

**BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

**PETITION TO CANCEL ALL REGISTRATIONS OF**

**GLYPHOSATE HERBICIDE**



<https://www.uppermichiganssource.com/content/news/Judge-weighs-science-behind-Monsanto-Roundup-cancer-claim-475799873.html>

**Center for Food Safety**

**December 13, 2023**

## **PETITIONERS**

### Center for Food Safety

The Center for Food Safety (CFS) is a nonprofit public interest organization whose mission is to empower people, support farmers, and protect the environment from the harmful impacts of industrial agriculture. CFS has more than one million members across the country, including many thousands of conservationists, consumers, and farmers, and maintains offices in Portland, Oregon, San Francisco, California, and Washington, D.C. CFS is a recognized national leader on the issue of industrial agriculture and combines myriad tools and strategies in pursuing its goals, including public education, grassroots organizing and campaigns, media, outreach, and when necessary public interest litigation and/or legal rulemaking petitions.

Since its inception over twenty-five years ago CFS has had a flagship program on pesticides and their impacts on humans and other wildlife, with multiple staff—science, policy, campaign, and legal—dedicated to that program. CFS’s pesticide program has long advocated for rigorous, science-based safety testing and proper regulation of pesticide product uses, including timely review of the possible health risks posed by pesticides. CFS and its members are concerned about the impacts of industrial agriculture, specifically pesticide use, on biodiversity and human health. CFS and its members are particularly concerned about the human health and ecological risks posed by glyphosate. As further explained below, CFS has communicated these concerns to EPA since 2009, through regulatory advocacy, public comments, and even litigation, to protect its members, the public, and our environment from this dangerous and highly ubiquitous pesticide.

### Lideres Campesinas

Organización en California de Líderes Campesinas (Líderes Campesinas) is a tax-exempt, nonprofit membership organization of farmworker women and girls located in Oxnard, California and has organized its Chapters around rural regions in California, including: Salinas, Greenfield, Soledad, Madera, Huron, Merced, Fresno, Ventura County, Coachella Valley, Northern Santa Barbara, Sonoma, Napa, and Kern. Líderes Campesinas represents a culmination of decades of work by farm working women (campesinas). Líderes Campesinas provides these long-time leaders and activists with the opportunity to coordinate their work statewide and has built collectives so that campesinas may become agents of change and be a more effective unified voice. Líderes Campesinas addresses a wide range of topics affecting campesinas, including the effects of pesticides on farmworkers and rural agricultural communities. Líderes Campesinas has educated farmworkers and created brochures in Spanish to provide written information for campesinas, including brochures on how to prevent pesticide poisoning. Líderes Campesinas has also worked with federal and state agencies and other organizations and

public service providers to achieve better results on rural health issues. When necessary, Líderes Campesinas also engages in public interest litigation to protect the interests of rural farmworkers and communities. Líderes Campesinas submitted organizational comments in 2019 to the EPA docket during its registration review of glyphosate. Líderes Campesinas and its members are being harmed by EPA's failure to properly register glyphosate.

### Beyond Pesticides

Beyond Pesticides is a Washington, D.C.-based, nonprofit organization that works to protect public health and the environment with regard to pesticide use. Beyond Pesticides has members in fifty states and the District of Columbia. Beyond Pesticides promotes safe air, water, land, and food and works to protect public health and the environment by encouraging a transition away from the use of toxic pesticides, including herbicides such as glyphosate that is at issue in this lawsuit. To achieve its goals, Beyond Pesticides provides the public with resources and information on the risks associated with pesticides, including glyphosate. Beyond Pesticides' *Gateway on Pesticide Hazards and Safe Pest Management* provides the public with easy access to current and historical information on pesticide hazards, and safe and organic pest management; drawing on and linking to numerous sources and organizations that include information related to pesticide science, policy, and action. The *Pesticide-Induced Disease Database (PIDD)*, with over 1,011 studies, facilitates access to epidemiologic and laboratory studies based on real world exposure scenarios that link pesticides to public health effects, including asthma, autism and learning disabilities, birth defects and reproductive dysfunction, diabetes, Parkinson's and Alzheimer's diseases, and several types of cancer. Additionally, Beyond Pesticides' *Genetic Engineering* program publicizes the serious health and pest resistance problems related to genetically engineered (GE) crops as well as provides important links to activists working in the pesticide community. When necessary, Beyond Pesticides also engages in public interest litigation to address the impacts of pesticides on the environment, its members, and the public interests. Beyond Pesticides submitted organizational comments in 2009, 2018 and 2019 on EPA's registration review of glyphosate. Many of the members of Beyond Pesticides are adversely affected by glyphosate; members live, work, and recreate in and near agricultural areas and other outdoor settings where glyphosate is being, or will be, applied or where crops treated with this harmful pesticide are being, or will be, planted.

### Farmworker Association of Florida

The Farmworker Association of Florida (FWAF) is a state-wide, community-based, non-profit, farmworker membership organization with over 10,000 Haitian, Hispanic, and African American members. FWAF is headquartered in Apopka, Florida, and has four other offices in Fellsmere, Homestead, Immokalee, and Pierson, Florida. Formed in 1983, FWAF's longstanding mission is to build power among farmworker and rural low-income

communities, to respond to and gain control over the social, political, economic, workplace, health, environmental and climate justice issues that impact their lives. FWAF's guiding vision is a social environment where farmworkers' contribution, dignity, and worth are acknowledged, appreciated, and respected through economic, social, and environmental justice. Toward this goal, FWAF's programs and activities build leadership, civic engagement, and activist skills among low-income communities of color who are disproportionately affected by pesticide exposure and health problems related to that exposure, environmental contamination, institutional racism, harassment and intimidation, exploitation, and political under-representation. Since 1996, FWAF has been conducting EPA-certified WPS pesticide health and safety trainings with farmworkers in Central and South Florida and has submitted complaints for WPS violations to the Florida Department of Agriculture for investigations into farmworkers' exposures to pesticides. When necessary, FWAF also engages in public interest litigation to protect the interests of rural farmworkers and communities. FWAF submitted organizational comments in 2019 to the EPA docket during its registration review of glyphosate, the pesticide product at issue in this petition. FWAF and its members are concerned by the detrimental impacts on farmworkers, landscapers, and on the public health of rural farm communities that will result from the continued registration and use of glyphosate. Many of FWAF's members are farmworkers and landscapers who live and work in rural areas where excessive amounts of glyphosate are used in ornamental plant nurseries, field crops, and in landscaping. These members are especially susceptible to the health risks associated with exposure to glyphosate.

#### Rural Coalition

Rural Coalition is a tax-exempt, nonprofit membership organization located in Washington, D.C. that represents fifty grassroots and community based organizational members. Rural Coalition seeks just and sustainable food systems that bring fair returns to diverse small farmers and ranchers, tribal and other small communities; fair and safe working conditions and dignity for farmworkers and food chain workers; protection of mother earth; and safe, adequate, and healthy food for all, especially the elders, youth, and most vulnerable among us. Rural Coalition addresses the needs and concerns of historically underserved minority family farming communities and the issue of worker protection, including protection of farmworkers. Rural Coalition submits comments to regulatory agencies, provides action alerts to its members to encourage effective participation in the administrative rule making process, and when necessary, engages in public interest litigation to address the impacts of the current industrial food production model and its impacts on farmworkers and rural communities. Rural Coalition submitted organizational comments in 2019 to the EPA docket during its registration review of glyphosate. Many of Rural Coalition's members are farmers and farmworkers who live in rural areas where excessive amounts of pesticides are applied to crops. Rural Coalition's member groups also represent workers in the nursery industry, and those who maintain golf courses and other landscapes where pesticides, including glyphosate, are routinely applied. Rural Coalition and its members are concerned about the detrimental impact

farmers, farmworkers, and rural farm communities will face from the continued use of glyphosate.

Alianza Nacional de Campesinas, Inc.

Alianza Nacional de Campesinas, Inc. (Alianza) is a tax-exempt, nonprofit organization of farmworker women, comprised of fifteen member organizations based across twenty states and Washington D.C. Its members include Petitioners Líderes Campesinas and Rural Coalition. Alianza addresses a wide range of topics affecting farmworker women (campesinas), including the effects of pesticide exposure on farmworker women and their families. Alianza maintains a campaign, the Satchel (Moralitos), dedicated to creating public awareness about the health risks posed by pesticide exposure to farmworker women and their families. Alianza members hold community events where they teach women how to protect themselves from pesticide exposure, what to do in the event of an exposure, and what the current EPA policies are on legal pesticide use. Alianza is actively working to strengthen pesticide protections for farmworkers, by pushing for more protective legislation, and as here, engaging in public interest litigation to protect the interests of farmworker women and their families. Alianza and its members are particularly concerned about the human health risks posed by glyphosate, specifically as they relate to the wellbeing of farmworker women.

## EXECUTIVE SUMMARY

This Petition seeks to immediately suspend and cancel all glyphosate registrations. The Environmental Protection Agency (EPA) is tasked with regulating pesticides in the United States, pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136 et seq. In accordance with FIFRA, EPA can register a pesticide only upon determining that it will cause no unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice. *Id.* § 136a(c)(5)(A)-(D). To remain registered, a pesticide must continue to meet this FIFRA safety standard. To ensure this, EPA is required to periodically review pesticide registrations in light of new science and uses. *Id.* § 136a(g)(1)(A). EPA began this review process for glyphosate in 2009 and despite spending eleven years, produced a review decision that was vacated by the Ninth Circuit because it was deemed insufficient with regard to its human health assessment and cancer classification decision. EPA subsequently withdrew the remainder of glyphosate's registration review decision, but has taken no further action. The result is that today, glyphosate remains registered despite no demonstration by EPA that it can meet the required FIFRA safety standard for this herbicide's currently approved uses. In other words, *glyphosate as it's currently used has no legal safety assessment on record.*

Petitioners are farmworkers, environmental, and agriculture public interest groups, all with a core mission interest in protecting human and environmental health from the dangers of glyphosate. Glyphosate is the most widely used pesticide in the world, with approximately 300 million lbs being applied annually just in the United States. The pesticide endangers human health in a myriad of ways. The world's foremost authority on carcinogens, the International Agency for Research on Cancer, and medical scientists the world over recognize the pesticide to be a probable carcinogen. Glyphosate's adverse impacts on the liver, kidney and reproductive system have been recognized for decades, and a growing body of evidence links glyphosate exposure to metabolic syndrome. The environment faces similarly devastating impacts from the potent herbicide, with 93% of threatened and endangered species likely being adversely affected, and Monarch butterfly populations facing decimation.

The wealth of evidence demonstrates glyphosate as registered today cannot meet FIFRA's required safety standard. FIFRA defines "unreasonable adverse effects on the environment" as "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). Glyphosate's harms are expansive and threaten human health, especially the health of applicators, farmworkers and landscapers, as well as our most vulnerable species, and these well-documented harms far outweigh any benefits glyphosate may have. And EPA has no valid assessment demonstrating otherwise. Cancellation and suspension are not simply warranted, they're necessary as glyphosate's continued registration is illegal.

This Petition seeks an immediate suspension of glyphosate, until such time that EPA can affirm the pesticide warrants cancellation or can demonstrate that glyphosate meets the required FIFRA safety standard, an eventuality of which Petitioners are skeptical. In the alternative, Petitioners request that at the very least, EPA initiate special review to assess the human health impacts of glyphosate and its formulations, particularly from occupational uses, as well as their adverse environmental impacts and costs.

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## I. ACTION REQUESTED

Because of the dangers posed by glyphosate to human health and the environment, Petitioners hereby petition EPA to:

- 1) Cancel glyphosate's registration pursuant to FIFRA § 136d(b); and
- 2) Suspend glyphosate's registration pending completion of cancellation proceedings pursuant to FIFRA § 136d(c)(1).

or, in the alternative,

- 1) Initiate the Special Review process pursuant to 40 C.F.R. § 154.10.

## II. LEGAL AND FACTUAL BACKGROUND

### a. Introduction

Glyphosate is the most heavily used pesticide in the world. In the United States, approximately 280 million lbs. of glyphosate are applied to 285 million acres in agriculture annually, and an additional 21 million lbs. are applied in non-crop settings.<sup>1</sup> Glyphosate's farm use is four times that of the second leading pesticide, atrazine.<sup>2</sup> Agricultural glyphosate use has increased roughly 10-fold since the introduction of Monsanto's genetically engineered, "Roundup Ready", glyphosate-resistant crops in the mid-1990s.<sup>3</sup>

Despite its enormous and pervasive use, EPA has continued to turn a blind eye to the harms of glyphosate herbicides. It was not always so. EPA once recognized glyphosate as a liver, reproductive, and kidney toxin,<sup>4</sup> as well as a possible carcinogen,<sup>5</sup> and subsequent studies have only proven EPA's original determinations correct.<sup>6</sup> The environment fares no better against the potent herbicide, with massive impacts befalling plants, animals, and their habitats, including threatened and endangered species.<sup>7</sup> To name just a few, glyphosate formulations are extremely toxic to aquatic-stage amphibians and are

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<sup>1</sup> See ENV'T PROT. AGENCY, *Glyphosate Executive Summary for Biological Evaluation*, 2-3, <https://www.epa.gov/endangered-species/final-national-level-listed-species-biological-evaluation-glyphosate#executive-summary> [hereinafter BE Executive Summary]

<sup>2</sup> U.S. GEOLOGICAL SURVEY, *Pesticide National Synthesis Project*, [https://water.usgs.gov/nawqa/pnsp/usage/maps/show\\_map.php?year=2019&map=ATRAZINE&hilo=L&disp=Atrazine](https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2019&map=ATRAZINE&hilo=L&disp=Atrazine) (last accessed 3/28/23).

<sup>3</sup> U.S. GEOLOGICAL SURVEY, *Pesticide National Synthesis Project*, [https://water.usgs.gov/nawqa/pnsp/usage/maps/show\\_map.php?year=2019&map=GLYPHOSATE&hilo=L&disp=Glyphosate](https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2019&map=GLYPHOSATE&hilo=L&disp=Glyphosate) (last accessed 3/28/23).

<sup>4</sup> See Center for Food Safety, *Comments to EPA on Proposed Interim Registration Decision for Glyphosate*, Sept. 3, 2019, pp. 12-14. [hereinafter, CFS Proposed IRRD Comments 2019].

<sup>5</sup> See ENV'T PROT. AGENCY, *Consensus Review of Glyphosate* (March 4, 1985), <https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-171.pdf>.

<sup>6</sup> See *infra* part II(d)(i)(1)-(4).

<sup>7</sup> See *infra* part II(c)(ii)(4)(b); see also *infra* part II(d)(ii).

implicated as a factor in their worldwide decline.<sup>8</sup> Glyphosate is also a significant driver of the Monarch butterfly decline because it has nearly eliminated the Monarch's host plant and food source, common milkweed, from Midwestern crop fields.<sup>9</sup>

To date, glyphosate remains registered under FIFRA, despite EPA's continued failure to properly analyze the full effects of current glyphosate use, and a wealth of evidence demonstrating glyphosate cannot meet FIFRA's required safety standard: no unreasonable adverse effects on the environment. EPA's recent efforts to prove glyphosate meets this standard failed miserably and resulted in the withdrawal of its interim registration review decision (IRRD). The Ninth Circuit found EPA's human health risk assessment, specifically its cancer safety finding, deficient and incapable of supporting the conclusion that glyphosate poses "no risks to human health."<sup>10</sup> In response, EPA withdrew its IRRD, and furthermore openly admitted glyphosate's ecological risk assessment requires further evaluation and that additional mitigation measures may be necessary to safeguard the environment.<sup>11</sup>

As things now stand, EPA's human health assessment of glyphosate has been held unlawful and set aside, and the remainder of the IRRD has been withdrawn. Accordingly, glyphosate's current registrations rely on the 1993 Reregistration Eligibility Decision (RED),<sup>12</sup> a decision based on a risk assessment conducted *thirty years* ago that fails to account for the 10-fold increase in use driven largely by over-the-top applications of glyphosate to crops genetically engineered to resist it. Further, since the completion of the 1993 RED, dozens of scientific studies have linked glyphosate and its formulations to non-

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<sup>8</sup> Rick Relyea, *The Lethal Impact of Roundup on Aquatic and Terrestrial Amphibians*, 15 *ECOLOGICAL ADAPTIONS* 1118, 1118-1124 (2005); see also Center for Food Safety, *Comments to EPA on the draft risk assessments for glyphosate registration review*, April 30, 2018, pp. 7-11 [hereinafter, CFS Risk Assessment Comments 2018].

<sup>9</sup> John Pleasants & Karen Oberhauser, *Milkweed loss in agricultural fields because of herbicide use: effect on the monarch butterfly population*, *INSECT CONSERVATION & DIVERSITY*, 2012, 1-10; Comments to EPA on "Risk Management Approach To Identifying Options for Protecting the Monarch Butterfly" By Professor Myron P. Zalucki, School of Biological Sciences, The University of Queensland, Australia, Aug. 14, 2015, <https://www.regulations.gov/comment/EPA-HQ-OPP-2015-0389-0052>; W. Thogmartin et al., *Restoring Monarch Butterfly Habitat in the Midwestern US: 'All Hands On Deck'*, 12 *ENV'T RSCH. LETTERS* 074005 (2017); CFS Risk Assessment Comments 2018, *supra* note 8, at 11-13.

<sup>10</sup> CFS/Nat. Res. Def. Council v. U.S. Env't Prot. Agency, 38 F.4th 34, 50-51 (9th Cir. 2022) [hereinafter *Glyphosate IRRD Challenge*].

<sup>11</sup> "For the ecological portion, EPA intends to address the issues for which it sought remand, including: to consider whether additional or different risk mitigation may be necessary based on the outcome of ESA consultation for glyphosate, prepare an analysis of in-field effects of glyphosate on monarch butterfly habitat, consider whether there are other aspects of its analysis of ecological risks and costs to revisit, and consider what risk mitigation measures may be necessary to reduce potential risk following completion of analyses left outstanding in the ID." *ENV'T PROT. AGENCY, EPA Withdraws Glyphosate Interim Decision* (Sept. 23, 2022), <https://www.epa.gov/pesticides/epa-withdraws-glyphosate-interim-decision>. Because EPA is allowing glyphosate use to continue despite not completing the ESA's consultation process, it is also in violation of the ESA.

<sup>12</sup> *ENV'T PROT. AGENCY, Reregistration Eligibility Decision (RED)* (Sept. 1993), [https://www3.epa.gov/pesticides/chem\\_search/reg\\_actions/reregistration/red\\_PC-417300\\_1-Sep-93.pdf](https://www3.epa.gov/pesticides/chem_search/reg_actions/reregistration/red_PC-417300_1-Sep-93.pdf).

Hodgkin’s lymphoma (NHL), as have courts. In addition, EPA itself has concluded that 93% of ESA listed species are likely to be adversely affected by glyphosate; and weed populations resistant to glyphosate have proliferated in response to intensive spraying of the herbicide. This continued registration of glyphosate violates FIFRA, the lack of current cancer safety finding alone ensures that. EPA cannot and has not demonstrated that glyphosate does not cause unreasonable adverse effects on the environment “when used in accordance with widespread and commonly recognized practice.”

Accordingly, pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution<sup>13</sup> and the Administrative Procedure Act (APA),<sup>14</sup> Center for Food Safety, Organización en California de Líderes Campesinas, Beyond Pesticides, Rural Coalition, The Farmworker Association of Florida, and Alianza Nacional de Campesinas, Inc. on behalf of themselves and their members, petition the U.S. Environmental Protection Agency (EPA) to cancel and immediately suspend all registrations of glyphosate.<sup>15</sup>

### **b. EPA’s Regulatory Authority Over Pesticides**

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),<sup>16</sup> provides the framework for the federal regulation of pesticides. FIFRA defines pesticide, inter alia, as any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest, with herbicides being one type of pesticide.<sup>17</sup> Under FIFRA, EPA licenses the sale, distribution, and use of pesticides, including herbicides, through the process of registration.<sup>18</sup> EPA can register a pesticide only upon determining that “its composition is such as to warrant the proposed claims for it,” “its labeling and other

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<sup>13</sup> Congress shall make no law . . . abridging . . . the right of the people . . . to petition Government for a redress of grievances.” U.S. CONST. Amend. I. The right to “petition for a redress of grievances [is] among the most precious of the liberties safeguarded by the Bill of Rights.” See *United Mine Workers of Am. v. Illinois State Bar Ass’n*, 389 U.S. 217, 222 (1967). It shares the “preferred place” accorded in our system of government to the First Amendment freedoms, and has “sanctity and a sanction not permitting dubious intrusions.” *Thomas v. Collins*, 323 U.S. 516, 530 (1945). The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. *United States v. Cruikshank*, 92 U.S. 542, 552 (1876).

<sup>14</sup> 5 U.S.C. § 553(e).

<sup>15</sup> See also 40 C.F.R. § 154.10.

<sup>16</sup> 7 U.S.C. § 136 et seq.

<sup>17</sup> Throughout the petition, glyphosate will be referred to as a pesticide and herbicide, both of which the chemical qualifies as. See ENV’T PROT. AGENCY, *What is a Pesticide?*, <https://www.epa.gov/minimum-risk-pesticides/what-pesticide#:~:text=Pesticide%20law%20defines%20a%20%E2%80%9Cpesticide,Any%20nitrogen%20stabilizer;%20https://www.epa.gov/ingredients-used-pesticide-products/types-pesticide-ingredients#:~:text=Herbicides%20kill%20weeds%20and%20other,feed%20on%20plants%20and%20animals> (last visited Nov. 28, 2023); ENV’T PROT. AGENCY, *Types of Pesticide Ingredients*, <https://www.epa.gov/ingredients-used-pesticide-products/types-pesticide-ingredients#:~:text=Herbicides%20kill%20weeds%20and%20other,feed%20on%20plants%20and%20animals> (last visited Nov. 28, 2023).

<sup>18</sup> 7 U.S.C. § 136a(5)(D).

material required to be submitted comply with the requirements. . .”, “it will perform its intended function without unreasonable adverse effect on the environment,” and that “*when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.*”<sup>19</sup> FIFRA defines “unreasonable adverse effects on the environment” as “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.”<sup>20</sup>

Once registered, a pesticide remains registered until EPA, or the registrant cancels it. However, to remain registered, a pesticide must continue to meet the FIFRA standard, that is, it must continue to cause no unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice.

EPA is empowered to reassess whether a pesticide meets the FIFRA standard at any time, and can do so via various processes.<sup>21</sup> One such process is special review, the purpose of which is “to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment.”<sup>22</sup> EPA may initiate special review on its “own initiative, or at the suggestion of any interested person.”<sup>23</sup>

Alternatively, EPA is required to reassess pesticides every 15 years via registration review. FIFRA requires pesticide registrations to be “periodically reviewed,”<sup>24</sup> a term Congress defined to require each pesticide be reviewed every 15 years.<sup>25</sup> Registration review is intended to assess the risks that a pesticide may pose to human health and the environment in the light of new scientific information, enhanced ability to detect risks, changes in pesticide policy, and alterations in pesticide usage practices, since the pesticide was last registered.<sup>26</sup> 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.”<sup>27</sup> EPA has the authority to call in additional data from registrants during the registration review process or if it determines additional data are necessary for a current

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<sup>19</sup> *Id.* § 136a(c)(5)(A)-(D).

<sup>20</sup> *Id.* § 136(bb).

<sup>21</sup> *Washington Toxics Coal. v. Env’t Prot. Agency*, 413 F.3d 1024, 1033 (9th Cir. 2005) (The “EPA retains discretion to alter the registration of pesticides for reasons that include environmental concerns.” (citing 7 U.S.C. §§ 136d(c)(1)-(2), 136(l)); see also *Nat. Res. Defense Council v. Johnson*, 422 F. Supp. 2d 105, 109 (D.D.C. 2006) (“The EPA uses numerous types of review processes to periodically reevaluate a registered pesticide’s risks and benefits.” (citations omitted))).

<sup>22</sup> 40 CFR § 154.1.

<sup>23</sup> *Id.* § 154.10.

<sup>24</sup> 7 U.S.C. § 136a(g)(1)(A).

<sup>25</sup> *Id.* § 136a(g)(1)(A)(iii)-(iv); 40 C.F.R. §§ 155.40-155.58.

<sup>26</sup> See ENV’T PROT. AGENCY, *Registration Review Process*, <https://www.epa.gov/pesticide-reevaluation/registration-review-process>; see ENV’T PROT. AGENCY, *GLYPHOSATE SUMMARY DOCUMENT REGISTRATION REVIEW: INITIAL DOCKET 4* (June 2004), <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0003>.

<sup>27</sup> 40 CFR § 155.40(a).

registration.<sup>28</sup> Registrants are also under a continuing obligation to provide EPA with any new data that arises regarding a pesticides ability to cause unreasonable adverse effects.<sup>29</sup>

Regardless of the process used, if EPA finds that a registered pesticide has “unreasonable adverse effects on the environment” when “used in accordance with widespread and commonly recognized practice,” then the agency may undertake cancellation proceedings.<sup>30</sup> Any interested person may petition EPA to cancel a registered pesticide product.<sup>31</sup>

Relatedly, EPA may suspend the registration of a pesticide immediately if EPA determines it is necessary “to prevent an imminent hazard during the time required for cancellation . . . .”<sup>32</sup> An imminent hazard exists if during the time required for cancellation the continued use of a pesticide would (1) “be likely to result in unreasonable adverse effects on the environment” or (2) “involve unreasonable hazard to the survival of a species declared endangered or threatened” by the Endangered Species Act (ESA).<sup>33</sup>

### **c. Glyphosate’s Regulatory History**

#### **i. Product Registration**

EPA first registered glyphosate in 1974. For two decades, glyphosate spraying in farming was limited because it kills crops and other desirable plants along with weeds. Thus, glyphosate could only be sprayed to kill weeds before crops like corn sprouted (“preemergence”), shortly before or after harvest, or between rows in orchards. However, following EPA’s reregistration of glyphosate in 1993, Monsanto created a significant new expansion: spraying over-the-top of commodity crops that Monsanto genetically engineered to be resistant to glyphosate. Glyphosate resistance enabled what was previously impossible: these “Roundup Ready” crops are sprayed directly, post-emergence, one to three times throughout the growing season. Near universal adoption of glyphosate-resistant soybeans, cotton, and corn since their introduction drove a massive increase in agricultural use of glyphosate, from less than 19 million pounds in 1993 to 280

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<sup>28</sup> 7 U.S.C. § 136a(c)(2); 40 C.F.R. § 155.48.

<sup>29</sup> 7 U.S.C. § 136d(a)(2); 40 C.F.R. § 159.152.

<sup>30</sup> 7 U.S.C. § 136d(b).

<sup>31</sup> *In re National Res. Def. Council, Inc.*, 956 F.3d 1134, 1136 (9th Cir. 2020) (“If the risks to the environment or human health are unreasonable, the EPA may initiate proceedings to cancel the pesticide’s registration, pursuant to 7 U.S.C. § 136d. Any interested person may petition the EPA to cancel a registered pesticide, 40 C.F.R. § 154.10; Wash. Toxics Coal. v. EPA, 413 F.3d 1024, 1033 (9th Cir. 2005), and the EPA is required by the Administrative Procedure Act (APA) to resolve the petition “within a reasonable time.” 5 U.S.C. § 555(b).”) (emphases added).

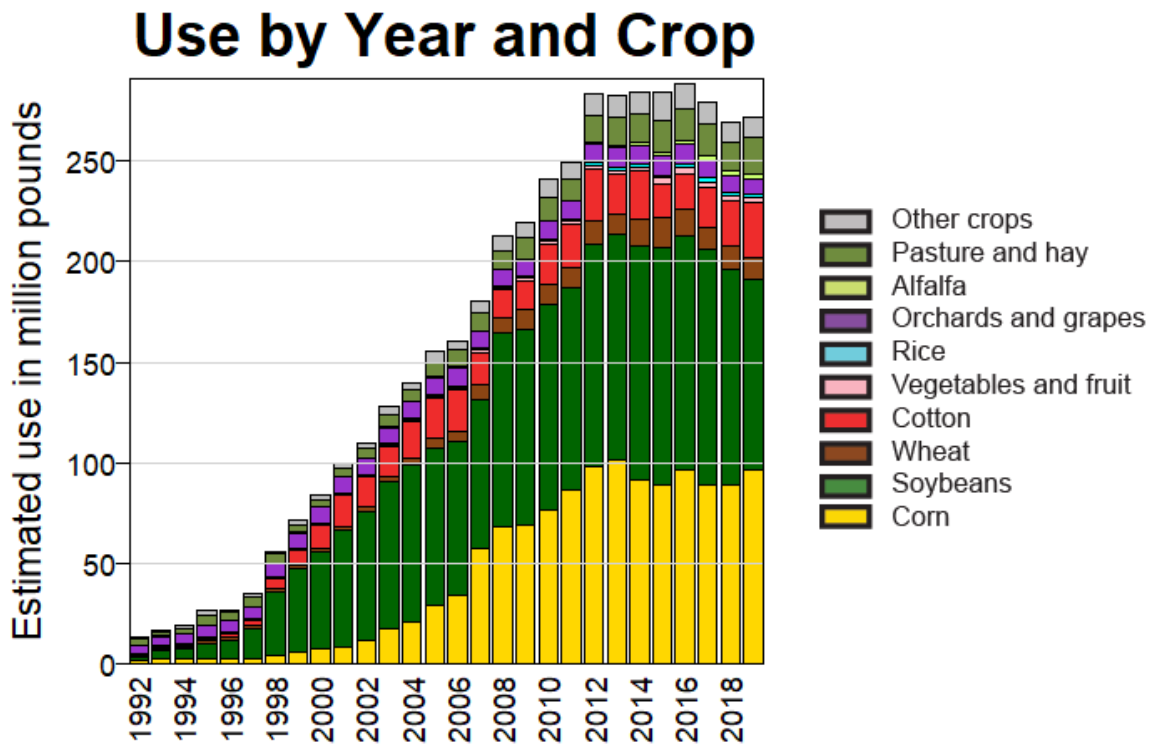
<sup>32</sup> 7 U.S.C. § 136d(c)(1).

<sup>33</sup> *Id.* § 136(l).

million pounds today. Today, the “acreage across which glyphosate is currently used is roughly equivalent to three times the size of California.”<sup>34</sup>

Another factor driving the explosion in glyphosate use was its reputation for safety, the fruit of a relentless, decades-long advertising campaign by Monsanto that made numerous false claims touting the supposed human and environmental safety of Roundup. These safety claims were banned as false and misleading by the New York State Attorney General in at least three separate actions in 1996, 1998, and 2023.<sup>35</sup> Nevertheless, this messaging has given rise to a lack of care in preventing dermal exposure among those who apply glyphosate products. Multiple plaintiffs in litigation against Monsanto who attributed their cancers to use of glyphosate products stated in depositions that they took no measures to reduce their dermal exposure because they were told Roundup was safe, for instance failing to wash off spray solution or change out of Roundup-soaked clothing.<sup>36</sup>

**Figure 1: Glyphosate Use Over Time<sup>37</sup>**



<sup>34</sup> Glyphosate IRRD Challenge, 38 F.4th at 41.

<sup>35</sup> See *infra* notes 307-309 and accompanying text.

<sup>36</sup> See *infra* notes 223-232.

<sup>37</sup> U.S. GEOLOGICAL SURVEY, *supra* note 3.

## ii. Controversy to Date

### 1. Interim Registration Review Decision

In accordance with its duty under FIFRA to review all registered pesticides every 15 years and determine whether the pesticide still meets the FIFRA registration standard, EPA initiated registration review for glyphosate in 2009.<sup>38</sup> In the same year, Petitioner CFS submitted detailed comments on the Agency's initial scoping documents, including evidence of glyphosate's cancer-causing potential.<sup>39</sup> This review was highly anticipated given that glyphosate use had changed so significantly since the pesticide was reregistered in 1993. At the start of the review, EPA anticipated it would take six years; instead, it took eleven years just for the *interim* registration review decision, which ultimately failed to demonstrate that glyphosate can meet the FIFRA standard.<sup>40</sup>

EPA's long delay was due in large part to activities it undertook in response to the March 2015 finding by the International Agency for Research on Cancer (IARC)<sup>41</sup> that glyphosate is "probably carcinogenic to humans,"<sup>42</sup> a classification one step below that of known carcinogens such as tobacco smoking, and which was widely supported by medical scientists.<sup>43</sup>

EPA officer Jess Rowland (who attended the IARC meeting) informed glyphosate manufacturer Monsanto of the IARC determination some time before its public release,

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<sup>38</sup> Registration Review: Glyphosate Docket Opened for Review and Comment, 74 Fed. Reg. 36217 (July 22, 2009).

<sup>39</sup> Center for Food Safety, *Comments to EPA on Glyphosate Registration Review Docket Opened*, Sept. 21, 2009.

<sup>40</sup> ENV'T PROT. AGENCY, GLYPHOSATE INTERIM REGISTRATION REVIEW DECISION (2020) [hereinafter FINAL IRRD]; see also *Glyphosate IRRD Challenge*, 38 F.4th 34.

<sup>41</sup> IARC, part of the World Health Organization, has been the world's leading authority on carcinogenic agents since the 1970s, and is funded by the governments of 24 countries, including through grants from the U.S. National Cancer Institute and the Environmental Protection Agency. See Neil Pearce et al., *IARC Monographs: 40 Years of Evaluating Carcinogenic Hazards to Humans*, 123 ENV'T HEALTH PERSPS 507, 507-514 (2015).

<sup>42</sup> The 16-member IARC Working Group that made this unanimous determination was led by an emeritus scientist from the U.S. National Cancer Institute, and included six other U.S. scientists, including one from the U.S. EPA. See: IARC (2017). INT'L AGENCY FOR RSCH. ON CANCER, SOME ORGANOPHOSPHATE INSECTICIDES AND HERBICIDES 3-5 (Volume 112 2017), <https://publications.iarc.fr/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Some-Organophosphate-Insecticides-And-Herbicides-2017> [hereinafter IARC Monographs]; Andrew Pollack, N.Y. TIMES, *Weed Killer, Long Cleared, Is Doubted* (Mar. 27, 2015), <https://www.nytimes.com/2015/03/28/business/energy-environment/decades-after-monsantos-roundup-gets-an-all-clear-a-cancer-agency-raises-concerns.html#:~:text=Thirty%20years%20ago%2C%20an%20Environmental,basis%20for%20the%20original%20conclusion.>

<sup>43</sup> Christopher J. Portier et al., *Differences in the carcinogenic evaluation of glyphosate between the International Agency for Research on Cancer (IARC) and the European Food Safety Authority (EFSA)*, 70 J. EPIDEMIOL COMMUNITY HEALTH 741, 741-45 (2016).



enabling the company to prepare a public relations campaign attacking the finding.<sup>44</sup> Rowland then led an EPA Office of Pesticide Programs' committee that was charged with developing the EPA's response to IARC's classification decision. The resulting October 2015 report mischaracterized IARC's findings,<sup>45</sup> and concluded that glyphosate was "not likely to be carcinogenic."<sup>46</sup> Monsanto officers had ghost-written key studies Rowland's committee relied upon in its determination.<sup>47</sup> Rowland and Jack Housenger, then head of EPA's Office of Pesticide Programs (OPP), helped Monsanto achieve a 4 to 5 year postponement of a separate toxicological assessment of glyphosate by the National Institutes of Health's Agency for Toxic Substances and Disease Registry (ATSDR), which Monsanto feared would support IARC's assessment, to ensure it would not conflict with EPA's cancer assessment.<sup>48</sup> Rowland was subsequently the subject of an EPA Office of Inspector General investigation into collusion between him and Monsanto.<sup>49</sup> The EPA's science division, the Office of Research and Development (ORD),<sup>50</sup> was then tasked with assessing and explaining the stark differences between the OPP and IARC carcinogenicity assessments of glyphosate. EPA ORD scientists found that OPP had

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<sup>44</sup> Danny Hakim, N.Y. TIMES, *Monsanto weed killer Roundup faces new doubts on safety in unsealed documents* (Mar. 14, 2017), <https://www.nytimes.com/2017/03/14/business/monsanto-roundup-safety-lawsuit.html#:~:text=The%20reputation%20of%20Roundup%2C%20whose,manufacturer%2C%20the%20chemical%20giant%20Monsanto.>

<sup>45</sup> Center for Food Safety, *Comments to California's Office of Environmental Health Hazard Assessment (OEHHA) in response to OEHHA's request for comments on two EPA OPP cancer assessments of glyphosate (2015, 2017)*, July 13, 2022, [https://oehha.ca.gov/media/dockets/20802/20877-center\\_for\\_food\\_safety/cfs\\_glyphosate\\_prop65\\_comments\\_-\\_7-13-22.pdf](https://oehha.ca.gov/media/dockets/20802/20877-center_for_food_safety/cfs_glyphosate_prop65_comments_-_7-13-22.pdf) [hereinafter Gly Prop 65 Comments].

<sup>46</sup> ENV'T PROT. AGENCY, GLYPHOSATE: REPORT OF THE CANCER ASSESSMENT REVIEW COMMITTEE, October 1, 2015. <https://www.documentcloud.org/documents/2835260-GLYPHOSATE-Report-of-the-Cancer-Assessment.>

<sup>47</sup> Joel Rosenblatt, Lydia Mulvany & Peter Waldman, BLOOMBERG, *EPA official accused of helping Monsanto 'kill' cancer study* (March 14, 2017), [https://www.bloomberg.com/news/articles/2017-03-14/monsanto-accused-of-ghost-writing-papers-on-roundup-cancer-risk#xj4y7vzkg.](https://www.bloomberg.com/news/articles/2017-03-14/monsanto-accused-of-ghost-writing-papers-on-roundup-cancer-risk#xj4y7vzkg)

<sup>48</sup> *Id.* For the anticipated 2015 release of the ATSDR report and Monsanto's concerns it would support IARC, see *Monsanto Worries About ATSDR*, U.S. RIGHT TO KNOW (Aug. 2017), <https://usrtk.org/wp-content/uploads/2017/08/57-Monsanto-Worries-About-ATSDR-Glyphosate-Review-Seeks-to-Rebut-IARC.pdf>. For the final ATSDR Toxicological Profile for Glyphosate, dated August 2020, see ATSDR, TOXICOLOGICAL PROFILE FOR GLYPHOSATE (Aug. 2020), <https://www.atsdr.cdc.gov/toxprofiles/tp214.pdf>.

<sup>49</sup> Paul D. Thacker, HUFFPOST, *The EPA's Inspector General is probing whether an agency staffer colluded with Monsanto* (June 6, 2017), [https://www.huffpost.com/entry/epa-inspector-general-probing-collusion-with-monsanto\\_n\\_59372108e4b0aba888b99dca](https://www.huffpost.com/entry/epa-inspector-general-probing-collusion-with-monsanto_n_59372108e4b0aba888b99dca); *Monsanto Worries About ATSDR*, *supra* note 48. Petitioner CFS has an outstanding FOIA with ongoing productions related to this matter.

<sup>50</sup> EPA's Office of Research and Development (ORD) is EPA's impartial, non-regulatory science division, home to the Integrated Risk Information System (IRIS), and "[t]he placement of the IRIS Program in ORD is intentional. It ensures that IRIS can develop impartial toxicity information independent of its use by EPA's program and regional offices...." See ENV'T PROT. AGENCY, *Integrated Risk Information System*, <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system#:~:text=The%20placement%20of%20the%20IRIS,and%20clean%20up%20hazardous%20sites.> (last visited Nov. 28, 2023).

contravened the Agency’s Cancer Guidelines<sup>51</sup> in concluding that glyphosate was “not likely to be carcinogenic,” and that the proper descriptor was either “likely to be carcinogenic” or “suggestive evidence of carcinogenicity.”<sup>52</sup>

In September of 2016, OPP issued a draft “Glyphosate Issue Paper: Evaluation of Carcinogenic Potential” that made no substantive changes in response to the ORD’s critique. This paper was subsequently referred to the FIFRA Scientific Advisory Panel (SAP), a congressionally created expert body that EPA appoints, for review.<sup>53</sup> Just days before the scheduled mid-October start of the SAP meeting, EPA received a letter from CropLife America, a pesticide industry trade group. CropLife demanded *inter alia* that Dr. Peter Infante, a distinguished scientist with extensive expertise in carcinogen evaluation and decades of government service who had been duly appointed to the Panel, be removed. EPA delayed the meeting two months, and without explanation removed Dr. Infante from the SAP, which arguably constituted a violation of the Federal Advisory Committee Act.<sup>54</sup>

The SAP found numerous problems with OPP’s assessment, most of which overlapped with those noted by EPA’s ORD.<sup>55</sup> The SAP determined that OPP, despite professing adherence to the EPA’s Cancer Guidelines,<sup>56</sup> contravened them in numerous ways in dismissing evidence of glyphosate’s carcinogenicity, for instance: discounting rising tumor trends in rodents fed increasing amounts of glyphosate in cancer bioassays; improperly dismissing tumor data in rodents fed more than a “limit” dose of glyphosate;

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<sup>51</sup> ENV’T PROT. AGENCY, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT (Mar. 2005), [https://www.epa.gov/sites/default/files/2013-09/documents/cancer\\_guidelines\\_final\\_3-25-05.pdf](https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf) [hereinafter EPA Cancer Guidelines].

<sup>52</sup> Glyphosate IRRD Challenge, 38 F.4th at 42. See also U.S. RIGHT TO KNOW, *Summary of ORD comments on OPP’s glyphosate cancer assessment* (Dec. 14, 2015), <https://usrtk.org/wp-content/uploads/2017/03/ORDcommentsonOPPglyphosate.pdf>; *ORD Emails on Proper Carcinogenicity Descriptor for Glyphosate*, THE NEW LEDE (April 2022), at 206-08, <https://www.thenewlede.org/wp-content/uploads/2022/04/EPA-ORD-emails-2015.pdf>.

<sup>53</sup> Glyphosate IRRD Challenge, 38 F.4th at 42.

<sup>54</sup> Carey Gillam, HUFFINGTON POST, *EPA bows to chemical industry in delay of glyphosate cancer review* (Oct. 19, 2016), [https://www.huffpost.com/entry/epa-bows-to-chemical-indu\\_b\\_12563438](https://www.huffpost.com/entry/epa-bows-to-chemical-indu_b_12563438); see also Center for Food Safety, *Letter to EPA Administrator Gina McCarthy urging reinstatement of Dr. Infante*, Dec. 12, 2016, [https://www.centerforfoodsafety.org/files/glyphosate-sap-infante-letter--cfs-12-12-16\\_02026.pdf](https://www.centerforfoodsafety.org/files/glyphosate-sap-infante-letter--cfs-12-12-16_02026.pdf).

<sup>55</sup> Glyphosate IRRD Challenge, 38 F.4th at 42.

<sup>56</sup> The Guidelines for Carcinogen Risk Assessment were drafted by the EPA’s Risk Assessment Forum, a “standing committee of senior EPA scientists which was established to promote Agency-wide consensus on difficult and controversial risk assessment issues and to ensure that this consensus is incorporated into appropriate Agency risk assessment guidance.” See ENV’T PROT. AGENCY, OFFICE OF SCI. ADVISOR, Risk Assessment Forum (Feb. 20, 2016), <https://archive.epa.gov/raf/web/html/index.html>.

utilizing historical rodent tumor data from different studies to dismiss, but never support, the significance of tumors observed in glyphosate feeding trials, among other violations.<sup>57</sup>

The SAP also determined that meta-analyses of epidemiology studies on glyphosate-using farmers “point to a statistically significant association with the increased risks [of non-Hodgkin lymphoma, NHL] from 30-50%...”<sup>58</sup> In addition, SAP members underscored the significance of the concordance between malignant *lymphomas* observed in glyphosate-treated mice and the increased risk of non-Hodgkin *lymphoma* in farmers,<sup>59</sup> a concordance between animal and human study results that “strengthen[s] the weight of evidence of human carcinogenicity,” according to EPA Cancer Guidelines.<sup>60</sup> Although the SAP did not reach unanimity, many Panel members supported the descriptor “suggestive evidence of carcinogenic potential” for glyphosate, rather than EPA’s “not likely to be carcinogenic.”<sup>61</sup>

One year later, in December of 2017, OPP published its revised glyphosate cancer Issue Paper,<sup>62</sup> which contained very few changes in response to the SAP’s extensive critiques and many concrete suggestions.<sup>63</sup> OPP continued to interpret the rodent tumor data in precisely the same way, in violation of the Agency’s Cancer Guidelines, and thus continued to dismiss multiple glyphosate-induced tumors as not “treatment related,” including the incriminating mouse lymphomas. Although Petitioner CFS had demonstrated to EPA that four of the rodent bioassays the Agency included in the draft Issue Paper should be excluded, either because *they did not even involve glyphosate*, had been previously invalidated by the Agency, or did not meet basic quality standards,<sup>64</sup> OPP removed only one from its final evaluation.<sup>65</sup> OPP insisted on including these four (then

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<sup>57</sup> FIFRA SCIENTIFIC ADVISORY PANEL, A SET OF SCIENTIFIC ISSUES BEING CONSIDERED BY THE ENVIRONMENTAL PROTECTION AGENCY REGARDING: EPA’S EVALUATION OF THE CARCINOGENIC POTENTIAL OF GLYPHOSATE, REPORT NO. 2017-01 18-19, 21, 52 (Mar. 16, 2017), [https://cfpub.epa.gov/si/si\\_public\\_file\\_download.cfm?p\\_download\\_id=532889&Lab=OPP](https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=532889&Lab=OPP) [hereinafter FIFRA SAP].

<sup>58</sup> *Id.* at 44; see also *id.* at 43 (correcting OPP’s mistake in concluding the meta-analysis results were not statistically significant).

<sup>59</sup> *Id.* at 48, 85-86.

<sup>60</sup> EPA Cancer Guidelines, *supra* note 51, at 2-3 to 2-4; see also Center for Food Safety, Comments to the FIFRA Scientific Advisory Panel on EPA’s Evaluation of Glyphosate’s Carcinogenic Potential, Oct. 12, 2016, at 5, 27. [hereinafter CFS Comments to FIFRA SAP].

<sup>61</sup> FIFRA SAP, *supra* note 57, at 48.

<sup>62</sup> EPA, OFFICE OF PESTICIDE PROGRAMS, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, (December 12, 2017), [https://cfpub.epa.gov/si/si\\_public\\_record\\_Report.cfm?Lab=OPP&dirEntryId=337935](https://cfpub.epa.gov/si/si_public_record_Report.cfm?Lab=OPP&dirEntryId=337935) [hereinafter EPA OPP Cancer 2017].

<sup>63</sup> Glyphosate IRRD Challenge, 38 F.4th at 42-43.

<sup>64</sup> CFS Comments to FIFRA SAP, *supra* note 60, at 2-4 (summary), 13-14 (Burnett et al. 1979), 17-18 (Pavkov and Wyand 1987), 19-21 (Reyna and Gordon 1973), 25 (Pavkov and Turnier 1987).

<sup>65</sup> EPA OPP Cancer 2017, *supra* note 62, at 74, n.15 (“Note: the original draft of this Issue Paper included 9 studies in rats; however, one study (Burnett, 1979) was removed since the study was conducted with a contaminant of glyphosate, not the active ingredient glyphosate.”).

three) unacceptable rodent studies in the evaluation because their negative results for tumors – in contrast to the other 11 rodent trials, in which tumors *were* observed – provided illicit support for OPP’s preferred “not likely to be carcinogenic” descriptor.<sup>66</sup>

Also in December 2017, EPA released its draft human health and ecological risks assessments of glyphosate. Not a single one of the many independent, peer-reviewed [aka open-literature] studies conducted on the human health effects of glyphosate had any effect on EPA’s assessment, which was instead based on registrant sponsored studies.<sup>67</sup> Likewise, EPA made no changes to its draft risk assessments, despite receiving over 238,000 comments, many of which raised substantive issues and suggested revisions.<sup>68</sup>

In March of 2019, EPA published the proposed interim registration review decision (IRRD), finalizing the human health and ecological risk assessments.<sup>69</sup> Yet again, thousands of comments submitted to OPP, including from Petitioners, raised significant issues concerning EPA’s human health and ecological risk assessments, as well as EPA’s cancer assessment, for glyphosate.<sup>70</sup> Nevertheless, in the January 2020 final IRRD, EPA “determined that there are no risks to human health” from glyphosate, and that it had “no additional human health data needs.”<sup>71</sup> EPA identified potential risks to mammals and birds, land and aquatic plants, and bees (for which it lacks adequate toxicity data),<sup>72</sup> but nevertheless determined that glyphosate’s putative benefits “outweigh the potential ecological risks” when used according to label directions.<sup>73</sup> The final IRRD put in place minimal mitigation measures, mostly changes in language on glyphosate labels, which were never implemented.<sup>74</sup> Petitioners, amongst others, subsequently challenged the IRRD.

## 2. *Rural Coalition v. U.S. Environmental Protection Agency*

The Ninth Circuit adjudicated the claims brought by Petitioners,<sup>75</sup> as well as NRDC. Specifically Petitioners challenged EPA’s human health assessment conclusions and

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<sup>66</sup> Brief for Center for Food Safety and Center for Biological Diversity as Amici Curiae, p. 20-23, *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021).

<sup>67</sup> EPA, GLYPHOSATE: RESPONSE TO COMMENTS ON THE HUMAN HEALTH DRAFT RISK ASSESSMENT 4 (April 23, 2018), <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-2343> (“None of the studies were found to have an impact on the hazard characterization or draft human health risk assessment for glyphosate.”).

<sup>68</sup> See EPA, GLYPHOSATE PROPOSED INTERIM REGISTRATION REVIEW DECISION 6-7 (April 2019), <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-2344> [hereinafter Proposed IRRD].

<sup>69</sup> *Id.*

<sup>70</sup> See FINAL IRRD, *supra* note 40, at 5 (noting roughly 283,300 comments on the proposed IRRD); CFS Proposed IRRD Comments 2019, *supra* note 4.

<sup>71</sup> FINAL IRRD, *supra* note 40, at 10, 12.

<sup>72</sup> *Id.* at 12-13.

<sup>73</sup> *Id.* at 15.

<sup>74</sup> *Id.* at 15-17.

<sup>75</sup> Petitioners included Center for Food Safety, Rural Coalition, Organización en California de Líderes Campesinas, Farmworker Association of Florida, and Beyond Pesticides.

EPA's failure to follow ESA consultation requirements before issuing the IRRD,<sup>76</sup> as well as EPA's deficient assessment of economic costs and environmental harms and the Agency's failure to assess the efficacy and feasibility of label instructions.<sup>77</sup> NRDC primarily challenged EPA's ecological risk assessment, cost benefit analysis, and risk mitigation requirements.<sup>78</sup> In response to Petitioners' opening briefs, rather than risk judicial review, EPA admitted the underlying decision needed to be reconsidered on several fronts and moved for voluntary remand of the portions of the IRRD related to glyphosate's ecological risks and the cost benefit analysis and failed to defend both issues on the merits as a result. Petitioners opposed the motion.

After completing briefing on the remaining issues and oral argument, the Court issued its decision on June 17, 2022. The Court focused heavily on Petitioners' challenge to EPA's conclusion that glyphosate poses no risks to human health, more specifically on Petitioners' challenge to EPA's evaluation of glyphosate's carcinogenic potential. The Ninth Circuit agreed with Petitioners, concluding OPP contravened the Cancer Guidelines it purported to follow and thus its reasoning and conclusion "that glyphosate is not likely to be carcinogenic to humans" was erroneous and not supported by substantial evidence.<sup>79</sup>

Moreover, the Court took great care to detail in factual findings exactly *how* OPP's conclusion "that glyphosate is not likely to be carcinogenic" was improper based on the evidence before OPP. To begin, the Court held the "not likely" descriptor conflicts with the earlier OPP conclusion that "the association between glyphosate exposure and risk of NHL cannot be determined based on available evidence."<sup>80</sup> The Court explained that "[a]ccording to EPA's Cancer Guidelines, [a not likely] hazard descriptor is appropriate when the agency determines that 'available data are considered robust for deciding that there is no basis for human hazard concern.' [OPP] therefore cannot reasonably treat its inability to reach a conclusion about NHL risk as consistent with a conclusion that glyphosate is "not likely" to cause cancer."<sup>81</sup>

The Court went on to assess and reject OPP's two main propositions in support of its "not likely" hazard descriptor.<sup>82</sup> First, OPP maintained that it did not consider any of the tumors observed in the fourteen animal carcinogenicity studies to be treatment related, more plainly it did not consider the tumors to have been caused by glyphosate.<sup>83</sup> However, the Court held that OPP's rationale for inferring that glyphosate did not cause rodent tumors was based on misapplication of at least two indicia— historical control data and pairwise statistical significance— issues also highlighted by ORD and the SAP. Historical control

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<sup>76</sup> Glyphosate IRRD Challenge, 38 F.4th at 44.

<sup>77</sup> Petitioner Rural Coalition Opening Br. 47-62, Glyphosate IRRD Challenge, 38 F.4th 34 (9th Cir. 2022).

<sup>78</sup> Glyphosate IRRD Challenge, 38 F.4th at 44.

<sup>79</sup> *Id.* at 45.

<sup>80</sup> *Id.* at 46.

<sup>81</sup> *Id.* at 46-47.

<sup>82</sup> *Id.* at 47-51.

<sup>83</sup> *Id.*

data refer to tumor data from untreated (control) animals in other feeding trials that show the natural frequency of different tumor types in an animal strain. Such data can either strengthen the case that tumors observed in a particular bioassay were caused by the treatment (here, glyphosate), or they can suggest the tumors arose by chance.<sup>84</sup>

As the Court explained, rather than using historical control data to either bolster or weaken the glyphosate-tumor link, as prescribed by EPA's Cancer Guidelines, OPP only used it to discount studies indicating that glyphosate caused the tumors, an improper and biased use of the data.<sup>85</sup> The second indicium involves two statistical tests to decide whether tumors observed in animals were caused by the treatment (of glyphosate) or arose by chance.<sup>86</sup> The pairwise test evaluates whether tumor incidence in a treatment group is higher than in the control group, while the trend test asks whether tumor incidence increases as the glyphosate dose increases. As the Court found, even though EPA's Cancer Guidelines provide that "[s]ignificance in *either* kind of test is sufficient to reject the hypothesis that chance accounts for the result," OPP improperly discounted tumors that lacked pairwise significance but that *did* exhibit a statistically significant trend. In so doing, OPP rejected clear evidence that glyphosate caused rodent tumors in violations of its Cancer Guidelines, as noted also by the SAP and ORD.<sup>87</sup>

Second, OPP supported its "not likely" hazard descriptor with the contention that tumors that "some believe" are caused by glyphosate occurred only at very high glyphosate dosage rates.<sup>88</sup> The Court was quick to point out how once again, this argument violated EPA's own Cancer Guidelines. The Court explained that disregarding tumors occurring at high dosages in animals is only appropriate when the chemical's mode of action is understood well enough to definitively conclude that tumor development would not occur at doses below a given high dose level. Despite this clear edict, OPP discounted high-dose tumors without providing any such mode of action explanation for glyphosate.<sup>89</sup>

The Court further found that EPA's attempt to discount animal tumors because they occurred at doses exceeding human exposure levels was not only inappropriate, but directly contrary to the purpose of a hazard assessment, as defined by its Cancer Guidelines, which is to determine whether the substance has the potential to cause cancer. Only when a cancer hazard is identified does EPA go on to consider "the conditions of human exposure," including human exposure levels, in a full cancer risk assessment, which the Agency did not carry out.<sup>90</sup>

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<sup>84</sup> *Id.* at 47.

<sup>85</sup> *Id.* at 48.

<sup>86</sup> *Id.* at 48.

<sup>87</sup> *Id.* at 48-49.

<sup>88</sup> Some SAP members did not accept this contention, pointing to several studies in which tumors consistent with carcinogenic potential occurred at lower doses. See FIFRA SAP, *supra* note 57, at 88.

<sup>89</sup> Glyphosate IRRD Challenge, 38 F.4th at 49-50.

<sup>90</sup> *Id.* at 50; see also CFS Comments to FIFRA SAP 2016, *supra* note 60, at 27-28.

As to remedy, in light of these “serious” violations of law, the Court concluded that setting aside, or vacatur, of the human health portion of the IRRD was warranted.<sup>91</sup> Due to the vacatur and remand, the Court did not reach Petitioners’ allegations of further errors in the human health assessment.

The Court went on to evaluate Petitioners’ claim that EPA failed to complete the required ESA consultation before issuing the IRRD, ultimately agreeing with Petitioners and concluding EPA also violated the ESA in failing to complete consultation prior to issuing the IRRD.<sup>92</sup> The Court adopted as a deadline for formal consultation that which Congress has already imposed: a October 2022 deadline to complete registration review for pesticides registered before 2007.<sup>93</sup> The Court declined to vacate the IRRD’s ESA portion on the basis of the ESA violation, reasoning that doing so would remove the few mitigation measures EPA had put in place via the IRRD to limit the ecological impacts of glyphosate use.<sup>94</sup>

Finally, the Court addressed NRDC’s challenges to the IRRD’s ecological risk assessment, cost-benefit analysis, and mitigation requirements, and EPA’s request for a voluntary remand. As noted above, EPA failed entirely to respond to the arguments explaining why the ecological portion of the IRRD was unlawful in its briefing. “[F]or practical reasons,” the Court opted to grant EPA’s motion to remand.<sup>95</sup> The Court reasoned that because EPA chose not to respond to the challenges to the ecological portion, further briefing and oral argument would be necessary to evaluate the merits of the claim, something that may not be feasible before the October 2022 deadline for registration review, a deadline that would be applicable to the remanded ecological portion.<sup>96</sup> Thus, the Court instead made plain that while the ecological portion is remanded to EPA, any revised ecological portion must be issued by the October 2022 registration review deadline.<sup>97</sup>

### 3. Withdrawal of Interim Decision

While the Ninth Circuit granted EPA’s request for a voluntary remand of the ecological portion, as is noted above, it imposed an October 1, 2022 deadline on EPA to issue a new ecological risk assessment, the same deadline Congress had initially set for EPA’s

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<sup>91</sup> Glyphosate IRRD Challenge, 38 F.4th at 51-52.

<sup>92</sup> *Id.* at 59.

<sup>93</sup> *Id.*

<sup>94</sup> *Id.* 59-60.

<sup>95</sup> *Id.* at 61.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 61-62.

completion of registration review for pesticides registered before 2007.<sup>98</sup> EPA sought relief from this deadline but was denied by the court in August of 2022.<sup>99</sup>

Rather than comply with the Court's deadline, in September of 2022, EPA instead withdrew what remained of the IRRD, that is what the Court had not already vacated, justifying its decision on the basis of being unable to finalize a new ecological portion correcting for past deficiencies and complete formal consultation before the October 1, 2022 deadline.<sup>100</sup> Thus, as of September 2022 the entirety of the IRRD was either struck down by the Court (the human health determination) or withdrawn by EPA (ecological portion). In any event, it is null and void.

#### 4. The Deficiencies of the IRRD

With the human health assessment of the 2020 IRRD vacated and the remainder of the IRRD withdrawn, EPA has no legal basis whatsoever to support the necessary EPA finding that glyphosate imposes no unreasonable adverse effects on man or the environment. Hence, the continued registration of glyphosate is illegal.

Given the lack of any currently legal risk assessments for glyphosate, Petitioners find the flaws present in the now-withdrawn IRRD instructive in illustrating just how far EPA is from demonstrating that glyphosate, as it is currently used, can meet the no unreasonable adverse effects standard.

##### a. *Human Health Assessment*

##### *EPA Cannot Continue to Claim Glyphosate Does Not Cause Cancer*

Regarding the human health assessment, as the Ninth Circuit made plain, the cancer hazard evaluation by EPA's OPP was fatally flawed. Despite NHL being the most well recognized form of cancer associated with glyphosate use, and OPP admitting it cannot support a conclusion that glyphosate is "not likely" to cause NHL, OPP still concluded that overall glyphosate is "not likely" to cause cancer. Put differently, OPP admitted that it

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<sup>98</sup> This deadline was recently extended until October 1, 2026, in a congressional rider. See FY 2023 Budget, H.R. 2617, 117<sup>th</sup> Cong., Title VI, Subtitle B, Section 711, pgs. 4145-46, <https://www.appropriations.senate.gov/imo/media/doc/JRQ121922.PDF> This same congressional rider provided that ESA consultation is not required in interim registration reviews, only measures to reduce the effects of the applicable pesticide on listed species and critical habitats. That said, the fact that Congress moved the deadline for that specific registration review action does not negate EPA's general duty to ensure all pesticides and pesticide products, like glyphosate and glyphosate-based products, have no unreasonable adverse effects on the environment or more generally to ensure that pesticides comply with both FIFRA and the ESA; these duties are ongoing.

<sup>99</sup> *Glyphosate*, ENV'T PROT. AGENCY, <https://www.epa.gov/ingredients-used-pesticide-products/glyphosate#:~:text=No%20risks%20of%20concern%20to%20human%20health%20from%20current%20uses,are%20more%20sensitive%20to%20glyphosate> (last visited May 9, 2023).

<sup>100</sup> *Id.*; EPA, WITHDRAWAL OF GLYPHOSATE INTERIM REGISTRATION REVIEW DECISION (Sept. 22, 2022), <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-14447>.



excluded the *most important cancer* linked to glyphosate in its overall cancer conclusion. As the Court instructed, doing so is nonsensical and improper, because the “not likely” descriptor requires “robust” data showing “there is *no basis* for human hazard concern.”<sup>101</sup>

OPP was unable to conclude glyphosate does not cause NHL because so much evidence demonstrates that it does. The World Health Organization’s IARC identified epidemiology studies of farmers in Canada, the U.S., and Sweden that all reported increased risks of NHL associated with glyphosate exposure.<sup>102</sup> The EPA’s Office of Research and Development (ORD) found that six of seven epidemiology studies it reviewed “reported at least some increased risk of NHL associated with exposure to glyphosate,”<sup>103</sup> and that *epidemiology studies alone ruled out OPP’s “not likely” designation.*<sup>104</sup> OPP focused heavily on one epidemiology study that did not find the glyphosate-NHL link, finding fault with the ones that did in an assessment that the Scientific Advisory Panel (SAP) found to be “highly imbalanced,”<sup>105</sup> and riddled with “incorrect or misleading statements.”<sup>106</sup> Significantly, three meta-analyses – studies that aggregate and analyze the results of individual studies – all demonstrated that glyphosate exposure increased the risk of contracting NHL by 30-50%, even *with* inclusion of OPP’s preferred study that did not find a link.<sup>107</sup> When OPP mistakenly attacked these meta-analysis results as lacking statistical significance, the SAP stepped in to correct the Agency’s error, showing they were in fact statistically significant.<sup>108</sup>

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<sup>101</sup> EPA Cancer Guidelines, *supra* note 51, at 2-57 (emphasis added).

<sup>102</sup> IARC Monographs, *supra* note 42, at 395.

<sup>103</sup> 2016 ORD Evaluation of Epidemiological Studies, at 1.

<sup>104</sup> ORD Emails on Proper Carcinogenicity Descriptor for Glyphosate, *supra* note 52.

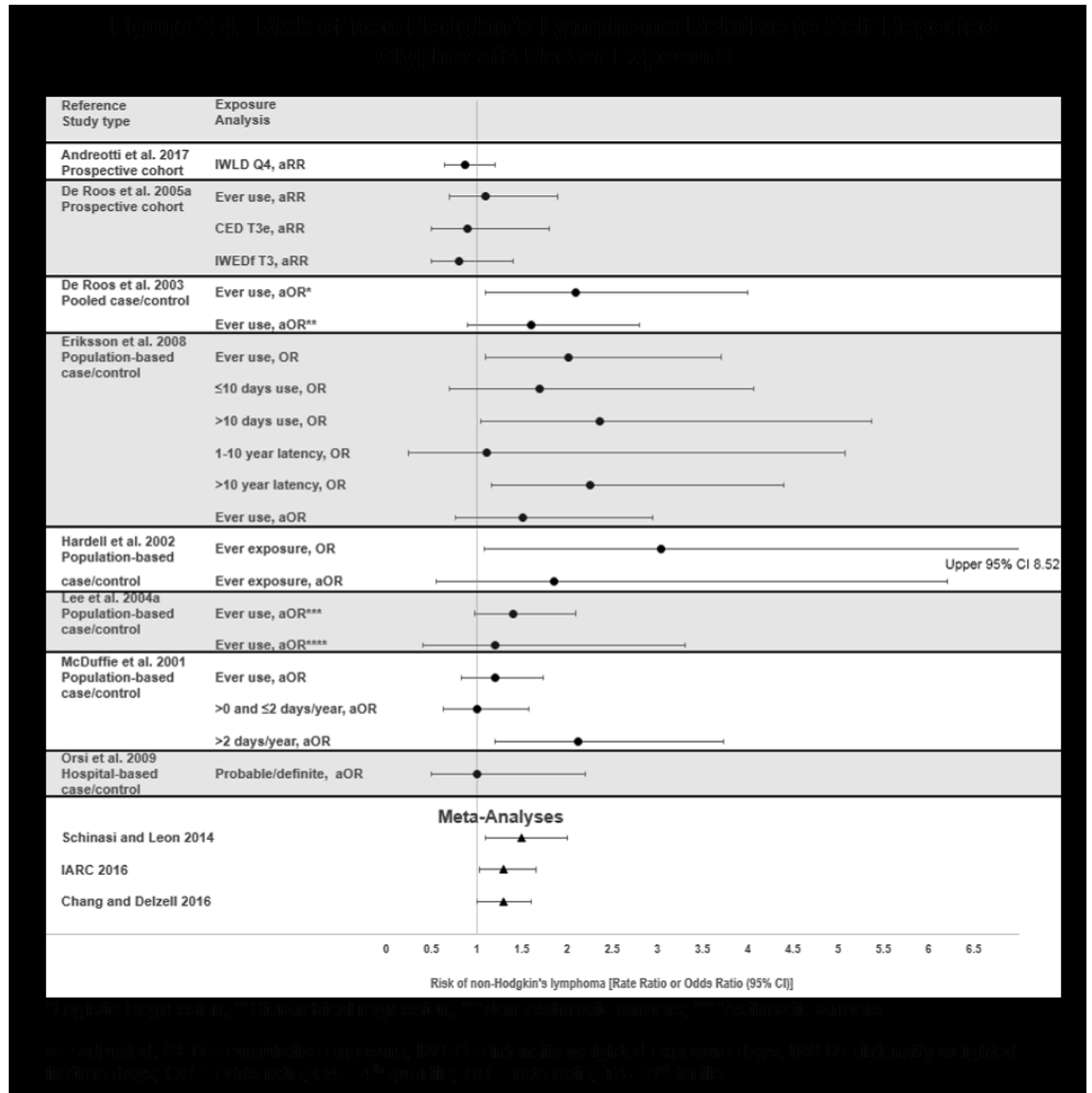
<sup>105</sup> FIFRA SAP, *supra* note 57, at 46.

<sup>106</sup> *Id.* at 39, 83.

<sup>107</sup> *Id.* at 44; see also *id.* at 45 (showing meta-analysis results, including OPP’s preferred De Roos et al. 2005 study).

<sup>108</sup> *Id.* at 43.

**Figure 2: Risk of non-Hodgkin’s Lymphoma Relative to Self-Reported Glyphosate Use or Exposure<sup>109</sup>**



<sup>109</sup> TOXICOLOGICAL PROFILE FOR GLYPHOSATE, *supra* note 48. Points to right of vertical line represent increased NHL risk.

The SAP noted that meta-analysis is the “best tool” to assess the epidemiology, particularly “to resolve uncertainty when reports disagree.”<sup>110</sup> In a 2016 evaluation of epidemiological studies, ORD concluded that the “weight of evidence is suggestive of carcinogenicity” and a “concern for potential carcinogenic effects in humans is raised.”<sup>111</sup> When ORD scientists evaluated both the human epidemiology and the animal studies, they favored an overall classification of either “likely to be carcinogenic” or “suggestive evidence of carcinogenicity.”<sup>112</sup>

In addition to animal studies and human epidemiology – the two main sources of evidence to assess carcinogenicity – scientists also consider cellular changes. Numerous studies show that glyphosate and its formulations are genotoxic (damage DNA) and exert oxidative stress, two pathways to cancer. For instance, those exposed to aerial spraying of glyphosate formulations have experienced chromosomal damage<sup>113</sup> and DNA strand breaks.<sup>114</sup> Glyphosate is similarly genotoxic in human<sup>115</sup> and animal lymphocytes,<sup>116</sup> in the bone marrow of rodents,<sup>117</sup> and overall in the majority of genotoxicity assays conducted by independent scientists.<sup>118</sup>

Finally, EPA failed to assess a glyphosate contaminant, N-nitrosoglyphosate, for carcinogenicity, despite the fact that it belongs to a carcinogenic class of compounds (nitrosamines), and is present in some glyphosate formulations at a concentration (1 part per million or greater) that according to EPA policy demands assessment for carcinogenicity.<sup>119</sup>

### Failure to Assess Aggregate Exposure

Even though OPP could not conclude that glyphosate exposure does not lead to NHL, and many medical scientists believe it does,<sup>120</sup> OPP failed to assess how progressively higher levels of exposure to glyphosate impact cancer risk.

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<sup>110</sup> FIFRA SAP, *supra* note 57, at 44.

<sup>111</sup> 2016 ORD Evaluation of Epidemiological Studies, *supra* note 103, at 9 (emphases added). Can also be found at: Lerner, *The Department of Yes: How Pesticide Companies Corrupted the EPA and Poisoned America*, THE INTERCEPT (June 30, 2021), <https://theintercept.com/2021/06/30/epa-pesticides-exposure-opp/>.

<sup>112</sup> ORD Emails on Proper Carcinogenicity Descriptor for Glyphosate, *supra* note 52.

<sup>113</sup> See generally C. Bolognesi et al., *Biomonitoring of genotoxic risk in agricultural workers from five Colombian regions: association to occupational exposure to glyphosate*, 72 J. OF TOXICOLOGY & ENV'T HEALTH 986, 986-97 (2009).

<sup>114</sup> See generally C. Paz-Y-Miño et al., *Evaluation of DNA damage in an Ecuadorian population exposed to glyphosate*, 30 GENETICS & MOLECULAR BIOLOGY 456, 456-60 (2007).

<sup>115</sup> IARC Monographs, *supra* note 42, at 366, 369-370 (Table 4.2).

<sup>116</sup> *Id.* at 368, 375 (Table 4.4).

<sup>117</sup> *Id.* at 366, 368, 372-74 (Table 4.3).

<sup>118</sup> See generally C. Benbrook, *How did the US EPA and IARC reach diametrically opposed conclusions on the genotoxicity of glyphosate-based herbicides*, 31 ENV'T SCI EUR 1, 1-16 (2019).

<sup>119</sup> CFS Proposed IRRD Comments 2019, *supra* note 4, at 26.

<sup>120</sup> 94 scientists jointly author a published article supporting IARC's “probably carcinogenic” determination for glyphosate. See Portier, *supra* note 43, at 741, 743.

Glyphosate enters our bodies via residues in food and water (dietary), skin contact (dermal) and inhalation. Farmers, groundskeepers, farmworkers serving as pesticide applicators or who encounter glyphosate spray drift or residue in the course of their work, and others who spray glyphosate formulations occupationally or at their homes and rural properties have higher exposure than others, and it occurs primarily through dermal contact.<sup>121</sup> Farmworkers and their families also face “take home” exposure, via the residues present on their clothes, tools, and person, another primarily dermal contact. Farmworkers also frequently live on or near the agricultural fields where pesticides are sprayed. Yet in the half-century since glyphosate was first registered, EPA has failed to require submission of a “dermal penetration” study to determine what portion of glyphosate contacting the skin is absorbed into the bloodstream,<sup>122</sup> where it can exert its toxic effects, including cancerous changes, throughout the body. Studies tracking the distribution of glyphosate administered to laboratory animals show that it spreads to the bone and bone marrow, the latter being one tissue where non-Hodgkin lymphoma can originate.<sup>123</sup> OPP failed to factor this into its cancer hazard assessment, despite the fact that the Agency’s own Cancer Guidelines explain that such distribution studies can “provide valuable insights into the likelihood of human cancer risk.”<sup>124</sup>

Lacking a dermal penetration study, EPA relied upon generic pesticide absorption data developed by a consortium of pesticide companies to estimate that a farmworker mixing or loading glyphosate would dermally absorb up to 7 milligrams of glyphosate per kilogram of body weight per day (mg/kg/day).<sup>125</sup> EPA assures us this exposure level is safe for humans because it is “well below the doses necessary to elicit the effects [tumors] seen in these animal carcinogenicity ... studies,” which EPA assumes occur only at doses of 1,000 mg/kg bw/day and above.<sup>126</sup>

This fails on two grounds. First, tumors in some animal studies occurred at far lower doses.<sup>127</sup> Second, EPA entirely failed to quantify the risk of cancer from glyphosate, which is done by calculating a cancer potency or slope factor based on animal tumor data, and applying it to an estimated human exposure level, with the result expressed as number of

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<sup>121</sup> TOXICOLOGICAL PROFILE FOR GLYPHOSATE, *supra* note 48, at 159.

<sup>122</sup> EPA, GLYPHOSATE DRAFT HUMAN HEALTH RISK ASSESSMENT FOR REGISTRATION REVIEW 12 (Dec. 12, 2017), <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0068> (“A dermal absorption study is not available in the toxicity database”) [hereinafter DRAFT HUMAN HEALTH RISK ASSESSMENT]; *id.* at 29 (“dermal penetration” study not submitted).

<sup>123</sup> CFS Proposed IRRD Comments 2019, *supra* note 4, at 24-25; Brewster et al., *Metabolism of Glyphosate in Sprague-Dawley Rats: Tissue Distribution, Identification, and Quantitation of Glyphosate-Derived Materials following a Single Oral Dose*, 17 FUNDAMENTALS & APPLIED TOXICOLOGY 43, 47 (1991); R. Pfeil & L. Niemann, FED. INSTIT. FOR RISK ASSESS., *Glyphosate*, JMPR 95, 96-103 (2004).

<sup>124</sup> EPA OPP Cancer 2017, *supra* note 62, at 93; see also EPA Cancer Guidelines, *supra* note 51, at 2-25.

<sup>125</sup> EPA OPP Cancer 2017, *supra* note 62, at 18, inclusive fts. 8, 9.

<sup>126</sup> *Id.* at 143.

<sup>127</sup> FIFRA SAP, *supra* note 57, at 74.

additional cancers per one million people so exposed.<sup>128</sup> California authorities calculated a cancer slope factor for glyphosate,<sup>129</sup> permitting estimation of the cancer risk posed by glyphosate at any given exposure level.<sup>130</sup> In contrast, OPP's statement that human exposure to glyphosate is "well below" a tumor-causing dose in rodents says nothing about human cancer risk, and violates EPA's duty under FIFRA to protect human health.

EPA also failed to assess how much glyphosate we inhale in the form of aerosols, droplets or glyphosate-laden dust particles, despite abundant evidence of its presence in the ambient air,<sup>131</sup> the greater amounts inhaled by workers,<sup>132</sup> and studies demonstrating that glyphosate adheres to ultrafine dust particles that blow long distances in the wind and are tiny enough to infiltrate deep into lung tissue.<sup>133</sup> OPP's justification for not assessing inhalational exposure is glyphosate's apparent lack of short-term toxicity in a 1983 rat study,<sup>134</sup> a study, however, that according to EPA Test Guidelines "is not capable of determining those effects that have a long latency period for development (e.g. carcinogenicity and life shortening)..."<sup>135</sup>

EPA's failure to assess aggregate exposure to glyphosate via all relevant routes – dietary, dermal and inhalational – and the risks such exposure entails, invalidates its human health assessment, especially as it pertains to more highly exposed occupational users, including farmers, landscapers, farmworkers, nursery attendants, as well as residential users of glyphosate. And exposure levels are critical not only to assessing glyphosate's carcinogenic impact, but its other health harms as well (discussed below).

### *b. Ecological Risk Assessment*

Like its treatment of human health, EPA's ecological risk assessment is deeply flawed. Well-documented risks are discounted; identified risks are not effectively mitigated; and

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<sup>128</sup> ENV'T PROT. AGENCY, AVAILABLE INFORMATION ON ASSESSING EXPOSURE FROM PESTICIDES IN FOOD: A USER'S GUIDE 8, 16 (June 21, 2000), <https://www.regulations.gov/document/EPA-HQ-OPP-2007-0780-0001>.

<sup>129</sup> *Initial Statement of Reasons for Glyphosate: Proposition 65 Safe Harbors*, OFFICE OF ENV'T HEALTH HAZARD ASSESS., CALIFORNIA ENV'T PROT. AGENCY (March 28, 2017), <https://oehha.ca.gov/media/downloads/proposition-65/chemicals/glyphosate032917isor.pdf>.

<sup>130</sup> Gly Prop 65 Comments, *supra* note 45.

<sup>131</sup> See generally F-C Chang et al., *Occurrence and fate of the herbicide glyphosate and its degradate aminomethylphosphonic acid in the atmosphere*, 30 ENV'T TOXICOLOGY & CHEMISTRY 548 (2011).

<sup>132</sup> A. Jauhiainen et al., *Occupational exposure of forest workers to glyphosate during brush saw spraying work*, 52 AM. INDUS. HYGIENE ASS'N J. 61, 61-64 (1991), <https://www.ncbi.nlm.nih.gov/pubmed/2011980>.

<sup>133</sup> C. Bento et al., *Glyphosate and AMPA distribution in wind-eroded sediment derived from loess soil*, 220 ENV'T. POLLUTION 1079-1089 (Jan. 2017), [https://www.researchgate.net/publication/310749189\\_Glyphosate\\_and\\_AMPA\\_distribution\\_in\\_wind-eroded\\_sediment\\_derived\\_from\\_loess\\_soil](https://www.researchgate.net/publication/310749189_Glyphosate_and_AMPA_distribution_in_wind-eroded_sediment_derived_from_loess_soil).

<sup>134</sup> DRAFT HUMAN HEALTH RISK ASSESSMENT, *supra* note 122, at 8, 30 (see study listed under Guideline No. 870.3465 in Table B.3).

<sup>135</sup> EPA (1998b). Health Effects Test Guidelines: OPPTS 870.3465 – 90-Day Inhalation Toxicity. EPA 712-C-98-204. August 1998, p. 1.

despite the 14 years that have passed since registration review began in 2009, the three decades since glyphosate was reregistered (1993), and the half-century since the original registration, EPA *still has significant data gaps* regarding the ecological impacts of glyphosate.

Although voluminous research shows that glyphosate formulations kill water-living amphibians (e.g. tadpoles) and other aquatic organisms at environmentally relevant levels,<sup>136</sup> *infra*, the Agency concluded there was little or no risk.<sup>137</sup> And while EPA did conclude that consuming glyphosate-treated foliage could adversely impact mammals and birds,<sup>138</sup> the Agency failed to prescribe any mitigations to reduce these risks, beyond ineffectual changes to label language on spray drift management.<sup>139</sup> Glyphosate spray drift clearly endangers terrestrial plants, and by EPA's own reckoning requires in-field buffer zones<sup>140</sup> ranging from 52 to 253 feet for ground applications, and 190 to over 1,000 feet for aerial applications, depending on the amount applied.<sup>141</sup>

Yet despite signaling the need for buffers, EPA ended by establishing none at all.<sup>142</sup> EPA has admitted that there may be direct impacts to honey bees and other pollinators from higher application rates (for which it lacks toxicity data), and indirect impacts via spray drift killing off wild flowering plants that provide them with critical nectar resources and habitat.<sup>143</sup> Despite this acknowledged risk, EPA has collected no toxicity data for honey bee larvae.<sup>144</sup> And 14 years after registration review was initiated, EPA has still *not even decided* what additional data are needed to evaluate risks to bees.<sup>145</sup> Rather than acquire these data, EPA finalized the IRRD with a toothless warning on glyphosate labels that it hoped would "alert users" of impacts to non-target organisms, including pollinators.<sup>146</sup>

Similarly, EPA admits in the IRRD that there are "risk[s] to [ESA-]listed species whose range and/or critical habitat co-occur with the use of glyphosate,"<sup>147</sup> something definitively confirmed by the BE completed after the IRRD was finalized.<sup>148</sup> In fact, the Fish and Wildlife Service recently determined that one species greatly impacted by glyphosate

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<sup>136</sup> See CFS Risk Assessment Comments 2018, *supra* note 8, at 7-11.

<sup>137</sup> EPA OPP, REGISTRATION REVIEW – PRELIMINARY ECOLOGICAL RISK ASSESSMENT OF GLYPHOSATE AND ITS SALTS 2, 6 (Sept. 8, 2015), Docket: EPA-HQ-OPP-2009-0361-0077 [hereinafter EPA OPP Ecological 2015]

<sup>138</sup> *Id.* at 2, 6.

<sup>139</sup> FINAL IRRD, *supra* note 40, at 15-17, 22.

<sup>140</sup> An in-field buffer zone is a no-spray zone extending from the last row sprayed to the downwind edge of the crop field, to confine non-target plant damage to farmland.

<sup>141</sup> Proposed IRRD, *supra* note 68, at 28-29, Table 3.

<sup>142</sup> FINAL IRRD, *supra* note 40, at 15-17, 22.

<sup>143</sup> *Id.* at 12, 17.

<sup>144</sup> EPA OPP Ecological 2015, *supra* note 137, at 54.

<sup>145</sup> FINAL IRRD, *supra* note 40, at 12-13.

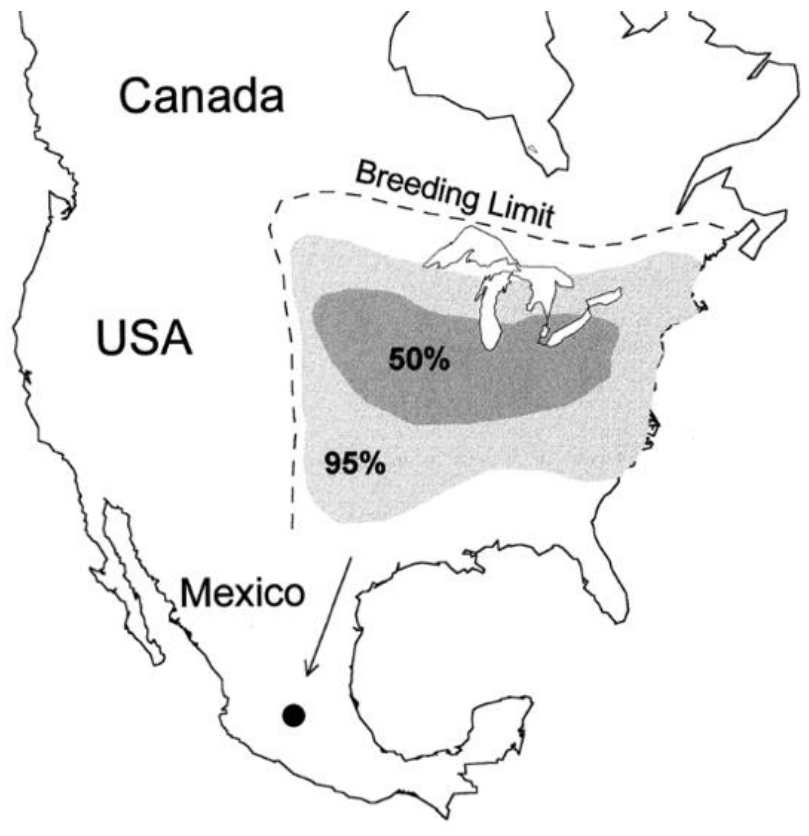
<sup>146</sup> *Id.* at 17.

<sup>147</sup> *Id.* at 15.

<sup>148</sup> See BE Executive Summary, *supra* note 1, at 4-5.

– the monarch butterfly – merits listing as threatened or endangered under the ESA.<sup>149</sup> Scientists know that vastly increased use of glyphosate is a major factor in the over 80% decline in the eastern monarch population,<sup>150</sup> which migrates to Mexico each year, over the past quarter century.<sup>151</sup> This is because intensive glyphosate use has nearly eradicated common milkweed, the monarch’s critical food source, from corn and soybean fields of its Midwest breeding grounds, the epicenter of monarch breeding (see graphs).<sup>152</sup>

**Figure 3: Natal origins of monarch butterflies overwintering in Mexico.**<sup>153</sup>



<sup>149</sup> U.S. Fish & Wildlife Service, *Endangered and threatened wildlife and plants; 12-month finding for the monarch butterfly*, Fed. Reg. 85: 81813-81822 (December 17, 2020). While listing has been found warranted it has not yet occurred as of the timing of this filing due to agency budgetary constraints and consequent backlog of species in line for listing.

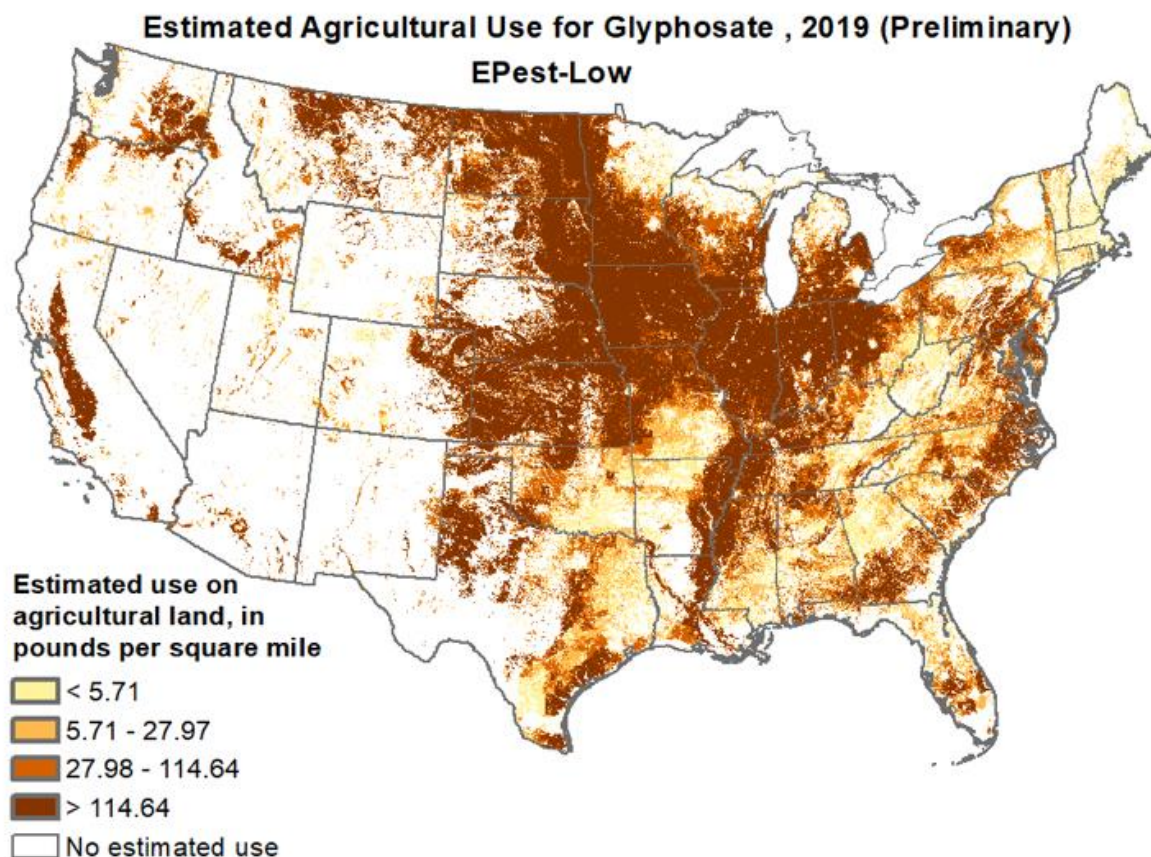
<sup>150</sup> See generally Pleasants & Oberhauser, *supra* note 9.

<sup>151</sup> WE Thogmartin et al, *Monarch butterfly population decline in North America: identifying the threatening processes* 4 R. Soc Open Sci 170760 (2017), <https://doi.org/10.1098/rsos.170760>.

<sup>152</sup> J. Pleasants, *Monarch butterflies and agriculture*. In Oberhauser KS, Nail KR, Altizer SM, eds. *Monarchs in a Changing World: Biology and Conservation of an Iconic Insect*. Ithaca, USA: Cornell University Press (2015).

<sup>153</sup> LI Wassenaar & KA Hobson, *Natal origins of migratory monarch butterflies at wintering colonies in Mexico: new isotopic evidence*, 95 U.S. Proceedings of the National Academy of Sciences 15436, 15436-439 (1998).

Figure 4: Estimated agricultural use of glyphosate in 2019 (pounds/sq. mile).<sup>154</sup>



Despite the well-recognized impact of glyphosate on monarchs, EPA’s assessment entirely fails to address how glyphosate kills mature common milkweed plants at the root, preventing regrowth; nor does EPA acknowledge that glyphosate and other herbicides used as part of herbicide-resistant crop systems are particularly effective at killing milkweed.<sup>155</sup> Instead, the Agency only assesses the effects of glyphosate spray drift on the “vegetative vigor” (growth) of young milkweed plants that have sprouted from seed. And even here, EPA picks the less sensitive of two toxicity thresholds, minimizing the effects of glyphosate drift on stunting the growth of young milkweed plants.<sup>156</sup> While EPA ecological scientists acknowledge the need for “conservation of milkweed to preserve monarch butterfly populations,”<sup>157</sup> EPA does nothing concrete to this end, such as restricting agricultural use of glyphosate where milkweed is present, or removing common milkweed as a target weed from glyphosate labels. Instead, EPA has included ineffectual

<sup>154</sup> U.S. GEOLOGICAL SURVEY, *supra* note 3.

<sup>155</sup> Center for Food Safety and Center for Biological Diversity, Comments to the EPA on “Risk Management Approach to Identifying Options for Protecting the Monarch Butterfly” 4-11 (August 24, 2015), <https://www.regulations.gov/comment/EPA-HQ-OPP-2015-0389-0097>.

<sup>156</sup> CFS Risk Assessment Comments 2018, *supra* note 8, at 11-13.

<sup>157</sup> EPA OPP Ecological 2015, *supra* note 137, at 93.



“environmental hazards language” on glyphosate labels that merely asks farmers to follow label directions regarding spray drift, but does not even mention monarchs or milkweed.

Additionally, EPA relied almost entirely on minor changes to language on glyphosate labels as a means to reduce its many ecological harms,<sup>158</sup> yet it failed to provide any demonstration that these proposed mitigation measures would actually mitigate identified risks if followed, or that it is feasible for farmers to consistently follow them in the real world. In any case, as EPA acknowledged in litigation and upon withdrawal of the IRRD, these label amendments were never put into place.

### c. Real World Formulations

Further, EPA’s risk assessments largely fail to consider studies on the glyphosate formulations that are used in the real world, but instead relied primarily upon data specific to the active ingredient—glyphosate technical. This is particularly true of the human health<sup>159</sup> and cancer assessments,<sup>160</sup> for which EPA eschewed formulation studies altogether.<sup>161</sup> That EPA relied so heavily on glyphosate-only studies is troubling, given its admission that glyphosate formulations are more toxic than the active ingredient,<sup>162</sup> a fact long recognized by the scientific community.<sup>163</sup>

Glyphosate formulations contain undisclosed “inert” ingredients, such as surfactants, which increase the absorption of glyphosate by plant tissue as well as skin.<sup>164</sup> A Monsanto-commissioned dermal absorption study found a huge difference (1.3% to 10%)

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<sup>158</sup> Final IRRD, *supra* note 40, at 22: Appendix A, noting language regarding spray drift management and (non-target organism) environmental hazards.

<sup>159</sup> DRAFT HUMAN HEALTH RISK ASSESSMENT, *supra* note 122, at 9. “[T]his evaluation focuses on studies performed with the active ingredient glyphosate and not studies performed with pesticide formulations containing glyphosate.”

<sup>160</sup> EPA OPP Cancer 2017, *supra* note 62, at 19 (Despite the availability of formulation studies, EPA OPP seeks the SAP’s advice “on this [EPA OPP’s] evaluation of human carcinogenic potential for the active ingredient glyphosate only...”); *id.* at 70 (EPA rejects rat feeding study because it was conducted “with a glyphosate formulated product and not the active ingredient glyphosate”); *id.* at 99 (“[T]he focus of this section is the genotoxic potential of glyphosate technical.”).

<sup>161</sup> The only exception is epidemiological cancer studies on farmers/applicators, which EPA considered only “in the absence of epidemiological data on the active ingredient alone” – data that are absent because in the real world, glyphosate is always used as part of formulations. EPA Response to Comments on HHRA, *supra* note 67, at 2.

<sup>162</sup> EPA, HEALTH EFFECTS DIVISION, *Glyphosate: Tier II Incident Report*, at 7-11 (Feb. 6, 2014), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-0069> [hereinafter EPA Tier II 2014] (noting “severe dermal effects” from exposure to glyphosate formulations, despite “low dermal toxicity” of glyphosate alone). See also EPA OPP Cancer 2017, *supra* note 62, at 137.

<sup>163</sup> In tests conducted on 9 glyphosate formulations and glyphosate alone “all formulations are more toxic than glyphosate.” See R Mesnage, B Bernay, & GE Seralini, *Ethoxylated adjuvants of glyphosate-based herbicides are active principles of human cell toxicity*, 313 *Toxicology* 122, 122-28 (2013) (cited by EPA Tier II 2014, *supra* note 162, at 5).

<sup>164</sup> C. Gustin, M. Martens, C. Bates, *Clustering glyphosate formulations with regard to the testing for dermal uptake. Monsanto Company* (July 2001), at p. MONGLY01839478.

in the glyphosate penetration rate of the two glyphosate formulations tested,<sup>165</sup> leading Monsanto officers to opine that: “[i]deally, all of the different glyphosate formulations would have to be tested for dermal uptake.”<sup>166</sup> Yet as of 2017, EPA did not have a single dermal absorption study for glyphosate or any of its formulations.<sup>167</sup> This also explains why Monsanto’s manager of Toxicology Programs, Donna Farmer, Ph.D., instructed colleagues that “you cannot say that Roundup is not a carcinogen ..... we have not done the necessary testing on the formulation to make that statement. The [sic] testing on the formulations are [sic] not anywhere near the level of the active ingredient.”<sup>168</sup>

Surfactants can also be toxic in their own right. EPA has some data on one class of surfactants used in many glyphosate formulations – polyethoxylated tallow amines (POEAs) – that are known to kill aquatic organisms;<sup>169</sup> be highly corrosive to skin and eyes, and have adverse reproductive effects at high internal doses;<sup>170</sup> and that, contrary to EPA’s assumption,<sup>171</sup> are persistent in soil and vulnerable to runoff.<sup>172</sup> Far less is known about the toxicity of non-POEA glyphosate formulations.<sup>173</sup> EPA was in the dark about this matter at the outset of registration review in 2009,<sup>174</sup> but failed to require testing it said was needed.<sup>175</sup> Instead, as late as 2016, EPA appealed informally to Monsanto to send what relevant information it might happen to have.<sup>176</sup>

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<sup>165</sup> In vitro percutaneous absorption study with [<sup>14</sup>C]glyphosate using viable rat skin membrane, TNO NUTRITION & FOOD RES. (June 14, 2002), at p. MONGLY00888355.

<sup>166</sup> C. Gustin et al., *supra* note 164, at p. MONGLY01839477.

<sup>167</sup> DRAFT HUMAN HEALTH RISK ASSESSMENT, *supra* note 122, at 12 (“A dermal absorption study is not available in the toxicity database.”).

<sup>168</sup> Donna R. Farmer to Sekhar Natarajan and other Monsanto colleagues, RE: Agitation against Roundup, email dated November 22, 2003.

<sup>169</sup> EPA OPP Ecological 2015, *supra* note 137, at 10.

<sup>170</sup> EPA, *Alkyl Amine Polyalkoxylates (JITF CST 4 inert ingredients). Human health risk assessment to support proposed exemption from the requirement of a tolerance when used as inert ingredients in pesticide formulations* (April 3, 2009), at 12, 53-54 (Table A.1) (see references to MON 0818).

<sup>171</sup> EPA OPP Ecological 2015, *supra* note 137, at 19, 27.

<sup>172</sup> CFS Risk Assessment Comments 2018, *supra* note 8, at 9-10 (citing D. Tush and MT Meyer, *Polyoxyethylene tallow amine, a glyphosate formulation adjuvant: soil adsorption characteristics, degradation profile, and occurrence on selected soils from agricultural fields in Iowa, Illinois, Indiana, Kansas, Mississippi, and Missouri*, 50 ENVIRONMENTAL SCIENCE & TECHNOLOGY 5781, 5781-89 (2016)).

<sup>173</sup> See generally CFS Proposed IRRD Comments 2019, *supra* note 5, at 10-12.

<sup>174</sup> *Registration Review – Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Glyphosate and its Salts*, ENV’T FATE & EFFECTS DIVISION, EPA (June 5, 2009); *id.* at 31 (Noting the toxicity of some non-POEA formulations and the paucity of studies on them: “For most formulations, we have no data” and the Agency’s ignorance: “There are many formulated products for glyphosate and the surfactants used in these products that [sic] must first be identified,”); *id.* at 32 (proposing to request toxicity testing of non-POEA surfactants).

<sup>175</sup> EPA, RESPONSE TO PUBLIC COMMENTS ON THE PRELIMINARY ECOLOGICAL RISK ASSESSMENT FOR GLYPHOSATE 3 (Nov. 21, 2018) [hereinafter EPA Response to Comments on PERA] (noting “limited toxicity data are available for other [non-POEA] surfactants, such as those that may be used in glyphosate formulations...”).

<sup>176</sup> EPA, *Glyphosate: 4/5/16 meeting between EPA and Monsanto – notes* (April 5, 2016) (EPA officer requests that Monsanto send EPA “information on the inert ingredients used in .... glyphosate formulations” from the 1980s to the present, and data Monsanto might have on the toxicity of glyphosate formulations “in an effort to resolve questions about the potential toxicity of glyphosate, glyphosate formulations and any co-formulants (inert ingredients and surfactants).”).

d. *Peer-reviewed Scientific Studies by Independent Scientists Rejected by EPA*

The human health and ecological risk assessments underlying EPA's interim registration review decision are based entirely on studies conducted or sponsored by glyphosate manufacturers (aka registrants), not on peer-reviewed studies by independent scientists. While EPA describes some independent studies in its assessments, they played no role in its formal, quantitative risk assessments.

In the case of human health, EPA identified 466 potentially relevant, peer-reviewed studies from about 2011 through 2015, but rejected all of them as "unacceptable" for use in risk assessment, with one major factor in the rejections being that the studies employed commercial glyphosate formulations rather than the pure active ingredient.<sup>177</sup>

With respect to glyphosate's ecological toxicity, EPA identified 1,880 peer-reviewed studies in its ECOTOX database,<sup>178</sup> but did not utilize a single one of them in its quantitative estimation of risk.<sup>179</sup> EPA's dismissal of quality independent peer reviewed studies on mostly spurious grounds in favor of registrant studies, where conflicts of interest present obvious motivations for bias and fraud, is unacceptable,<sup>180</sup> and leads the Agency to miss or downplay many of glyphosate's harmful effects.

e. *Costs*

Finally, EPA also failed to consider the costs posed by glyphosate in the 2020 IRRD, namely the environmental and economic costs. Widespread use of glyphosate has spawned an epidemic of glyphosate-resistant weeds, infesting an estimated 120 million acres of U.S. cropland,<sup>181</sup> the great majority of which have emerged in fields planted with glyphosate resistant (GR) crops, particularly GR soybeans, cotton, corn, and sugar beets. In a 2017 survey of 4,000 growers, 73% report glyphosate-resistant weeds in their fields.<sup>182</sup>

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<sup>177</sup> DRAFT HUMAN HEALTH RISK ASSESSMENT, *supra* note 122, at 10-11 (describing two literature searches conducted at different times that turned up 67 and 399 studies).

<sup>178</sup> For a description of ECOTOX, see <https://cfpub.epa.gov/ecotox/help.cfm?sub=so-site-info>.

<sup>179</sup> EPA, *Appendix G: Bibliography of Ecotox Papers*, <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0078> (listing 609 studies "acceptable for both ECOTOX and OPP [Office of Pesticide Programs]" and 1,271 studies "acceptable for ECOTOX but not OPP").

<sup>180</sup> JR Rohr & KA McCoy, *Preserving environmental health and scientific integrity: a practical guide to reducing conflicts of interest*, 3 Conservation Letters 143, 143-50 (2010).

<sup>181</sup> J. Pucci, *The war against weeds evolves in 2018*, CROPLIFE (March 20, 2018), <https://www.croplife.com/crop-inputs/the-war-against-weeds-evolves-in-2018/>.

<sup>182</sup> *Id.*

Farmers bear substantial additional costs to control these weeds, including increased expenditures on additional herbicides and increased use of soil-eroding tillage.<sup>183</sup>

In 2013, agronomists estimated that glyphosate-resistant weeds increased farmers' pesticide expenditures by six-fold in both Arkansas cotton (from \$50-\$75 to \$370 per hectare) and Illinois soybeans (\$25 to \$160 per hectare).<sup>184</sup> Georgia cotton growers saw their pesticide costs double by paying for additional pesticides to kill the rapidly spreading glyphosate resistant Palmer amaranth.<sup>185</sup> And even these additional expenditures were often insufficient to eradicate the resistant amaranth, requiring farmers to spend even more money on hand-weeding crews and increased tillage operations.<sup>186</sup>

The response to GR weeds is a major factor driving the 34% increase in agricultural herbicide use from just 2005 to 2012.<sup>187</sup> The unsustainable "fixes" are an expanding suite of new genetically engineered crops resistant to both glyphosate and one or more other toxic herbicide, such as dicamba, 2,4-D, glufosinate, and isoxaflutole. Monsanto's dicamba-resistant soybeans and cotton increased overall dicamba use on these crops to nearly 10 million lbs in 2018, an amount roughly 12-fold greater than was used, on average, from 2012 to 2016.<sup>188</sup> Because these crop systems were specifically introduced to control weeds resistant to glyphosate and other herbicides, the millions of acres of crops damaged because of dicamba drift<sup>189</sup> represent another significant cost of U.S. agriculture's glyphosate addiction.

These higher costs are borne not only by the farmers whose glyphosate use triggered the rapid evolution of resistant weeds, but also by other farmers. This is because once a glyphosate-resistant weed population has emerged, gene flow can spread the resistance to other weeds of the same species via cross-pollination, or to new areas via long distance travel of weed seeds bearing the glyphosate-resistance trait.<sup>190</sup>

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<sup>183</sup> *The economics of glyphosate resistance management in corn and soybean production*. ECONOMIC RESEARCH REPORT NO. 184, US DEPT. OF AGRIC. (April 2015), <https://www.ers.usda.gov/publications/pub-details/?pubid=45357>.

<sup>184</sup> CFS Proposed IRRD Comments 2019, *supra* note 4, at 35; Robert F. Service, *What Happens When Weed Killers Stop Killing* (Sept. 20, 2013), <http://www.justlabelit.org/wp-content/uploads/2013/10/Science-2013-What-Happens-1.pdf>.

<sup>185</sup> CFS Proposed IRRD Comments 2019, *supra* note 4, at 35-36; Service, *supra* note 184.

<sup>186</sup> CFS Proposed IRRD Comments 2019, *supra* note 4, at 35-36; Service, *supra* note 184.

<sup>187</sup> EPA, PESTICIDE INDUSTRY SALES AND USAGE: 2008-2012 MARKET ESTIMATES 12 (2017).

<sup>188</sup> EPA, *Over-the-top dicamba products for genetically modified cotton and soybeans: benefits and impacts* 5 (Nov. 1, 2018), EPA-HQ-OPP-2016-0187-0966.

<sup>189</sup> See *Nat'l Family Farm Coalition v. EPA* (NFFC II), 960 F.3d 1120 (9th Cir. 2020).

<sup>190</sup> See generally JT Dauer et al., *Effects of landscape composition on spread of an herbicide-resistant Weed*, 24 *LANDSCAPE ECOLOGY* 735, 735-47 (2009); see also HJ Beckie et al., *Herbicide resistance gene flow in weeds: under-estimated and underappreciated*, 283 *AGRIC. ECOSYSTEMS & ENV'T* 106566 (2019); TM Webster & LM Sosnoskie, *Loss of glyphosate efficacy: a changing weed spectrum in Georgia cotton*, 58 *WEED SCIENCE* 73, 73-79 (2010).

Neither has EPA accounted for the costs of glyphosate drift, despite acknowledging that glyphosate drifts at plant-damaging concentrations well beyond the edge of sprayed fields, and the existence of evidence showing it to be among the leading herbicides implicated in drift episodes.<sup>191</sup> Organic and pesticide-free conventional farmers often have to take costly measures to protect their crops from glyphosate drift.

### iii. *The Current State of the Registration*

With the 2020 IRRD null and void, glyphosate's continued registration relies solely on the 1993 RED.<sup>192</sup> In the three decades since, glyphosate use has increased more than 10-fold, driven by the introduction and broad adoption of the first genetically engineered crops. The bulk of spraying has shifted from planting time to late spring/early summer, spurring both herbicidal drift damage and an epidemic of glyphosate-resistant weeds on at least 120 million acres of farmland, far more extensive than any past resistant weed outbreak. Scores of scientific studies have uncovered unsuspected or suppressed risks to human health and the environment, including threats to 93% of threatened and endangered species. The passage of the 1996 Food Quality Protection Act has fundamentally altered pesticide policy and regulation. Since 1993, the number of glyphosate products registered has increased from 56 to 555, and the annual pounds used have increased from 19 million to 280, a more than 1000% increase in use.

Given these profound changes, the 1993 decision *cannot*—factually, legally, scientifically—justify the registration of glyphosate as it is used today. Not only was it made in ignorance of the extensive scientific literature on glyphosate's risks that has accumulated over the last three decades, it was also completed when exposure to glyphosate was a small fraction of what it is today.

While EPA states it is working on issuing a final registration review decision for glyphosate, in which it will act in accordance with the Ninth Circuit's decision,<sup>193</sup> until it issues such decision, glyphosate cannot be said to meet the FIFRA safety standard. And EPA has given no indication that it intends to issue such decision before its October 2026 deadline, a date still nearly three years out. Yet EPA is under a *continuous* duty to ensure all registered pesticides can meet the FIFRA safety standard, and the thirty-year-old 1993 IRRD does not come close to analyzing glyphosate in the context of its approved uses today or current science. Thus, no lawful EPA analysis exists demonstrating glyphosate can currently meet the required FIFRA safety standard.

Instead, the weight of the scientific evidence strongly supports glyphosate's unreasonable adverse effects on the environment. If EPA can eventually demonstrate glyphosate, as it is

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<sup>191</sup> See *generally* 1999 Pesticide Drift Enforcement Survey, ASSOCIATION OF AMERICAN PESTICIDE CONTROL OFFICIALS (Nov. 30, 1999); See *generally* 2005 Pesticide Drift Enforcement Survey, ASSOCIATION OF AMERICAN PESTICIDE CONTROL OFFICIALS (2005).

<sup>192</sup> 1993 RED, *supra* note 12.

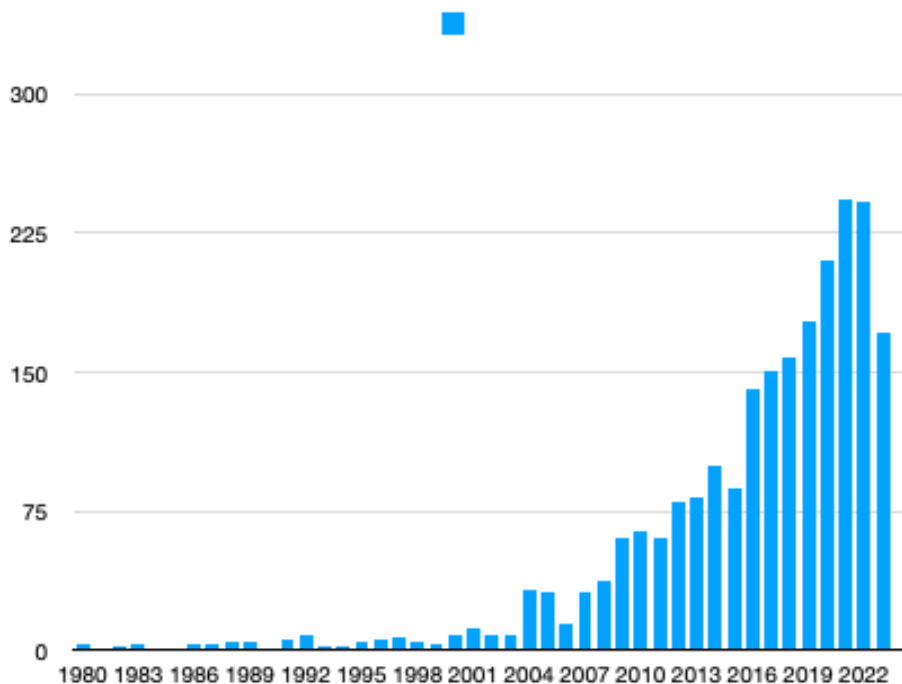
<sup>193</sup> *Glyphosate*, *supra* note 99.

currently registered, will cause no unreasonable adverse effects on the environment, re-registration of glyphosate would be warranted.<sup>194</sup> But for the time being, the continued registration of glyphosate is illegal. Before registering a pesticide and as an ongoing duty through the life of the registration, EPA must ensure it has no unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice, and EPA plainly has not done so for glyphosate as it is used today.

**d. The State of the Science**

For years now there has been mounting concern about the risks posed by glyphosate, for both humans and the environment, as demonstrated by the enormous and growing amount of scientific research into the herbicide’s toxicity, with a study appearing more than every other day, on average, since 2020 (see graph below). While innumerable EPA regulatory decisions have facilitated vastly broader and more intensive use of glyphosate, the weight of the scientific evidence can no longer allow such actions. Below, we briefly sketch the “state of the science” on glyphosate and its formulations.

**Figure 5: Scientific Publications on Toxicity of Glyphosate by Year<sup>195</sup>**



<sup>194</sup> EPA might determine that a lawful re-registration necessitates revocation of or additional restrictions on some but not all of glyphosate’s registered uses, however, Petitioners reiterate this seems unlikely given the weight of the evidence.

<sup>195</sup> Results of PubMed search on keywords *glyphosate toxicity* (without quotation marks) by year. Search conducted 9/26/23.

## **i. Human Health Risks**

The evidence demonstrating that glyphosate causes cancer has only grown stronger since the Ninth Circuit vacated OPP's human health risk assessment. Moreover, there has been substantial research into glyphosate's other harms, particularly damage to the liver, kidney and reproductive system. OPP once acknowledged glyphosate's toxicity to these organs/systems, but then buried the associated findings and dismissed the concerns.<sup>196</sup> Nevertheless, these harms have since been corroborated by independent scientists, who have explored other adverse effects as well.

Despite the wealth of evidence demonstrating glyphosate's toxicity, over the past four decades EPA has instead issued innumerable new glyphosate tolerances,<sup>197</sup> and raised pre-existing tolerances repeatedly, dramatically increasing dietary exposure to glyphosate in the American population, with infants and toddlers experiencing over twice the exposure of adults, on a body weight basis.<sup>198</sup> EPA has accommodated this increasing exposure by raising the safety threshold – the overall level of daily glyphosate intake regarded as safe over a lifetime – by 20-fold since the late 1970s.<sup>199</sup>

### **1. Cancer Risk**

Evidence of glyphosate's carcinogenicity continues to accumulate on all fronts. Two recent meta-analyses corroborate the findings of increased NHL risk in farmers. In one extremely large study, 2,430 cases of NHL diagnosed in over 300,000 farmers in the U.S., France, and Norway were pooled and analyzed, and glyphosate exposure was associated with a 36% greater risk of diffuse large B-cell lymphoma, the most common subtype of NHL.<sup>200</sup> Another meta-analysis analyzed those applicators who, in each of the six underlying epidemiology studies, had the highest cumulative exposure to glyphosate, finding a 41% increased risk of NHL in this more highly exposed group.<sup>201</sup> A comprehensive re-analysis of 13 rodent carcinogenicity bioassays concluded that they provided clear

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<sup>196</sup> CFS Proposed IRRD Comments 2019, *supra* note 4, at 12-14.

<sup>197</sup> A "tolerance" is the maximum level of a pesticide residue that is legally permitted on a particular food commodity, as established by EPA. For current glyphosate tolerances, see 40 CFR 180.364. *Glyphosate Tolerances*, <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-180/subpart-C/section-180.364>.

<sup>198</sup> CFS Proposed IRRD Comments 2019, *supra* note 4, at 15-17.

<sup>199</sup> *Id.* at 12-14.

<sup>200</sup> M.E. Leon et al., *Pesticide use and risk of non-Hodgkin lymphoid malignancies in agricultural cohorts from France, Norway and the USA: a pooled analysis from the AGRICOH consortium*, 48 INT'L J. OF EPIDEMIOLOGY 1519, 1519-35 (2019).

<sup>201</sup> L. Zhang, I. Rana, E. Taioli, R.M. Schaffer, L. Sheppard, *Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence*, 781 MUTATION RESEARCH 186, 186-206 (2019).

evidence glyphosate caused malignant lymphomas, hemangiosarcomas, kidney tumors and liver tumors, as well as carcinomas of the adrenal gland and skin tumors.<sup>202</sup>

A review of genotoxicity studies published since IARC's decision found that 82 of 94 determined that glyphosate was genotoxic, that is, capable of causing cancer-predisposing changes in cells.<sup>203</sup> Likewise, a review of 175 studies found that glyphosate and its formulations have 5 of 10 key characteristics of carcinogens.<sup>204</sup> One of these characteristics is glyphosate's ability to induce DNA-damaging oxidative stress,<sup>205</sup> which is implicated especially in blood cell cancers such as non-Hodgkin lymphoma.<sup>206</sup> In a state-of-the-art molecular epidemiology study conducted by U.S. National Institutes of Health scientists, farmers with recent or long-term exposure to glyphosate formulations had higher levels of urinary biomarkers of oxidative damage to DNA and/or lipids, which supports the association between glyphosate and NHL.<sup>207</sup> Similar findings have been made in Thai<sup>208</sup> and Brazilian<sup>209</sup> farmers, as well as in pregnant women in Puerto Rico<sup>210</sup> and school children in Cyprus.<sup>211</sup>

NHL expert Dr. Dennis Weisenburger observes that glyphosate herbicides induce forms of DNA damage that lead to NHL in lymphocytes, "the normal cell of origin of NHL,"<sup>212</sup> including DNA double strand breaks,<sup>213</sup> chromosomal aberrations and micronuclei.<sup>214</sup>

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<sup>202</sup> C. Portier, *A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies*, 19 *Environmental Health* 1, 1-18 (2020).

<sup>203</sup> Charles Benbrook, Robin Mesnage, William Sawyer, *Genotoxicity assays published since 2016 shed new light on the oncogenic potential of glyphosate-based herbicides*, 2 *AGROCHEMICALS* 47, 47-68 (2022).

<sup>204</sup> Imaan Rana et al., *Mapping the key characteristics of carcinogens for glyphosate and its formulations: a systematic review*, 339 *CHEMOSPHERE* 139572 (2023).

<sup>205</sup> Xiaojing Wang et al., *Oxidative stress and metabolism: a mechanistic insight for glyphosate toxicology*, 62 *ANNUAL REVIEW OF PHARMACOLOGY AND TOXICOLOGY* 617, 617-639 (2022).

<sup>206</sup> Alba Rodriguez-Garcia et al., *Protein carbonylation and lipid peroxidation in hematological malignancies*, 9 *ANTIOXIDANTS* 1212 (2020), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7761105/>.

<sup>207</sup> Vicky C. Chang et al., *Glyphosate exposure and urinary oxidative stress biomarkers in the Agricultural Health Study*, 115 *J. NATIONAL CANCER INSTITUTE* 394, 394-404 (2023).

<sup>208</sup> Sutthinee Sidthilaw et al., *Effects of exposure to glyphosate on oxidative stress, inflammation, and lung function in maize farmers, Northern Thailand*, *BMC PUBLIC HEALTH* 22: 1343 (2022).

<sup>209</sup> Aline de Souza Espindola Santos et al., *Exposure to pesticides and oxidative stress in Brazilian agricultural communities*, *Biomarkers* (2021).

<sup>210</sup> Jarrod L. Eaton et al., *The association between urinary glyphosate and aminomethylphosphonic acid with biomarkers of oxidative stress among pregnant women in the PROTECT birth cohort study*, *ECOTOXICOL ENVIRON SAF* 233:113300 (2022).

<sup>211</sup> Konstantinos C Makris et al., *Oxidative stress of glyphosate, AMPA and metabolites of pyrethroids and chlorpyrifos pesticides among primary school children in Cyprus*, *ENVIRONMENTAL RESEARCH* 212: 113316 (2022).

<sup>212</sup> Dennis D. Weisenburger, *A review and update with perspective of evidence that the herbicide glyphosate (Roundup) is a cause of non-Hodgkin lymphoma, Clinical Lymphoma, Myeloma and Leukemia*, 21 *CLINICAL LYMPHOMA, MYELOMA AND LEUKEMIA* 621, 626, 621-30 (2021).

<sup>213</sup> See generally Karen Suarez-Larios et al., *Screening of pesticides with the potential of inducing DSB and successive recombinational repair*, *J. OF TOXICOLOGY*, Article ID 3574840 (2017).

<sup>214</sup> See generally Alfredo Santovito et al., *In vitro evaluation of genomic damage induced by glyphosate on human lymphocytes*, 25 *ENV'T SCI. & POLLUTION RESEARCH* 34693, 34693-700 (2018).



Other research demonstrates that a glyphosate formulation causes similar DNA damage in peripheral mononuclear blood cells,<sup>215</sup> and glyphosate alone triggers epigenetic changes in lymphoma-related genes,<sup>216</sup> among other NHL-relevant genetic damage.<sup>217</sup> These are just a few of the studies showing various ways that glyphosate can induce cancer-predisposing damage to DNA and cells, which strongly supports the epidemiology and animal studies demonstrating glyphosate causes cancer, and in particular NHL.

Finally, both animal and human research points to glyphosate exposure as a causative factor in leukemia, which like NHL is a blood cancer involving white blood cells. A soon-to-be-published rat carcinogenicity study demonstrates that glyphosate and two glyphosate formulations induced leukemia in rats at doses EPA regards as safe for humans.<sup>218</sup> A team led by U.S. NIH scientists found an association between glyphosate exposure and acute myeloid leukemia in farmers enrolled in the Agricultural Health Study.<sup>219</sup> When National Cancer Institute scientists examined the blood of a subset of these same male farmers, they found that a blood cell mutation linked to blood cancers — mosaic loss of chromosome Y — was progressively more prevalent in farmers as their self-reported, lifetime exposure to glyphosate increased.<sup>220</sup> This study “represents a critical step forward in filling knowledge gaps about the mechanisms of glyphosate carcinogenicity in humans,” and is strongly recommended to “inform future hazard assessments” of glyphosate’s carcinogenicity by EPA and others.<sup>221</sup>

Additionally, numerous courts have found Bayer-Monsanto’s<sup>222</sup> glyphosate-containing Roundup pesticides are a “substantial factor” in causing users’ cancer. For example, in *Hardeman v. Monsanto*, the jury unanimously found Edwin Hardeman’s exposure to Roundup was a “substantial factor” in causing his non-Hodgkin’s lymphoma, and the

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<sup>215</sup> Ewelina Wozniak et al., *The mechanism of DNA damage induced by Roundup 360 PLUS, glyphosate and AMPA in human peripheral blood mononuclear cells – genotoxic risk assessment*, 120 FOOD AND CHEMICAL TOXICOLOGY 510, 510-522 (2018).

<sup>216</sup> Ewelina Wozniak et al., *Glyphosate affects methylation in the promoter regions of selected tumor suppressors as well as expression of major cell cycle and apoptosis drivers in PBMCs (in vitro study)*, 63 TOXICOLOGY IN VITRO 104736 (2020).

<sup>217</sup> Lei Wang et al., *Glyphosate induces benign monoclonal gammopathy and promotes multiple myeloma progression in mice*, 12 J. HEMATOLOGY & ONCOLOGY 70 (2019).

<sup>218</sup> P. Landrigan, *New study in rats establishes strong link between Roundup exposure and early onset leukemia*, HEARTLAND HEALTH RESEARCH ALLIANCE (Nov. 6, 2023), <https://hh-ra.org/2023/11/06/new-study-in-rats-establishes-strong-link-between-roundup-exposure-and-early-onset-leukemia/>. See also Ramazzini Days 2023, *Global Glyphosate Study: Firsts Results from the Long-Term Integrated Study*, Bologna, Italy (Oct. 25, 2023).

<sup>219</sup> Gabriella Andreotti et al., *Glyphosate use and cancer incidence in the Agricultural Health Study*, 110 J. NAT’L CANCER INST. 509, 509-516 (2018).

<sup>220</sup> VC Chang et al., *Glyphosate use and mosaic loss of chromosome Y among male farmers in the Agricultural Health Study*, 131 ENV’T HEALTH PERSPECTIVES 127006 (2023).

<sup>221</sup> Leah H Schinasi & Anneclaire J De Roos, *Invited Perspective: Important new evidence for glyphosate hazard assessment*, 131 ENV’T HEALTH PERSPECTIVES 121305, 121305-1 (2023).

<sup>222</sup> Monsanto is now owned by Bayer.

court ultimately awarded Hardeman \$25,313,383.02 in damages.<sup>223</sup> The United States Court of Appeals for the Ninth Circuit found that Monsanto, in trying to prevent the plaintiff from introducing evidence to establish general causation, “contradict[ed] its own argument[s].”<sup>224</sup> According to the *Hardeman* court, Monsanto also “specifically requested bifurcation [of the trial] to preclude evidence of its ‘attempting to influence regulatory agencies and manipulate public opinion regarding glyphosate.’”<sup>225</sup>

Further, the Agricultural Health Study (AHS), which Monsanto considered to be “the most powerful evidence on the relationship between glyphosate and NHL,” was regarded by Monsanto’s own employees as “inaccurate” and “scary,” with some groups going as far as calling it “junk science.”<sup>226</sup> In reviewing the permissibility of the jury’s initial award of \$75 million in punitive damages, the Court found that “[s]ubstantial evidence of Monsanto’s malice...support[ed] punitive damages under [the statute],” such that the district court’s finding that Monsanto’s approach to the safety of its product was reprehensible was “reasonable and supported by the facts presented to the jury.”<sup>227</sup> Because Monsanto “intentionally downplayed and ignored calls to test Roundup’s carcinogenic risks,” the Court found that the evidence presented justified a damages ratio far higher than 1 to 1.

*Johnson v. Monsanto* was the first Roundup-NHL case to go to trial. It was brought by school-grounds manager Dewayne “Lee” Johnson. Mr. Johnson had routinely utilized Roundup in his work prior to his NHL diagnosis and had experienced two very high exposure episodes. A California trial court jury found Roundup was a substantial contributing factor in Johnson’s cancer and that Monsanto had not done enough to warn Johnson of Roundup’s cancer risk.<sup>228</sup> Johnson even made several attempts to contact Monsanto to find out more information about the risks associated with their Roundup products, but no one ever returned his calls, even though representatives from Monsanto informed him that someone would reach out to him.<sup>229</sup> The lesions Johnson developed as a result of his condition were “so painful that it was sometimes difficult for him to put on shoes or wear certain clothes...”<sup>230</sup> Johnson was ultimately awarded \$20,506,418.64 in damages, though the jury initially awarded Johnson \$250 million in punitive damages alone.<sup>231</sup>

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<sup>223</sup> *Hardeman v. Monsanto Co.*, No. C 16-00525-VC (N.D. Cal. 2019); *Hardeman v. Monsanto Co.*, 997 F.3d 941 (9th Cir. 2021), *cert. denied*, 213 L. Ed. 2d 1064, 142 S. Ct. 2834 (2022) (affirming district court’s finding of liability).

<sup>224</sup> *Hardeman*, 997 F.3d at 963.

<sup>225</sup> *Id.* at 968.

<sup>226</sup> *Id.* at 963-64.

<sup>227</sup> *Id.* at 972.

<sup>228</sup> *Johnson v. Monsanto Co.*, No. CGC-16-550128, 2018 WL 4261442 (Cal. Super. Ct. 2018).

<sup>229</sup> *Johnson v. Monsanto Co.*, 52 Cal. App. 5th 434, 439-40 (2020), as modified on denial of reh’g (Aug. 18, 2020).

<sup>230</sup> *Johnson*, 52 Cal. App. 5th at 450.

<sup>231</sup> *Johnson v. Monsanto Co.*, 266 Cal.Rptr.3d 111, 136 (Ct. App. 2020) (affirming trial court’s finding of liability but reducing jury awards of noneconomic and punitive damages in accordance with Supreme Court guidance on the relationship between compensatory and punitive damage levels).

And in *Pilliod v. Monsanto*, husband and wife Albera and Alva Pilliod *both* developed non-Hodgkin's lymphoma after using glyphosate-containing herbicides on their property for over twenty years. The couple received a total of \$86,742,310 million after a California trial court found Monsanto's Roundup to have been a substantial factor in causing both individuals non-Hodgkin's lymphoma.<sup>232</sup> The court rejected Monsanto's argument that the prevailing scientific research did not establish a potential cancer risk from Roundup, finding that the jury could infer not only that the cancer risk associated with Monsanto's products were known or knowable, but also that "Monsanto labored for decades to suppress knowledge of the risk."<sup>233</sup> The court criticized Monsanto's "conclusory contentions" regarding plaintiffs' experts' testimony as "unpersuasive in light of Monsanto's failure to fairly present the substance of their testimony."<sup>234</sup>

And the lawsuits and liability findings are by no means over for Monsanto. On June 15, 2023, Bayer AG entered a multi-million-dollar settlement with the New York AG's office that requires, among other things, Bayer to stop advertising glyphosate-containing products such as Roundup as a safe and non-toxic product.<sup>235</sup> The settlement between Bayer and the New York AG's office does not, however, include an injunction for the sale of Bayer's glyphosate-containing products.

While Monsanto has announced that it reached settlement agreements for \$11 billion in approximately 80% of all Roundup claims (approximately 100,000 lawsuits), there are still more than 40,000 Roundup lawsuits to be tried or settled. In addition, several hundred new Roundup-NHL cases are expected annually in light of the approximately 65,000 new cases of NHL diagnosed per year.<sup>236</sup> Further, class actions to date have not included farmworkers, leaving open another huge class of potential litigants. Monsanto is also facing a new series of Roundup trials in state courts across the United States,<sup>237</sup> with four back to back wins for Plaintiffs in recent months, despite continued efforts by Monsanto to suppress Roundup's long-term association with cancer.<sup>238</sup>

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<sup>232</sup> *Pilliod v. Monsanto Co.*, No. RG17862702, JCCP No. 4953 (Cal. Super. Ct. 2019); *Pilliod v. Monsanto Co.*, 67 Cal. App. 5th 591 (2021) (affirming trial court's ruling), *reh'g denied* (Aug. 25, 2021), *review denied* (Nov. 17, 2021), *cert. denied*, 142 S. Ct. 2870, 213 L. Ed. 2d 1092 (2022).

<sup>233</sup> *Pilliod*, 67 Cal. App. 5th at 623.

<sup>234</sup> *Id.* at 625.

<sup>235</sup> Jonathan Stempel, *Bayer reaches \$6.9 million settlement with New York over Roundup safety claims* (2023), <https://www.reuters.com/legal/government/bayer-reaches-69-mln-settlement-with-new-york-over-roundup-safety-claims-2023-06-15/>.

<sup>236</sup> Ronald V. Millier, *Monsanto Roundup Lawsuit Update* (Sept. 19, 2023), <https://www.lawsuit-information-center.com/roundup-mdl-judge-question-10-billion-settlement-proposal.html>.

<sup>237</sup> *In re: Roundup Products Liability Litigation* (MDL No. 2741) (N.D. Cal.); Jef Feeley and Tim Loh, *Bayer Hit With \$332 Million Roundup-Cancer Verdict by Jury* (October 31, 2023), <https://www.bloomberg.com/news/articles/2023-10-31/bayer-jury-returns-332-million-verdict-in-roundup-cancer-trial#xj4y7vzkg>.

<sup>238</sup> Brendan Pierson, *As Bayer Confronts Mounting Roundup Losses, All Eyes on Philadelphia Trial* (Dec. 5, 2023), <https://www.reuters.com/business/healthcare-pharmaceuticals/bayer-confronts-mounting->

In *Dennis v. Monsanto*, a San Diego jury ordered Bayer-Monsanto to pay \$332,000,000 (\$7,000,000 in actual damages and \$325,000,000 in punitive damages) to Michael Dennis, a 57-year-old former land surveyor who developed non-Hodgkin's lymphoma after using Roundup on his lawns and gardens for decades. This case represented the third trial loss relating to weedkiller cases for Bayer-Monsanto just in October of 2023. The Jury in *Dennis* concluded that Monsanto failed to adequately warn Dennis about the health risks posed by Roundup. Further, the jury found that Monsanto defectively designed the herbicide itself and deserved to pay substantial punitive damages over its mishandling of the weedkiller product. Just one week prior to the decision in *Dennis*, a Philadelphia jury ordered Monsanto to pay \$175,000,000 (\$25,000,000 in compensatory and \$150,000,000 in punitive damages) to a retired pizza-shop owner who developed cancer after using Roundup on his garden.<sup>239</sup> Additionally, another week prior, a jury in state court in St. Louis awarded \$1,250,000 to John Durnell after finding Bayer-Monsanto liable for his non-Hodgkin's lymphoma. Durnell's victory represents the first verdict against Bayer-Monsanto outside of California.<sup>240</sup>

Bayer-Monsanto fared no better in November, facing a fourth loss after being ordered to pay more than \$1.5 billion to three former Roundup users by a Missouri jury, "one of the largest damages awards handed down against a US corporate defendant this year."<sup>241</sup> James Draeger, Valerie Gunther, and Dan Anderson were awarded a combined \$61.1 million in compensatory damages and \$500 million each in punitive damages.<sup>242</sup> Bayer has set aside \$16,000,000,000 in anticipation of further Roundup-related litigation.<sup>243</sup>

Roundup-NHL litigation will continue for some time with over 40,000 cases still in need of resolution.<sup>244</sup> The number of trials finding Monsanto liable is very likely to increase, a

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roundup-losses-all-eyes-philadelphia-trial-2023-12-04/ (detailing Monsanto's attempt to prevent jury members from learning about Petitioners' win in the 9<sup>th</sup> circuit vacating EPA's human health risk assessment); Maureen Farrell, *Years After Monsanto Deal, Bayer's Roundup Bills Keep Piling Up* (Dec. 6, 2023), [https://www.nytimes.com/2023/12/06/business/monsanto-bayer-roundup-lawsuit-settlements.html?unlocked\\_article\\_code=1.D00.l8Z6.cGBZHPjhncvcsmid=url-share](https://www.nytimes.com/2023/12/06/business/monsanto-bayer-roundup-lawsuit-settlements.html?unlocked_article_code=1.D00.l8Z6.cGBZHPjhncvcsmid=url-share).

<sup>239</sup> Jef Feeley, *Bayer Hit With \$175 Million Award in Roundup Cancer Trial* (October 27, 2023), <https://www.bloomberg.com/news/articles/2023-10-27/bayer-hit-with-175-million-jury-award-in-roundup-cancer-trial#xj4y7vzkg>.

<sup>240</sup> Joey Schneider, *Missouri man gets \$1.25M in ruling over Bayer-Monsanto's 'Roundup'* (October 20, 2023), <https://news.yahoo.com/missouri-man-gets-1-25m-024335095.html>.

<sup>241</sup> Jef Feely, BLOOMBERG, *Monsanto Ordered to Pay Over \$1.5 Billion in Roundup Verdict* (Nov. 18, 2023), <https://www.bloomberg.com/news/articles/2023-11-18/monsanto-ordered-to-pay-over-1-5-billion-in-roundup-verdict>.

<sup>242</sup> *Id.*; Tom Hals, *Bayer ordered to pay \$1.56 billion in latest US trial loss over Roundup weedkiller* (Nov. 20, 2023), <https://www.reuters.com/legal/bayer-ordered-pay-156-billion-latest-us-trial-loss-over-roundup-weedkiller-2023-11-19/>.

<sup>243</sup> Feeley & Loh, *supra* note 237.

<sup>244</sup> Carey Gillam & Aliya Uteuova, *Popular Weedkiller Roundup on Trial Again as Cancer Victims Demand Justice* (Aug. 23, 2022) <https://www.theguardian.com/us-news/2022/aug/23/bayer-roundup-monsanto-epa-trial-cancer-victims>; *Roundup Lawsuit* (last edited Nov. 21, 2023), <https://www.drugwatch.com/legal/roundup-lawsuit/>.

reality which Monsanto has already acknowledged and responded to by announcing it will remove glyphosate from all residential products beginning in 2023.<sup>245</sup> Bayer's announcement that it would pull glyphosate for residential use came in July 2021, and was not motivated by a concern for human or environmental health, but rather according to Bayer is part of a larger "five-point plan" to "close the door on this litigation" and "ensure that any claims brought by individuals who use Roundup™ in the future are few in number and unlikely to succeed."<sup>246</sup>

## 2. Liver Effects and Metabolic Syndrome

The human health dangers associated with glyphosate are not limited to cancer. A considerable body of evidence supports glyphosate exposure as a contributing factor to both fatty liver disease and metabolic syndrome.

The liver is the body's primary detoxification organ, and exposure to certain environmental chemicals induces the accumulation of fat in liver cells, which can lead to fatty liver disease.<sup>247</sup> Glyphosate was shown to have precisely this effect in a 1973 rat feeding study sponsored by Monsanto and submitted to the EPA.<sup>248</sup> EPA used this study to establish a human safety threshold of 0.05 mg/kg bw/day, known as the acceptable daily intake (ADI), which was in effect through 1981.<sup>249</sup> This fatty liver finding has since been corroborated in many other animal studies of glyphosate and its formulations.<sup>250</sup> Glyphosate formulations

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<sup>245</sup> Gil Gullickson, *Bayer to discontinue lawn and garden market glyphosate-based products starting in 2023* (July 29, 2021), <https://www.agriculture.com/news/business/bayer-to-discontinue-lawn-and-garden-market-glyphosate-based-products-starting-in-2023>.

<sup>246</sup> BAYER, *Bayer Provides Update on Path to Closure of Roundup™ Litigation* (2021), <https://www.bayer.com/media/en-us/bayer-provides-update-on-path-to-closure-of-rounduptm-litigation/>.

<sup>247</sup> L. Al-Eryani et al., *Identification of environmental chemicals associated with the development of toxicant-associated fatty liver disease in rodents*, 43 *Toxicologic Pathology* 482, 482-497 (2015).

<sup>248</sup> *Request for the establishment of final tolerances for combined negligible residues of the herbicide N-phosphonomethyl glycine (glyphosate) and its metabolite aminomethyl phosphonic acid in or on forage grasses (crop group) and soybean forage and hay at 0.2 ppm; and various crop grains and soybeans at 0.1 ppm*, Diana M Reisa, Ph.D., Toxicology Branch, U.S. EPA (Jan. 22, 1975).

<sup>249</sup> *EPA Reg. #524-308; Roundup (glyphosate); PP#0F2422; Glyphosate in or on forage grasses and forage legumes*, From William Dykstra, Ph.D., Toxicology Branch, U.S. EPA (Feb. 3, 1981). Note: mg/kg bw/day stands for milligrams of glyphosate ingested per kilogram of body weight per day; thus, the maximum "safe" amount of glyphosate a 60 kilogram person could consume each day for a lifetime was then 3 mg (60 kg \* 0.05).

<sup>250</sup> Mesnage et al., *Multiomics reveal non-alcoholic fatty liver disease in rats following chronic exposure to an ultra-low dose of Roundup herbicide* 7 *SCI. REPORTS* 39328 (2017); Pandey, Dhabade, & Kumarasamy, *Inflammatory effects of subacute exposure of Roundup in rat liver and adipose tissue*, 17 *Dose Response* (2019); Ren X et al., *Effects of chronic glyphosate exposure to pregnant mice on hepatic lipid metabolism in offspring*, 254 *ENV'T POLLUTION* 112906 (2019); El-Shenawy, *Oxidative stress responses of rats exposed to Roundup and its active ingredient glyphosate*, 28 *ENV'T TOXICOLOGY & PHARMACOLOGY* 379, 379-85 (2009); B. Ford et al., *Mapping proteome-wide targets of glyphosate in mice*, 24 *CELL CHEMICAL BIOLOGY* 1, 1-8 (2017); R. Mesnage et al., *Comparative toxicogenomics of glyphosate and Roundup herbicides by mammalian stem cell-based genotoxicity assays and molecular profiling in Sprague-Dawley rats*, 186 *TOXICOLOGICAL SCIENCE* 83, 83-101 (2022).

also increased liver enzyme levels indicative of hepatocyte injury in rodent studies,<sup>251</sup> and elevated levels of these same enzymes in humans is most commonly caused by fatty liver disease.<sup>252</sup> Glyphosate-based herbicides are recognized as environmental contributors to fatty liver disease by experts in the field.<sup>253</sup>

These animal studies are supported by human epidemiology. In a cohort of patients with nonalcoholic fatty liver disease (NAFLD), significantly more glyphosate was excreted by those with the more advanced form of the disease, nonalcoholic steatohepatitis, than by those with non-progressive fatty liver; glyphosate excretion also increased with stage of liver fibrosis.<sup>254</sup> In addition, Chinese workers in glyphosate manufacturing plants with high inhalational exposure were reported to have abnormal hepatic function.<sup>255</sup> Fatty liver can progress to more serious conditions, steatohepatitis and cirrhosis, which in turn are the most important risk factors for liver cancer.<sup>256</sup> According to EPA scientists, fatty liver disease is “a growing epidemic” that affects 20-30% of the U.S. population,<sup>257</sup> and the incidence of liver cancer tripled from 1975 to 2005.<sup>258</sup>

Glyphosate’s adverse effects on the liver take on added significance when considered in light of the many other liver toxins to which humans are exposed,<sup>259</sup> including at least 93 pesticides that cause fatty changes in the livers of experimental animals.<sup>260</sup> For instance, pregnant rats dosed with a combination of glyphosate and seven other pesticides at very

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<sup>251</sup> A. Benedetti et al., *The effects of subchronic exposure of Wistar rats to the herbicide Glyphosate-Biocarb*, 153 TOXICOLOGY LETTERS 227 (2004); K. Cavusoglu et al., *Protective effect of Ginkgo biloba L. leaf extract against glyphosate toxicity in Swiss albino mice*, 14 J. MEDICINAL FOOD 1263 (2011); R. Jasper et al., *Evaluation of biochemical, hematological and oxidative parameters in mice exposed to the herbicide glyphosate-Roundup*, 5 INTERDISCIPLINARY TOXICOLOGY 133 (2012); Mesnage et al., *Potential toxic effects of glyphosate and its commercial formulations below regulatory limits*, 84 FOOD & CHEMICAL TOXICOLOGY 133 (2015).

<sup>252</sup> G. Aragon et al., *When and how to evaluate mildly elevated liver enzymes in apparently healthy patients*, 77 CLEVELAND CLINIC J. MEDICINE 195 (2010).

<sup>253</sup> B. Wahlang et al., *Mechanisms of environmental contributions to fatty liver disease*, 6 CURRENT ENV’T HEALTH REPORTS 80 (2019).

<sup>254</sup> P. Mills et al., *Glyphosate Excretion is Associated With Steatohepatitis and Advanced Liver Fibrosis in Patients With Fatty Liver Disease*, 18 CLINICAL GASTROENTEROLOGY & HEPATOLOGY 741 (2019).

<sup>255</sup> F. Zhang et al., *Study of the Effect of Occupational Exposure to Glyphosate on Hepatorenal Function*, 51 CHINESE J. PREVENTIVE MEDICINE 615 [abstract only].

<sup>256</sup> B. Wahlang et al., *Toxicant-associated steatohepatitis*, 41 TOXICOLOGIC PATHOLOGY 343 (2013).

<sup>257</sup> M. Angrish, *Tipping the balance: hepatotoxicity and the four apical key events of hepatic steatosis*, 150 TOXICOLOGICAL SCIENCES 261, 261 (2016).

<sup>258</sup> S. Altekruse et al., *Hepatocellular carcinoma incidence, mortality, and survival trends in the United States from 1975 to 2005*, 27 J. CLINICAL ONCOLOGY 1485 (2009).

<sup>259</sup> See generally K. Tolman et al., *Occupational hepatotoxicity*, 2 CLINICS IN LIVER DISEASE 563 (1998); see also *NIOSH Pocket Guide to Chemical Hazards*, CDC, <https://www.cdc.gov/niosh/npg/default.html>.

<sup>260</sup> Elsa Nielsen et al., *Identification of Cumulative Assessment Groups of Pesticides, External Scientific Report submitted to the European Food Safety Authority*, TECHNICAL UNIVERSITY OF DENMARK, 122 - Table 17.3 CAG level 2b: Hepatocellular fatty changes (2012).

low, environmentally relevant levels during gestation exhibited increased liver lipids.<sup>261</sup> Glyphosate and other chemicals induce fatty liver and hepatocyte injury in similar ways: via oxidative stress<sup>262</sup> that involves disruption of hepatic mitochondrial metabolism.<sup>263</sup>

Glyphosate also appears to promote metabolic syndrome, a risk factor for fatty liver disease and diabetes.<sup>264</sup> A prospective study of mother-child dyads in California found that childhood exposure to glyphosate and its breakdown product AMPA was associated with a 55% increased risk of metabolic syndrome in early adulthood.<sup>265</sup> Metabolic syndrome has reached epidemic proportions, affecting 42% of the U.S. population in 2018, up from 38% in 2011.<sup>266</sup> Scientists ascribe a role to environmental chemicals like glyphosate based on research, such as the studies described above, as well as the fact that major risk factors, such as high-caloric diets and insufficient exercise, cannot explain the extremely high prevalence of this condition.<sup>267</sup>

### 3. Reproductive Impairment

The reproductive system of mammals and other vertebrates is extremely sensitive to disruption by chemicals released into the environment, and the developing organism is particularly sensitive to toxin-induced injury.<sup>268</sup> Glyphosate is one of such reproductive toxins.

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<sup>261</sup> N. Bonvallot et al., *Metabolome disruption of pregnant rats and their offspring resulting from repeated exposure to a pesticide mixture representative of environmental contamination in Brittany*, 13 PLoS ONE e0198448 (2018).

<sup>262</sup> M. Astiz et al., *Antioxidant defense system in rats simultaneously intoxicated with agrochemicals*, 28 ENV'T TOXICOLOGY & PHARMACOLOGY 465 (2009).

<sup>263</sup> J. Myers et al., *Concerns over use of glyphosate-based herbicides and risks associated with exposures: a consensus statement*, 15 ENV'T HEALTH 15 (2016); Mesnage, *supra* note 250; Bonvallot, *supra* note 261; D. Bagchi et al., *In vitro and in vivo generation of reactive oxygen species, DNA damage and lactate dehydrogenase leakage by selected pesticides*, 104 TOXICOLOGY 129 (1995).

<sup>264</sup> N. De Long et al., *Early-life chemical exposures and risk of metabolic syndrome*, 10 DIABETES, METABOLIC SYNDROME AND OBESITY: TARGETS AND THERAPY 101 (2017).

<sup>265</sup> B. Eskenazi et al., *Association of lifetime exposure to glyphosate and aminomethylphosphonic acid (AMPA) with liver inflammation and metabolic syndrome at young adulthood: findings from the CHAMACO study*, 131 ENV'T HEALTH PERSPECTIVES 37001 (2023); K. Christensen, *Looking beyond cancer: glyphosate and liver, metabolic diseases in youth*, 131 ENV'T HEALTH PERSPECTIVES 054002 (2023).

<sup>266</sup> X. Liang et al., *Prevalence of metabolic syndrome in the United States National Health and Nutrition Examination Survey: 2011-2018*, 99 POSTGRADUATE MEDICAL J. 985 (2023).

<sup>267</sup> See generally De Long, *supra* note 264.

<sup>268</sup> T. Colborn et al., *Developmental effects of endocrine-disrupting chemicals in wildlife and humans*, 101 ENV'T HEALTH PERSPECTIVES 378 (1993).

In a three-generation rat study submitted to EPA by Monsanto, glyphosate was found to induce “reduced mating, fertility and pregnancy indices” in 2<sup>nd</sup> and 3<sup>rd</sup> generation rats.<sup>269</sup> Effects occurred in the group of animals fed 300 ppm glyphosate in feed,<sup>270</sup> equivalent to roughly 15 mg/kg bw/day.<sup>271</sup> Reproductive impacts are a common finding in glyphosate (formulation) studies, particularly in males, and include testicular atrophy<sup>272</sup> as well as reduced ejaculate volume and sperm concentration, lower sperm quality and vigor, and greater proportions of dead and abnormal sperm in rabbits.<sup>273</sup> Rat studies with glyphosate and/or its formulations have demonstrated damage to testicular tissue; reduced sperm quality, counts, and mobility; lower levels of testosterone and other sex hormones, and/or delayed onset of puberty.<sup>274</sup> Treatment of female rats during one week of pregnancy produced higher incidences of testes and ovarian pathologies in untreated F2 and F3 descendants (grandchildren and great-grandchildren), transgenerational effects ascribed to epigenetic changes.<sup>275</sup>

*In vitro* studies provide evidence that glyphosate formulations produce some of these effects – such as reduced synthesis of sex hormones – via endocrine disruption.<sup>276</sup> Other research shows that short-term exposure of rat testes and Sertoli cells (testicular cells that promote formation of sperm) to Roundup-triggered oxidative stress, leading to cellular necrosis.<sup>277</sup>

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<sup>269</sup> EPA, *Glyphosate, N-phosphonomethyl glycine, and its metabolite, aminomethylphosphonic acid, tolerances requested at 0.05 ppm in or on sugarcane and at 0.5 ppm for sugarcane molasses, TB evaluation of*, From Mary L. Quaife, Ph.D., Toxicology Branch, EPA (Feb.16, 1977), <https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-027.pdf>.

<sup>270</sup> *Id.*

<sup>271</sup> *Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data*, 10 EUROPEAN FOOD SAFETY AUTHORITY 2579 (2012) (Divide doses reported in parts per million in feed by 20 to convert to mg/kg body weight in rats).

<sup>272</sup> EPA, *Review of toxicity studies for Roundup, registration no. 524-GNI*, Robert D. Coberly, Toxicology Branch, Registration Division, U.S. EPA, at 10-11 (May 24, 1973).

<sup>273</sup> M. Yousef et al., *Toxic effects of carbofuran and glyphosate on semen characteristics in rabbits*, 30 J. ENV'T SCIENCE & HEALTH 513 (1995).

<sup>274</sup> R. Romano et al., *Prepubertal exposure to commercial formulation of the herbicide glyphosate alters testosterone levels and testicular morphology*, 84 ARCHIVES OF TOXICOLOGY 309 (2010); F. Owagboriaye et al., *Reproductive toxicity of Roundup herbicide exposure in male albino rat*, 69 EXPERIMENTAL AND TOXICOLOGIC PATHOLOGY 461 (2017).

<sup>275</sup> D. Kubsad et al., *Assessment of Glyphosate Induced Epigenetic Transgenerational Inheritance of Pathologies and Sperm Epimutations: Generational Toxicology*, 9 SCIENTIFIC REPORTS 6372 (2019); M. Skinner, *What is an epigenetic transgenerational phenotype? F3 or F2*, 25 REPROD TOXICOLOGY 2 (2008).

<sup>276</sup> L. Walsh et al., *Roundup inhibits steroidogenesis by disrupting steroidogenic acute regulatory (StAR) protein expression*, 108 ENV'T HEALTH PERSPECTIVES 769 (2000); S. Richard et al., *Differential effects of glyphosate and Roundup on human placental cells and aromatase*, 113 ENV'T HEALTH PERSPECTIVES 716 (2005).

<sup>277</sup> De Liz Oliveira Cavalli VL et al., *Roundup disrupts male reproductive functions by triggering calcium-mediated cell death in rat testis and Sertoli cells*, 65 FREE RADICAL BIOLOGY & MEDICINE 335 (2013).



These animal and mechanistic studies may help explain the greater risk of miscarriage and preterm delivery experienced by Canadian women whose farmer husbands were exposed to glyphosate formulations in the three months prior to conception.<sup>278</sup> The U.S. Agency for Toxic Substances and Disease Registry, a division of the Centers for Disease Control and Prevention, flagged impairment of male reproductive function as one concerning effect of exposure to glyphosate formulations that deserves further study.<sup>279</sup> The EPA's Office of Water warns that long-term exposure to high levels of glyphosate in drinking water could result in reproductive impacts.<sup>280</sup>

Sperm counts and quality have been declining for decades, with an over 50% reduction in sperm counts in men in developed countries from 1973 to 2011.<sup>281</sup> Scientists attribute this decline in large part to increasing exposure to environmental chemicals, including pesticides.<sup>282</sup> The evidence discussed above suggests that glyphosate is contributing to these worrying trends in declining male reproductive health.

Numerous studies also implicate glyphosate as adversely affecting female fertility and reproduction via endocrine disruption. Mounting evidence demonstrates glyphosate is an endocrine disrupting chemical, meaning it interferes with the hormone system. Numerous animal studies indicate glyphosate exposures impact reproductive organs and threaten fertility.<sup>283</sup>

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<sup>278</sup> D. Savitz et al., *Male pesticide exposure and pregnancy outcome*, 146 AM. J. EPIDEMIOLOGY 1025 (1997).

<sup>279</sup> TOXICOLOGICAL PROFILE FOR GLYPHOSATE, *supra* note 48, at 71, 79, 142, 205.

<sup>280</sup> EPA (5/4/00). National Primary Drinking Water Regulations: Public Notification Rule. Final Rule. U.S. Environmental Protection Agency. Federal Register Vol. 65, No. 87: 25982-26049, see p. 26029.

<sup>281</sup> H. Levine et al., *Temporal trends in sperm count: a systematic review and meta-regression analysis*, 23 HUMAN REPRODUCTION UPDATE 646 (2017).

<sup>282</sup> S. Martenies et al., *Environmental and occupational pesticide exposure and human sperm parameters: a systematic review*, 307 TOXICOLOGY 66 (2013); A. Gore et al., *EDC-2: The Endocrine Society's Second Scientific Statement on Endocrine-Disrupting Chemicals*, 36 ENDOCRINE REVIEWS E1 (2013); Y-H Chiu et al., *Intake of Fruits and Vegetables with Low- to-Moderate Pesticide Residues Is Positively Associated with Semen-Quality Parameters among Young Healthy Men*, 146 J. NUTRITION 1084 (2016).

<sup>283</sup> Fabiana Manservigi et al., *The Ramazzini Institute 13-week pilot study glyphosate-based herbicides administered at human-equivalent dose to Sprague Dawley rats: effects on development and endocrine system*, ENV'T HEALTH (2019) (finding exposure to glyphosate product, Roundup Bioflow, at dose levels considered "safe" induced endocrine effects and altered reproductive development); Roy R. Gerona et al., *Glyphosate exposure in early pregnancy and reduced fetal growth: a prospective observational study of high-risk pregnancies*, ENV'T HEALTH (2022) (linking higher glyphosate exposures during the first trimester with lower birthweight and higher NICU admission risk); Pablo Ingaramo et al., *Are glyphosate and glyphosate-based herbicides endocrine disruptors that alter female fertility?*, MOLECULAR & CELLULAR ENDOCRINOLOGY (2020) (finding low doses of glyphosate may have adverse effects on fertility of female reproductive tract); Ganesan & Keating, *Ovarian Mitochondrial and Oxidative Stress Proteins are Altered by Glyphosate Exposure in Mice*, TOXICOLOGY & PHARMACOLOGY (2020) (finding "chronic low-level exposure to glyphosate alters ovarian proteome and may ultimately impact ovarian function."); Medardo Avila-Vazquez et al., *Environmental Exposure to Glyphosate and Reproductive Health Impacts in Agricultural Population of Argentina*, 9 J. ENV'T PROT. 241 (2018) (Noting an association between high exposure to glyphosate and

#### 4. Kidney Damage

Studies suggest glyphosate exposure is also contributing to the U.S.'s rapidly increasing kidney disease. Kidneys filter and process blood, removing waste products and toxins for elimination in urine. As part of the kidney apparatus, renal tubules come into intimate contact with toxins like glyphosate on their way out of the body.

In a three-generation rat reproduction study submitted by Monsanto to EPA, third generation male rats exhibited increased incidence of renal tubular dilation.<sup>284</sup> EPA used this study to establish a new chronic Reference Dose (cRfD) of 0.1 mg/kg bw/day,<sup>285</sup> double the ADI of 0.05 mg/kg bw/day based on fatty liver. Tubular dilation (aka ectasia) is one form of toxic injury that is associated with degeneration and necrosis.<sup>286</sup> As with fatty liver, these kidney findings in a registrant study have been corroborated by independent scientists, who have also found renal tubular dilation and/or necrosis in rats that received glyphosate formulations orally,<sup>287</sup> with effects beginning at the low dose of 3.6 mg/kg bw/day.<sup>288</sup> Pregnant rats given low doses of glyphosate exhibited renal tubular dysfunction and increased blood urea nitrogen levels,<sup>289</sup> while in another study low doses of a glyphosate formulation fed to young rats caused mild kidney damage.<sup>290</sup>

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increased frequency of reproductive disorders (spontaneous abortion and congenital abnormalities)); Maria M. Milesi et al., *Perinatal exposure to a glyphosate-based herbicide impairs female reproductive outcomes and induces second-generation adverse effects in Wistar rats*, 92 ARCHIVES OF TOXICOLOGY 2629 (2018) (linking perinatal glyphosate exposure to impaired female reproductive performance); S. Parvez et al., *Glyphosate exposure in pregnancy and shortened gestational length: a prospective Indiana birth cohort study*, ENV'T HEALTH (2018) (linking glyphosate exposure in pregnant women to shorter gestation)

<sup>284</sup> EPA, *Addendum to pathology report for a three-generation reproduction study in rats with glyphosate*. R.D. #374; Special report MSL-1724; July 6, 1982. EPA Registration No. 524-308, Action Code 401, Accession No. 24773 (July 21, 1982), <https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/103601/103601-135.pdf>.

<sup>285</sup> A chronic Reference Dose is conceptually equivalent to a chronic ADI. For the source of the new glyphosate cRfD, see *Glyphosate: CASRN 1071-83-6*, INTEGRATED RISK INFORMATION SYSTEM, CHEMICAL ASSESSMENT SUMMARY, U.S. EPA (1/31/87), [https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/subst/0057\\_summary.pdf](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0057_summary.pdf).

<sup>286</sup> *Nonneoplastic Lesion Atlas: Kidney, Renal Tubule Dilation*, NAT'L TOXICOLOGY PROGRAM, U.S. DEPT. OF HEALTH & HUMAN SERVICES, <https://ntp.niehs.nih.gov/nnl/urinary/kidney/rtdilat/index.htm>.

<sup>287</sup> L. Hamdaoui et al., *Nephrotoxicity of Kalach 360 SL: biochemical and histopathological findings*, 26 TOXICOLOGY MECHANISMS & METHODS 685 (2016).

<sup>288</sup> G. Dedeker et al., *Comparative Assessment on Mechanism Underlying Renal Toxicity of Commercial Formulation of Roundup Herbicide and Glyphosate Alone in Male Albino Rat*, 37 INT'L J. TOXICOLOGY 285 (2018).

<sup>289</sup> A. O. Docea et al., *Effect of perinatal exposure to glyphosate and its mixture with 2,4-D and dicamba on rat dam kidney and thyroid function and offspring's health*, 237 ENV'T RESEARCH 116908 (2023).

<sup>290</sup> C. Gadotti et al., *Prepubertal to adulthood exposure to low doses of glyphosate-based herbicide increases the expression of the *Havcr1* (*Kim1*) biomarker and causes mild kidney alterations*, 467 TOXICOLOGY & APPLIED PHARMACOLOGY 116496 (2023).

F2 and F3 descendants of pregnant rats treated with glyphosate exhibited fluid filled cysts that were likely derived from dilated renal tubules, with an epigenetic mechanism proposed.<sup>291</sup> In female rats fed low daily doses of Roundup over two years, changes indicative of kidney damage were found at the anatomorphological level, in biochemical markers in the blood and urine, as well as at the genetic level, as reflected in the rats' transcriptome profile.<sup>292</sup> In a renal tubule cell line (HK-2), glyphosate exposure induced apoptosis of epithelial cells via an oxidative stress pathway.<sup>293</sup>

Glyphosate's adverse effects on kidney tubules may extend to cancer. This is evidenced by the development of rare renal tubule adenomas and carcinomas in male mice treated with glyphosate in a 1983 Monsanto-commissioned study, a finding upon which EPA based its 1984-1991 classification of glyphosate as a possible human carcinogen.<sup>294</sup> Indeed, the U.S. Centers for Disease Control and Prevention regards exposure to environmental chemicals, including some herbicides, as potential risk factors for kidney cancer.<sup>295</sup>

There is also human evidence of glyphosate's adverse renal effects. Chinese workers in glyphosate manufacturing plants experienced abnormalities in renal function, with higher incidence rates in workers with greater inhalational exposure.<sup>296</sup> Others have proposed glyphosate, among other toxins, as a contributing factor to the epidemic of chronic interstitial nephritis in agricultural communities (CINAC), which is marked by damage to renal tubules and the surrounding interstitial tissue, among farmworkers in Central America, Sri Lanka and India who do not have typical risk factors for chronic kidney

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<sup>291</sup> D. Kubsad et al., *supra* note 275.

<sup>292</sup> R. Mesnage et al., *Transcriptome profile analysis reflects rat liver and kidney damage following chronic ultra-low dose Roundup exposure*, 14 ENV'T HEALTH (2015).

<sup>293</sup> H. Gao et al., *Activation of the N-methyl-D-aspartate receptor is involved in glyphosate-induced renal proximal tubule cell apoptosis*, 39 J. APPLIED TOXICOLOGY 1096 (2019).

<sup>294</sup> EPA (4/3/85). Glyphosate; EPA Reg. #524-308; mouse oncogenicity study. Caswell #661A; Accession #251007-014. From William Dykstra, Toxicology Branch, U.S. Environmental Protection Agency, April 3, 1985; CFS Comments to FIFRA SAP 2016, *supra* note 60, at Section 4.2.  
[https://www.centerforfoodsafety.org/files/sap-glyphosate-cancer-comments--cfs-20161\\_35863.pdf](https://www.centerforfoodsafety.org/files/sap-glyphosate-cancer-comments--cfs-20161_35863.pdf).

<sup>295</sup> Ctrs. for Disease Control, *Kidney Cancer and the Environment* (last updated Oct. 26, 2016), <https://web.archive.org/web/20201205234627/https://ephtracking.cdc.gov/showCancerKidneyRenalEnv.action>.

<sup>296</sup> F. Zhang et al., *supra* note 255.

disease.<sup>297</sup> EPA has also specified the kidney as a target organ of glyphosate that could be impacted with prolonged exposure to high levels in drinking water.<sup>298</sup>

It is now widely accepted that a broad range of chemicals and heavy metals have adverse renal effects,<sup>299</sup> including a number of pesticides.<sup>300</sup> Like glyphosate, “the large majority” of kidney toxins target renal tubules,<sup>301</sup> and tubulointerstitial injury is the best indicator of impaired renal function.<sup>302</sup> Chronic kidney disease is increasing in prevalence globally, and afflicts more than one in seven U.S. adults.<sup>303</sup> The incidence of the most common form of kidney cancer – renal cell carcinoma, which originates in renal tubules – has increased five-fold since 1971 in the U.S.<sup>304</sup> *Needless to say, the above evidence suggests that exposure to glyphosate is one factor contributing to the rapidly increasing kidney disease burden in the U.S.*

## **ii. Ecological Risks**

There is no denying that glyphosate poses significant ecological risks. EPA’s own 2015 ecological risk assessment, despite its deficiencies, concluded glyphosate may impair the growth and reproduction of mammals, the growth of birds and terrestrial-phase amphibians, and the survival of both terrestrial and various aquatic plants.<sup>305</sup> And EPA’s recent Biological Evaluation (BE) for glyphosate and its formulations made plain that thousands of species and hundreds of habitats are likely being adversely affected, in addition to plainly stating:

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<sup>297</sup> C. Jayasumana et al., *Chronic interstitial nephritis in agricultural communities: a worldwide epidemic with social, occupational and environmental determinants*, 32 NEPHROLOGY, DIALYSIS, TRANSPLANTATION 234 (2017); C. Jayasumana et al., *Drinking well water and occupational exposure to herbicides is associated with chronic kidney disease, in Padavi-Sripura, Sri Lanka*, 14 ENV’T HEALTH 6 (2015); C. Jayasumana, *Chronic interstitial nephritis in agricultural communities (CINAC) in Sri Lanka*, 39 SEMINARS IN NEPHROLOGY 278 (2019); B. Vervaet et al., *Chronic interstitial nephritis in agricultural communities is a toxin-induced proximal tubular nephropathy*, 97 KIDNEY INTERNATIONAL 350 (2020); B. Vervaet et al., *Chronic interstitial nephritis in agricultural communities: a new perspective on etiology, diagnosis and mechanism*, 17 NEOPHROLOGIE & THERAPEUTIQUE 45 (2021).

<sup>298</sup> National Primary Drinking Water Regulations, *supra* note 280, at 26029.

<sup>299</sup> A. Kataria et al., *The Effects of Environmental Chemicals on Renal Function*, 11 NATURE REVIEWS NEPHROLOGY 610 (2015).

<sup>300</sup> M. Scammel et al., *Environmental and occupational exposures in kidney disease*, 39 Seminars in Nephrology 230 (2019).

<sup>301</sup> J. Commandeur and N. Vermeulen, *Molecular and biochemical mechanisms of chemically induced nephrotoxicity: a review*, 3 CHEMICAL RSCH. IN TOXICOLOGY 171 (1990).

<sup>302</sup> K. Nath, *Tubulointerstitial changes as a major determinant in the progression of renal damage*, 20 AMERICAN J. KIDNEY DISEASES 1 (1992).

<sup>303</sup> U.S. DEP’T OF HEALTH & HUMAN SERVS., CTRS. FOR DISEASE CONTROL, CHRONIC KIDNEY DISEASE IN THE UNITED STATES (2023), <https://www.cdc.gov/kidneydisease/pdf/CKD-Factsheet-H.pdf>.

<sup>304</sup> P. Cairns, *Renal cell carcinoma*, 9 CANCER BIOMARKERS 461 (2011).

<sup>305</sup> See generally EPA OPP Ecological 2015, *supra* note 137, at 2.

Formulated glyphosate is moderately to highly toxic to fish, highly to very highly toxic to aquatic invertebrates, moderately toxic to mammals, and slightly toxic to birds on an acute exposure basis. In both terrestrial and aquatic animals, technical and formulated glyphosate demonstrate a variety of growth and reproductive effects at a range of chronic exposure concentrations. Glyphosate has demonstrated adverse effects on growth to both vascular and non-vascular aquatic plants as well as terrestrial plants.<sup>306</sup>

Decades of false advertising by Monsanto has in large part shielded the public from these findings of ecological harm, despite efforts to expose the truth. In 1996, the New York State Attorney General (NY AG) fined Monsanto and forced it to cease airing false and misleading ads in New York claiming that Roundup is biodegradable, and practically non-toxic to mammals, birds and fish, among similar claims.<sup>307</sup> In 1998, the NY AG again fined Monsanto and ordered it to cease airing TV ads implying Roundup lawn and garden products could be used in water to kill aquatic weeds, contrary to product labels.<sup>308</sup> And in 2023, the NY AG fined Monsanto \$6.9 million dollars for false and deceptive ads claiming that Roundup products “won’t harm anything but weeds,” “do not pose a threat to the health of animal wildlife,” and permit farmers to “protect the environment for insects, birds and wildlife” including “pollinator species,” among similar false claims.<sup>309</sup>

## 1. Generally

### a. Toxicity to Terrestrial Plants

As discussed *infra*,<sup>310</sup> EPA failed to require in-field, no-spray buffer zones needed to protect land plants from glyphosate spray drift, thus permitting plant injury exceeding EPA’s toxicity threshold from hundreds to over 1,000 feet from the edge of a sprayed field. However, the true situation is still worse. EPA did not, as its regulations prescribe, base the toxicity threshold on the most sensitive plant tested. In choosing the cucumber, based on a registrant study,<sup>311</sup> EPA passed over at least two dozen species, from prairie plants to potato, that were shown to be up to 25-fold more sensitive than cucumber in peer-

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<sup>306</sup> BE Executive summary, *supra* note 1, at 3.

<sup>307</sup> Attorney General of the State of New York, In the matter of Monsanto Company, Assurance of discontinuance pursuant to executive law § 63(15) (1996).

<sup>308</sup> Attorney General of the State of New York, In the matter of Monsanto Company, Assurance of discontinuance pursuant to executive law § 63(15) (1998).

<sup>309</sup> Investigation by Letitia James, Attorney General of the State of New York, of Bayer CropScience LP and Monsanto Company, Assurance of Discontinuance 8, 9, 11 (2023).

<sup>310</sup> See Part II(c)(ii)(4).

<sup>311</sup> EPA OPP Ecological 2015, *supra* note 137, at 55-57 (where the toxicity threshold – the application rate of glyphosate that causes a 25% inhibition in plant biomass (weight) or height – is abbreviated IC<sub>25</sub>).

reviewed studies conducted by EPA plant scientists and others.<sup>312</sup> This means more severe spray drift damage, at greater distances from the treated field, and thus a need for wider buffer zones than indicated by EPA's assessment. However, as already noted, EPA's interim decision established no buffer zone at all.

Nor is evidence of glyphosate spray drift damage limited to experimental studies. In two surveys of state pesticide regulators covering the six years from 1996-1998 and 2002-2004, glyphosate was second only to the notoriously volatile 2,4-D among pesticides cited in confirmed drift complaints.<sup>313</sup> EPA has also received many hundreds of reports of glyphosate damage and mortality to a wide variety of terrestrial plants, including crops, grasses, and even incidents of trees being damaged or killed,<sup>314</sup> incidents that EPA admits are very likely heavily underreported.<sup>315</sup>

### *b. Impacts on Monarch Butterflies*

Glyphosate also continues to devastate the monarch. The eastern monarch population that migrates to Mexico each fall/winter remains dangerously low, with a 11% to 57% risk of quasi-extinction by 2036.<sup>316</sup> As discussed earlier, FWS has now determined that its listing and protection under the ESA is warranted.

It is estimated that boosting monarch numbers to a level high enough to avoid extinction requires a population occupying at least 6 hectares (15 acres) of overwintering habitat in the Mexican mountains.<sup>317</sup> This in turn demands restoring well over 1 billion milkweed

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<sup>312</sup> See CFS Risk Assessment Comments 2018, *supra* note 4, at 13-14 (citing two EPA scientist-led studies: D. Olszyk et al., *Effects of low levels of herbicides on prairie species of the Willamette Valley, Oregon*, 32 ENV'T TOXICOLOGY & CHEMISTRY 2542 (2013); and T. Pflieger et al., *Comparing effects of low levels of herbicides on greenhouse- and field grown potatoes (*Solanum tuberosum* L.), soybeans (*Glycine max* L.) and peas (*Pisum sativum* L.)*, 30 ENV'T TOXICOLOGY & CHEMISTRY 455 (2011); and one other: C. Boutin et al., *Toxicity testing of fifteen non-crop plant species with six herbicides in a greenhouse experiment: implications for risk assessment*, 13 ECOTOXICOLOGY 349 (2004)).

<sup>313</sup> 1999 Pesticide Drift Enforcement Survey, *supra* note 191; 2005 Pesticide Drift Enforcement Survey, *supra* note 191.

<sup>314</sup> EPA OPP Ecological 2015, *supra* note 137, at 61-62.

<sup>315</sup> "The Agency believes many incidents are unreported." *Pesticide Registration (PR) Notice 2001-X Draft: Spray and Dust Drift Label Statements for Pesticide Products*, EPA (August 9, 2001), <https://www.epa.gov/pesticide-registration/prn-2001-x-draft-spray-and-dust-drift-label-statements-pesticide-products#:~:text=Pesticide%20Registration-,PRN%202001%20DX%20Draft%3A%20Spray%20and%20Dust%20Drift,Label%20Statements%20for%20Pesticide%20Products&text=This%20Notice%20sets%20forth%20the,these%20statements%20for%20risk%20mitigation.>

<sup>316</sup> B. Semmens et al., *Quasi-extinction risk and population targets for the Eastern, migratory population of monarch butterflies (*Danaus plexippus*)*, 6 NATURE SCIENTIFIC REPORTS 23265 (2016). Quasi-extinction is defined as the loss of a viable migratory population.

<sup>317</sup> The White House Pollinator Health Task Force, *National Strategy to Promote the Health of Honey Bees and Other Pollinators 2* (May 19, 2015), <https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf> [hereinafter Pollinator Task Force].

plants in the monarch’s breeding range, most of which have been extirpated by glyphosate.<sup>318</sup> Despite an Obama White House-led effort to restore pollinator and monarch habitat,<sup>319</sup> the monarch is still less than half the viable size, occupying on average just 2.7 hectares of overwintering sites (see graph).

**Figure 6: Extent of eastern monarch butterfly overwintering habitat in Mexico: 1993 to 2022.**<sup>320</sup>



Milkweed restoration efforts will likely fail unless they address rampant glyphosate use in agriculture. “Agricultural lands are essential to reaching [milkweed] restoration targets because they occupy 77% of all potential monarch habitat.”<sup>321</sup> This requires conservation of existing milkweeds in agricultural lands; incorporating milkweeds along with other

<sup>318</sup> J. Pleasants, *Milkweed Restoration in the Midwest For Monarch Butterfly Recovery: Estimates of Milkweeds Lost, Milkweeds Remaining & Milkweeds That Must Be Added to Increase the Monarch Population*, 10 INSECT CONSERVATION & DIVERSITY 42 (2017).

<sup>319</sup> Pollinator Task Force 2015, *supra* note 317, at 28-32.

<sup>320</sup> K. Oberhauser, *Monarch winter 2022-2023 population numbers released*, UNI. OF WISCONSIN-MADISON ARBORETUM, <https://arboretum.wisc.edu/news/arboretum-news/monarch-winter-2022-2023-population-numbers-released/>. Based on E. Rendon-Salina et al., *Area of forest occupied by the colonies of monarch butterflies in Mexico during the 2022-2023 overwintering period*, [https://files.worldwildlife.org/wwfcmsprod/files/Publication/file/3oj167d505\\_WWF\\_Monarch\\_Butterfly\\_Report\\_2022\\_2023\\_FINAL.pdf?\\_ga=2.34270561.1537687296.1699244309-138092667.1699244309](https://files.worldwildlife.org/wwfcmsprod/files/Publication/file/3oj167d505_WWF_Monarch_Butterfly_Report_2022_2023_FINAL.pdf?_ga=2.34270561.1537687296.1699244309-138092667.1699244309).

<sup>321</sup> W. Thogmartin et al., *supra* note 9.

native plants into prairie strips that support monarchs and other pollinators and provide many other benefits; and creating favorable habitat in marginal farmlands.<sup>322</sup> However, these conservation and restoration efforts will not succeed unless EPA enacts prudent restrictions on glyphosate to protect mature milkweeds,<sup>323</sup> and as the White House Task Force recommended, spray drift buffers<sup>324</sup> to protect monarch seedlings.

### c. Risks to Aquatic Organisms

Aquatic organisms face similarly bleak fates in the face of exposure to glyphosate formulations. Glyphosate and its breakdown product aminomethylphosphonic acid (AMPA) are widely detected in streams, rivers, ditches, lakes, groundwater, soils and sediments across the U.S.<sup>325</sup> Glyphosate even contaminates the atmosphere and comes to earth in rainfall: 60% to 100% of both air and rain samples in Iowa, Mississippi and Indiana tested positive for glyphosate in the mid-2000s.<sup>326</sup>

This water contamination is disturbing because glyphosate formulations are quite toxic to aquatic organisms, especially amphibians.<sup>327</sup> Renowned ecotoxicologist Rick Relyea found that Roundup Original MAX killed 50% of the tadpoles of nine species of frogs and toads after 96 hours of exposure to concentrations of just 0.8 to 2.0 mg/l glyphosate a.e.<sup>328</sup> In another study, Relyea found that half of wood frog tadpoles died when exposed for 16 days to 0.98 mg/l glyphosate a.e., but that in the presence of a predator, the LC<sub>50</sub> value dropped to 0.41 mg/l glyphosate a.e., showing how predator stress can amplify the toxicity of a pesticide.<sup>329</sup> Numerous studies by other scientists document similar and in some

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<sup>322</sup> *Id.*

<sup>323</sup> CFS, MONARCHS IN PERIL: HERBICIDE-RESISTANT CROPS & THE DECLINE OF MONARCH BUTTERFLIES IN NORTH AMERICA (2015), [http://www.centerforfoodsafety.org/files/cfs-monarch-report\\_4-2-15\\_design\\_87904.pdf](http://www.centerforfoodsafety.org/files/cfs-monarch-report_4-2-15_design_87904.pdf).

<sup>324</sup> Pollinator Task Force, *supra* note 317, at 51.

<sup>325</sup> W. Battaglin et al., *Glyphosate & its Degradation Product AMPA Occur Frequently & Widely in U.S. Soils, Surface Water, Groundwater & Precipitation*, 50 J. AMERICAN WATER RES. ASS'N 275 (2014); R. Coupe et al., *Fate & Transport of Glyphosate & Aminomethylphosphonic Acids in Surface Waters of Agricultural Basins*, 68 PEST MGMT. SCI. 16 (2012).

<sup>326</sup> F-C Chang et al., *supra* note 131.

<sup>327</sup> Relyea, *supra* note 8.

<sup>328</sup> R. Relyea and D. Jones, *The toxicity of Roundup Original MAX to 13 species of larval amphibians*, 28 ENV'T TOXICOLOGY & CHEMISTRY 2004 (2009). Note that a.e. stands for acid equivalent, a unit that provides a standardized metric of glyphosate acid across its different salts (forms). For formulations containing the isopropylamine salt of glyphosate as the active ingredient (a.i.), the a.i. value is multiplied by 0.74 to obtain the amount of glyphosate in a.e. units; for the potassium salt of glyphosate, the a.i. value is multiplied by 0.81. See EPA (6/5/09), Table 2, p. 12. Where a.i. values were reported in the studies discussed below, we have converted them to a.e.

<sup>329</sup> R. Relyea, *The lethal impacts of Roundup and predatory stress on six species of North American tadpoles*, 48 ARCH ENV'T CONTAMINATION TOXICOLOGY 351 (2005).



cases even greater toxicity. Glyphosate formulations killed 80%<sup>330</sup> and 55%<sup>331</sup> of western chorus frog tadpoles at 0.57 and 0.56 mg/l glyphosate a.e., respectively, the latter after just 24 hours' exposure. Another team tested the effects of Roundup Regular herbicide on the larvae of six amphibian species of the Pacific Northwest for different periods of time. The concentrations that killed half of the test populations (LC<sub>50</sub> values) of the most sensitive species, the Pacific tree frog, were 0.32, 0.24 and 0.22 mg/l glyphosate a.e. for exposures of 1, 7, and 15 days, respectively.<sup>332</sup> Spraying glyphosate formulations also has sublethal effects. For instance, one study found tail damage, gonadal abnormalities, decreased size and delayed metamorphosis in northern leopard frog tadpoles after 42 days' exposure to low concentrations of several glyphosate formulations.<sup>333</sup> A French team found that exposure to ultra-low (< 1 part per billion) levels of the glyphosate degradate AMPA decreased survival and delayed development of spined toad larvae.<sup>334</sup>

Other aquatic organisms are also impacted by glyphosate and/or the surfactants used with it. For instance, exposure to just 0.002 to 0.005 mg/l of three different POEA surfactant mixtures killed half the fairy shrimp exposed to them for two days.<sup>335</sup>

Actual concentrations of glyphosate observed in wetlands, from 0.3 to 5.2 mg/l,<sup>336</sup> overlap and exceed the lethal and sublethal exposure levels established in the experiments discussed above. EPA fails to recognize the adverse impacts of Roundup formulations on amphibians (aside from threatened and endangered species) because its assessments deny the fact that amphibian habitat is often inadvertently sprayed, and that glyphosate concentrations reach much higher levels in the small vernal pools where amphibians breed<sup>337</sup> than EPA models for much larger bodies of water.<sup>338</sup>

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<sup>330</sup> B. Williams & R. Semlitsch, *Larval responses of three Midwestern anurans to chronic, low-dose exposures of four herbicides*, 58 ARCH ENV'T CONTAMINATION TOXICOLOGY 819 (2010).

<sup>331</sup> G. Smith, *Effects of acute exposure to a commercial formulation of glyphosate on the tadpoles of two species of anurans*, 67 BULL ENV'T CONTAMINATION TOXICOLOGY 483 (2001).

<sup>332</sup> J. King and R. Wagner, *Toxic effects of the herbicide Roundup Regular on Pacific Northwestern amphibians*, 91 NORTHWESTERN NATURALIST 318 (2010).

<sup>333</sup> C. Howe et al., *Toxicity of glyphosate-based pesticides to four North American frog species*, 23 ENV'T TOXICOLOGY & CHEMISTRY 1928 (2004).

<sup>334</sup> M. Cheron & F. Brischoux, *Aminomethylphosphonic acid alters amphibian embryonic development at environmental concentrations*, 190 ENV'T RSCH. 109944 (2020).

<sup>335</sup> J. Brausch & P. Smith, *Toxicity of three polyethoxylated tallowamine surfactant formulations to laboratory and field collected fairy shrimp*, *Thamnocephalus platyurus*, 52 ARCH ENV'T CONTAM TOXICOL 217 (2007).

<sup>336</sup> R. Relyea, *A Response to Monsanto*, <http://web.archive.org/web/20120507020525/http://www.pitt.edu/~relyea/site/Roundup.html>.

<sup>337</sup> W. Battaglin et al., *The occurrence of glyphosate, atrazine, and other pesticides in vernal pools and adjacent streams in Washington, DC, Maryland, Iowa and Wyoming, 2005-2006*, 155 ENV'T MONITORING ASSESSMENT 281 (2009).

<sup>338</sup> CFS Risk Assessment Comments 2018, *supra* note 4, at 9-11.

#### d. Risks to Pollinators

Glyphosate and its formulations can harm pollinators through either direct exposure or indirectly through effects on the floral resources (pollen and nectar) they require for survival. While EPA was unable to reach definitive conclusions about glyphosate's toxicity to bees, several studies document lethal effects. In one, application of two different glyphosate formulations at as little as one-quarter the recommended application rate killed from 30% to 98% of the sprayed bumblebees; the authors attributed the deaths to the surfactants, which may have asphyxiated the bumblebees by clogging the spiracles that enable airflow.<sup>339</sup> Similarly, honey bees enclosed for 24 hours with plants freshly sprayed with a glyphosate formulation at either the recommended or twice the recommended rate experienced significantly greater mortality than control bees.<sup>340</sup>

Glyphosate also causes serious sublethal effects not assessed by EPA. A series of elegant experiments has shown that exposure to trace amounts of glyphosate in sucrose or brood food impairs the navigational abilities of foraging honey bees,<sup>341</sup> degrades their learning performance and short-term memory retention,<sup>342</sup> and can even delay larval development.<sup>343</sup> Exposure of honey bees to glyphosate also alters the composition of their gut microbiota.<sup>344</sup> Both glyphosate<sup>345</sup> and a Roundup formulation<sup>346</sup> had the same effect in honey bees, and thereby increased their mortality when subsequently challenged with the honeybee bacterial pathogen *Serratia marcescens*. A Roundup formulation administered in sucrose solution was similarly shown to reduce the diversity of gut microbiota of bumble bees.<sup>347</sup>

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<sup>339</sup> E. Straw et al., *Roundup causes high levels of mortality following contact exposure in bumble bees*, 58 J. APPLIED ECOLOGY 1167 (2021).

<sup>340</sup> J Abraham et al., *Commercially formulated glyphosate can kill non-target pollinator bees under laboratory conditions*, 166 ENTOMOLOGIA EXPERIMENTALIS ET APPLICATA 695 (2018).

<sup>341</sup> M. Balbuena et al., *Effects of sublethal doses of glyphosate on honeybee navigation*, 218 J. EXPERIMENTAL BIOLOGY 2799 (2015).

<sup>342</sup> L. Herbert et al., *Effects of field-realistic doses of glyphosate on honeybee appetitive behaviour*, 217 J. EXPERIMENTAL BIOLOGY 3457 (2014).

<sup>343</sup> D. Vazquez et al., *Glyphosate affects the larval development of honey bees depending on the susceptibility of colonies*, 13 PLoS ONE e0205074 (2018).

<sup>344</sup> N. Blot et al., *Glyphosate, but not its metabolite AMPA, alters the honeybee gut microbiota*, 14 PLOS ONE e0215466 (2019).

<sup>345</sup> E. Motta et al., *Glyphosate perturbs the gut microbiota of honey bees*, 115 PNAS 10305 (2018) (“Our results show that glyphosate reduces the protective effect of the gut microbiota against opportunistic pathogens . . .”).

<sup>346</sup> E. Motta et al., *Oral and topical exposure to glyphosate in herbicide formulation impact the gut microbiota and survival rates of honey bees*, 86 APPLIED ENV'T MICROBIOLOGY e01150 (2020).

<sup>347</sup> M. Helander et al., *Glyphosate and a glyphosate-based herbicide affect bumblebee gut microbiota*, 99 FEMS MICROBIOLOGY ECOLOGY 1 (2023).

A 2019 study found a 33% decline in butterfly abundance in Ohio from 1996 to 2016, in part due to agricultural practices, in particular a six-fold increase in glyphosate use.<sup>348</sup>

*e. Toxicity to Birds, Reptiles, Terrestrial-Phase Amphibians*

EPA's preliminary ecological assessment reveals glyphosate poses chronic risks of concern for birds (which serve as surrogates for reptiles and terrestrial-phase amphibians) in at least six glyphosate application scenarios.<sup>349</sup> The extent of the harm is uncertain, though, because mallard ducks suffered reduced body weight in a registrant reproduction study at the lowest dose tested (501 mg ae/kg body weight), leaving it unclear how little glyphosate it would take to stunt the growth of mallards and potentially other birds.<sup>350</sup>

A 2023 British study found that glyphosate negatively affected the abundance of house sparrows, a fast-declining bird species in the UK, in gardens, with house sparrow abundance 24.9% lower in gardens where glyphosate is used.<sup>351</sup>

*f. Lack of Mitigation Post Withdrawal of 2020 IRRD*

The Ninth Circuit justified not vacating the ESA portion of the IRRD despite EPA's failure to comply with the ESA, on account of the mitigation measures intended to limit the ecological impacts of glyphosate use.<sup>352</sup> However, these wholly inadequate mitigation measures were never put into place and with the IRRD now withdrawn in its entirety, they never will be. Thus, those ecological impacts the Ninth Circuit acknowledged existed and maintained were being mitigated by the IRRD are in full force today.

## 2. Endangered and Threatened Species

In addition to its admissions of ecological risk in the 2015 risk assessment, EPA conceded the devastating impacts of glyphosate on endangered and threatened species in its 2021 final BE.

In the litigation surrounding the IRRD, the Ninth Circuit detailed these findings: "The BE found that glyphosate "may affect" *all* ESA-listed species that experience glyphosate exposure—that is, 1,795 species—and is likely to adversely affect 93% of those species."<sup>353</sup> In other words, glyphosate is likely to adversely affect (LAA) 1,676 ESA listed species, including 75 mammals, 88 birds, 36 amphibians, 33 reptiles, 179 fish, 940

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<sup>348</sup> T. Wepprich et al., *Butterfly abundance declines over 20 years of systematic monitoring in Ohio, USA*, PLoS ONE e0216270 (2019).

<sup>349</sup> Proposed IRRD, *supra* note 68, at 26-27.

<sup>350</sup> EPA OPP Ecological 2015, *supra* note 137, at 51-52.

<sup>351</sup> C. de Montaigne & D. Goulson, *Habitat quality, urbanization & pesticides influence bird abundance and richness in gardens*, SCI. TOTAL ENV'T (2023).

<sup>352</sup> Glyphosate IRRD Challenge, 38 F.4th at 60-61.

<sup>353</sup> *Id.* at 55 (emphasis added).

plants, 185 aquatic invertebrates, and 140 terrestrial invertebrates, as well as 759 critical habitats for these imperiled species.<sup>354</sup>

Endangered plants in particular will be heavily impacted, a fact that comes as little surprise considering glyphosate is an herbicide. However, other iconic species and endangered pollinators critical to our food system face grave danger, including, to give just a few examples, the whooping crane, Indiana bat, and rusty-patched bumble bee.<sup>355</sup>

The iconic whooping crane is among the world's most endangered animals. In 1954, there were as few as twenty-one left.<sup>356</sup> And while conservation efforts have led to a limited recovery, there are now just a few hundred in the wild,<sup>357</sup> about 4% of its historic numbers.

Indiana bats are a significant source of natural insect control, typically consuming up to half their body weight in insects each night.<sup>358</sup> Only half of those that existed when the species was listed as endangered remain, with pesticide contamination of their food supply and pesticidal reduction in insects they feed on among the factors responsible for their decline.<sup>359</sup>

The rusty-patched bumble bee was the first bumble bee listed in the continental U.S. under the ESA.<sup>360</sup> While once considered abundant across a broad geographic range, since 2000, the rusty patched bumble bee has been reported in only a few places in 13 states and one province and its current distribution is only 13% of its historical extent. Various pesticides increase the susceptibility of the rusty patch to disease, while herbicides like glyphosate deprive the bumble bee of floral resources.<sup>361</sup>

Under the ESA, a “likely to adversely effect” (LAA) determination requires formal consultation, concluding with a final biological opinion from the expert wildlife agencies.<sup>362</sup> Thus, EPA must now consult the Services to determine if their actions will jeopardize any species or adversely modify any critical habitat.<sup>363</sup> “Jeopardize” means

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<sup>354</sup> BE Executive Summary, *supra* note 1, at 4; BE at 4-3

<sup>355</sup> Final BE, APPENDIX 4-1. Species Effects Determination Tables (XLSX), <https://www.epa.gov/endangered-species/final-national-level-listed-species-biological-evaluation-glyphosate#chap4>.

<sup>356</sup> See U.S. FWS, INTERNATIONAL RECOVERY PLAN: WHOOPING CRANE (*GRUS AMERICANA*) 1 (Mar. 2007), [https://ecos.fws.gov/docs/recovery\\_plan/070604\\_v4.pdf](https://ecos.fws.gov/docs/recovery_plan/070604_v4.pdf).

<sup>357</sup> *Id.* at 13-14.

<sup>358</sup> U.S. FWS, *Midwest Region Endangered Species: Indiana Bat (Myotis Sodalis)*, <https://www.fws.gov/species/indiana-bat-myotis-sodalis>.

<sup>359</sup> *Id.*

<sup>360</sup> Sarina Jepsen, *Rusty Patched Bumble Bee: The First Bee in the Continental U.S. to be Protected under the Endangered Species Act* (Jan. 11, 2017), <https://www.xerces.org/blog/rusty-patched-bumble-bee-first-bee-in-continental-us-to-be-protected-under-endangered-species>.

<sup>361</sup> U.S. FWS, *Rusty patched bumble bee (Bombus affinis)*, <https://ecos.fws.gov/ecp/species/9383>.

<sup>362</sup> 50 C.F.R. §§ 402.02; 402.14(a); 402.14(h)(3), (i).

<sup>363</sup> 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14. “Jeopardize” means taking an action that “reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution . . .” 50 C.F.R. § 402.02(d).

taking an action that “reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution . . .”<sup>364</sup>

Evidence suggests eventual jeopardy and adverse modification determinations made by the Services are likely to be numerous. While EPA claims 96% and 97% of listed species and critical habitats LAA determinations are supported by moderate evidence, rather than strong,<sup>365</sup> in reality, the evidence supporting the LAA determinations is much stronger than that suggested by EPA.<sup>366</sup> EPA’s inappropriate selection of toxicity endpoints resulted in the strength of the evidence for LAA determinations being underestimated. Thus, eventual jeopardy and adverse modification determinations are very possible for numerous species.

Despite these admissions of grave and widespread harm to hundreds of federally protected plants, birds, insects, and animals, EPA has continued to register glyphosate. But the ESA requires that all agencies “insure” that any agency action is “not likely to jeopardize the continued existence” of listed species or “result in the destruction of adverse modification” of their critical habitats.<sup>367</sup> This is done through the ESA Section 7 consultation process, which EPA has begun but not yet completed. This process culminates with a Biological Opinion issued by the Services (the expert agencies charged with overseeing implementation of the ESA) determining whether the agency action will jeopardize the continued existence of a species and/or impair critical habitat, and also whether the action will “take” any members of a listed species—thus requiring the agency to implement additional measures to minimize and mitigate the take.<sup>368</sup> In the absence of such a Biological Opinion/Incidental Take Statement, the federal agency has no legal authorization to proceed with an action that causes any level of take.<sup>369</sup> Agencies must consult – and finish consultation – *before* taking action like registering pesticides.

In addition to violating section 7(a)(2)’s flat prohibition on proceeding with potentially harmful actions before the consultation process has run its course, EPA’s failure to complete the consultation process yet still keeping glyphosate registered also runs afoul of the ESA’s prohibition on making any “irreversible or irretrievable commitment of resources” that “has the effect of foreclosing the formulation or implementation of any

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<sup>364</sup> 50 C.F.R. § 402.02(d).

<sup>365</sup> BE Executive Summary, *supra* note 1, at 5-6.

<sup>366</sup> Petitioners incorporate by reference CFS comments on the Draft BE for Glyphosate. See CFS, *Comments on EPA’s Draft Endangered Species Act Biological Evaluation of Glyphosate*, Mar. 12, 2021 (discussing why the evidence supporting the LAA determinations is strong rather than moderate for many of LAA determinations).

<sup>367</sup> 16 U.S.C. § 1536(a)(2); 50 C.F.R. § 402.14.

<sup>368</sup> *Id.* Note that while the Section 7 consultation process culminates in a BiOp, agency’s duties don’t end with the issuance of a final BiOp because “[f]ollowing the issuance of a biological opinion, the Federal agency shall determine whether and in what manner to proceed with the action in light of its Section 7 obligations and the Service’s biological opinion.” 50 CFR 402.15(a).

<sup>369</sup> See *Bennett v. Spear*, 520 U.S. 154, 170 (1997).

reasonable and prudent alternative measures” that may be required by the Services at the culmination of the consultation process.<sup>370</sup>

### III. STATEMENT OF LEGAL GROUNDS

FIFRA prohibits the registration and use of pesticides that cause unreasonable adverse effects on the environment. As detailed *supra*,<sup>371</sup> EPA lacks the data necessary to conclude current glyphosate uses do not cause “unreasonable adverse effects on the environment.” Rather, the evidence demonstrates the present uses of glyphosate have caused and continue to cause unreasonable risk to humans and the environment, and furthermore, that the benefits of continued glyphosate use do not outweigh the costs. The harms caused by glyphosate are ongoing, and thus present an imminent hazard. Pursuant to its obligations under FIFRA, EPA must cancel all registrations of glyphosate and suspend all glyphosate registrations pending completion of cancellation proceedings.

#### a. Glyphosate Must be Cancelled for Causing an Unreasonable Risk to People and the Environment in Violation of FIFRA

Cancellation is warranted when the EPA finds that when “used in accordance with widespread and commonly recognized practice,” a registered pesticide has “unreasonable adverse effects on the environment,” that is “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.”<sup>372</sup> Here, all registrations of glyphosate must be cancelled because the uses for which glyphosate is approved — “a wide array of both agricultural and non-agricultural settings”<sup>373</sup> — are causing unreasonable risk to humans, the environment, and endangered and threatened species, in addition to costing farmers economically. Stated another way, how glyphosate is “used in accordance with widespread and commonly recognized practice,” is causing unreasonable risk to humans, the environment, and endangered and threatened species, in addition to imposing significant indirect costs on farmers.

Human health is directly endangered by continued glyphosate use. The medical scientific community overwhelmingly agrees that glyphosate is a probable carcinogen and that there is strong epidemiological evidence of an association between glyphosate exposure and NHL.<sup>374</sup> IARC classifies glyphosate as “probably carcinogenic to humans,” while

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<sup>370</sup> 16 U.S.C. § 1536(d).

<sup>371</sup> See Section II (c) – (d).

<sup>372</sup> 7 U.S.C. § 136d(b); 7 U.S.C. § 136(bb).

<sup>373</sup> More specifically, “agricultural uses include stone and pome fruits, citrus fruits, berries, nuts, vegetables, legumes, cereal grains, and other field crops. . . use on the following glyphosate-resistant (transgenic) crops: corn, soybean, cotton, canola, sugar beets, and alfalfa [and the following] . . . non-agricultural uses: tree injections, residential spot treatments, aquatic areas, forests, rights-of-way, recreational turf, ornamentals, non-food tree crops, and Conservation Reserve Program land.” See FINAL IRRD, *supra* note 40, at 8.

<sup>374</sup> See *generally* Section II(d)(i)(1).

scientists in EPA's impartial, non-regulatory science division, ORD, favor "likely carcinogenic" or "suggestive evidence" of carcinogenic potential. While EPA OPP<sup>375</sup> settled on a "not likely" descriptor, this conclusion was vacated by the Ninth Circuit due to numerous flaws and improprieties<sup>376</sup> and thus is invalid and does nothing to negate the consensus of the larger scientific community.

Further, the flaws present in OPP's cancer analysis and thus resulting conclusion are unmistakable. The OPP focused its assessment overwhelmingly on dietary exposure, that is, ingestion of glyphosate residues in or on food and water, stating in its final cancer evaluation: "Oral exposure is considered the primary route of concern for glyphosate."<sup>377</sup> OPP never satisfactorily explains why it is not equally or far more concerned with *occupational* exposure to glyphosate, which occurs primarily through dermal absorption, and by its own reckoning could reach levels that are 30 to over 100 times greater than maximum dietary (oral) exposure.<sup>378</sup> As discussed earlier,<sup>379</sup> OPP is content to dismiss cancer concerns for workers by casually estimating that their exposure to glyphosate is somewhat less than that which causes tumors in rodents. However, this in no way constitutes a valid risk assessment, much less one that can rival the larger scientific communities' consensus.

Further, glyphosate exposure does not just increase cancer risk, it also has adverse effects on the liver, kidney, and reproductive system.<sup>380</sup> Human and animal studies demonstrate that glyphosate exposure is a contributing factor to both fatty liver disease and metabolic syndrome, diminished male and female fertility, and reproductive health, as well as kidney disease.<sup>381</sup>

The harms associated with glyphosate's registered uses are by no means limited to humans and EPA admitted as much when it acknowledged glyphosate's ecological risks include impairment of growth and reproduction of mammals, growth of birds and terrestrial-phase amphibians, and the survival of both terrestrial and various aquatic plants.<sup>382</sup> As is discussed *supra*, honeybees and other pollinators are also being impacted by higher application rates, and spray drift which degrades their habitat and nectar sources.<sup>383</sup> The past few decades have also seen the migratory Monarch butterfly populations decimated, with a more than 80% decline between 1999 and 2012 because of

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<sup>375</sup> See Lerner, *supra* note 111 (for pesticide industry's historical influence on OPP).

<sup>376</sup> See Section II(c)(ii)(2).

<sup>377</sup> EPA OPP Cancer 2017, *supra* note 62, at 15.

<sup>378</sup> *Id.* at 18, 200 (Appendix E). Compare EPA estimates of high-end dietary exposure to glyphosate for various age groups (ranging from 0.061258 mg/kg/day for 50-99 year-old adults to 0.228379 mg/kg/day for 1-2 year olds) to a maximum exposure of 7 mg/kg/day for workers who mix and load glyphosate for large-scale spraying operations. 7 divided by each dietary exposure level yields the range cited in the text.

<sup>379</sup> See note 125 and accompanying text.

<sup>380</sup> See *generally* Section II(d)(i)(2)-(4).

<sup>381</sup> *Id.*

<sup>382</sup> See note 305 and accompanying text.

<sup>383</sup> See *generally* Section II(d)(ii)(1)(d).

glyphosate's decimation of milkweed.<sup>384</sup> Most concerning, however, is the danger glyphosate poses to federally protected endangered and threatened species, likely adversely affecting 1,676 species and 759 critical habitats.<sup>385</sup>

Thus, there can be no doubt that glyphosate's currently approved uses pose "unreasonable risk to man [and] the environment."<sup>386</sup> However, the costs of glyphosate do not end here.<sup>387</sup> The explosion in glyphosate use since the 1993 reregistration brought with it an epidemic of glyphosate-resistant weeds. As a result, farmers now bear substantial additional costs to control these weeds via additional herbicides, hand weeding crews, and increased use of tillage. And these higher costs are borne by all farmers due to the glyphosate-resistant gene flow, not just those who choose to use Roundup Ready crop systems. Glyphosate-resistant weeds are also in large part to blame for the 34% increase in agricultural herbicide use from just 2005 to 2012,<sup>388</sup> and thus the resulting drift damage from additional pesticides like dicamba and 2,4-D used to control them. Glyphosate drift has also driven up costs for organic, non-GMO, and pesticide free conventional farmers, who must take costly measures to protect their crops from drift.

Petitioners believe that the facts pertinent to balancing the risks and benefits of glyphosate are peculiarly within the knowledge of the EPA, and thus the burden should not fall to Petitioners to conduct such balancing test in order to prove cancellation is warranted.<sup>389</sup> Nevertheless, Petitioners do so based on the evidence before them in an attempt to demonstrate the impossibility of EPA concluding the purported benefits of glyphosate outweigh the risks. The harms caused by glyphosate use are numerous and significant and cannot be outweighed by the putative benefits of continued use.<sup>390</sup> While no longer operative, EPA's 2020 IRRD offers insight into what the agency views as glyphosate's benefits. Overarchingly, EPA highlights glyphosate's versatility and affordability as its major benefits.<sup>391</sup> However, these two factors are more than counterbalanced by the costs just discussed. While glyphosate may be inexpensive, the weed resistance it has spurred forces farmers to buy additional pesticides or utilize tillage to tackle those weeds glyphosate is no longer effective against. The growth in GR weeds also negates glyphosate's versatility, limiting the contexts in which it is effective.

So, while Petitioners fail to see how glyphosate offers any durable benefits, even if EPA concludes *some* benefits exist, such benefits simply cannot outweigh the laundry list of

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<sup>384</sup> See *generally* Section II(d)(ii)(1)(b).

<sup>385</sup> BE Executive Summary, *supra* note 1, at 4.

<sup>386</sup> 7 U.S.C. § 136(bb).

<sup>387</sup> See *generally* Section II(c)(ii)(4)(e).

<sup>388</sup> PESTICIDE INDUSTRY SALES AND USAGE, *supra* note 187, at 12: Table 3.2.

<sup>389</sup> "[T]he ordinary rule, based on considerations of fairness, does not place the burden upon a litigant of establishing facts peculiarly within the knowledge of his adversary." See *Ellis v. Housenger*, 252 F. Supp. 3d 800, 809 n.7 (N.D. Cal. 2017) (citing *Campbell v. United States*, 365 U.S. 85, 96 (1961)).

<sup>390</sup> See also *Public Employees for Environmental Responsibility et al., Petition for Rulemaking to Amend EPA's 1984 Pesticide Regulation that Waived Efficacy Data Requirements* (2023).

<sup>391</sup> See FINAL IRRD, *supra* note 40, at 13-14.



costs and irreparable environmental and public health harm. Farmers, farmworkers, landscapers, amongst others, are getting cancer and suffering reproductive harms. Endangered species are being driven to extinction. This must outweigh any alleged benefits.

And further, “alternative pest control [methods are] available,”<sup>392</sup> a reality made plain by farmers already turning to various other pesticide formulations or non-chemical weed control methods in the wake of the spread of glyphosate-resistant weeds. Sustainable farming systems that involve more complex crop rotations that include small grains and legumes are both profitable and achieve excellent weed control with a 76% to 82% reduction in herbicide use in Midwest corn-soybean farming systems.<sup>393</sup> Organic farmers do not use synthetic pesticides like glyphosate at all, and organic is a steadily growing agricultural sector with higher rates of return for producers compared to farmers who continue practicing conventional, pesticide-intensive agriculture.<sup>394</sup>

In sum, evidence abounds demonstrating that currently approved uses of glyphosate are causing unreasonable adverse impacts on public health and the environment, including “unreasonable risk to man [and] the environment.”<sup>395</sup> These impacts, coupled with the costs of glyphosate’s continued use heavily outweigh any purported benefit the pesticide offers. Cancellation of all glyphosate registrations is not only warranted by EPA but absolutely critical to safeguard the public, farmers, farmworkers, children, the environment, and imperiled wildlife.

#### **b. Immediate Suspension of Glyphosate’s Registration Pending Cancellation is Necessary to Prevent an Imminent Hazard**

Because cancellation takes time, EPA may suspend the registration of a pesticide immediately if it determines it is necessary “to prevent an imminent hazard during the time required for cancellation . . .”<sup>396</sup> An imminent hazard exists if during the time required for cancellation the continued use of a pesticide would (1) “be likely to result in unreasonable adverse effects on the environment” or (2) “involve unreasonable hazard to the survival of a species declared endangered or threatened” by the Endangered Species Act (ESA).<sup>397</sup> “[C]ancellation . . . proceedings may take one or two years to

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<sup>392</sup> See *Ellis*, 252 F. Supp. 3d at 810, n. 8 (citing *Env’t Def. Fund*, 465 F.2d 528, 539 (D.C. Cir. 1972)) (noting what has been considered sufficient grounds for showing harms outweighs benefits within the unreasonable adverse effects analysis).

<sup>393</sup> M. Liebman et al., *Agronomic & Economic Performance Characteristics of Conventional & Low-External-Input Cropping Systems in the Central Corn Belt*, 100 *AGRONOMY J.* 600 (2008).

<sup>394</sup> D. Crowder & J. Reganold, *Financial Competitiveness of Organic Agriculture on a Global Scale*, 112 *PNAS* 7611 (2015); see also Press Release: Sylvia Kantor, Wash. State Univ., *Organic agriculture more profitable to farmers* (June 1, 2015), <https://news.wsu.edu/press-release/2015/06/01/organic-agriculture-more-profitable-to-farmers/>.

<sup>395</sup> 7 U.S.C. § 136d(b); *id.* § 136(bb).

<sup>396</sup> 7 U.S.C. § 136d(c)(1).

<sup>397</sup> *Id.* § 136(l).

complete.”<sup>398</sup> Courts have explained that an “‘imminent hazard’ is not limited to a concept of crisis[.]”<sup>399</sup> Rather, “[i]t is enough if there is substantial likelihood that serious harm will be experienced during the year or two required. . . .”<sup>400</sup>

As is laid out in great detail *supra*, the continued registration and use of glyphosate is resulting in unreasonable adverse effects on the environment and likely involves unreasonable hazard to the survival of hundreds of endangered and threatened species. These harms are occurring now and will continue to occur during the one to two years it will take EPA to complete cancellation proceedings for glyphosate registrations. Thus, it is well within EPA’s authority to take action and suspend glyphosate registrations and Petitioners urge EPA to take said action.

***i. Continued Use of Glyphosate During Cancellation Proceedings is Likely to Result in Unreasonable Adverse Effects on the Environment***

As is detailed *supra* in Section III(a), the currently approved uses of glyphosate are causing unreasonable adverse effects on the environment, including “unreasonable risk to man [and] the environment” and these effects coupled with the costs of glyphosate’s continued use heavily outweigh any benefit the pesticide offers. These unreasonable adverse effects are happening *now*. Monarch butterflies are being decimated, farmers are incurring the costs of GR weeds season after season, glyphosate drift is destroying off field plants and driving up costs for nearby organic farmers, nearly all endangered and threatened species are being injured, and farmers, farmworkers, landscapers, and many others are suffering negative health effects ranging from cancer to infertility to metabolic syndrome and kidney disease.

While some of the impacts of glyphosate take time to manifest (e.g., cancer), the glyphosate applications that are causing the disease are occurring and will continue to occur during the time required for cancellation if suspension does not occur. Preventing 1-2 years of exposure may very well prevent an eventual NHL diagnosis, safeguard a vulnerable child from metabolic syndrome, and may mean the difference between a family being able to have a child or not. Petitioners urge EPA to safeguard public health now and not delay acting any further.

***ii. Continued Use of Glyphosate Will Involve Unreasonable Hazard to the Survival of Endangered or Threatened Species***

FIFRA does not define unreasonable hazard, and no court has clearly interpreted the meaning of the phrase to date. Thus, Petitioners reasonably interpret the phrase based on

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<sup>398</sup> *Ellis*, 252 F. Supp. 3d at 806 (citing *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988), cert. denied, 490 U.S. 1035 (1989)).

<sup>399</sup> *Env’t Def. Fund v. EPA*, 510 F.2d 1292, 1297 (D.C. Cir. 1975) (citing *Env’t Def. Fund v. EPA*, 465 F.2d 528, 540 (D.C. Cir. 1972)).

<sup>400</sup> *Id.*

its plain language and the Northern District of California’s discussion of the standard in *Ellis v. Housenger*,<sup>401</sup> to mean when the survival of an endangered or threatened species will be directly or indirectly threatened.

The facts pertinent to any effects glyphosate might have on endangered or threatened species are peculiarly within the knowledge of the EPA and other expert agencies, and thus Petitioners alone should not bear the burden of proving the reality of unreasonable hazard.<sup>402</sup> Nevertheless, Petitioners make their case with the facts EPA has already shared via the recently published final BE. In the final BE, EPA found that glyphosate “may affect” all ESA-listed species that experience glyphosate exposure and is likely to adversely affect 1,676 ESA listed species and 759 critical habitats, that is 93% of listed species and 96% of critical habitats designated.<sup>403</sup> Thus by EPA’s own admission, *thousands* of federally protected species and habitats are endangered by glyphosate use.

Only formal consultation will confirm where the potential adverse effect is likely to jeopardize the continued existence of a species or destroy or adversely modify critical habitat. However, as is noted *supra*, many of these determinations are supported by strong evidence, despite EPA’s conclusions to the contrary, suggesting eventual jeopardy and adverse modification determinations are very well possible. Further, above detailed evidence demonstrates such possibility is especially likely for numerous endangered plant species and pollinators.<sup>404</sup> As also explained above, waiting for this analysis and decision from the expert wildlife agencies is required by the ESA, and thus EPA’s continued registration of glyphosate also violates the ESA.

Further, even EPA’s deficient analysis concludes that strong evidence exists for one listed species and six critical habitats, seemingly implying the possibility of a jeopardy determination for the California clapper rail, and adverse modification determinations for the critical habitat associated with the Mississippi sandhill crane, the Hoover’s spurge, Gypsum wild-buckwheat, Greene’s tuctoria, Willamette daisy, and the Large-flowered woolly meadowfoam.<sup>405</sup>

So, there can be no doubt that an imminent hazard exists. Ongoing unreasonable adverse effects on the environment undeniably exist. And all evidence to date points to an unreasonable hazard to the survival of likely hundreds or thousands of endangered and threatened species. EPA should accordingly suspend the registration of all glyphosate

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<sup>401</sup> See *Ellis*, 252 F. Supp. 3d at 809, n.6 (detailing that a claim of unreasonable hazard alone is insufficient and that the failure to “cite to a study or article” to show an unreasonable hazard to the survival of an endangered or threatened species renders such showing invalid).

<sup>402</sup> *Id.* at 809 n.7 (N.D. Cal. 2017) (citing *Campbell v. United States*, 365 U.S. 85, 96 (1961) (“[T]he ordinary rule, based on considerations of fairness, does not place the burden upon a litigant of establishing facts peculiarly within the knowledge of his adversary.”)).

<sup>403</sup> BE Executive Summary, *supra* note 1, at 4-6.

<sup>404</sup> See *generally* Section II(d)(ii)(2).

<sup>405</sup> See Final BE, APPENDIX 4-1, *supra* note 355.

registrations pending cancellation to safeguard human health, the environment, and threatened and endangered species.

**c. EPA Must, at a Minimum, Initiate Special Review**

Finally, if EPA is not convinced by the wealth of research recounted herein detailing the dangers of glyphosate, Petitioners implore EPA to initiate a special review and undertake its own evaluation of glyphosate's effects on the environment, taking care not to repeat the deficiencies seen in EPA's recent attempt at registration review.<sup>406</sup> The purpose of Special Review is "to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment."<sup>407</sup> Special review is warranted for the foregoing reasons and thus, Petitioners urge EPA to initiate special review immediately.<sup>408</sup>

In accordance with FIFRA regulations

- (a) The Administrator may conduct a Special Review of a pesticide use if he determines. . .that the use of the pesticide. . .:
  - (1) May pose a risk of serious acute injury to humans or domestic animals.
  - (2) May pose a risk of inducing in humans an oncogenic, heritable genetic, teratogenic, fetotoxic, reproductive effect, or a chronic or delayed toxic effect, which risk is of concern in terms of either the degree of risk to individual humans or the number of humans at some risk, based upon:
    - (i) Effects demonstrated in humans or experimental animals.
    - (ii) Known or predicted levels of exposure of various groups of humans.
    - (iii) The use of appropriate methods of evaluating data and relating such data to human risk.
  - (3) May result in residues in the environment of nontarget organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms, or at levels which produce adverse reproductive effects in such organisms, as determined from tests conducted on representative species or from other appropriate data.
  - (4) May pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973, as amended.
  - (5) May result in the destruction or other adverse modification of any habitat designated by the Secretary of the Interior or the Secretary of Commerce under

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<sup>406</sup> See generally Section II(c)(ii).

<sup>407</sup> 40 CFR § 154.1.

<sup>408</sup> As is noted *supra* "[t]he Administrator may evaluate a pesticide use under the criteria of § 154.7 either on his own initiative, or at the suggestion of any interested person." 40 C.F.R. § 154.10 (emphasis added).

the Endangered Species Act as a critical habitat for any endangered or threatened species.

(6) May otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration.

(b) In making any determination that a pesticide use satisfies one of the criteria for issuance of a Special Review specified by paragraph (a) of this section, the Administrator shall consider available evidence concerning both the adverse effect in question and the magnitude and scope of exposure of humans and nontarget organisms associated with use of the pesticide.

40 C.F.R. § 154.7.

Glyphosate implicates more than one of the above detailed criteria for special review; in fact, it implicates practically *all* the above criteria. Such stark reality should demonstrate the danger glyphosates poses and the urgency this situation necessitates. Each day EPA fails to act, these risks continue.

To begin, glyphosate poses risk of an oncogenic effect which is of concern based on the herbicide's inducement of tumors in experimental animals and genotoxic effects, together with a strong epidemiological association with NHL in farmers. Evaluation of this evidence by qualified experts with the International Agency for Research on Cancer, and scientists with EPA's Office of Research and Development, resulted in a determination that glyphosate is probably or likely carcinogenic to humans. Moreover, glyphosate's extensive and intensive use as the most heavily applied pesticide in the country means large numbers of people are exposed, with users of glyphosate formulations, including but not limited to farmers, farmworkers, and landscapers, subjected to particularly high exposures via dermal absorption.<sup>409</sup>

Further, appropriate data indicates glyphosate does result in toxic residues in the environment of non-target organisms. Incident reports, surveys of state pesticide regulators, and numerous peer-reviewed studies demonstrate the extensive damage to terrestrial plants as a result of glyphosate drift;<sup>410</sup> and numerous independent studies demonstrate the toxicity of glyphosate formulations to aquatic phase amphibians.<sup>411</sup>

So too may glyphosate and its formulations pose a risk to the survival of endangered and threatened species and result in the destruction or adverse modification of critical habitat. In fact, EPA itself has detailed that it likely adversely affects 1,676 species and

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<sup>409</sup> See *generally* Section II(d)(i)(1).

<sup>410</sup> See note 191 and accompanying text; EPA OPP Ecological 2015, *supra* note 137; CFS Risk Assessment Comments 2018, *supra* note 8.

<sup>411</sup> See *generally* Section II(d)(ii)(1)(a), (c).

759 critical habitats.<sup>412</sup> And while the expert agencies still have yet to release biological opinions establishing jeopardy indeed exists, the above detailed evidence demonstrates such possibility is likely for numerous species, especially endangered plant species and pollinators.

And finally, glyphosate unquestionably poses risk to humans and the environment of a magnitude large enough to warrant proper analysis of whether its benefits outweigh its risks in support of continued registration. Glyphosate's risks and harms include predisposing hundreds of thousands of people, if not millions, to a lethal cancer, contributing to near eradication of the Monarch butterfly, suppressing pollinators, reducing populations of aquatic organisms, and adversely effecting almost all endangered and threatened species, to name just a few.<sup>413</sup> These severe effects surely are of sufficient magnitude to warrant a proper cost benefit analysis.

#### **IV. CONCLUSION**

For the reasons stated herein, Petitioners request that EPA cancel all registrations of glyphosate pursuant to Section 136d(b) and suspend all glyphosate registrations pending completion of cancellation proceedings pursuant to Section 136d(c)(1). Cancellation is warranted because the wide array of both agricultural and non-agricultural uses for which glyphosate is approved, are causing unreasonable risk to humans, the environment, and endangered and threatened species, in addition to costing farmers economically. And none of glyphosate's purported benefits outweigh these costs. Suspension is similarly supported as it is necessary to prevent imminent hazards during the cancellation process. Imminent hazards exist in the form of both ongoing unreasonable adverse effects on the environment and unreasonable hazard to the survival of thousands of endangered and threatened species. EPA cannot continue to rely upon the outdated 1993 re-registration decision as justification for glyphosate's continued registration. It must immediately provide evidence that glyphosate can in fact meet the FIFRA safety standard or suspend and cancel glyphosate until it can do so.

In the alternative, Petitioners request EPA initiate special review for glyphosate and undertake a robust analysis of the pesticide's effects, taking special care to address the deficiencies noted in its recent IRRD attempt. This action is necessary for EPA to properly discharge its duty under FIFRA to protect the public and environment.

To date EPA has failed to ensure glyphosate's current uses meet the required safety standard and thus immediate action is necessary. Petitioners urge EPA to act on this petition without delay. The APA requires an agency to conclude a matter presented to it, such as a legal petition like the one at issue here, "within a reasonable time."<sup>414</sup> While the reasonableness of the time taken by the agency to respond varies depending on the

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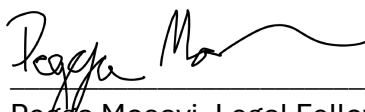
<sup>412</sup> BE Executive Summary, *supra* note 1, at 4.

<sup>413</sup> See *generally* Section II(d).

<sup>414</sup> 5 U.S.C. § 555(b).

circumstances, where public health is in danger, like here, a reasonable time will be interpreted to require quick action.<sup>415</sup> If EPA fails to respond to this petition “within a reasonable time”, Petitioners will not hesitate to take EPA to court to compel a response.<sup>416</sup>

Respectfully Submitted,



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<sup>415</sup> *In re Pesticide Action Network N. Am.*, 798 F.3d 809, 814 (9th Cir. 2015) (concluding with “little difficulty” that EPA needed to act quickly on plaintiff’s petition considering the significant human health effects of chlorpyrifos).

<sup>416</sup> The APA grants a right of judicial review to “[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action.” 5 U.S.C. § 702. “Agency action” is defined to include not just affirmative agency action but also the “failure to act,” *id.* § 551(13), such as the failure to respond to a legal petition. Under the APA, courts “shall compel agency action unlawfully withheld or unreasonably delayed” *id.* § 706(1).

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