U.S.C. § 136a(c)(5), and EPA may not simply ignore it.

**C. EPA failed to consider and respond to comments identifying gaps in EPA’s analysis of the health impacts of glyphosate**

EPA’s proposed decision stated that “[n]o human health data needs have been identified for glyphosate.” NRDC\_ER-103. In its

comments, NRDC provided a long list of specific, important data gaps in the human health risk assessment. NRDC\_ER-80–81. In the final decision, however, EPA finalized its human health risk assessment without change, NRDC\_ER-7, and again stated that “[n]o additional human health data needs have been identified,” NRDC\_ER-15.

NRDC’s comments highlighted missing information regarding the health effects of glyphosate, discussing extensively a report by the Agency for Toxic Substances and Disease Registry (ATSDR) that pointed out these gaps. NRDC\_ER-80. Among other shortcomings, NRDC identified a lack of data analyzing effects of pure glyphosate on whole organ systems, including respiratory, cardiovascular, and endocrine effects. NRDC\_ER-80. NRDC’s comments also highlighted missing information about children’s susceptibility to glyphosate exposure, inhalation risks, and the total amount of glyphosate consumed by people through contaminated food and water. NRDC\_ER-80–81.

EPA did not respond to the specific human health data gaps identified by NRDC. Comments raising serious blind spots in EPA’s human health risk assessment call into question the agency’s ultimate

determination whether glyphosate poses unreasonable adverse effects to human health, 7 U.S.C. § 136a(c)(5)(C); *id.* § 136(bb), and the agency must consider those comments and respond. *See Action on Smoking & Health*, 699 F.2d at 1216. EPA did not even include the ATSDR report in the administrative record, even though it was discussed at length by NRDC and other commenters in submissions to EPA, and was attached to comments filed by the Center for Food Safety (CFS).<sup>11</sup> EPA apparently failed to consider this evidence at all.

While the agency ultimately may not agree that these types of studies are integral to their human health risk assessment, EPA must at least review information placed before it, acknowledge issues raised in comments, and explain its decision in response to comments. EPA did none of those things.

**D. EPA failed to consider and respond to comments about the economic costs of glyphosate-resistant weeds**

As discussed earlier, NRDC commented on the substantial economic costs of glyphosate weed resistance, and EPA failed to

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<sup>11</sup> *See* Comment ID EPA-HQ-OPP-2009-0361-14431 (Nov. 12, 2019), <https://bit.ly/3nsqf1q>.

acknowledge or account for those costs, or attempt to compare them to the costs and benefits of alternatives to glyphosate use such as organic farming. NRDC\_ER-98. This comment is significant for the reasons discussed in the cost-benefit section above, *supra* pp. 33-34, and EPA unlawfully ignored it.

In sum, EPA's failure to respond to these significant comments and proposed alternatives violates its own regulations and the APA.

#### **IV. Petitioners have standing to challenge the decision**

Petitioners have standing because their members are injured by EPA's approval of glyphosate in the decision. "An association has standing to bring suit on behalf of its members when its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *WildEarth Guardians v. U.S. Dep't of Agric.*, 795 F.3d 1148, 1154 (9th Cir. 2015) (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000)).



Petitioners NRDC and PANNA satisfy this test. The interests Petitioners seek to protect are germane to both organizations' purposes, which include protecting the public and the environment from harmful exposure to pesticides. Reeves Decl. ¶¶ 5–6 (ADD44); Trujillo Decl. ¶ 6 (ADD4). Petitioners seek no individualized relief for their members, and the participation of individual members is therefore not required. *See Hunt v. Wash. State Apple Adver. Comm'n*, 432 U.S. 333, 343-44 (1977).

Finally, Petitioners' members would have standing to challenge EPA's procedural violations on their own. To establish injury-in-fact arising from these violations, Petitioners' members must demonstrate that (1) they have a "procedural right that, if exercised, could have protected" their concrete interests; (2) "the procedures in question are designed to protect those concrete interests;" and (3) the challenged action poses a "reasonably probable" threat to those concrete interests. *California v. Azar*, 911 F.3d 558, 570 (9th Cir. 2018).

**A. Petitioners challenge the violation of procedural rights**

Petitioners claim that EPA's decision "misapplied FIFRA's procedural requirements and lacked substantial evidence." *Family*

*Farm II*, 966 F.3d at 909. As the Ninth Circuit recently held: “These are procedural injuries.” *Id.*

Specifically, Petitioners assert that EPA’s decision is without substantial evidence “because of the agency’s failure to follow the ‘basic procedural requirement’ of providing a reasoned explanation” for its cost/benefit and mitigation analyses. *California v. Bernhardt*, 460 F. Supp. 3d 875, 890 (N.D. Cal. 2020), quoting *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) (“[O]ne of the basic procedural requirements of administrative rulemaking is that an agency must give adequate reasons for its decisions.”). Petitioners further challenge EPA’s procedural failure to consider and respond to significant comments and proposed alternatives. See *Idaho Farm Bureau Fed’n v. Babbitt*, 58 F.3d 1392, 1401, 1404-05 (9th Cir. 1995) (analyzing, among “a number of procedural violations,” the adequacy of the agency’s response to public comments).

**B. Petitioners have a concrete interest in the decision**

Petitioners’ members have a concrete interest in the decision on glyphosate. First, the members face a “credible threat” of health harms from exposure to glyphosate, which constitutes an “actual and

imminent” injury-in-fact. *NRDC v. EPA*, 735 F.3d at 878; accord *Susan B. Anthony List v. Driehaus*, 134 S. Ct. 2334, 2341 (2014). Glyphosate is linked to serious health harms, including non-Hodgkin lymphoma and other non-cancer health harms. NRDC\_ER-76–88 (summarizing health effects detected in human health studies), 174 (summarizing non-cancer effects detected in animal studies), 178 (“glyphosate is *probably carcinogenic to humans*”). Petitioners’ members are reasonably concerned that their exposure to glyphosate may harm them. Gruber Decl. ¶¶ 2, 5–8 (ADD17, 18–20); Moravec Decl. ¶¶ 14–16 (ADD12–14); Bristol Decl. ¶¶ 7–9 (ADD48–50); Hart-Kapic Decl. ¶ 10 (ADD37); Dodd Decl. ¶¶ 7, 12–13 (ADD26–27, 28–29). They live and work in rural or agricultural areas where glyphosate use is ubiquitous, and they have no control over whether and when glyphosate will be sprayed on nearby fields. Gruber Decl. ¶ 8 (ADD20); Moravec Decl. ¶ 15 (ADD13); Bristol Decl. ¶¶ 2–3 (ADD47); Hart-Kapic Decl. ¶ 11 (ADD37). They cannot eliminate the risk of breathing in glyphosate in the air or being exposed through their skin, in addition to consuming glyphosate residues through the food they eat and the water they drink. Dodd Decl. ¶¶ 13–

15 (ADD29–30); Bristol Decl. ¶ 5 (ADD48); Moravec Decl. ¶ 16 (ADD13–14); NRDC\_ER-88 (listing routes of glyphosate exposure).

PANNA’s members also suffer economic harms from the reapproval of glyphosate. For example, one PANNA member owns and operates a farm following organic practices and does not use glyphosate or glyphosate-resistant crops. Hart-Kapic Decl. ¶¶ 1, 6 (ADD34, 35).

The rampant use of glyphosate by surrounding farms, without pesticide buffer zones or sufficient spray drift mitigation, is a serious risk to the broadleaf crops he grows using organic practices. Hart-Kapic Decl. ¶ 11 (ADD37). It also affects his crew’s work schedules and ability to use the farm for educational purposes. Hart-Kapic Decl. ¶¶ 13–15 (ADD38–39).

Third, Petitioners’ members have aesthetic, recreational, and personal interests observing monarch butterflies. Gruber Decl. ¶¶ 10–12 (ADD20–21); Moravec Decl. ¶¶ 9–11 (ADD10–11); Bristol Decl. ¶ 16 (ADD52); Hart-Kapic Decl. ¶¶ 16–18 (ADD39–40); Dodd Decl. ¶¶ 16–18 (ADD30–31). The rampant use of glyphosate in fields near these individuals’ work and homes, and across more than 298 million acres of land in the United States, is a leading cause of monarch decline. NRDC\_ER-90. This harms Petitioners’ members and is “undeniably a

cognizable interest for purpose of standing.” *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562-63 (1992); see *Ecological Rights Found. v. Pac. Lumber Co.*, 230 F.3d 1141, 1147-50 (9th Cir. 2000).

**C. Petitioners satisfy the relaxed causation and redressability requirements to show procedural standing**

Once a procedural injury-in-fact is shown, the traditional “causation and redressability requirements are relaxed.” *W. Watersheds Project v. Kraayenbrink*, 632 F.3d 472, 485 (9th Cir. 2011) (quotations and citations omitted). The members need only show that the “procedures in question are designed to protect those concrete interests, and [] that the challenged action’s threat to the plaintiff’s concrete interests is reasonably probable.” *California v. Azar*, 911 F.3d at 570. The FIFRA “registration provisions at issue are designed to protect the environment” and human health, which is precisely “what [Petitioners’] members are concerned about.” *Family Farm II*, 966 F.3d at 909. There is a reasonable probability that the decision threatens the members’ health, recreational, and economic interests because it reapproves the use of glyphosate without substantial evidence and without sufficient risk mitigation to protect monarch butterflies.

## V. Judicial review is proper now

The court can and should review the decision now. FIFRA section 16(b) provides for direct appellate review of “any order issued by the [EPA] Administrator following a public hearing.” 7 U.S.C. § 136n(b). The decision is an order issued by the EPA Administrator pursuant to the registration review process, amending and reapproving the glyphosate registration. *Cf. Family Farm I*, 960 F.3d at 1131-32 (finding that a “decision to conditionally amend [a] registration[]” is an order under FIFRA). And the order was subjected to public notice and comment, which satisfies the “public hearing” requirement of section 16(b). *Id.* at 1132.

The decision is also final for purposes of judicial review. Final agency action generally requires that “[f]irst, the action must mark the ‘consummation’ of the agency’s decisionmaking process, . . . it must not be of a merely tentative or interlocutory nature. And second, the action must be one by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’” *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citations omitted).

EPA's glyphosate decision is final because it (1) consummates the agency's decisionmaking process and (2) determines obligations of registrants (while simultaneously limiting legal protections for the public). Courts interpret the finality of agency action "in a pragmatic and flexible manner." *Havasupai Tribe v. Provencio*, 906 F.3d 1155, 1163 (9th Cir. 2018) (quoting *Or. Nat. Desert Ass'n v. U.S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006)). "It is the effect of the action and not its label that must be considered." *Abramowitz v. EPA*, 832 F.2d 1071, 1075 (9th Cir. 1987).

Because EPA concluded notice-and-comment procedures, articulated EPA's final determinations as to the human health and ecological risks of glyphosate, and imposed certain requirements in the decision, it "consist[s] of the agency's settled position, a position it plans to follow." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000). The language of the decision makes clear that it consummates EPA's decisionmaking on the enumerated final actions: it "finalizes" the human health risk assessment, NRDC\_ER-23, finds that EPA needs "[n]o additional human health data," NRDC\_ER-15, and "determine[s] that there are no risks to human health from the current

registered uses of glyphosate,” NRDC\_ER-13. It also “finalizes” the ecological risk assessment, NRDC\_ER-23, and “concludes” that while there are potential ecological risks to mammals, birds, and terrestrial and aquatic plants, “the benefits outweigh the potential ecological risks,” NRDC\_ER-18. EPA issued the decision “so that it can (1) *move forward* with aspects of the registration review case that are *complete* and (2) implement interim risk mitigation.” NRDC\_ER-6 (emphasis added).

The decision also meets the second prong of *Bennett*, because it determines the obligations of registrants and the rights of the public. *Or. Nat. Desert Ass’n*, 465 F.3d at 986. EPA clearly defines the obligations of registrants in the decision, which “*requir[es] label changes*”—for example, the requirement that “[a]pplicators *must not* spray during temperature inversions.” NRDC\_ER-18–22, 31–35 (emphases added).

In other words, these new restrictions amend the “license that establishes the terms and conditions under which a pesticide may be lawfully sold, distributed, and used within the United States.” *Family Farm II*, 966 F.3d at 912 (citing 7 U.S.C. § 136a(c)). Amending a license



is a quintessential final agency action. *E.g.*, *Columbia Riverkeeper v. U.S. Coast Guard*, 761 F.3d 1084, 1092 (9th Cir. 2014).

EPA's decision also determines the rights of the public regarding protection from glyphosate exposure. It establishes the many things that EPA is *not* requiring registrants and users to do despite risks to health and the environment, including implementing pesticide-free buffer zones, planting prairie strips, or adopting other measures suggested by commenters. For all of these reasons, the decision is a final agency action under *Bennett*.

## **VI. The court should vacate the decision and the glyphosate product registrations that depend on it**

Because glyphosate use causes unreasonable adverse effects, and EPA's approval decision violates core requirements of FIFRA, this Court should vacate the decision and accordingly vacate EPA's registration of glyphosate products.

Where agency action is found to be unlawful, vacatur is the presumptive remedy. 5 U.S.C. § 706(2) (courts shall "hold unlawful and set aside" agency action that is arbitrary, capricious, or contrary to law); 7 U.S.C. § 136n(b) (courts of appeal have jurisdiction to "affirm or set aside the order complained of in whole or in part"). Courts "order

remand without vacatur only in limited circumstances.” *Family Farm I*, 960 F.3d at 1144 (quotations omitted). To determine whether a case warrants the narrower remedy of remand without vacatur, courts “weigh the seriousness of the agency’s errors against the disruptive consequences of an interim change that may itself be changed.”

*Pollinator Stewardship Council*, 806 F.3d at 532 (quotations omitted).

Courts also consider whether vacating the rule would result in more environmental harm and whether the agency could “adopt the same rule on remand, or whether such fundamental flaws in the agency’s decision make it unlikely that the same rule would be adopted on remand.” *Family Farm I*, 960 F.3d at 1145 (quotations omitted).

Each of these considerations weighs in favor of vacatur. First, EPA’s decision makes clear that continued use of glyphosate threatens serious environmental harm, including “potential ecological risk to mammals and birds,” NRDC\_ER-18, and “potential adverse effects to terrestrial plants” and “to other taxa that rely on terrestrial plants,” NRDC\_ER-196. These acknowledged ecological risks exist across the hundreds of millions of acres nationwide where glyphosate is sprayed. NRDC\_ER-12.

Second, EPA's errors are substantial and numerous, meaning that the agency is likely unable to adopt the same rule on remand. Where EPA "substantially understate[s]" risks and "entirely fail[s] to acknowledge other[s]" during a registration decision, these alone are fundamental flaws that justify vacatur. *Family Farm I*, 960 F.3d at 1145. Here, EPA failed to account for the severe economic and environmental costs of glyphosate-resistant weeds, harm to monarch butterflies from destruction of milkweed in agricultural fields, and degraded soil health from glyphosate use. *See supra* Section I.A.; Part III. Nor did EPA consider reasonable alternatives to its final decision, such as mandating buffer zones. *Supra* Section III.A. EPA's failure to acknowledge numerous substantial costs is alone enough to justify vacatur. *Family Farm I*, 960 F.3d at 1145.

Moreover, EPA identified unreasonable adverse effects, and relied on the assumption that minimal, unproven mitigation measures will reduce glyphosate's risks to acceptable levels to reapprove the registration. *See supra* Part II. Reconsideration of any of these issues could result in a finding that glyphosate does not meet the safety standard required for registration, or that at minimum, greater

restrictions are necessary. *Pollinator Stewardship Council*, 806 F.3d at 532–33 (once EPA obtains missing data “it may conclude that a lower maximum application rate of sulfoxaflor is warranted, or that sulfoxaflor cannot be registered at all”).

Vacatur of the decision means that continued use of glyphosate would be unlawful. EPA separately registers each pesticide product for sale and use, meaning there are numerous registrations for products containing different mixtures of glyphosate and other chemicals. Each product-specific registration rests on EPA’s determination that the product does not cause “unreasonable adverse effects on the environment.” 7 U.S.C. § 136a(c)(5)(C), (D). For products containing glyphosate, the registration decision necessarily assumes that glyphosate—by itself—satisfies this same standard. EPA’s registration review decision reflects the most up-to-date assessment of whether glyphosate satisfies the FIFRA safety standard, *see* 40 C.F.R. § 155.53(a), and as explained above, is deeply flawed and unlawful. If the Court vacates the decision, EPA cannot rely on old, outdated analyses to permit continued use of glyphosate. Without a valid determination, based on current evidence, that glyphosate products

satisfy the safety standard, glyphosate use cannot continue. *See* 7 U.S.C. § 136a(a) (“no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter”). Accordingly, each registration should be vacated.

### CONCLUSION

For the foregoing reasons, the Court should grant the petition for review and vacate EPA’s Interim Registration Review Decision for glyphosate, thereby vacating glyphosate product registrations.

Dated: December 17, 2020

Respectfully submitted,

*/s/ Lucas Rhoads*

Lucas Rhoads

Aaron Colangelo

Natural Resources Defense Council

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Washington, D.C. 20005

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*Counsel for Petitioners NRDC and  
PANNA*

## **STATEMENT OF RELATED CASES**

There are no known related cases pending in this Court.

## CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Cir. R. 32-1(a) because it contains 13,043 words, excluding the parts of the brief exempted by Cir. R. 32-1(c) and Fed. R. App. P. 32(f).

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using 14-point Century Schoolbook font.

Dated: December 17, 2020

*/s/ Lucas Rhoads*

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*Counsel for Petitioners NRDC and  
PANNA*

## CERTIFICATE OF SERVICE

I hereby certify that on December 17, 2020, I electronically filed the foregoing brief and the accompanying declarations of Gina Trujillo, Shelby Moravec, LeRoy Gruber, Catherine Dodd, Maceo Hart-Kapic, Margaret Reeves, and Joan Bristol with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system.

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

Dated: December 17, 2020

*/s/ Lucas Rhoads*  
\_\_\_\_\_  
*Counsel for Petitioner NRDC and  
PANNA*



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**ADDENDUM OF DECLARATIONS IN SUPPORT OF STANDING**

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(consolidated)

Case No. 20-70801  
(consolidated)

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DECLARATION OF GINA TRUJILLO

I, Gina Trujillo, declare as follows:

1. I am the director of Membership at the Natural Resources Defense Council, Inc. (NRDC). I have been the director of membership since January 1, 2015, and have worked at NRDC in the membership department for more than twenty-five years.

2. My duties include supervising the preparation of materials that NRDC distributes to members and prospective members. Those materials describe NRDC and identify its mission.

3. NRDC is a membership organization incorporated under the laws of the State of New York, with offices in New York, NY, Washington, DC, Chicago, IL, Los Angeles, CA, San Francisco, CA, Bozeman, MT, and Beijing, China. It is recognized as a not-for-profit corporation under Section 501(c)(3) of the United States Internal Revenue Code.

4. NRDC's mission statement declares that: "NRDC works to safeguard the earth—its people, its plants and animals, and the natural systems on which all life depends."

5. NRDC currently has more than 440,000 members nationwide, including members in all fifty states and the District of Columbia. When an individual becomes a member of NRDC, he or she authorizes NRDC to take legal action on his or her behalf to protect the environment and public health.

6. Since its inception in 1970, NRDC has worked on issues relating to wildlife. NRDC frequently brings cases and carries out advocacy to protect its members' interests in species threatened by governmental actions, including those that result in habitat destruction. Protecting people from dangerous chemicals is also central to NRDC's purpose. In particular, NRDC works to protect people and wildlife from toxic pesticides.

7. When an individual becomes a member of NRDC, his or her current residential address is recorded in NRDC's membership database. When a member renews his or her membership, or otherwise contributes to NRDC, the database entry reflecting the member's residential address is verified or updated.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on December 11, 2020, in New York, NY.

*/s/ Gina Trujillo*

Gina Trujillo

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DECLARATION OF SHELBY MORAVEC

ADD6

I, SHELBY MORAVEC, do hereby affirm and state:

1. I am currently a member of the Natural Resources Defense Council (NRDC) and have been for almost fifteen years.

2. I support NRDC because I am concerned about the profound impacts of human activities on the environment; I worry about how these impacts affect the well-being of both humans and wildlife, including monarch butterflies. I understand that preservation of wildlife is one of NRDC's core missions, and it is one that I stand firmly behind.

3. For many years, I lived in Beverly Shores, Indiana, along the Indiana Dunes National Lakeshore. Beverly Shores is an idyllic spot that is only one hour away from Chicago. Despite the proximity, Beverly Shores is worlds apart from the city; the difference between the two areas is like the difference between night and day. I used to live in Chicago, but purchased my property in Beverly Shores back in October 1999. My husband and I moved to this area in part because of our love for the outdoors, including our desire to be close to nature and wildlife. The Indiana Dunes National Lakeshore and surroundings support some of the most diverse flora and fauna in the Midwest. Hosts of migrating



birds and insects, including monarch butterflies, used to travel through this magical area.

4. In Beverly Shores, I enjoyed taking regular walks along the lakeshore, into town, and in the National Park. I have a Border Collie and would frequently take her on walks within a one- to two-mile radius of my home. It was a joy to observe wildlife and experience nature during these walks.

5. Monarch butterflies used to be abundant in the Beverly Shores/Indiana Dunes area. When I first moved to this area, there were too many butterflies to count. I remember walking along the sun-drenched dunes during my first spring there, and seeing countless monarchs flitting amongst the native milkweed, wildflowers, and grasses. Monarch chrysalises hung from the milkweed on the dunes, and it gave me great pleasure to see the butterflies emerging from their chrysalises. The butterflies, chrysalises, and caterpillars were a part of the natural landscape and could be seen all along the lakeshore. At certain times of year, I could walk down the street and see monarchs everywhere.

6. Over the years, however, there has been a dramatic decline in the number of monarchs that migrate through the Beverly Shores/Indiana Dunes area. While the decline has taken place gradually, I have become acutely aware of it over the past ten years. When I first moved to the Indiana Dunes area, there were so many monarchs that, when I walked along the lakefront after a storm, the ground would be covered with butterflies that had been battered by the rain. I have not seen a sight like this for years. Nowadays, there are so few monarchs that I hardly notice any downed butterflies even after heavy storms. And even on clear days, it is now unusual to see a monarch butterfly.

7. In May 2015, I moved to La Porte, Indiana, which is in the same general area as Beverly Shores, approximately half an hour away. La Porte is a rural community, and my house is on an idyllic five-acre site surrounded by farmland. I enjoy experiencing the natural beauty of the area, including on walks with my dog, much as I did in Beverly Shores. Since I moved, I have continued counting monarch butterflies and have seen shockingly few around my home. I have also driven around the surrounding countryside looking for milkweed. While I have

seen some on my own property, I rarely see it among the numerous corn and soybean fields near my home. There has been no indication that the decline in monarchs that I have witnessed in this area has abated.

8. Through conversations with other naturalists in the area, I have learned to help monarchs by not removing milkweed. To support the butterflies, I have also consulted the owner of a local nursery many times to seek advice on what butterfly-attractive plants to grow on my property. In addition to following his advice, I refrain from using pesticides, so as to avoid harming monarchs.

9. Throughout the years, I have read field guides and followed news on monarchs with great interest. I have browsed the internet to learn more about these wonderful creatures. Several years ago, I read Barbara Kingsolver's *Flight Behavior*, a novel about the plight of monarch butterflies that struck a deep chord with me.

10. Watching monarchs means a great deal to me. Seeing them makes me feel connected to the natural world, and each sighting is a poignant reminder that humans and wildlife are co-inhabitants of this earth. It is a great pleasure to see the butterflies, and I enjoy sharing these increasingly rare sightings with others. I am acutely aware of the

dwindling number of monarchs, and the decline of this beautiful species is of great concern to me. I fear that monarchs will disappear entirely, a loss that would fill me with sadness. I see hundreds and hundreds of other butterflies in my quarter-acre vegetable garden each year. But so far this year I have not seen a single monarch.

11. As minimal as the monarch migration has now become, I absolutely plan to continue watching the butterflies every year. I will continue growing butterfly-attractive plants on my property and refraining from herbicide use. I encourage milkweed to grow on my property and will continue to do so. The only area I try to keep free of milkweed is my small kitchen garden. But this year I saw a few monarch eggs on milkweed growing in the kitchen garden, and I just couldn't bring myself to disturb them. So for now I have milkweed in the kitchen garden, as well.

12. A few years ago, we were able to add ten acres of woodland to our property. We keep it pretty wild and encourage all kinds of wildlife to visit. We have Nanking Cherries and American Hazelnuts that the migrating birds return to each year, and milkweed grows among the trees. I hope that this milkweed will provide habitat for

monarchs. I go down and check on the milkweed, but I haven't seen a monarch yet this year.

13. I am aware that use of herbicides containing glyphosate has contributed to the monarch's decline. I understand that these herbicides destroy milkweed, which monarch caterpillars need to survive. I am concerned that further increases in the use of glyphosate would be devastating to monarchs, bringing an end to their annual migration through my area and my ability to watch them.

14. I am sensitive to the dangers of pesticides because of my family's own tragic experiences. My husband is from a family of farmers in Illinois. Both his maternal grandparents died of awful cancers. I painfully recall that both of them attributed their illnesses to their having breathed pesticides on their farms. I am also troubled because of my experience with my previous dog, who died of leukemia. My husband and I first took him to a veterinary oncologist. The first question the oncologist asked us was whether our dog had been exposed to lawn chemicals, which he said were the leading cause of cancer in dogs.

15. Since I moved to La Porte, I have become particularly concerned about the health effects of exposure to pesticides. My property is adjacent to farms on two sides, and my house is separated from those farms only by small wooded areas. I've seen my neighbors spraying chemicals in those woodlands and asked what they were using. They told me that they were using pesticides containing glyphosate. I know that they don't understand the danger to their health because they were not even wearing masks. I am confident that the other farmers near my house use similar chemicals, although there is no way for me to know on each occasion exactly what they are spraying. I planned to raise bees on my property, and spoke to a local beekeeper about getting beehives. But when I told him where I live, he told me not to do it. He told me that because of all of the pesticides sprayed in the area, I would lose my entire hive.

16. My drinking water comes from a well on my property, and I fear that pesticides will contaminate my well water. I purchased a filtration system because of these concerns, and I plan to have the water tested again soon, because I have seen so much spraying recently. I also worry that pesticides could contaminate groundwater more broadly,

threatening the health of my entire community. I take care to avoid such exposure to pesticides, including glyphosate, for example, by purchasing organic produce. But I am troubled to know that my husband and I might nonetheless suffer because we live near farms to which glyphosate might be applied. I also continue to worry about the health of my dog. Because I fear she might be exposed to toxic pesticides through the air or by direct contact, including glyphosate, I avoid taking her on walks next to farms, though it is not so easy to do so in such an agricultural area.

17. I am aware that the U.S. Environmental Protection Agency (EPA) recently issued an interim registration review decision for glyphosate. I am also aware that NRDC has challenged EPA's decision in part because the agency found that glyphosate didn't pose a risk to human health, and proposed only minimal mitigation measures to protect monarchs.

18. I support NRDC's lawsuit seeking to compel the agency to reconsider. I think stronger mitigation measures are needed to protect monarchs. And I am aware that in spring 2015, the World Health

Organization determined that glyphosate is probably carcinogenic in humans, so I disagree with EPA's findings about human health.

19. If the court were to require EPA to reconsider its decision and look more closely at the science, I think they would be more likely to impose more restrictions on glyphosate's use, which would help protect monarchs and the health of people like me who live in agricultural areas.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 12, 2020

/s/ Shelby Moravec

Shelby Moravec



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**DECLARATION OF LEROY GRUBER**

I, LEROY GRUBER, do hereby affirm and state:

1. I am currently a member of the Natural Resources Defense Council (NRDC) and first became a member in 1975.

2. Among other reasons, I support the NRDC because I am concerned about the impacts of chemicals, including pesticides, on human health and the environment. Reading Rachel Carson's *Silent Spring* was a major turning point in my life, opening my eyes to the detrimental effects of indiscriminate pesticide use on the natural world. Another critical moment in my life occurred when I read *The Limits to Growth*, a report commissioned by the Club of Rome. Through this report, I became convinced that mankind is releasing chemicals into the environment much more quickly than we can neutralize the resulting harmful effects; I firmly believe that we must take action to reverse this trend. I understand that one of NRDC's central purposes is to safeguard human health and the environment from the toxic effects of pesticides and other chemicals, and I strongly support this objective.

3. I worked in the environmental field for thirty-five years. As a Supervising Engineer at the Hamilton County Department of Environmental Services (DES) in Ohio, I became acutely aware of the

human health risks, such as cancers and neurodevelopmental harms, posed by exposure to chemicals in the environment. I realized that exposures to even low concentrations of chemicals can pose serious health risks over time. I also realized that exposures to high concentrations of chemicals, even if briefly, can result in significant health harms. This awareness has heightened my concerns regarding exposure to pesticides, including the herbicide glyphosate.

4. Since 2001, I have lived in rural Goshen, Ohio. My property is situated near large agricultural fields planted with soybeans and corn. I am aware that chemicals are sprayed on these fields, even though I do not know the exact identity of those substances. I have seen machines spraying chemicals in the morning, even when winds are blowing at higher speeds.

5. I am aware that EPA recently completed an interim registration review of glyphosate and is planning to adopt only limited mitigation measures for ecological risks and no measures to protect human health. I have read that glyphosate is a probable human carcinogen. I am concerned that glyphosate will be used on the fields next to my property, and that I will be exposed to this herbicide and the

health risks it poses, including increased risk of developing cancer.

6. I am particularly concerned about exposure to glyphosate through aerial pathways between my property and the adjacent fields. I am aware that pesticides may not end up only on target crops. Rather, they can travel off site, including through spray drift and volatilization. Among my other responsibilities at the Hamilton County DES, I used to model air pollutant emissions. Through this experience, I became aware of the ease with which chemicals can be borne through the air. I am thus especially worried about breathing in glyphosate through spray drift and volatilization from the fields next to my home.

7. I had a three-quarter acre pond put on my property after moving in. I stocked the pond with fish. We planned to eat fish we caught from the pond. But I am concerned that pesticides and herbicides could settle out from the air into the pond or be carried in by the stream that feeds into the pond. The fish could be contaminated, and I do not have any way of analyzing the fish to find out if they are safe to eat. I decided that it was safer to buy wild-caught fish from the grocery store, and we rarely eat fish from the pond anymore. We also grow vegetables to eat. Herbicide drift onto our garden is also a concern.

8. When I first moved to Goshen, I obtained drinking water from a cistern on my property. Because I was concerned about pesticide spray drift contaminating my cistern water, however, I spent about \$5,000 installing a water line that would allow me to obtain public drinking water from Clermont County. Although I am now less concerned about herbicide exposure through my drinking water, I remain concerned that I may be exposed to glyphosate through drift and volatilization of airborne glyphosate from the neighboring fields.

9. I avoid using herbicides on my own property, in part because I am concerned about the health risks associated with exposure to these chemicals. However, there is nothing I can do to prevent glyphosate from being used on the fields next to my property, where I intend to stay.

10. I have read that the overwintering Eastern monarch butterfly population has decreased by more than 50% compared to 2019, and that their population has significantly decreased over the past twenty years. A main cause of this decline probably is the destruction of milkweed, their food source, by pesticides such as glyphosate.

11. I love to watch butterflies and even started a collection of

photographs of butterflies. When I was in college in downtown Cincinnati many years ago, I used to watch countless monarchs fly by my window. There do not seem to be as many now.

12. Several years ago, I planted milkweed on my property. I now have a quarter acre of milkweed growing. It's been a personal joy of mine this year and every year to watch the monarch caterpillars, observe them going through the chrysalis stage, release them and have them fly on to their destinations in their final stage. Although there are fewer now, I plan to watch them as long as I have eyes and monarchs continue to go through the area.

13. Two years ago I began raising monarchs. I look for caterpillars on the milkweed on my property. When I find them, I bring them in and care for them until I can release the butterflies. I plan to continue raising monarchs because it is very exciting. It is hard to believe how much milkweed each caterpillar eats. Once it is ready to form into a chrysalis it attaches to the top of the container it's growing in and curves into a J-shape. Soon after, as you watch, the caterpillar suddenly transforms into a little, pale-green chrysalis with gold dots. Watching the monarch emerge a week or so later is breathtaking. The

chrysalis turns dark green and within a few minutes it sheds and the butterfly comes out.

14. I enjoy visiting a website that tracks the migration of the monarchs from Mexico each year as it is happening. I watch the progression of the monarchs starting in January. I heard on the news that monarch populations in Mexico are down 50% this year compared to last year and that worries me.

15. Seeing fewer monarchs lessens my enjoyment of my property and makes me concerned that I will not be able to raise monarchs in the future.

16. EPA has a duty to protect the public from the health risks and to ensure the evaluation of environmental consequences posed by exposure to herbicides. I am aware that NRDC has sued EPA over its recent decision on glyphosate, alleging that the agency did not follow the proper processes and failed to take into account adequately the health and environmental risks the pesticide poses. I strongly support NRDC's lawsuit.

17. If the court were to order EPA to reconsider its decision on glyphosate and more carefully look at all of the needed data and

evaluate the information on risks and alternatives to rampant glyphosate use, I would have more confidence that the decision would impose restrictions that would protect my health and others' health. And I would have more confidence that it would help protect the annual migration of monarchs through my area and the joy that I attain from watching and raising them.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: December 5, 2020

*/s/ LeRoy Gruber*

LeRoy Gruber



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**DECLARATION OF CATHERINE DODD**

I, Catherine Dodd, declare as follows:

1. I am a member of Pesticide Action Network of North America (PANNA). I support PANNA's work on pesticide issues and human health and protecting the environment, including monarch butterflies.

2. I became familiar with PANNA's work twenty years ago, through our mutual involvement with Breast Cancer Prevention Partners (then the Breast Cancer Fund). I am also on the policy committee of Safe Ag Safe Schools, a program of Californians for Pesticide Reform, which PANNA sponsors.

3. I have lived in San Francisco since 1977. I also have a home in suburban Santa Rosa in Sonoma County, less than one mile from vineyards. I live with my partner and we have one big dog.

4. I grew up in the San Francisco Bay area in suburban neighborhoods. I went to college at University of California, Berkeley. I then attended University of California, San Francisco (UCSF) for nursing school, and graduated nursing school in 1979. I also earned a Master of Science in nursing and PhD from UCSF in sociology and health policy.

5. I retired in 2017, after a long career in healthcare and public policy. I worked as a nurse for several years, before moving into management and policy positions within healthcare. In 1999, I was appointed by President Clinton to the role of Regional Director for Health and Human Services for Region IX, which includes AZ, NV, CA, HI and the six Pacific jurisdictions. I served for two years, before becoming the District Director in San Francisco for House Speaker Nancy Pelosi. I later worked as the Director of the San Francisco Health Service System, where I was responsible for managing and negotiating health benefits for over 100,000 people.

6. I have been exposed to pesticides, including glyphosate, throughout much of my life. I regularly used Roundup, a glyphosate-based herbicide, over many years that I lived in San Francisco. It just seemed like an easy way to control weeds, and I never used any protective equipment. I still have the twenty-year old cannisters of Roundup in my garage.

7. In 2013, I was diagnosed with mantle cell lymphoma, a rare type of B-cell non-Hodgkin Lymphoma. The International Agency for Research on Cancer found there was strong evidence of an association

between glyphosate exposures and non-Hodgkin lymphoma and further science has specified mantel cell as one of the types associated with glyphosate. I am concerned that my past exposures to glyphosate may have caused my cancer.

8. I took about a year's worth of leave from my executive job as the Director of the San Francisco Health Service System to receive treatment, including seven hospitalizations for chemotherapy and a bone marrow transplant. After my bone marrow biopsies showed no evidence of disease, I returned to work for two years to qualify for my modest pension. Because of continued concerns about my health, I retired on my birthday in March of 2017, nearly ten years earlier than I had planned. I had intended to work until I was at least 70 (full Social Security age) to ensure a secure retirement, but will have to forfeit those extra Social Security dollars.

9. My prognosis when I was diagnosed was that I would live for three to four years without the cancer returning and progressing. It has now been seven years since my initial diagnosis, and I am still in remission. But the nurse told me that this type of cancer would come back, and I have anxiety about that every day. It is very important that

I take care of myself and stay healthy. That includes taking extra care to avoid being exposed again to glyphosate and other pesticides and chemicals.

10. I have a metabolic disorder leading me to develop Type II diabetes as an adult. My diabetes was made worse by drugs used to treat my cancer. Now I poke my finger to check my blood sugar 4 times a day and give myself a dose of insulin 4 times a day.

11. In doing research on glyphosate, I learned that glyphosate is an endocrine disrupting chemical (EDC). I have also read that glyphosate is an obesogen, interferes with the mitochondria in cells (the energy makers in cells) and interferes with the gut microbiome. I am concerned that my slight obesity and diabetes are related to eating foods that may have been contaminated with glyphosate. Because of these conditions, I take expensive probiotics for my gut microbiome and have to pay co-pays for insulin and related supplies.

12. I no longer use glyphosate products anymore because of my health concerns, but I can't completely control my exposure to it. There are vineyards that use glyphosate not far from my house in Sonoma. I

am concerned about glyphosate in the air or water in Sonoma affecting my health.

13. Part of what worries me about glyphosate is that its use is so widespread and unrestricted, that it is nearly impossible to know where and when it is being sprayed so that I can avoid it. I saw a neighbor across the street in Santa Rosa using glyphosate, and he also wasn't wearing any protection. I explained the dangers and convinced him to use diluted vinegar instead. There is also a condominium complex across the street from my home in San Francisco that I believe sprays glyphosate. A good friend of mine saw the California Department of Transportation spraying glyphosate alongside the highway (CA 116) near her home, she called the CA Ag Commissioner and was told that the Department of Transportation has control over spraying and nothing could be done.

14. My partner and I like to recreate and take our dog out in the local and regional parks, and there is no way for me to know whether they use glyphosate or if there is glyphosate "drift" from the nearby vineyards. It doesn't stop me from going to the park, but I do worry about it when I am there, and this fear lessens my enjoyment of the

parks. One of my dogs died of lymphoma, the same kind of cancer I had. I went to a committee meeting for the Department of Environment for San Francisco and testified how both my dog and I had cancer, and we had walked around the edge of a park twice a day where the city was spraying glyphosate. The city at least has since changed their Integrated Pest Management Practices, but it is still used on hard-to-kill weeds.

15. I take other precautions to avoid being exposed to glyphosate. I try to only eat organic food (which is expensive) and I stay away from processed flour. I do occasionally eat cereal, and I'm very concerned about the levels of glyphosate in that food, because of the way glyphosate is sprayed on to wheat crops as a desiccant to kill the grains just before harvesting.

16. In addition to my health concerns, I am also aware that glyphosate kills milkweed, the only source of food for the monarch caterpillar, and that glyphosate has been linked to the decline of monarch populations. It would be devastating to lose monarch butterflies.

17. In fifth grade we collected caterpillars and watched them hatch into butterflies. I remember going to San Luis Obispo to see the monarch butterflies as a child. They were magical to me, and all children should be able to have that experience.

18. I grow milkweed in my raised garden beds and watch for monarch butterflies when I go outside. This summer I only saw three monarchs. I've seen other butterflies, but not many monarchs. I am concerned that the widespread use of glyphosate is contributing to the decline in their numbers.

19. I believe based on my research and involvement in pesticide issues, and based on my personal health experiences, that glyphosate as it is currently used is not safe. Advocating for change around glyphosate is piecemeal—it happens one neighbor at a time, one park at a time. What we need is a comprehensive approach: for EPA to protect the public, the animals, and the insects and plants they pollinate, by banning glyphosate, or to greatly restrict its use. I am concerned that EPA and other regulatory agencies are more concerned about profit and the economy than protecting the health of people and the environment.



20. EPA recently issued a decision on glyphosate that allows its continued, widespread use with very few restrictions. I support PANNA's lawsuit challenging EPA's decision on glyphosate. If glyphosate were restricted further or banned, there would be less of a threat to my health from glyphosate exposure. That would also protect my interest in monarch butterflies and in a healthier environment generally. EPA should be required to reevaluate the health and environmental harms of glyphosate and follow the proper procedures and use the best science before reapproving it. I am hopeful that a decision borne out of a comprehensive safety evaluation would lead to meaningful restrictions that would better protect my health and the health of those around me, and monarch butterflies.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: December 14, 2020

/s/ Catherine Dodd

Catherine Dodd

UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT

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Case No. 20-70801  
(consolidated)

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DECLARATION OF MACEO HART-KAPIC

ADD33

I, Maceo Hart-Kapic, declare as follows:

1. I am member of Pesticide Action Network North America (PANNA). I joined because I use organic practices at my farm and believe in PANNA's mission and work.
2. I live in Rio Linda, California, with my mother. I have lived here since I was fourteen, except for the four years I attended college at University of California, Berkeley.
3. I graduated from Berkeley in 2020, and majored in conservation and resource studies. My studies focused on agroecological farming, meaning natural farming systems and farming methods used by indigenous populations and in other cultures. I studied agriculture and food sovereignty as social movements and how they affect food production and food systems. I also studied general biology, microbiology, and soil microbes and health and participated in lab research on long-term carbon sequestration as affected by tillage and soil organic matter. In my coursework, I learned about the basic principle of herbicide resistance, the EPA pesticide registration process, and about environmental policy and law more generally.

4. I am the founder and director of H&K Farms, and oversee all operations from field to market as well as administrative and planning work. I founded the farm in 2013 when I was in high school and have grown it from 1 acre to over 140 acres as it stands today. We sell weekly boxes of produce to community members, and also sell produce at farmer's markets.

5. My mom, Sherrie, joined the farm when I started college. She helps manage the farm, works in the fields, and works at the farmer's markets. She is a former Montessori teacher and conducts experiential learning opportunities with classrooms of all ages to teach about food and farm literacy.

6. At our farm, we use organic practices and agroecological methods. By that I mean we use minimum till, no pesticide/herbicide sprays, and only use compost and manure for fertilizer.

7. I have been acutely exposed to glyphosate and experienced its negative health effects first-hand. During college, I worked on another farm and they asked me to spray a driveway with glyphosate. I was given a backpack sprayer and no protective equipment. The sprayer malfunctioned and I was doused with glyphosate all over my

head and entire body. I felt very sick after that exposure, and had chronic headaches for about a year. That incident caused me a lot of anxiety, both about the harm from that one exposure, but also about the health effects of the chronic, lower-level exposure to glyphosate that is a part of my farming work, as described below. I worry about what effects glyphosate may have on my health and my family's health in the long term.

8. Two of the three farm areas we use are completely surrounded by conventional farms that spray herbicides, including glyphosate, and use various salts and other fertilizers. Glyphosate is the most commonly used herbicide in the area, because it is inexpensive. These treated fields are just on the other side of a small ditch, or just a few feet away from my fields, with a thin strip of weeds in between.

9. I know they use glyphosate because I talk to the farmers around me. I can also see them using ground sprayers to apply glyphosate and other pesticides, usually in the morning. I can smell it in the air after it is sprayed. It has a distinctive oily, diesel and chemical smell.

10. I have multiple concerns stemming from the use of glyphosate in the fields surround my farm. I am concerned about glyphosate spray drift affecting my health, my mom's health, and the other workers' health. We are all constantly exposed to glyphosate through spray drift in the air from working in the fields and driving around the area. There is no way to avoid it.

11. I also have concerns about spray drift from the application of glyphosate to fields that are mere feet away from my broadleaf crops, which glyphosate is intended to kill. So far I have avoided major harms to my crops by proactively communicating with the farmers and workers on the land around me, to make sure they know what I am growing. I sometimes ask them to take certain precautions, such as change the direction of their spray nozzles depending on which direction the wind is blowing.

12. I am most worried about spray drift when a neighboring farm is a big, corporate operation with an absentee farmer. I like to talk to the farmers managing lands that neighbor mine to understand what they will be spraying and when so I can time my work around it to some extent, and make sure they understand what my crops are and where

they are. But when the farmer is never on site, I'm not able to have that conversation.

13. There are added costs to my business from the rampant use of glyphosate in the area. Some mornings I'll bring a crew in to harvest and workers will be spraying glyphosate on a neighboring field, and the wind is blowing towards our fields. In that case, we aren't able to do our work because we don't want to be exposed to the glyphosate spray drift. If we are not able to work in a particular field because of drift, I am forced to move my crew to a different field, meaning I incur additional costs from the unexpected travel time and fuel use.

14. I have to do a fair bit of extra work before leasing farmland to learn who else is farming nearby and what farming practices they use, including glyphosate use, because that will affect my farming. I need to protect all of us who work the farm and the crops from constant exposure to pesticides from a farmer who is very liberal with their use. I can't completely avoid it, but I do put in an effort to farm only near those who use pesticides at more moderate levels. That does limit where I can lease fields.

15. Additionally, part of the farm's business is educational services and field trips for school children. We can't have field trips to our primary production fields, because I am concerned about the safety of bringing school-age children onto a farm surrounded by pesticide use. We typically have to go to the schools or occasionally to the one site I have where pesticides are not sprayed frequently in the area.

16. Finally, I am also concerned about glyphosate's devastating impact on monarch butterflies. I go to Santa Cruz every year in January for a farming convention. It lines up perfectly with the western monarch migration, and I enjoy seeing them there every year. I plan to go again next year or the year after and will look for monarchs.

17. The last two years there has been a huge drop in the monarch numbers. It was very alarming. The trees are usually just dripping with monarchs and there were barely any of them. I didn't see them floating through the air like I usually do.

18. My neighbors grow monocrops and spray glyphosate and don't leave any patches of milkweed for the monarchs. I let a big patch of milkweed grow in my fields for the monarchs, and I let other plants grow as well to bring in other beneficial insects and pollinators.



Farmers typically also spray down any weeds after the harvest and the fields sit barren. I'd like to see a culture change where farmers move past the mantra of "I have to have a clean field."

19. I know that EPA has issued an interim registration review decision on glyphosate, approving its continued use with minimal restrictions. I don't think the decision puts the protections in place that are needed to protect humans and the environment from glyphosate.

20. For example, I think there should be mandatory buffer zones around schools, hospitals, and assisted care facilities to protect the most sensitive populations from exposure to glyphosate. To help mitigate the harms of glyphosate and monocrops, EPA could require farmers to use prairie strips or swaths, and leave the fields to go wild over the winter.

21. I support PANNA's lawsuit challenging EPA's interim registration review decision for glyphosate. If PANNA were to prevail, and the Court required EPA to reevaluate the health and environmental harms of glyphosate, I think this could lead to a better decision that would impose meaningful restrictions on glyphosate.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 19, 2020

*/s/ Maceo Hart-Kapic*  
Maceo Hart-Kapic

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FOR THE NINTH CIRCUIT

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(consolidated)

Case No. 20-70801  
(consolidated)

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**DECLARATION OF MARGARET REEVES**

I, MARGARET REEVES, declare as follows:

1. My name is Margaret Reeves. I have personal knowledge of the matters stated herein.

2. I am a senior scientist at Pesticide Action Network North American (PANNA). I have been employed at PANNA for nearly twenty-five years.

3. I have a Ph.D. in Agricultural Ecology from the University of Michigan (1991), and I spent two years of post-doctoral research in Agronomy at Ohio State University (1991-1993). Before joining PANNA in 1996, I spent about nine years in Central America, teaching and conducting research in agricultural ecology.

4. As a senior scientist at PANNA, I conduct research to support the organization's advocacy campaigns seeking stricter regulation of dangerous pesticides, better enforcement of existing regulations, and stronger incentives for less toxic alternatives. I monitor peer-reviewed scientific literature to keep abreast of the health hazards associated with exposure to specific pesticides. I educate the public about my research findings by writing reports and contributing to PANNA's blog. And I share this information with PANNA's members

and allies, including grassroots community groups and farmworkers unions through regular conference calls and other communications.

5. PANNA is the North American Regional Center of the Pesticide Action Network, an international coalition of hundreds of public interest organizations in more than 90 countries. The network, including PANNA, challenges the global proliferation of pesticides, defends basic rights to health and environmental quality, and works to ensure the transition to a just and viable society.

6. PANNA's mission focuses on two related goals: (1) protecting people from exposure to dangerous pesticides; and (2) promoting a shift to less toxic alternatives.

7. PANNA is a not-for-profit membership organization with offices in Berkeley, California, and Minneapolis, Minnesota. PANNA currently has more than 62,000 members nationwide.

8. PANNA has submitted multiple comments to EPA during the registration review process for glyphosate. Nearly 15,000 PANNA members and supporters signed a PANNA public comment in opposition to the Proposed Interim Registration Review Decision, raising significant issues with the decision, and urging EPA to move

toward systems of weed control that do not rely on chemicals like glyphosate that put our health at risk.

9. EPA finalized the human health and ecological risk assessments, and the Interim Registration Review Decision, without considering or responding to many of our comments. The faulty decision reapproves glyphosate without much-needed protections for humans and the environment. This decision harms PANNA and its members.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct, to the best of my knowledge, information, and belief.

Dated: November 16, 2020  
Berkeley, CA

/s/ Margaret Reeves  
Margaret Reeves

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**DECLARATION OF JOAN BRISTOL**

ADD46

I, Joan Bristol, declare as follows:

1. I am currently a member of NRDC, and have been for about twenty years. I appreciate and support NRDC's work on human health and wildlife protection.

2. I live about an hour west of Philadelphia in a rural area. I'm always concerned about what farmers are putting into their crops because there are many agricultural fields around where I live. We're on an eight-acre farm surrounded by other farms, and we also live right along a run which goes into the Brandywine and Delaware Rivers. In addition, a lot of land around here has been put into conservancy, but they can still be affected by pesticide use on nearby farms.

3. My neighbors' fields are extremely close, less than a football field away from my house. Fields that are directly adjacent to our property have always been used for hay, but around here there are also soy, corn, and wheat fields. I have noticed the farms nearby use a sprayer attached to a big tractor. I tried to find out which pesticides they use but couldn't get an answer.

4. I know that EPA has issued an interim registration review decision on glyphosate, resolving most of the issues they are required to



address when performing their safety review. And EPA is planning to adopt only very limited requirements to address the risks glyphosate poses to people, plants, and animals. I understand that glyphosate has been linked to a number of human health harms. I am concerned that products containing glyphosate will be applied to the corn and soybean fields near my property, and especially concerned about cancer and other health risks to me and my family related to its use.

5. There are fields near our property that are also adjacent to our water supply. We being rural are on our own well water, so even people just spraying their lawns upstream can have an impact on our aquifer. I believe that pesticides from adjacent fields—including glyphosate—could get into our water supply, and I am concerned about being exposed to glyphosate in that way without knowing it.

6. We ride horses in our neighbors' fields three or four times a week for an hour-and-a-half to two hours each time. We also walk twice a day, for about an hour each day. I plan to continue living in my current home, and riding horses and going for walks regularly.

7. I am concerned about being exposed to glyphosate since it can travel through the air after being sprayed. If we're walking around

the neighboring farms and a farmer has sprayed recently, I worry about inhaling the spray, and also worry about my dog and other domestic pets in the area which might be impacted by inhaling the spray, or coming into contact with the sprayed plants.

8. I also worry that residue on my own foods can contain glyphosate. I purchase fresh corn from local farmers every week during the summer, and although I try to verify with the farmers that they do not use genetically modified seeds or spray pesticides on their crops, I fear that the corn I purchase from them may still contain traces of glyphosate that is applied to neighboring fields. Additionally, I fear that my horses could be eating hay contaminated with glyphosate that has drifted through the air or hay grown in soil which has been exposed to the pesticide. I make efforts to buy hay that is not treated with glyphosate, but can't always be sure.

9. I see farm workers spraying fields nearby my home, often without masks or other protective gear. I worry that they might be spraying pesticides containing glyphosate, since it is so commonly used in this area, but do not know for sure. I am concerned about the farm workers becoming sick or dying from this constant exposure. And I am

concerned for mine and others health who are living nearby and also exposed.

10. I worked in the pharmaceutical industry for over thirty years, and understand that if a new drug is going into the market that people are going to ingest or swallow, it goes through rigorous testing. I believe a pesticide should have to go through that process, too. A doctor must prescribe a drug, and if EPA is “prescribing” glyphosate, it should make sure that the pesticide is actually safe for people and the environment. I also think there should be a greater emphasis on measuring and reining in the amount of contamination from chemicals like glyphosate.

11. I am also aware that glyphosate kills milkweed, the only source of food for the monarch caterpillar, and that glyphosate has been linked to the decline of monarch populations.

12. As a kid I was always interested in the monarch butterfly, but at that point they weren’t imperiled. Back then they were fairly common; I saw them all the time and just considered them as part of nature. I remember going to camp and easily catching butterflies. Now they’re much more rare, and when I see them it’s such a treat.

13. Eight or nine years ago I learned about the monarchs' plight, through organizations like NRDC, World Wildlife Fund, and Friends of the Earth, as well as through films made by PBS, NRDC, World Wildlife Fund, and National Geographic. There is a group called Natural Habitat Adventures which I have travelled with in the past, which takes people on tours down to Mexico to watch the monarch migration. I have not yet participated in the tour because spots fill up quickly and the timing has not worked out so far, but I still plan to do so in the future.

14. Where I live in Pennsylvania is also in the path of the monarch migration, and I observe monarchs whenever they're here. Whenever I walk outside I keep an eye out for monarchs. My husband and I have milkweed in the garden, and if there are monarch eggs on them we try to observe without harming them. I hope to continue watching the monarch migration in future years.

15. I am concerned that my neighbors do not understand the dangers of glyphosate. I have spoken to landowners and farmers in my area about the dangers of glyphosate and some of them were surprised to hear that it might be dangerous to themselves and the wildlife they

care about. In previous years, the farmer who works the property adjoining mine used products containing glyphosate on the hay he grows on that property. My husband and I worked hard to educate the neighbor who owns that land about glyphosate. The landowner has since not allowed glyphosate to be used on her properties. Also, one of her workers recently tragically lost her daughter, and monarchs are special to the worker because they remind her of her daughter. This year she asked the farmer who works her land not to use the pesticide on the property she owns, in part because we educated her about the danger glyphosate poses to monarchs.

16. Monarchs are beautiful and wonderful insects, and the fact that monarch populations have dropped so low over the past twenty years is pathetic and heartbreaking. We need to do something about it. Even though I have made some progress educating my neighbors, I know that it is not enough. I'm hopeful that the milkweed on my property and on the property of the neighbors I have encouraged to grow milkweed will help, but I cannot save the monarchs in the area on my own. And monarchs need milkweed during their entire migration, not just while they're in my area.

17. My understanding of EPA's role in regulating pesticides is that it is required to make sure that they don't pose unreasonable risks to people and the environment. I think EPA should be required to take a rigorous and thorough look at the effects of glyphosate, and use the most recent science to determine its effects. I think EPA should put a hold on this chemical until it has the information to prove that it is safe, which is what the agency is required to do by law. And, in the meantime, nobody should be able to use it.

18. I support NRDC's lawsuit challenging EPA's interim registration review decision for glyphosate. If NRDC were to prevail, and the Court required EPA to reevaluate the health and environmental harms of glyphosate, I think this could lead to a better decision that would protect my health and monarch butterflies.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: November 10, 2020

*s/Joan Bristol*

Joan Bristol

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## ADDENDUM OF STATUTES AND REGULATIONS

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**APA, 5 U.S.C. § 706**

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

....

(2) hold unlawful and set aside agency action, findings, and conclusions found to be--

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

....

**FIFRA, 7 U.S.C. § 136**

....

(bb) Unreasonable adverse effects on the environment

The term “unreasonable adverse effects on the environment” means (1) 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, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of Title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

....

**FIFRA, 7 U.S.C. § 136a**

(a) Requirement of registration

Except as provided by this subchapter, no person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this subchapter and that is not the subject of an experimental use permit under section 136c of this title or an emergency exemption under section 136p of this title.

....

(c) Procedure for registration

....

(5) Approval of registration

The Administrator shall register a pesticide if the Administrator determines that, when considered with any restrictions imposed under subsection (d)--

(A) its composition is such as to warrant the proposed claims for it;

(B) its labeling and other material required to be submitted comply with the requirements of this subchapter;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

(g) Registration review

(1) General rule

(A) Periodic review

(i) In general

The registrations of pesticides are to be periodically reviewed.

(ii) Regulations

In accordance with this subparagraph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registrations.

(iii) Initial registration review

The Administrator shall complete the registration review of each pesticide or pesticide case, which may be composed of 1 or more active ingredients and the products associated with the active ingredients, not later than the later of--

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingredient is registered.

(iv) Subsequent registration review

Not later than 15 years after the date on which the initial registration review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subsequent registration review for each pesticide or pesticide case.

(v) Cancellation

No registration shall be canceled as a result of the registration review process unless the Administrator follows the procedures and substantive requirements of section 136d of this title.

....

**FIFRA, 7 U.S.C. § 136a-1**

(a) General rule

The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section, that--

(1) there are no outstanding data requirements; and

(2) the requirements of section 136a(c)(5) of this title have been satisfied.

....

**FIFRA, 7 U.S.C. § 136n**

....

(b) Review by court of appeals

In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the Administrator's order, as provided in section 2112 of Title 28. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of Title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

**40 C.F.R. § 23.6**

Unless the Administrator otherwise explicitly provides in a particular order, the time and date of entry of an order issued by the Administrator following a public hearing for purposes of section

16(b) shall be at 1:00 p.m. eastern time (standard or daylight, as appropriate) on the date that is two weeks after it is signed.

**40 C.F.R. § 155.40**

(a) Purpose. These regulations establish procedures for the registration review program required in FIFRA section 3(g). Registration review is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration. Under FIFRA section 3(g), each pesticide is required to be reviewed every 15 years.

(1) Among other things, FIFRA requires that a pesticide generally will not cause unreasonable adverse effects on the environment. Registration review is intended to 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.

(2) If a product fails to satisfy the FIFRA standard for registration, the product's registration may be subject to cancellation or other remedies under FIFRA.

....

**40 C.F.R. § 155.53**

....

(a) Assess changes since a pesticide's last review. The Agency will 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. The Agency will consider whether to conduct a new risk assessment to take into account, among other things, any changes in statutes or regulations, policy, risk assessment procedures or methods, or data requirements. The Agency will consider whether any new data

or information on the pesticide, including any data or information submitted under § 155.50 or in response to a Data Call–In notice, warrant conducting a new risk assessment or a new risk/benefit assessment. The Agency will also consider whether any new data or information regarding an individual pesticide product, including any data or information submitted under § 155.50 or in response to a Data Call–In notice, such as data or information about an inert ingredient in the pesticide product or other information or data relating to the composition, labeling or use of the pesticide product, warrant additional review of a pesticide product's registration. . . .

#### **40 C.F.R. § 155.56**

The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review. A FIFRA 3(c)(2)(B) notice requiring the needed data or information may precede, accompany, or follow issuance of the interim registration review decision. The Agency will follow procedures in § 155.58 when issuing an interim registration review decision.

#### **40 C.F.R. § 155.57**

A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA.

#### **40 C.F.R. § 155.58**

(a) The Agency will publish a notice in the Federal Register announcing the availability of a proposed registration review decision or a proposed interim registration review decision. At that time, the Agency will place

in the pesticide's registration review docket the Agency's proposed decision and the bases for the decision. There will be a comment period of at least 60 calendar days on the proposed decision.

(b) In its proposed decision, the Agency will, among other things:

(1) State its proposed findings with respect to the FIFRA standard for registration and describe the basis for such proposed findings.

(2) Identify proposed risk mitigation measures or other remedies as needed and describe the basis for such proposed requirements.

(3) State whether it believes that additional data are needed and, if so, describe what is needed. A FIFRA 3(c)(2)(B) notice requiring such data may be issued in conjunction with a proposed or final decision on the registration review case or a proposed or final interim decision on a registration review case.

(4) Specify proposed labeling changes; and

(5) Identify deadlines that it intends to set for completing any required actions.

(c) After considering any comments on the proposed decision, the Agency will issue a registration review decision or interim registration review decision. This decision will include an explanation of any changes to the proposed decision and the Agency's response to significant comments. The Agency will publish a notice in the Federal Register announcing the availability of a registration review decision or interim registration review decision. The registration review case docket will remain open until all actions required in the final decision on the registration review case have been completed.