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Pesticide Registration Fails to Protect Human Health: Damages from Exposure to Glyphosate-Based Herbicides

Introduction 69
I. Registration of Pesticides 78
II. Cost-Benefit Analysis 81
A. Costs and Benefits under FIFRA 82
B. Information for an Analysis 85
C. Cumulative Exposure 87
D. Evaluating Data 89
III. Glyphosate-Based Herbicides 93
A. Agricultural Uses 96
B. Health Studies 99
C. Health Concerns 102
IV. Challenging Registrations and Uses 106
A. Cancellation and Suspension 108
B. Revocation of Tolerances 112
C. Mitigation Measures 114
D. Litigation for Health Damages 116
V. New Directions for Pesticide Liability 120
A. Undervaluing Human Health 123
B. Mitigation Measures 124
Conclusion 125

INTRODUCTION

In the United States, approximately 125,000 people have alleged that they are suffering health problems from their exposure to

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Monsanto's glyphosate-based herbicide products.[1] Monsanto, a company that was bought by Bayer AG in 2018, is well known for its Roundup glyphosate products that are widely used in agricultural, commercial, and residential settings.[2] The use of glyphosate is part of an evolution of food production practices dependent on usage of synthetic pesticide products.[3] In the 1940s, agricultural producers started using dichloro-diphenyl-trichloroethane (DDT), parathion, and malathion in the production of crops, in some cases replacing more dangerous natural pesticides containing arsenic or lead.[4] In other cases, synthetic pesticides were used heavily to address outbreaks of new pests, which sometimes led to environmental damages.[5] Recent data suggest that nearly six billion pounds of pesticides are being used each year around the world,[6] valued at $56 billion in 2012.[7] At this rate, the use is projected to be valued at $90 billion by 2023.[8] Annually in the United States, more than 3.3 pounds of pesticides are used per person.[9]

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1 *See Bayer Reaches a Series of Agreements*, BAYER (June 24, 2020), https://www.bayer.com/en/bayer-reaches-series-agreements [https://perma.cc/W5MU-8FGR].

2 *See* Nathan Bomey, *Monsanto Shedding Name: Bayer Acquisition Leads to Change for Environmental Lightning Rod*, USA TODAY (June 4, 2018), https://www.usatoday.com/story/money/2018/06/04/monsanto-bayer-name/668418002/ [https://perma.cc/M6NA-DV8V]. The purchase was proposed in 2016 but needed Department of Justice approval before becoming final. *Id.*

3 *See* Charles M. Benbrook, *Trends in Glyphosate Herbicide Use in the United States and Globally*, 28 ENV'T. SCIS. EUR. 1, 1–3 (2016), https://enveurope.springeropen.com/track/pdf/10.1186/s12302-016-0070-0 [https://perma.cc/KGR8-3F2C].

4 *See, e.g.*, Lloyd B. Tepper & Jeffrey H. Tepper, *The Rise and Fall of the Tacoma Arsenic Industry*, 39 J. SOC'Y FOR INDUS. ARCHEOLOGY 65, 74 (2013) (discussing the manufacture of arsenical pesticides and the cancellation of their registrations).

5 *See, e.g.*, Dan Fagin, *Toxic Legacy Pesticides Used Heavily for Years Tainted Water Supply, LI Water: How Safe*, NEWSDAY Sept. 7, 1993 (reporting on the use of pesticides on Long Island, New York, potato fields and the contamination of groundwater).

6 DONALD ATWOOD & CLAIRE PAISLEY-JONES, EPA, OFFICE OF PESTICIDE PROGRAMS, PESTICIDES INDUSTRY SALES AND USAGE: 2008 – 2012 MARKET ESTIMATES 9 (2017) [hereinafter EPA INDUSTRY SALES]. *See infra* notes 174–210 and accompanying text for information on the uses of glyphosate).

7 EPA INDUSTRY SALES, *supra* note 6, at 4.

8 Research and Markets, *Global Pesticides Market Analysis 2013-2018 & Forecasts 2018-2023*, CISION PR NEWSWIRE (Aug. 10, 2018), https://www.prnewswire.com/news-releases/global-pesticides-market-analysis-2013-2018--forecasts-2018-2023-300695468.html [https://perma.cc/9PXY-36P9]. Insecticides accounted for about $14 billion of the market in 2018. *Insect Pest Control Market 2019 Global Size, Share, Sales, Competitive Analysis, Upcoming Opportunities, and Forecast to 2023*, PR NEWSWIRE (Apr. 30, 2019), https://www.prnewswire.com/news-releases/global-pesticides-market-analysis-2013-2018--forecasts-2018-2023-300695468.html.

9 EPA INDUSTRY SALES, *supra* note 6, at 10. Approximately 90% of these pesticides were used in agricultural production in 2012. *Id.* at 11.

Opprobrium to glyphosate and herbicides also exists because usage supports the production of genetically engineered crops.[10]

A strong federal law, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), governs the administration of pesticide uses and the implementation of human safety requirements.[11] FIFRA is administered by the U.S. Environmental Protection Agency (EPA).[12] Each product used for a different crop or with a different concentration must be registered separately.[13] Despite protections for human health, there is considerable evidence that pesticide usage causes injury to peoples' health.[14] For example, an examination of pesticides containing glyphosate highlights concerns about the lack of sufficient safety provisions.[15]

Given the dangers posed by a pesticide's chemical ingredients, FIFRA includes a provision stating that no pesticide can be registered unless it performs its intended function without "unreasonable adverse effects on the environment."[16] "Unreasonable adverse effects on the environment" require consideration of two risk categories.[17] First, the EPA must consider whether any unreasonable risk to humans or the environment is based on economic, social, or environmental costs from the use of a pesticide.[18] This consideration uses a cost-benefit analysis.[19] Second, the EPA considers the human dietary risk from

10 *See* Rita Barnett-Rose, *Judicially Modified Democracy: Court and State Pre-Emption of Local GMO Regulation in Hawaii and Beyond*, 26 DUKE ENV'T. L. & POL'Y F. 71, 81 (2015) (highlighting the problem of superweeds due to GBH uses on genetically engineered crops). Opprobrium for these crops extends to insect-resistant crops containing a gene from the soil bacterium *Bacillus thuringiensis*. *Id.*

11 7 U.S.C. § 136 (2018). While pesticides have been regulated since 1947, the major provisions of FIFRA were adopted in 1972. Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 92-516, 86 Stat. 973 (1972).

12 7 U.S.C. § 136a(c) (2018).

13 *Id.* § 136a(a).

14 *See infra* Part IIB.

15 *See infra* Part IIC.

16 *Id.*

17 7 U.S.C. § 136(bb) (2018).

18 *Id.* "The term 'unreasonable adverse effects on the environment' means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide. . . ." *Id.*

19 *Id.* This is established in the definition of "[u]nreasonable adverse effects on the environment." *Id.*

pesticide residues.[20] This consideration relies on maximum residue limits called "tolerances" established under the requirements of the Federal Food, Drug, and Cosmetic Act.[21] The EPA establishes tolerances at levels for which there is "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue. . . ."[22] Tolerances apply to both raw agricultural commodities and processed food.[23] To reduce adverse effects from the use of a pesticide, pesticide products are labeled with restrictions concerning concentrations, crops, pests, applicators, and locations for use.[24] Additional provisions incorporated in directions for use further restrict usage to prevent injury and harm.[25]

While the chemical mixtures present in many pesticides are dangerous and can adversely affect human health, producers and marketers of many food products continue to use them to control pests that markedly reduce crop yields and product quality.[26] Agricultural producers also prophylactically use pesticides to optimize plant health and reduce yield losses from pests.[27] Current quantities and prices of

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20 *Id.* "The term 'unreasonable adverse effects on the environment' means (1) . . . or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21." *Id.*

21 21 U.S.C. §§ 301–399d (2018).

22 *Id.* § 346a(b)(2)(A)(ii). *See* 40 C.F.R. pt. 180 (2019) for specific tolerances.

23 21 U.S.C. § 346a(a)(1)(B) (2018).

24 EPA, OFFICE OF PESTICIDE PROGRAMS, LABEL REVIEW MANUAL 11-1 (2013) [hereinafter MANUAL]. *See* 40 C.F.R. § 156.10(i)(2)(iii–vii) (2019) (delineating items needed in registrations); *see also* Nimish B. Vyas, *Untested Pesticide Mitigation Requirements: Ecological, Agricultural, and Legal Implications*, 18 DRAKE J. AGRIC. L. 335, 337 (2013) (noting that risk mitigation measures on labels include various restrictions on purchases, applications, and "application rates, methods, and practices; and requirements for personal protection . . .").

25 40 C.F.R. § 156.10(i) (2019). "[D]irections must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment." *Id.* Persons who fail to follow the label instructions violate federal law: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." *Id.* § 156.10(i)(2)(ii) (2019); *see also* MANUAL, *supra* note 24, at 3–6.

26 *See, e.g.*, Alicia Rosburg & Luisa Menapace, *Factors Influencing Corn Fungicide Treatment Decisions*, 43 J. AGRIC. & RES. ECON. 151, 153 (2018); Adriana Radosavac & Desimir Knežević, *Economic Importance of Use of Pesticides in Wheat Production*, 4 ECON. AGRIC. 1323, 1331 (2017).

27 *See* Matthew P. Hill, Sarina Macfadyen & Michael A. Nash, *Broad Spectrum Pesticide Application Alters Natural Enemy Communities and May Facilitate Secondary Pest Outbreaks*, PEERJ, Dec. 2017; Renan F. Nascentes et al., *Low Doses of Glyphosate Enhance Growth, CO_2 Assimilation, Stomatal Conductance and Transpiration in Sugarcane and Eucalyptus*, 74 PEST MGMT. SCI. 1197 (2018).

food are dependent upon the use of pesticides.[28] Furthermore, pesticides are used to control pests that transmit diseases like malaria and Zika virus.[29] Pesticides are also used to control pests that denigrate peoples' health, such as bed bugs and cockroaches.[30] While efforts to reduce pesticide usage should be encouraged, the elimination of synthetic pesticides would adversely affect food security and human health.[31]

Given the widespread use of pesticides in the production of most agricultural crops, it is not surprising that pesticide residuals remain in soils,[32] eroded sediments,[33] air particulates from wind-eroded

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28 COMMITTEE ON THE FUTURE ROLE OF PESTICIDES IN US AGRICULTURE ET AL., *Benefits, Costs and Contemporary Use Patterns*, *in* THE FUTURE ROLE OF PESTICIDES IN US AGRICULTURE 33 (2000) [hereinafter FUTURE ROLE] (observing that herbicides lead to increased yields and other pesticides help protect crops to increase yields).

29 *See* Abraham P. Mnzava et al., *Implementation of the Global Plan for Insecticide Resistance Management in Malaria Vectors: Progress, Challenges and the Way Forward*, 14 MALARIA J. 173, 173 (2015). Between 2000 and 2013, the use of insecticides and insecticide-treated nets was able to reduce by nearly one-half malaria morbidity. *Id.* For the Zika virus, there is no definite treatment, so individuals and communities employ insecticide spray programs and destroy larval breeding grounds. Ebenezer Bonyah et al., *A Theoretical Model for Zika Virus Transmission*, PLOS ONE, Oct. 2017, at 2.

30 *See* BENJAMIN ADRIAN ET AL., UNIV. WASH. EVANS SCH. PUB. POL'Y & GOVERNANCE, TACKLING BED BUGS: A STARTER GUIDE FOR LOCAL GOVERNMENT (2016) (discussing the use of pesticides to limit bed-bug infestations); Chen Zha et al., *Pest Prevalence and Evaluation of Community-Wide Integrated Pest Management for Reducing Cockroach Infestations and Indoor Insecticide Residues*, 111 J. ECON. ENTOMOLOGY 795, 795 (2018) (discussing the control of cockroaches that can serve as vectors for *Salmonella* ssp., *Pseudomonas aerugionsa*, and *Klebsiella oxytoca*).

31 *See* Terence J. Centner, Levi Russell & Matthew Mays, *Viewing Evidence of Harm Accompanying Uses of Glyphosate-Based Herbicides Under US Legal Requirements*, 648 SCI. TOTAL ENV'T 609 (2019) (examining banning uses of glyphosate that would decrease yields of corn and soybeans and increase food prices); *see also* Graham Brookes, Farzad Taheripour & Wallace E. Tyner, *The Contribution of Glyphosate to Agriculture and Potential Impact of Restrictions on Use at the Global Level*, 8 GM CROPS & FOOD 216, 225 (2017) (concluding that ceasing to grow herbicide-tolerant genetically modified crops would result in higher production costs for soybeans, corn, and sugar beets, as well as lower yields).

32 *See, e.g.*, Vera Silva et al., *Distribution of Glyphosate and Aminomethylphosphonic Acid (AMPA) in Agricultural Topsoils of the European Union*, 621 SCI. TOTAL ENV'T 1352, 1354 (2018) (conducting research that suggests 42% of agricultural soils in the European Union contain glyphosate and its main metabolite aminomethylphosphonic acid).

33 *See, e.g.*, Célia P.M. Bento et al., *Dynamics of Glyphosate and AMPA in the Soil Surface Layer of Glyphosate-Resistant Crop Cultivations in the Loess Pampas of Argentina*, 244 ENV'T. POLLUTION 323, 330 (2019) (finding higher concentrations of glyphosate and its main metabolite aminomethylphosphonic acid in eroded sediments than their parent soils).

sediments,[34] precipitation,[35] surface waters,[36] and food products.[37] The provisions of FIFRA provide a structure to preclude any use of pesticides where the accompanying residuals are above harmful threshold levels.[38] Oversight of this structure is challenging given there are approximately 1,250 active ingredients being used in nearly 17,000 registered products.[39]

Over the past several decades, research studies have shown that some pesticides cause more severe health problems than recognized at the time of their registration.[40] As scientific studies link exposure to a

34 *See, e.g.*, Célia P.M. Bento et al., *Glyphosate and AMPA Distribution in Wind-Eroded Sediment Derived from Loess Soil*, 220 ENV'T. POLLUTION 1079, 1088 (2017) (observing a high risk of off-site airborne transport of glyphosate and its main metabolite aminomethylphosphonic acid that could adversely affect humans). In fact, research shows that glyphosate and its main metabolite aminomethylphosphonic acid are found in environments in which glyphosate has never been used, probably due to being transported by wind currents. Virginia C. Aparicio et al., *Environmental Fate of Glyphosate and Aminomethylphosphonic Acid in Surface Waters and Soil of Agricultural Basins*, 93 CHEMOSPHERE 1866, 1870 (2013).

35 *See, e.g.*, W.A. Battaglin et al., *Glyphosate and Its Degradation Product AMPA Occur Frequently and Widely in U.S. Soils, Surface Water, Groundwater, and Precipitation*, 50 J. AM. WATER RES. ASS'N 275, 286 (2014) (detecting glyphosate and aminomethylphosphonic acid in 70% of precipitation samples).

36 *See, e.g.*, Aparicio et al., *supra* note 34, at 1870 (finding glyphosate in 35% of the surface water samples tested near farms in Buenos Aires province in Argentina); Battaglin et al., *supra* note 35, at 285 (finding glyphosate "in 52.5% of stream and 53.1% of large river samples"). Given the presence of glyphosate and aminomethylphosphonic acid in surface waters, water treatment plants need to be concerned. Alexis Grandcoin, Stéphanie Piel & Estelle Baurès, *AminoMethylPhosphonic Acid (AMPA) in Natural Waters: Its Sources, Behavior and Environmental Fate*, 117 WATER RSCH. 187, 194 (2017).

37 *See, e.g.*, Carl J. Berg et al., *Glyphosate Residue Concentrations in Honey Attributed Through Geospatial Analysis to Proximity of Large-Scale Agriculture and Transfer Off-Site by Bees*, PLOS ONE, July 2018, at 1 (evaluating the presence of glyphosate in honey samples to observe that 27% contained glyphosate); Fernando Rubio, Emily Guo & Lisa Kamp, *Survey of Glyphosate Residues in Honey, Corn and Soy Products*, 5 J. ENV'T. & ANALYTICAL TOXICOLOGY 1000249, 1000249 (2014) (finding that 59% of honey samples and 36% of soy sauce analyzed contained glyphosate); Gibson v. Quaker Oats Co., No. 16-cv-4853, 2017 WL 3508724 (N.D. Ill. Aug. 14, 2017) (considering allegations of mislabeling of a 100% natural breakfast cereal that contained glyphosate); Scholder v. Riviana Foods Inc., 16-cv-6002, 2017 WL 2773586 (E.D.N.Y. June 23, 2017) (considering the legality of labeling a product as "100% Whole Grain" pasta when it contained glyphosate).

38 7 U.S.C. § 136a(c) (2018).

39 E-mail from EPA Pesticide Program Webmail Support, EPA to Terence J. Centner (August 4, 2017) (on file with author).

40 *See* OFF. PESTICIDE PROGRAMS, EPA, CHLORPYRIFOS ISSUE PAPER: EVALUATION OF BIOMONITORING DATA FROM EPIDEMIOLOGY STUDIES (2016) (discussing EPA's stepwise evaluation of chlorpyrifos uses to end those that no longer qualified for registration) [hereinafter EPA CHLORPYRIFOS ISSUE PAPER].

pesticide with health problems, the increased damages associated with the use of a pesticide may justify discontinuation.[41] In other situations, changing the application method or using alternative products can reduce damages.[42] The benefits of using a pesticide may decrease if the pest develops an immunity to it.[43] In those situations, after several years have passed, pesticide registration materials may not accurately account for the costs and benefits that accompany usage.[44] A pesticide may no longer qualify for registration so its registration should be canceled.[45] FIFRA requires pesticides to be re-registered within "15 years after the date on which the first pesticide product containing a new active ingredient is registered."[46] Given this time period, pesticides may remain on the market despite newly discovered health damages

41 *See, e.g.*, OFF. PESTICIDE PROGRAMS HEALTH EFFECTS DIV., EPA, HUMAN HEALTH RISK ASSESSMENT: CHLORPYRIFOS (2000) [hereinafter RISK ASSESSMENT: CHLORPYRIFOS]. If additional factual information shows "unreasonable adverse effects on the environment," the information must be submitted to the Administrator, and appropriate action taken. 7 U.S.C. § 136d(a)–(b) (2018); *see, e.g.*, Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations, 57 Fed. Reg. 22224 (May 27, 1992) (delineating requests to cancel 201 pesticides); Chlorpyrifos; Cancellation Order, 65 Fed. Reg. 76233 (Dec. 6, 2000) (highlighting registration amendments and use deletions) [hereinafter Chlorpyrifos Cancellation Order]; Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations, 68 Fed. Reg. 36786 (June 19, 2003) (delineating the cancellation of 45 pesticide products).

42 *See, e.g.*, Ashley E. Larsen, Michael Patton & Emily A. Martin, *High Highs and Low Lows: Elucidating Striking Seasonal Variability in Pesticide Use and Its Environmental Implications*, 651 SCI. TOTAL ENV'T 828, 836 (2019) (recommending collection of data to reduce uses of pesticides); Minghua Zhang, Larry Wilhoit & Chris Geiger, *Assessing Dormant Season Organophosphate Use in California Almonds*, 105 AGRIC. ECOSYSTEM & ENV'T 41, 54 (2005) (finding almond growers switching from using dormant organophosphates to alternative practices); Lynn Epstein & Susan Bassein, *Patterns of Pesticide Use in California and the Implications for Strategies for Reduction of Pesticides*, 41 ANN. REV. PHYTOPATHOLOGY 351, 359 (2003) (reporting the replacement of organophosphates with pyrethroids for almonds and stone fruits).

43 *See, e.g.*, OFF. CHEM. SAFETY & POLLUTION PREVENTION, EPA, GLYPHOSATE: RESPONSE TO COMMENTS, USAGE, AND BENEFITS (PC Codes: 103601, 03604, 103605, 103607, 103608, 103613, 417300) 26 (2019) (noting glyphosate-resistant weeds lead producers to use other pesticide mixes or cultivate other crops).

44 *See, e.g.*, John Frank Knox, *Sowing the Seeds of Controversy: What the Dicamba Debacle Reveals About the Modern Pesticide Registration Process and Why the EPA Must Act*, 48 ENV'T. L. 835, 855–56 (2018) (reporting unanticipated crop damages from dicamba spray drift that would alter a cost-benefit analysis).

45 Although the regulations require registrants to submit new information on the adverse effects accompanying a pesticide use, 7 U.S.C. § 136d(a)(2), registrants may not do so because of profitable sales. However, if a manufacturer is concerned about an action in common law tort, there is an incentive to amend or cancel a registration.

46 7 U.S.C. § 136a(g)(1)(A)(iii)(II) (2018).

that alter the cost-benefit registration analysis.[47] EPA administrators can engage in a proceeding for the cancellation of a registration[48] or enter into a voluntary cancellation agreement with a registrant.[49] However, the volume of pesticide products needing attention may mean that the EPA does not commence timely proceedings to rectify situations for which uses of existing pesticides are unworthy of their registrations.[50]

Glyphosate-based herbicides (GBHs) are manufactured by more than ninety producers in twenty countries, and GBHs are the most heavily used herbicides in the world.[51] Thousands of people have alleged that exposure to Monsanto's GBHs caused health damages.[52] Plaintiffs in three lawsuits have secured jury verdicts that included

47 *See, e.g.*, OFF. PREVENTION, PESTICIDES & TOXIC SUBSTANCES, EPA, INTERIM REREGISTRATION ELIGIBILITY DECISION FOR AZINPHOS-METHYL, Case No. 0235, at 9–10 (Oct. 2001) [hereinafter EPA AZINPHOS-METHYL INTERIM DECISION] (showing how changed health and environmental risks altered qualifications for registration). Despite the risks posed by this pesticide, it was allowed to be used for several more years on a few specialized crops. OFF. PREVENTION, PESTICIDES & TOXIC SUBSTANCES, EPA, FINAL DECISIONS FOR THE REMAINING USES OF AZINPHOS-METHYL 1 (Nov. 16, 2006) [hereinafter EPA AZINPHOS-METHYL FINAL DECISIONS].

48 7 U.S.C. § 136d(b) (2018). *See* Chem. Specialties Mfrs. Ass'n v. U.S. EPA, 484 F. Supp. 513, 516 (D.D.C. 1980) (acknowledging the ability of the EPA administrator to change pesticide labeling requirements and to cancel registrations).

49 7 U.S.C. § 136d(f)(1) (2018); *see* Nat'l Grain Sorghum Producers Ass'n v. EPA, No. 95-1244 (D.C. Cir. Apr. 22, 1996) (considering a challenge to a voluntary cancellation agreement).

50 *See Registration Review Process*, EPA, https://www.epa.gov/pesticide-reevaluation/registration-review-process#implementing%20reg%20review [https://perma.cc/N2XA-F93T] (last visited Sept. 18, 2018) (acknowledging that the agency is handling more than 700 registration review cases involving roughly 1,140 pesticide active ingredients); EPA, Letter from Lois A. Rossi, Special Rev. & Reregistration Div. Dir., to Registrant, Doc. No. EPA-R-01-003 (Dec. 30, 2000) (acknowledging that "[t]he major means by which the [EPA] reassesses tolerances" for pesticide residues in or on food is through its reregistration process).

51 Benbrook, *supra* note 3, at 1.

52 *See* BAYER, *supra* note 1.

millions of dollars in compensatory and punitive damages.[53] These verdicts have been appealed.[54]

New information about the effects of using GBHs raises questions of whether existing registrations meet FIFRA's statutory requirements.[55] Though the health costs related to the use of GBHs may be considerably greater now than when considered at the time of registration, in 2020 the EPA issued an Interim Registration Review Decision in which it "conclude[d] that the benefits outweigh the potential ecological risks. . . ."[56] While a few members of Congress would like to enact specific legislation on glyphosate residues, legislation is unlikely.[57] However, existing and potential lawsuits seeking compensation for health-related damages from glyphosate exposure may lead some registrants to modify their registrations by adding warnings and better directions on how to use the product.[58]

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53 Verdict Form, Johnson v. Monsanto Co., No. CGC-16-550128 (Cal. Super. Ct. S.F. Cnty. Aug. 10, 2018), https://www.baumhedlundlaw.com/pdf/monsanto-documents/johnson-trial/Johnson-vs-Monsanto-Verdict-Form.pdf [https://perma.cc/J3QB-EVS7] [hereinafter *Johnson*]; Verdict Form, Hardeman v. Monsanto Co., No. 16-cv-00525-VC (N.D. Cal. Mar. 27, 2019), https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/03/Hardeman-Jury-Verdict-Form-Damages.pdf [https://perma.cc/7MYF-6M27] [hereinafter *Hardeman*]; Reporter's Transcript of Proceedings at 5748, 5750-51, Pilliod v. Monsanto Co., No. RG17862702, JCCP No. 4953 (Cal. Super. Ct., Alameda Cnty. May 13, 2019), https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/05/Trial-Transcript-Pilliod-Verdict.pdf [https://perma.cc/CD4P-3LS2] [hereinafter *Pilliod*].

54 *See* BAYER, *supra* note 1.

55 *See, e.g.*, *In re* Roundup Prod. Liab. Litig., 364 F. Supp. 2d 1085 (N.D. Cal. Mar. 7, 2019) (ruling on various motions in litigation concerning liability for damages from glyphosate exposure); Pretrial Order No. 85, *In re* Roundup Prod. Liab. Litig., 358 F. Supp. 3d 956 (N.D. Cal. Feb. 24, 2019) (finding that expert opinions of health problems were admissible in legislation); Pretrial Order No. 81, *In re* Roundup Prod. Liab. Litig., Case No. 16-md-02741-VC (N.D. Cal. Feb. 18, 2019) (rulings on motions in limine to exclude information).

56 EPA, GLYPHOSATE INTERIM REGISTRATION REVIEW DECISION, CASE NUMBER 0178 15 (2020) [hereinafter EPA DECISION 0178].

57 *See* Keep Food Safe from Glyphosate Act, H.R. 1783, 116th Cong. (2019) (proposing changes to oversee glyphosate tolerances on oats).

58 Registrants could amend labels to require users to employ greater care when applying glyphosate and warning users of possible dangers. *See* Michelle Martin & Sabine Wollrab, *Bayer Considering Stopping Sales of Glyphosate to Private Users*, REUTERS (Jan. 29, 2020), https://www.reuters.com/article/us-bayer-glyphosate/bayer-considering-stopping-sales-of-glyphosate-to-private-users-newspaper-idUSKBN1ZT0ER.

I
REGISTRATION OF PESTICIDES

FIFRA requires the registration of all pesticide products used in the United States.[59] Registrants have found the required process to be demanding and costly.[60] Registration of a pesticide "is a product-specific license describing the terms and conditions under which the product can be legally distributed, sold, and used."[61] The registrant provides the information that is then used by the EPA for the registration of a pesticide.[62] Manufacturers submit research data "concerning the product's health, safety, and environmental effects."[63] While the EPA can request additional data if it feels it is needed to justify registration, it basically relies on the information supplied by the registrant, some of which is confidential business information.[64]

Pesticide registration omits an adversarial mechanism that could identify data and information about potential harm that may be associated with pesticide use.[65] With the information provided by the registrant, the EPA conducts a pesticide's cost-benefit analysis without the benefit of information from nongovernmental, disinterested, or

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59 7 U.S.C. § 136a(a), (c)–(e) (2018).

60 *See* Brief of Croplife America as Amicus Curiae Support of Respondents, Nat'l Fam. Farm Coal. v. EPA, Case Nos. 17-70810, 17-70817 (9th Cir. July 18, 2018) [hereinafter Brief of Croplife America] (addressing limitations on the use of pesticide products due to the requirements of the Endangered Species Act and estimating that the registration of a new pesticide may involve expenditures of more than $100 million).

61 Reckitt Benckiser, Inc. v. EPA, 613 F.3d 1131, 1133 (D.C. Cir. 2010) (considering an action for the misbranding of a registered rodenticide product).

62 7 U.S.C. § 136a(c) (2018). Applicants provide risk-related data used to calculate costs and data on benefits. However, efficacy data in support of the claimed benefits are not required. *See* Mary Jane Angelo, *Embracing Uncertainty, Complexity and Change: An Eco-Pragmatic Reinvention of a First Generation Environmental Law*, 33 ECOLOGY L.Q. 105, 202 (2006) [hereinafter Angelo, *Embracing Uncertainty*].

63 Thomas v. Union Carbide Agric. Prods. Co., 473 U.S. 568, 571 (1985) (enunciating this requirement in consideration of data-sharing provisions that allow the same or similar products to be registered without resubmission of data); 7 U.S.C. § 136a(c) (2018).

64 7 U.S.C. § 136a(g)(1)(B)(ii) (2018). Each applicant shall file "a full description of the tests made and the results thereof upon which the claims are based. . . ." *Id.* § 136a(c)(1)(F) (2018). *See* Richard Brain, Jane Staveley & Lisa Ortego, *In Response: Resolving the Perception of Bias in a Discipline Founded on Objectivity – A Perspective from Industry*, 35 ENV'T. TOXICOLOGY & CHEM. 1070, 1071 (2016) (claiming much of the pesticide industry-generated data is confidential).

65 An adversary system may foster enhanced representation of different interests and provide incentives for developing relevant facts and arguments. *See* Daniel A. Farber & Anne Joseph O'Connell, *Agencies as Adversaries*, 105 CALIF. L. REV. 1375, 1468 (2017) (noting possible improvements accompanying an adversarial system).

opposing parties.[66] After registration, the registrant has a legal obligation to reveal any "additional factual information regarding unreasonable adverse effects on the environment[,]"[67] but there is little incentive for registrants to look for disparaging information and no clear duty to report information or data gathered by others.[68]

FIFRA delineates options for unconditional or conditional registration of new pesticides.[69] Unconditional registration is the normal registration procedure,[70] which requires registrants to submit sufficient data to the EPA for an evaluation of environmental risks that involves a full accounting of costs and benefits.[71] However, for special circumstances, FIFRA provides three options for temporary conditional registration.[72] A pesticide product granted conditional registration might lack documentation supporting a conclusion that it performs its intended function without unreasonable adverse effects on the environment, but usage is allowed.[73]

In addition, a pesticide's registration must satisfy FIFRA's requirement on human dietary risk through tolerances for pesticide residues in or on food.[74] Safety precautions set forth in section 408 of

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66 7 U.S.C. § 136a(c) (2018). This may be contrasted with the approval of discharge permits under the Clean Water Act's National Pollution Discharge Elimination System (NPDES). The Clean Water Act provides for public participation in the development and revision of effluent limitations delineated in NPDES permits. 33 U.S.C. § 1251(e) (2018). This includes enabling the public to assist in the development and enforcement of effluent limitations. *Id.*

67 7 U.S.C. § 136d(a)(2) (2018). *See* Chem. Specialties Mfrs. Ass'n v. EPA, 484 F. Supp. 513, 517 (D.D.C. 1980) (requiring information of any adverse effects to be reported to the EPA).

68 This may be distinguished from an agency's proposal for a new or changed regulation for which opponents have the right to be heard as set forth by the Administrative Procedure Act, 5 U.S.C. §§ 500–596 (2018).

69 7 U.S.C. § 136a(c)(5), (7) (2018).

70 *Id.* § 136a(c)(5).

71 *See* Pollinator Stewardship Council v. EPA, 806 F.3d 520, 526 (9th Cir. 2015) (finding that gaps in the data precluded the EPA from giving unconditional approval to the pesticide sulfoxaflor).

72 7 U.S.C. § 136a(c)(7) (2018). *See* NRDC v. EPA, 857 F.3d 1030, 1033 (9th Cir. 2017) (noting that there may be sufficient data to allow the short-term use of a pesticide but not enough data to meet the safety requirements for unconditional registration); *Pollinator Stewardship Council*, 806 F.3d at 526–32 (considering a change from conditional to unconditional registration of sulfoxaflor).

73 *See* NRDC v. EPA, 857 F.3d 1030, 1033 (9th Cir. 2017) (noting that under conditional registration, the registrant only needs to submit data showing that short-term use of a pesticide is reasonable).

74 7 U.S.C. § 136(bb) (2018).

the Federal Food, Drug, and Cosmetic Act (FFDCA) protect humans from dangerous pesticide residues in or on food.[75] This FFDCA requirement is distinct from the FIFRA cost-benefit analysis under which benefits may offset minor health risks.[76] Under the FFDCA, pesticide residues are allowed only if a food is safe for human consumption.[77] Any food with a pesticide residue that has not been shown to be safe for humans fails to meet this legal requirement,[78] and such unsafe food products cannot legally be moved in interstate commerce.[79]

An FFDCA tolerance considers a person's health risk from aggregate exposure to a pesticide over a lifetime.[80] Food is safe only if it is "determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."[81] This determination requires the identification of "a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health. . . ."[82] An existing tolerance may be left in effect only if there is "reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue."[83]

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75 21 U.S.C. § 346a(a)(1) (2018).

76 The cost-benefit analysis is pursuant to requirements of 7 U.S.C. § 136(bb), while pesticide residues in or on food must meet the requirements of 21 U.S.C. § 346a(a). *See* Nader v. EPA, 859 F.2d 747, 748 (9th Cir. 1988) (noting that tolerances govern pesticide residues in or on food); NRDC v. EPA, 658 F.3d 200, 204 (2d Cir. 2011) (recognizing EPA's need to establish tolerance levels).

77 21 U.S.C. § 346a(b)(2)(A)(i) (2018). *See* NRDC v. Johnson, 461 F.3d 164, 167 (2d Cir. 2006) (observing that residues can only be on agricultural commodities if a tolerance has been set); *see also* Gregory C. Keating, *Is Cost-Benefit Analysis the Only Game in Town?*, 91 S. CALIF. L. REV. 195, 251 (2018) (examining cost-benefit analysis and noting that health may be singled out for special protection).

78 *See, e.g.*, *Nader*, 859 F.2d at 748 (observing that no residue of a pesticide not recognized as safe is allowed on a raw agricultural product); Nat'l Corn Growers Ass'n v. EPA, 613 F.3d 266, 269 (D.C. Cir. 2010) (observing that under the FFDCA, a tolerance for a pesticide residue must provide for human safety).

79 *See, e.g.*, EDF v. U.S. Dep't Health, Educ. & Welfare, 428 F.2d 1083, 1086 (D.C. Cir. 1970) (observing that unauthorized residues cause a food product to be adulterated).

80 21 U.S.C. § 346a(b)(2)(B)(i)(II) (2018).

81 *Id.* § 346a(b)(2)(A)(ii). *See* 40 C.F.R § 180.1(a) (2019) (denoting that the Administrator of the EPA is in charge of tolerances).

82 21 U.S.C. § 346a(b)(2)(B)(i)(I) (2018).

83 League of United Latin Am. Citizens v. Wheeler, 899 F.3d 814, 818 (9th Cir. 2018) (quoting 21 U.S.C. § 346a(b)(2)(A)(i)–(ii)), *rev'd en banc* 922 F.3d 443 (9th Cir. 2019) (issuing a writ of mandamus to vacate an order maintaining tolerances for chlorpyrifos).

Because the FFDCA provisions on tolerances commence with the assumption that pesticide residues in or on food are unsafe and do not weigh costs and benefits, whenever it cannot be determined that a residue in or on food is safe, the residue is classified as a deleterious substance.[84] Any deleterious substance in or on a food means the food is adulterated and cannot be sold in commerce.[85] If an agency does not have evidence that a residue on a food product is safe, any action that facilitates the entry of such a product into commerce may be enjoined for being contrary to the law.[86] Residues on food above a tolerance are subject to seizure by the government.[87] For glyphosate, the EPA has established tolerances for numerous food products.[88]

II
COST-BENEFIT ANALYSIS

Governmental policies have incorporated a cost-benefit analysis since the 1930s to balance costs to society and social benefits.[89] The analysis allows for the consideration of external effects and the quantification of benefits through the use of economic tools, including contingent valuation.[90] It is touted as providing for economic efficiency

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84 21 U.S.C. § 342(a) (2018). *See League of United Latin Am. Citizens*, 899 F.3d at 818 (noting tolerances depend on qualifying as safe).

85 21 U.S.C. §§ 342(a)(2)(B), 331(a) (2018). *See* Physicians Comm. for Responsible Med. v. EPA, No. C 05-04093 CRB, 2006 WL 3000657 (N.D. Cal. Oct. 20, 2006) (noting that, in the absence of a tolerance, pesticide residues in or on foods cause them to be adulterated).

86 *See* NRDC v. Johnson, 461 F.3d 164, 167 (2d Cir. 2006) (observing that a tolerance can only be established if the food containing a pesticide residue is safe, and in the absence of a tolerance, a food containing a residue is deemed adulterated and cannot be sold in interstate commerce).

87 *Setting Tolerances for Pesticide Residues in Foods*, EPA (2017), https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods (last visited Sept. 18, 2020) [https://perma.cc/4PX9-VCLL] (acknowledging the enforcement of tolerances).

88 40 C.F.R. § 180.354(a)(1) (2019). Compliance is "determined by measuring only glyphosate (N-(phosphonomethyl)glycine)." *Id.*

89 *See* Tünde Vörös, *Methodological Challenges in Cost-Benefit Analysis*, 63 PUB. FIN. Q. 402, 403 (2018) (listing the Flood Control Act of 22 June 1936 as the initial implementation of cost-benefit analysis on public projects).

90 *See id.* at 405, 410. Contingent valuation often involves an approach through which people are asked to report their willingness to pay for a specified good rather than inferring prices from observed behaviors in regular marketplaces. Peter A. Diamond & Jerry A. Hausman, *On Contingent Valuation Measurement of Nonuse Values*, in 220 CONTRIBUTIONS TO ECON. ANALYSIS 3, 11–12 (Jerry A. Hausman ed., 1993).

by not allowing activities that are too costly.[91] A cost-benefit analysis generally assumes that an activity should occur only if benefits outweigh costs.[92] A benefit is anything that increases human well-being, while a cost is anything that decreases it.[93]

A. Costs and Benefits under FIFRA

The calculation of costs and benefits accruing from the use of a pesticide requires the delineation of a base situation for comparison with future pesticide use.[94] The calculation involves the monetization of intangible items, such as averted health harms, illnesses, impaired lives, deaths, and ecological destruction.[95] Persons using a pesticide may simultaneously have costs, such as expenses for equipment needed to apply the pesticide,[96] and benefits from usage, such as better health

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91 *See* Angelo, *Embracing Uncertainty*, *supra* note 62, at 121 (highlighting that economic efficiency is the goal of regulatory systems); Alexandra B. Klass, *Pesticides, Children's Health Policy, and Common Law Tort Claims*, 7 MINN. J.L. SCI. & TECH. 89, 99 (2006) (observing that activities are allowed if their benefits outweigh their costs); Sanne H. Knudsen, *The Flip Side of Michigan v. EPA: Are Cumulative Impacts Centrally Relevant?*, 2018 UTAH L. REV. 1, 2–4 [hereinafter Knudsen, *The Flip Side*] (highlighting literature that posits drawbacks to employing cost-benefit analysis).

92 *See* Headwaters, Inc. v. Talent Irrigation Dist., 243 F.3d 526, 531 (9th Cir. 2001) (noting "the overall economic benefits of allowing the use of the product outweigh adverse environmental effects" (quoting Amicus Curiae Brief of the United States at 12)). However, a cost-benefit analysis does not necessarily mean that benefits must outweigh costs. Rather a regulatory provision may infer that costs should not be "wholly out of proportion to the magnitude of the estimated environmental gains." Entergy Corp. v. Riverkeeper, Inc., 556 U.S. 208, 225 (2009) (quoting Seacoast Anti-Pollution League v. Costle, 597 F.2d 306, 311 (1st Cir. 1979) (considering costs of cooling technologies for large power plants to reduce environmental damage).

93 *See* Keating, *supra* note 77, at 223–24 (arguing that coherent alternatives to cost-benefit analysis are available and should be used in some situations to avoid harm).

94 *See* EPA, GUIDELINES FOR PREPARING ECONOMIC ANALYSES pt. 5.1 (2014) [hereinafter EPA GUIDELINES]. Determinations of future costs and benefits involves discounting which is controversial. Some claim that discounting tends to defer making hard decisions that may adversely affect future generations. Lauren Packard, *Michigan: An Intrusive Inquiry into EPA's Rulemaking Process*, 42 COLUM. J. ENV'T. L. 117, 121 (2016) (discussing issues with formal cost-benefit analysis including monetization and discounting).

95 David M. Driesen, *Is Cost-Benefit Analysis Neutral?*, 77. U. COLO. L. REV. 335, 339 (2006) [hereinafter Driesen, *Cost-Benefit*] (arguing the analysis tends to be neutral rather than favoring economic interests over the environment); William H. Rodgers, Jr., *Benefits, Costs, and Risks: Oversight of Health and Environmental Decisionmaking*, 4 HARV. ENV'T. L. REV. 191, 193 (1980) (observing that cost-benefit analysis reduces every concern to a monetary value).

96 *See* J. Barroso et al., *Simulating the Effects of Weed Spatial Pattern and Resolution of Mapping and Spraying on Economics of Site-Specific Management*, 44 WEED RSCH. 460, 461–62 (2004) (modeling costs for weed control showing application and technology costs);

or increased yields.[97] Correspondingly, pesticide use may involve costs related to health maladies due to exposure to the chemicals in pesticides,[98] but provide consumers benefits in the form of lower food prices.[99]

For agricultural pesticides, costs involve the expense of pesticide products, outlays for the application of the pesticide, human health damages, and damages to ecological systems.[100] Producers using a pesticide have benefits due to reduced damage to crops.[101] They use insecticides to reduce numbers of insects that adversely affect yields by eating plants.[102] In some cases, the control of insect populations reduces damage to the commodity being grown, resulting in a higher quality crop.[103] Producers employ herbicides to reduce numbers of weeds that compete with crops for light, nutrients, and water.[104] Benefits include

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P.A. Paul et al., *Meta-Analysis of Yield Response of Hybrid Field Corn to Foliar Fungicides in the U.S. Corn Belt*, 101 PHYTOPATHOLOGY 1122, 1125 (2011) (estimating pesticide application costs and yield increases to show the profitable use of a fungicide).

97 *See* Anamika Sharma, Prashant Jha & Gadi V.P. Reddy, *Multidimensional Relationships of Herbicides with Insect-Crop Food Webs*, 643 SCI. TOTAL ENV'T 1522, 1523 (2018) (observing the use of herbicides for controlling weeds to increase yields); Yongbo Liu, Xubin Pan & Junsheng Li, *A 1961–2010 Record of Fertilizer Use, Pesticide Application and Cereal Yields: A Review*, 35 AGRONOMY FOR SUSTAINABLE DEV. 83, 84 (2015) (noting that use of fertilizers and pesticides in the past decades has increased yields).

98 *See* Ricky L. Langley & Sandra Amiss Mort, *Human Exposures to Pesticides in the United States*, 17 J. AGROMEDICINE 300, 312 (2012) (citing "approximately 20 deaths per year from pesticides" and costs of "at least $192–275 million dollars annually" from pesticide exposure).

99 FUTURE ROLE *supra* note 28, at 255. The higher prices would occur due to decreased yields. *See* David Zilberman et al., *Biotechnology and Food Security*, 67 J. INT'L AFFS. 91, 93 (2014) (noting that enhanced productivity due to pesticide use reduces food prices).

100 *See* Ctr. for Biological Diversity v. EPA, 861 F.3d 174, 188–89 (D.C. Cir. 2017) (noting environmental values using ecological risk assessments).

101 *See* Pollinator Stewardship Council v. EPA, 806 F.3d 520, 528 (9th Cir. 2015) (noting benefits in controlling pests).

102 *See* Rajib Karmakar & Gita Kulshrestha, *Persistence, Metabolism and Safety Evaluation of Thiamethoxam in Tomato Crop*, 65 PEST MGMT. SCI. 931, 936 (2009) (conducting trials on usage of a pesticide on tomatoes to determine rates for enhanced yields); Ryan S. Henry, William G. Johnson & Kiersten A. Wise, *The Impact of a Fungicide and an Insecticide on Soybean Growth, Yield, and Profitability*, 30 CROP PROT. 1629, 1631 (2011) (reporting that an insecticide can increase soybean yields).

103 Eric Bohnenblust et al., *Corn Earworm (Lepidoptera: Noctuidae) in Northeastern Field Corn: Infestation Levels and the Value of Transgenic Hybrids*, 106 J. ECON. ENTOMOLOGY 1250, 1257 (2013) (noting that producers can improve their corn quality by reducing damaged corn kernels that facilitate *Aspergillus* and *Fusarium* rots from corn earworm damage and by "reducing the risk of mycotoxin contamination").

104 *See, e.g.*, Avishek Datta et al., *Managing Weeds Using Crop Competition in Soybean [*Glycine max *(L.) Merr.]*, 95 CROP PROT. 60, 60 (2017) (examining alternatives to herbicide

reduced use of mechanical weed control, less soil erosion, and, in some cases, reduced use of toxic chemicals.[105] Fungicides control organisms that reduce yields and product quality.[106]

Performing a cost-benefit analysis under FIFRA is controversial due to difficulties in ascertaining health damages and the monetization of benefits and costs.[107] The statute itself does not specifically enunciate a cost-benefit requirement; rather, it precludes registration of pesticides that cause unreasonable adverse effects.[108] However, as articulated by the Ninth Circuit Court of Appeals in *Save Our Ecosystems v. Clark*, FIFRA has been interpreted as delineating a cost-benefit analysis.[109] The cost-benefit nomenclature has been affirmed in subsequent cases.[110] The EPA weighs the costs of adverse effects that would accompany the registration of a pesticide against the benefits from its uses.[111]

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use for controlling weeds); Jessica A. Finch et al., *Wheat Root Length and Not Branching Is Altered in the Presence of Neighbours, Including Blackgrass*, PLOS ONE, May 2017, at 1, 2 (finding that a single weed species can decrease wheat yield up to 10%); Éva Lehoczky, Péter Reisinger & Tamas Komives, *Loss of Nutrients Caused by Excessive Weediness at the Early Stage of Maize Vegetation Period*, 36 COMM. SOIL SCI. & PLANT ANALYSIS 415, 421 (2011) (finding that weeds could decrease corn yields by 55%).

105 *See* NRDC v. EPA, 857 F.3d 1030, 1038–39 (9th Cir. 2017) (considering lower application rates of a pesticide as a benefit); Gerald M. Dill et al., *Glyphosate: Discovery, Development, Applications, and Properties, in* GLYPHOSATE RESISTANCE IN CROPS AND WEEDS: HISTORY, DEVELOPMENT, AND MANAGEMENT 2–3 (Vijay K. Nandula, ed., 2010) (noting that use of herbicides reduces soil erosion and allows for enhanced water percolation).

106 *See* Henry, Johnson & Wise, *supra* note 102, at 1633 (reporting that a fungicide can increase soybean yields); H. Scherm et al., *Quantitative Review of Fungicide Efficacy Trials for Managing Soybean Rust in Brazil*, 28 CROP PROT. 774, 780 (2009) (reporting positive results from controlling soybean rust to increase yields).

107 *See* Angelo, *Embracing Uncertainty*, *supra* note 62, at 132 (observing that FIFRA is unusual in its requirement of a cost-benefit regime of environmental protection).

108 7 U.S.C. § 136a(a) (2018).

109 Save Our Ecosystems v. Clark, 747 F.2d 1242, 1248 (9th Cir. 1984) (considering whether the federal government's use of herbicides met the requirements of the National Environmental Policy Act).

110 *See* Pollinator Stewardship Council v. EPA, 806 F.3d 520, 522–23 (9th Cir. 2015) (noting that no pesticide can be registered without the support of a cost-benefit analysis); Wash. Toxics Coal. v. EPA, 413 F.3d 1024, 1032 (9th Cir. 2005) (observing a cost-benefit analysis is set forth in FIFRA to protect human health); Headwaters, Inc. v. Talent Irrigation Dist., 243 F.3d 526, 532 (9th Cir. 2001) (observing that FIFRA's cost-benefit analysis is quite different from the effluent limitations imposed to protect water quality under the Clean Water Act).

111 *See* Ctr. for Biological Diversity v. EPA, 847 F.3d 1075, 1085 (9th Cir. 2017) (citing *Headwaters, Inc. v. Talent Irrigation Dist.*, 243 F.3d 526, 532 (quoting *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248)) (noting the judicial interpretation of the FIFRA requirement to consider the "economic, social and environmental costs and benefits of the use of any

B. Information for an Analysis

For each pesticide registration, the registrant controls the generation of data and submitted evidence.[112] The EPA has no funds to use in generating its own data, so it does not look at topics or issues not considered by the registrant.[113] The registrant-based analysis requires submission of evidence concerning potential health risks, but absent use of a pesticide, not all the risks can be identified.[114] Omissions of a pesticide's nonlethal human health effects may preclude an accurate accounting and the registration may fail to protect human health.[115] Costs and benefits also ignore ethical considerations.[116]

While federal regulations provide a process for balancing costs and benefits,[117] weighing the costs and benefits of food production is challenging.[118] Scientific studies on the consequences of using a

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pesticide"); *see also* Klass, *supra* note 91, at 94 (quoting 7 U.S.C. § 136(bb) (2000)) (observing "that economic, social, and environmental costs and benefits" need to be considered).

112 *See* Knox, *supra* note 44, at 847, 865 (observing that the FIFRA provisions are "a legacy of agricultural industry recommendations" and that registrants can selectively present data supporting registration).

113 *See* EPA, FY 2019 EPA BUDGET IN BRIEF 47–48 (2018) (delineating funds going to licensing that does not include testing).

114 *See, e.g.*, Michael A. Livermore & Richard L. Revesz, *Rethinking Health-Based Environmental Standards*, 89 N.Y.U.L. REV. 1184, 1194 (2014) (contrasting cost-benefit analysis with a health-based standard that would elevate environmental issues); John P. Dwyer, *The Pathology of Symbolic Legislation*, 17 ECOLOGY L.Q. 233, 248 (1990) (observing that health costs are harder to quantify).

115 *See supra* notes 59–68 and accompanying text (noting the registrant controls what information is submitted for registration).

116 *See* Angelo, *Embracing Uncertainty*, *supra* note 62, at 126 (noting the omission of "ethical, religious, aesthetic, and other normative values of environmental protection"); David M. Driesen, *The Ends and Means of Pollution Control: Toward a Positive Theory of Environmental Law*, 2017 UTAH L. REV. 57, 76 [hereinafter Driesen, *Pollution Control*] (observing that the cost-benefit analysis "creates an extremely difficult analytical burden"); Dorothy Du, *Rethinking Risks: Should Socioeconomic and Ethical Considerations Be Incorporated into the Regulation of Genetically Modified Crops?*, 26 HARV. J.L. & TECH. 375, 401 (2012) (arguing "that non-scientific issues surrounding GMOs warrant regulatory attention"); Debra M. Strauss, *Defying Nature: The Ethical Implications of Genetically Modified Plants*, 3 J. FOOD L. & POL'Y 1, 33–34 (2007) (discussing advancing education on ethics to allow consumers to reach an informed opinion).

117 *See* 40 C.F.R. §§ 154.7, 154.31 (2020) (delineating provisions on special reviews of pesticides for which the EPA has a reason to believe may result in unreasonable adverse effects on people or the environment).

118 *See* Terence J. Centner, Brady Brewer & Isaac Leal, *Reducing Damages from Sulfoxaflor Use Through Mitigation Measures to Increase the Protection of Pollinator Species*, 75 LAND USE POL'Y 70, 75 (2018) (showing that an assignment of values for lower food prices affects the preferred regulatory strategy).

pesticide may estimate health damages using different approaches,[119] and sometimes will report contrasting results about anticipated health damages.[120] For many registrations of new pesticides, the absence of consideration of the long-term exposure will lead to an underestimation of damages.[121] Given that evidence on costs is dependent on the submission of documentation by the registrant, failure to evaluate all the potential health issues associated with the use of a pesticide underreports costs.[122] As shown by subsequent agreements and actions to cancel pesticide registrations, the omission of risks during registration has occurred for scores of pesticides,[123] offering evidence

119 *See* Memorandum from Off. Chem. Safety & Pollution Prevention on Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review to Dana Friedman, Chem. Rev. Manager, Risk Mgmt. & Implementation Branch II Pesticide Re-evaluation Div. 3 (Nov. 3, 2016) (reporting in a revised human health risk assessment for chlorpyrifos that the Scientific Advisory panel "appears to have rejected both the approach the EPA put forward in its proposed rule derived from the 2014 risk assessment as well as the EPA's initial efforts to address the results of the [Columbia Center for Children's Environmental Health] study quantitatively.") [hereinafter EPA Chlorpyrifos Human Health].

120 *See* EPA CHLORPYRIFOS ISSUE PAPER, *supra* note 40, at 130–35. In evaluating the carcinogenic potential of glyphosate, the EPA noted conflicting results that were explained by lack of adjustment for co-exposure. OFF. PESTICIDE PROGRAMS, EPA, GLYPHOSATE ISSUE PAPER: EVALUATION OF CARCINOGENIC POTENTIAL. 65 (2016) [hereinafter EPA GLYPHOSATE ISSUE PAPER] https://www.epa.gov/sites/production/files/2016-09/documents/glyphosate_issue_paper_evaluation_of_carcincogenic_potential.pdf [https://perma.cc/P98W-ZMJC].

121 *See* Nat'l Fam. Farm Coal. v. EPA, 960 F.3d 1120 (9th Cir. 2020) (discussing difficulties of estimating damages from dicamba spray drift). For cases concerning health, the problem is that not all health damages related to the use of a new pesticide are known when a pesticide is registered. For pesticides used on tobacco, the EPA's policy in the early 2000s was not to "assess intermediate or long-term risks to smokers because of the severity of health effects linked to use of tobacco products themselves." U.S. GOV. ACCT. OFF., PESTICIDES ON TOBACCO: FEDERAL ACTIVITIES TO ASSESS RISKS AND MONITOR RESIDUES preface (2003).

122 For example, pesticide poisonings of agricultural workers would presumably not be reported by a registrant. *See* Danica Li, *Toxic Spring: The Capriciousness of Cost-Benefit Analysis Under FIFRA's Pesticide Registration Process and Its Effect on Farmworkers*, 103 CALIF. L. REV. 1405, 1412 (2015); *see also* Keith Cunningham-Parmeter, *A Poisoned Field: Farmworkers, Pesticide Exposure, and Tort Recovery in an Era of Regulatory Failure*, 28 N.Y.U. REV. L. & SOC. CHANGE 431, 444–45 (2004) (noting that 300,000 poisonings of workers from pesticide exposure may occur yearly); Mary Jane Angelo, *The Killing Fields: Reducing the Casualties in the Battle Between U.S. Species Protection Law and U.S. Pesticide Law*, 32 HARV. ENV'T. L. REV. 95, 100 (2008) [hereinafter Angelo, *The Killing Fields*] (noting that underreporting of bird mortality from pesticide use underestimates damages to wildlife).

123 *See generally*, RISK ASSESSMENT: CHLORPYRIFOS *supra* note 41; *see also* Christos A. Damalas & Ilias G. Eleftherohorinos, *Pesticide Exposure, Safety Issues, and Risk Assessment Indicators*, 8 INT'L J. ENV'T. RSCH. & PUB. HEALTH 1402, 1404 (2011) (noting that despite many studies on the toxicity of pesticides, there are gaps causing uncertainty of long-term health effects).

that some pesticide registrations were approved without full knowledge of accompanying health costs.[124] In situations where new research suggests higher health costs, cancellation proceedings may involve years of gathering data before the EPA makes a determination whether a registration meets the statutory requirements.[125] This may allow persons to be exposed to unhealthy pesticides pending cancellation decisions.[126]

C. Cumulative Exposure

A noted problem in the cost-benefit analysis of FIFRA is that it does not consider cumulative exposure to multiple substances.[127] Rather, the analysis of a pesticide considers only a person's exposure over a lifetime to the cumulative risk of pesticides with a common mechanism of toxicity.[128] Such an analysis ignores exposure from other chemicals that produce a common and adverse outcome on a target organ.[129]

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124 *See* EPA AZINPHOS-METHYL INTERIM DECISION, *supra* note 47, at 54 (finding that the human health and ecological effects of a pesticide meant all uses were ineligible for registration). Twenty-eight azinphos-methyl uses were proposed for immediate cancellation. *Id.* at 68.

125 *See, e.g.*, League of United Latin Am. Citizens v. Wheeler, 899 F.3d 814, 820 (9th Cir. 2018) (quoting 21 U.S.C. § 346a(b)(2)(A)(i)–(ii)), *rev'd en banc* 922 F.3d 443 (9th Cir. 2019) (reporting egregious delay in responding to a cancellation petition for uses of chlorpyrifos).

126 The cancellation proceeding for azinphos-methyl took more than 10 years, allowing the pesticide to remain on the market despite evidence that it was toxic, and use was subjecting workers to adverse neurological effects. *Azinphos-Methyl Phase-Out*, EPA (Nov. 2012), https://archive.epa.gov/pesticides/reregistration/web/html/phaseout_fs.html.

127 *See* Sanne H. Knudsen, *Regulating Cumulative Risk*, 101 MINN. L. REV. 2313, 2390 (2017) [hereinafter Knudsen, *Cumulative Risk*] (arguing for interpreting FIFRA's cost-benefit analysis to include all the risks of pesticide use); Hilko van der Voet et al., *The MCRA Model for Probabilistic Single-Compound and Cumulative Risk Assessment of Pesticides*, 79 FOOD & CHEM. TOXICOLOGY 5, 5 (2015) (noting that traditional risk assessments considering single compounds overlook the cumulative health effects of multiple similar pesticides).

128 *See, e.g. Overview of Risk Assessment in the Pesticide Program*, EPA, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program#assessing_pesticide (last visited Nov. 3, 2020) [https://perma.cc/5U8T-5FZT]; *see also About Pesticide Registration*, EPA, https://www.epa.gov/pesticide-registration/about-pesticide-registration (last visited Nov. 3, 2020) [https://perma.cc/L49R-QL34].

129 *See* Thomas Colnot & Wolfgang Dekant, *Approaches for Grouping of Pesticides into Cumulative Assessment Groups for Risk Assessment of Pesticide Residues in Food*, 83 REGUL. TOXICOLOGY & PHARMACOLOGY 89, 97 (2017) (calling for a more detailed assessment of toxicity data to evaluate risk of health damages from pesticide mixtures); Knudsen, *Cumulative Risk*, *supra* note 127, at 2395 (observing that the evaluation of

Because humans are exposed to multiple substances, the risks and damages from pesticides with a common mechanism of toxicity often do not fully account for a pesticide's potential damages.[130] Further protection of human health may be warranted.[131]

The problem of not considering cumulative exposure with respect to pesticides' residues in or on food products was one of the issues that Congress addressed in the Food Quality Protection Act of 1996.[132] The Act acknowledged that a cap on the residue of a single pesticide on a food product would not keep people safe.[133] Instead, the cumulative effects of pesticides and all other substances having a common mechanism of toxicity needed to be considered for the development of pesticide-residue tolerances on food.[134] This "cumulative effects" requirement goes beyond the cost-benefit analysis of FIFRA so that pesticide residues on food may be a limiting factor in pesticide registrations.

As noted by a district court in Washington State, pesticide exposure adversely affecting endangered species also needs to be evaluated for cumulative effects.[135] The requirements of the Endangered Species Act

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pesticide safety ignores existing studies and institutions devoted to health and safety); James R. Roberts, Catherine J. Karr & Council on Environmental Health, *Pesticide Exposure in Children*, 130 PEDIATRICS 1765, 1768 (2012) (observing that an evaluation of pesticide contamination of groundwater supplies used for drinking water only considers levels of individual pesticides rather than mixtures).

130 *See, e.g.*, Zijian Li, *Introducing Relative Potency Quotient Approach Associated with Probabilistic Cumulative Risk Assessment to Derive Soil Standards for Pesticide Mixtures*, 242 ENV'T. POLLUTION 198, 206 (2018) (arguing that the EPA's risk assessment of pesticides in soils fails to fully account for the cumulative risks of multiple pesticides).

131 *See* William J. Aceves, *Valuing Life: A Human Rights Perspective on the Calculus of Regulation*, 36 L. & INEQ. 1, 65 (2018) (advocating the removal of "partisan influence and bureaucratic bias" from the calculation of regulations affecting human life).

132 Food Quality Protection Act, Pub. L. No. 104-170, 110 Stat. 1489 (1996). *See* Klass, *supra* note 91, at 90–92 (identifying the lack of protection of children and recommending state action to offer greater protection to children); Knudsen, *The Flip Side*, *supra* note 91, at 12 (citing literature that concludes public health values are often not fully considered in the registration of pesticides).

133 Food Quality Protection Act, Pub. L. No. 104-170, 110 Stat. 1489 (1996); *see* NRDC v. EPA, 658 F.3d 200, 204 (2d Cir. 2011) (challenging the safety factor for pesticide exposure of children).

134 21 U.S.C. § 346a(b)(2)(C)(iii)(III), (d)(v) (2018). In addition, it was decided that the health of children deserved further protection. A tenfold margin of safety was implemented for pesticide residues in or on food products. *Id.* § 346a(b)(2)(C).

135 Wash. Toxics Coal. v. U.S. Dep't of Interior, Fish & Wildlife Serv., 457 F. Supp. 2d 1158, 1187 (W.D. Wash. 2006) (requiring consideration of the cumulative effects of a species in a biological opinion by the Fish and Wildlife Service and the National Marine Fisheries Service).

preclude actions that "take" a species.[136] Because the EPA's single-chemical focus for determining adverse effects fails to consider other stressors that can endanger a species, the EPA cannot establish evidence that a registration does not result in a taking of a species.[137] Rather than examining the effects of a single pesticide, all evidence of cumulative effects likely to jeopardize a listed species needs to be considered.[138] Any agency decision omitting consideration of cumulative effects of a pesticide's use that jeopardizes a listed species is arbitrary and capricious as it fails to comply with the mandate of the Endangered Species Act.[139]

D. Evaluating Data

Evaluating data is not a clear-cut and simple process. Persons evaluate information and respond to risks based on what they dread and the mental availability of relevant experiences.[140] Because scientists, regulators, and agricultural producers have different experiences that cause them to interpret risks dissimilarly, they may reach contradictory conclusions in their cost-benefit analysis as opposed to another analysis.[141] Thinking strategies known as heuristics and biases affect evaluations of costs and benefits, and concerns exist as to whether data on pesticides are being evaluated in a manner that fairly reflects human health concerns.[142]

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136 16 U.S.C. § 1532(19) (2018). "The term 'take' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct." *Id.*

137 *Wash. Toxics Coal.*, 457 F. Supp. 2d at 1185. "Under FIFRA, the focus is on the chemical and the registration of that chemical . . . ." *Id.* (quoting comment from National Marine Fisheries Service at 109).

138 *Id.* at 1187.

139 *Id.* at 1193.

140 *See* Thorsten Pachur, Ralph Hertwig & Florian Steinman, *How Do People Judge Risks: Availability Heuristic, Affect Heuristic, or Both?* 18 J. EXPERIMENTAL. PSYCH.: APPLIED 314, 316 (2012) (defining the affect heuristic and examining how it affects perceptions of risk).

141 *See* Benjamin Minhao Chen, *What's in a Number: Arguing About Cost-Benefit Analysis in Administration Law*, 22 LEWIS & CLARK L. REV. 923, 930–31 (2018) (noting that reliance on the availability heuristic may lead to overestimation); Cass R. Sunstein, *Beyond the Precautionary Principle*, 151 U. PA. L. REV. 1003, 1009 (2003) (observing risks that are cognitively available are more likely to be addressed).

142 *See* Kristina C. Miler, *The Limitations of Heuristics for Political Elites*, 30 POL. PSYCH. 863, 885 (2009) (noting that due to the availability heuristic, active and wealthy people are favored over others).

Availability and affect heuristics lead persons to judge risks differently.[143] Decisions by registrants, producers, and agency personnel may be affected by their backgrounds. In sorting through information available on an issue involving the use and regulation of pesticides, persons rely on personal experiences in evaluating risk that may subjugate superior information.[144] The availability of a personal experience can lead a person to reach a faulty judgment;[145] the affect heuristic involves judgments based in part on a person's feelings that overshadow alternative viewpoints.[146] Availability and affect heuristics lead to different interpretations of what complies with the law in safeguarding human safety and environmental quality.[147]

Disputes concerning the registration of pesticides, as well as proceedings for the cancellation of registrations, suggest that registrants and agricultural producers do not view the use of pesticides in the same manner as the general population.[148] Registrants expend

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143 *See* Amber S. Mase, Hyunyi Cho & Linda S. Prokopy, *Enhancing the Social Amplification of Risk Framework (SARF) by Exploring Trust, the Availability Heuristic, and Agricultural Advisors' Belief in Climate Change*, 41 J. ENV'T. PSYCH. 166, 171 (2015) (examining the availability heuristic and the different viewpoints of agricultural advisors toward adaptation to climate change); JONATHAN WEINER ET AL., THE REALITY OF PRECAUTION: COMPARING RISK REGULATION IN THE US AND EUROPE, Washington, DC: Resources for the Future (2014) (observing that what people can recall influences their judgments).

144 *See* Jeffrey A. Friedman, *Priorities for Preventive Action: Explaining Americans' Divergent Reactions to 100 Public Risks*, 63 AM. J. POL. SCI. 181, 194 (2019) (observing that factual information fails to overcome personal values).

145 *See* Miler, *supra* note 142, at 866 (observing that reliance on a subset of biased information leads to inferior judgments).

146 *See* Paul Slovic et al., *Risk as Analysis and Risk as Feelings: Some Thoughts About Affect, Reason, Risk, and Rationality*, 24 RISK ANALYSIS 311, 314 (2004) (observing that "qualities of real or imagined stimuli" can evoke images affecting perceptions and judgments); WEINER ET AL., *supra* note 143 (observing that what people can recall influences their judgments).

147 *See* Terence J. Centner & Ludivine Petetin, *Divergent Approaches Regulating Beta Agonists and Cloning of Animals for Food: USA and European Union*, 26 SOC'Y & ANIMALS 1, 2 (2018) (discussing how American and European policy makers reached different conclusions about allowing the use of beta agonists and cloning in animal production).

148 This may be explained by the availability heuristic and the cascade effect. Gregory N. Mandel, *Technology Wars: The Failure of Democratic Discourse*, 11 MICH. TELECOMM. & TECH. L. REV. 117, 167–68 (2005). The availability heuristic would involve the tendency for producers to be familiar with safely using pesticides and the enhanced yields and profits that accompany use. The cascade effect occurs as producers' information on pesticides mainly comes from other producers, sellers, and agricultural interest groups that focus on benefits. This would result in an "all benefit, no risk" belief. *Id.* at 170. The United States is facilitating the use of dangerous pesticides that the European Union, China, and Brazil feel should not be used due to health concerns. Nathan Donley, *The USA Lags Behind Other*

considerable money in developing new pesticides and seek profits from subsequent sales.[149] In complying with the registration requirements, registrants decide what studies to conduct and what issues to examine.[150] Registrants' heuristics and biases may lead to decisions to interpret studies in a manner that is biased.[151]

Agricultural producers using pesticides seek to enhance the profitability of their food production activities.[152] They believe they need to use pesticides to reduce damages from pests that lower yields.[153] Given that pesticides are used to enhance profitability, producers are biased and object to actions that might limit pesticide usage.[154] Their emotional interest in sustaining their livelihoods leads them to discount scientific studies suggesting a relationship between

Agricultural Nations in Banning Harmful Pesticides, 18 ENV'T. HEALTH 44 (2019). Producers would be unlikely to be aware of scientific studies delineating health and environmental concerns.

149 *See* Brief of Croplife America, *supra* note 60. Monsanto reported net sales for its Agricultural Productivity Segment, which includes seeds and chemicals, of $3.7 billion in 2017. MONSANTO, SHARING VALUE, SUSTAINING INNOVATION 2017 ANNUAL REPORT 24 (2017).

150 *Data Requirements for Pesticide Registration*, EPA, https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration (last visited Nov. 5, 2020) [https://perma.cc/VYR8-B45V] (noting that registrants "generate scientific data necessary to address concerns pertaining to the identity, composition, potential adverse effects, and environmental fate of each pesticide.").

151 *See* G.M. Williams et al., *Corrigendum*, 48 CRITICAL REVS. TOXICOLOGY 893, 893–94 (2018) (discussing how authors' research might be biased due to previously paid compensation and funding for the research).

152 *See* Jose A. Lopez, Kandy Rojas & James Swart, *The Economics of Foliar Fungicide Applications in Winter Wheat in Northeast Texas*, 67 CROP PROT. 35, 36 (2015) (acknowledging that use of a fungicide on winter wheat can increase yields by more than 30%).

153 *See* Rosburg & Menapace, *supra* note 26, at 153 (observing that use of a pesticide reduces damages rather than increasing yields). By reducing risks of losses from pests, the use of a pesticide can increase profits. *Id.* at 153–54.

154 *See* Cass R. Sunstein, *On the Divergent American Reactions to Terrorism and Climate Change*, 107 COLUM. L. REV. 503, 523 (2007) (opining "that beneficial activities contain low risks").

pesticides and health problems.[155] Producers' reactions to risk lie "more with their values than with their grasp of factual information."[156]

Scientists may also have biases that cause them to evaluate data differently. In some cases, industry funds scientists with guidelines about what to research and what may be published.[157] Research studies suggest that industry-funded scientific studies tend to favor the funder.[158] Research journals are more likely to publish studies showing effects of environmental problems than studies finding no effect.[159] Related to this problem is the decision of a researcher to terminate a study prematurely due to the belief that an uninteresting null finding appears imminent and the results are unlikely to be published.[160] Another issue is that research funded by industry sometimes may be discounted.[161]

For some research, a bias occurs because a scientist's findings are based on studies with inadequate numbers.[162] Studies using small

155 *See* Mauro Maldonato & Silvia Dell'Orco, *How to Make Decisions in an Uncertain World: Heuristics, Biases, and Risk Perception*, 67 WORLD FUTURES: J. GEN. EVOLUTION 569, 575 (2011) (discussing how an emotive reaction to anxiety can lead to judgments that decline to use rational reactions). For producers, their anxiety about losing income from not using a pesticide causes them to compromise their health when using pesticides. Melissa J. Perry & Frederick R. Bloom, *Perceptions of Pesticide Associated Cancer Risks Among Farmers: A Qualitative Assessment*, 57 HUM. ORG. 342, 346 (1998).

156 Friedman, *supra* note 144, at 194.

157 *See* Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1489–91 (1999) (highlighting how the tobacco industry used funding to perpetuate controversy about the health effects of tobacco).

158 *See* Glenn W. Suter II & Susan M. Cormier, *Bias in the Development of Health and Ecological Assessments and Potential Solution*, 22 HUM. & ECOLOGICAL RISK ASSESSMENT: INT'L J. 99, 101–02 (2016) (claiming the literature shows industry-funded science favors the funder).

159 *See id.* at 102–03. In addition, replication studies contradicting earlier studies are more likely to be published. *Id.* at 102–03.

160 *See* Erica C. Yu et al., *When Decision Heuristics and Science Collide*, 21 PSYCHONOMIC BULL. Rev. 268, 280 (2014) (noting the bias that occurs when experiments are canceled because they are expected to show a null result). *See also* Williams et al., *supra* note 151.

161 *See* Carol Reeves, *Of Frogs & Rhetoric: The Atrazine Wars*, 24 TECH. COMMC'N Q. 328, 345 (2015) (compiling documentation that nonindustry-funded papers were not citing industry-funded papers).

162 *See* Yu et al., *supra* note 160, at 279 (reporting that too many scientists are embracing research "results based on small samples"); Rebecca Renner, *Controversy Clouds Atrazine Studies*, 38 ENV'T. SCI. & TECH. 107A, 107A–08A (2004) (discussing a controversy concerning studies which found the use of the herbicide atrazine was harming frogs).

numbers are unlikely to reflect the features of those being evaluated.[163] Case studies involving only a few observations lack statistical relevance yet may be assumed to validate a position.[164] Research findings based on small numbers may lead to false positives and incorrect inferences.[165]

Another bias occurs when scientists seek publicity and funding.[166] Reports that are provocative, rife with speculation, or stretch credibility garner publicity even when they are misleading or inaccurate.[167] Although most scientists adhere to the scientific method and couch their findings in a manner that does not exaggerate the limitations of their studies, dramatic conclusions offending scientific inquiry are a problem.[168] Occasionally, researchers engage in a faulty experiment.[169] Science is messy, compounding regulators' efforts to conduct a meaningful and fair cost-benefit analysis.[170]

III
GLYPHOSATE-BASED HERBICIDES

Scientists, regulatory authorities, and members of the public have expressed concerns about the uses of GBHs in controlling unwanted

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163 *See* Lewis G. Halsey et al., *The Fickle P Value Generates Irreproducible Results*, 12 NATURE METHODS 179, 180 (2015) (noting that small sample sizes limit the meaningfulness of a p-value).

164 *See id.*

165 *See* Tamar R. Makin & Jean-Jacques Orban de Xivry, *Ten Common Statistical Mistakes to Watch Out for When Writing or Reviewing a Manuscript*, ELIFE, Oct. 2019 (noting problems accompanying research based on small sample sizes); Matthew Rabin, *Inference by Believers in the Law of Small Numbers*, 117 Q. J. ECON. 775, 775 (2002) (modeling how small numbers may exaggerate parent populations).

166 *See* Reeves, *supra* note 161, at 328 (acknowledging contrasting results between industry-funded research and research funded by nonindustry sources).

167 *See, e.g.*, Kevin Trenberth, *Study Predicts Multi-Meter Sea Level Rise This Century, But Not Everyone Agrees*, CONVERSATION (July 23, 2015, 4:09 PM), https://theconversation.com/study-predicts-multi-meter-sea-level-rise-this-century-but-not-everyone-agrees-45139 [https://perma.cc/JGJ2-WSRZ] (critiquing a reported study claiming it was "rife with speculation").

168 *See* Rex Dalton, *E-mails Spark Ethics Row*, 466 NATURE 913, 913 (2010) (reporting an ethics row over "trash-talking" emails).

169 *See, e.g.*, Renner, *supra* note 162, at 108A (reporting the discovery by an EPA Scientific Advisory Panel of flawed studies based on "inadequate toxicant sampling, poor statistical power, and inappropriate sample site selection procedures").

170 *See* Daniela M. Witten & Robert Tibshirani, *Scientific Research in the Age of Omics: The Good, the Bad, and the Sloppy*, 20 J. AM. MED. INFO. ASS'N 125, 125 (2013) (noting problems of published research findings that are false and problems with the design and analysis of large studies).

plant species in the production of agricultural foodstuffs.[171] Glyphosate is a phosphonomethyl amino acid herbicide that was initially registered in 1974.[172] It inhibits the 5-enolpyruvylshikimate-3-phosphate synthase enzyme in plants, which is not present in mammalian systems.[173] GBHs are used to control weeds on more than 100 food crops and in nonagricultural settings.[174] More than 750 products containing glyphosate are marketed in the United States[175] and more than 2,000 in Europe.[176] In 2014, an estimated 1.8 million pounds of GBHs were used yearly for the production of crops around the world.[177] Glyphosate is usually mixed with a co-formulant, sometimes referred to as an adjuvant or surfactant,[178] to enhance its effectiveness or provide other desired properties.[179] In some cases, the co-formulants are not

171 *See* Fernando P. Carvalho, *Pesticides, Environment, and Food Safety*, 6 FOOD & ENERGY SEC. 48, 54 (2017) (suggesting measures to mitigate adverse effects of pesticide uses); Laura N. Vandenberg et al., *Is It Time to Reassess Current Safety Standards for Glyphosate-Based Herbicides?*, 71 J. EPIDEMIOLOGY & CMTY. HEALTH 613, 616 (2017) (observing that there is inadequate information to determine whether glyphosate uses are safe for humans); *see also* EFSA, *Peer Review of the Pesticide Risk Assessment of the Potential Endocrine Disrupting Properties of Glyphosate*, 15 EURO. FOOD SAFETY AUTH. J. 4979 (2017); *EFSA Statement Addressing Allegations on the Renewal Assessment Report for Glyphosate*, EFSA (Sept. 22, 2017) https://www.efsa.europa.eu/sites/default/files/170922_glyphosate_statement.pdf [https://perma.cc/7PTM-JSM6].

172 EPA GLYPHOSATE ISSUE PAPER, *supra* note 120, at 12. Glyphosate was first used "to control perennial weeds on ditch banks, in right of ways, and fallow fields." Dill et al., *supra* note 105, at 2. With the adoption of no-till practices, it was used on some agricultural crops. *Id.*

173 EPA GLYPHOSATE ISSUE PAPER, *supra* note 120, at 12. Glyphosate was reregistered in 1993, *id.*, and the EPA published updated information on its safety in 2017. *EPA Releases Draft Risk Assessments for Glyphosate*, EPA (Dec. 18, 2017), https://www.epa.gov/pesticides/epa-releases-draft-risk-assessments-glyphosate [https://perma.cc/5PCM-8ZH6].

174 EPA GLYPHOSATE ISSUE PAPER, *supra* note 120, at 15; *see also* Rebecca K. Stewart, *Weeds, Seeds & Deeds Redux: Natural and Legal Evolution in the U.S. Seed Wars*, 18 STAN. TECH. L. REV. 101 (2014) (castigating the use of glyphosate that has allowed the mutation of superweeds and the increased use of more dangerous chemicals).

175 *Glyphosate*, NAT'L PESTICIDE INFO. CTR., (Mar. 2019), http://npic.orst.edu/factsheets/glyphogen.html[https://perma.cc/N4SY-P9XU].

176 *See* Robin Mesnage, Charles Benbrook & Michael N. Antoniou, *Insight into the Confusion over Surfactant Co-Formulants in Glyphosate-Based Herbicides*, 128 FOOD & CHEM. TOXICOLOGY 137, 138 (2019) [hereinafter Mesnage, *Surfactant Co-Formulants*].

177 *Glyphosate Use Worldwide from 1994 to 2014 (in 1,000 kilograms)**, STATISTA, (2018), https://www.statista.com/statistics/567250/glyphosate-use-worldwide/.

178 *See* Eszter Takács et al., *Effects of Neonicotinoid Insecticide Formulations and Their Components on* Daphnia magna *– The Role of Active Ingredients and Co-Formulants*, 97 INT'L J. ENV'T. ANALYTICAL CHEMISTRY. 885, 885 (2017) (listing adjuvant and surfactant as keywords that correspond to co-formulants).

179 *See* N. Defarge, J. Spiroux de Vendômois & G.E. Séralini, *Toxicity of Formulants and Heavy Metals in Glyphosate-Based Herbicides and Other Pesticides*, 5 TOXICOLOGY

identified as they are claimed to qualify as trade secrets.[180] Due to the use of various co-formulants, formulations of GBHs have dissimilar levels of toxicity.[181] Research suggests that co-formulants often increase the toxicity of glyphosate products.[182]

A small but important use of GBHs is to control weeds in highways, railroads, utility rights-of-way, and urban and suburban areas to eliminate unwanted vegetation.[183] By replacing noisy mechanical controls, GBHs are less bothersome in developed areas.[184] They also reduce mechanical equipment costs, fuel consumption, and injuries accompanying the use of weed-cutting equipment.[185] By eliminating vegetation next to roads and highways, GBHs increase drivers'

REPS. 156, 160 (2018) (discussing uses of co-formulants as surfactants, diluents, or adjuvants to stabilize glyphosate and allow its penetration in plants).

180 *See* Mesnage, *Surfactant Co-Formulant*, *supra* note 176, at 138 (noting that co-formulants are considered by many firms to be confidential business information and thereby are not disclosed).

181 *See id.* at 144. (advocating laws to identify co-formulants so that the toxic effects can be more readily evaluated).

182 *See* Magdalena Chłopecka et al., *The Effect of Glyphosate-Based Herbicide Roundup and Its Co-Formulant, POEA, on the Motoric Activity of Rat Intestine –* In Vitro *Study*, 40 ENV'T. TOXICOLOGY & PHARMACOLOGY 156, 160 (2017); Isis Coalova, María del Carmen Ríos de Molina & Gabriela Chaufan, *Influence of the Spray Adjuvant on the Toxicity Effects of a Glyphosate Formulation*, 28 TOXICOLOGY IN VITRO 1306, 1310 (2014); Nicolas Defarge et al., *Co-Formulants in Glyphosate-Based Herbicides Disrupt Aromatase Activity in Human Cells Below Toxic Levels*, 13 INT'L J. ENV'T. RSCH. & PUB. HEALTH 1, 13 (2016); Károly Nagy et al., *Systematic Review of Comparative Studies Assessing the Toxicity of Pesticide Active Ingredients and Their Product Formulations*, 181 ENV'T. RSCH. 108926 (2019) (analyzing data of pesticides to conclude that most products possess a higher toxicity than their active ingredient).

183 *See* Benjamin Ballard & Christopher A. Nowak, *Timing of Cut-Stump Herbicide Applications for Killing Hardwood Trees on Power Line Rights-of-Way*, 32 ARBORICULTURE & URB. FORESTRY 118, 118 (2006) (noting herbicides are important in maintaining power lines); Battaglin et al., *supra* note 35, at 287 (2014) (noting urban uses result in runoff that contaminate drainage systems); B. Melander et al., *Weed Occurrence on Pavements in Five North European Towns*, 49 WEED RSCH. 516, 517 (2008) (noting damage to pavements); F. Schweinsberg et al., *Herbicide Use on Railway Tracks for Safety Reasons in Germany?* 107 TOXICOLOGY LETTERS 201, 204 (1999) (discussing contamination from the use of herbicides on railroads in Germany).

184 S. Benvenuti, *Weed Dynamics in the Mediterranean Urban Ecosystem: Ecology, Biodiversity and Management*, 44 WEED RSCH. 341, 351 (2004) (observing less damage to masonry and fewer weeds with pollen for allergies); C. Kempenaar et al., *Trade Off Between Costs and Environmental Effects of Weed Control on Pavements*, 26 CROP PROT. 430, 430 (2007) (explaining that controlling weeds enhances "the functionality, durability and/or aesthetic value of the pavements").

185 *See* Melander et al., *supra* note 183, at 517 (noting that weed control by herbicides reduces maintenance costs).

visibility, making roads safer.[186] Moreover, glyphosate use extends the life of paved surfaces, contributes to visual appeal, and reduces weed control costs.[187] Homeowners also use GBHs to control weeds, as it is an efficient way to enhance their landscaping and gardens.[188] Research suggests that urban sources of GBHs contribute significantly to glyphosate loads in surface waters.[189]

A. Agricultural Uses

Most GBHs are used in agricultural settings, especially in conjunction with genetically modified soybean, corn, cotton, canola, and sugar beet crops.[190] The glyphosate-resistant crops can be sprayed with GBHs and survive while nonresistant weed species are killed.[191] Fifty-six percent of glyphosate use in the world is on herbicide-resistant crops.[192] More recently, uses of GBHs at lower levels, multiple

186 *See* Allen V. Barker & Randall G. Prostak, *Alternative Management of Roadside Vegetation*, 19 HORTTECHNOLOGY 346, 346 (2009) (observing that the control of weeds enhances aesthetics and safety).

187 *See* Benvenuti, *supra* note 184, at 351 (noting herbicides reduce functional damage to structures); A.M. Rask & P. Kristoffersen, *A Review of Non-Chemical Weed Control on Hard Surfaces*, 47 WEED RSCH. 370, 371 (2007) (observing that weeds make streets and pavements unsightly).

188 *See, e.g.*, Irene Hanke et al., *Relevance of Urban Glyphosate Use for Surface Water Quality*, 81 CHEMOSPHERE 422, 422 (2010) (noting the popularity of GBHs due to their "low toxicity and high efficiency"); Ting Tang et al., *Quantification and Characterization of Glyphosate Use and Loss in a Residential Area*, 517 SCI. TOTAL ENV'T 207, 207 (2015) (noting that, in many European countries, GBHs are "the most widely-used herbicides for urban and residential weed control").

189 *See* Fabrizio Botta et al., *Transfer of Glyphosate and Its Degradate AMPA to Surface Waters Through Urban Sewerage Systems*, 77 CHEMOSPHERE 133, 138 (2009) (evaluating a site in France to conclude that nonagricultural applications of GBHs make a relevant contribution of glyphosate to surface waters); Hanke et al., *supra* note 188, at 429 (evaluating a site in Switzerland and finding contributions from nonagricultural areas); Christian Skark et al., *Contribution of Non-Agricultural Pesticides to Pesticide Load in Surface Water*, 60 PEST MGMT. SCI. 525, 529 (evaluating a site in Germany that suggested nonagricultural herbicides were making a relevant contribution to glyphosate concentration in surface waters).

190 *See* Graham Brookes, *Weed Control Changes and Genetically Modified Herbicide Tolerant Crops in the USA 1996–2012*, 5 GM CROPS & FOOD 321, 321 (2014). Soybeans were the first herbicide-resistant field crop, followed by corn, cotton, canola, and sugar beets. *Id.*

191 *See, e.g.*, Ian Heap & Stephen O. Duke, *Overview of Glyphosate-Resistant Weeds Worldwide*, 74 PEST MGMT. SCI. 1040, 1042 (2018) (discussing resistant food crops and weeds that are not killed by glyphosate).

192 Benbrook, *supra* note 3, at 7 (reporting that the crop using the most glyphosate is soybeans); Brookes, Taheripour & Tyner, *supra* note 31, at 220 (reporting that genetically modified corn and soybean crops were the most prominent users of herbicide-tolerant technologies).

applications to control weeds, and combinations of applications with other herbicides have become important components of producers' weed control strategies.[193]

The net economic benefits at the farm level associated with the use of GBHs in 2016 were estimated to be $18.2 billion.[194] These economic benefits accrue from several sources. For many uses, GBHs eliminate or minimize cultivation through their use with no-till or conservation tillage.[195] Due to reduced tilling, producers need less equipment, use less fuel, and have lower labor costs for controlling weeds.[196] Reductions in tillage lower greenhouse gas emissions and help producers curtail erosion.[197] Subsequently, uses of GBHs preserve soil resources and lessen the impairment of surface waters.[198] GBHs increase crop yields by reducing competing weeds so that more sunlight and nutrients are available to the crop.[199] The increased yields

193 *See* Thomas Pfleeger et al., *Effects of Single and Multiple Applications of Glyphosate or Aminopyralid on Simple Constructed Plant Communities*, 33 ENV'T. TOXICOLOGY & CHEM. 2368, 2377 (2014) (conducting trials of multiple use of herbicides for controlling weed populations); Brookes, *supra* note 190, at 328 (noting that producers of herbicide-resistant crops are diversifying their weed management programs by supplementing glyphosate use with other herbicides).

194 Graham Brookes & Peter Barfoot, *Farm Income and Production Impacts of Using GM Crop Technology 1996-2016*, 9 GM CROPS & FOOD 59, 71 (2018) [hereinafter Brookes & Barfoot 2018]. For soybeans, corn, canola, and cotton, genetically modified crops added 5.4% to the global production. *Id.* The income gain came mostly from higher yields, but part was due to lower production costs. Graham Brookes & Peter Barfoot, *Farm Income and Production Impacts of Using GM Crop Technology 1996–2015*, 8 GM CROPS & FOOD 156, 166 (2017). Herbicide tolerance accounted for 58% of the income gain, while insect resistance accounted for 42%. *Id.*

195 *See* Brookes, *supra* note 190, at 322 (discussing the adoption of herbicides and reductions of tillage).

196 *See* Leonard P. Gianessi, *The Increasing Importance of Herbicides in Worldwide Crop Production*, 69 PEST MGMT. SCI. 1099, 1099 (2013) (reporting that the adoption of no-till reduces plowing and cultivation practices that depend on the use of fuel). A weed sprayer may use seventeen times less fuel per unit area than a moldboard plow, and one-fourth the amount of fuel as cultivator. *Id.*

197 *See* Brookes, *supra* note 190, at 322 (commenting on environmental benefits).

198 *See* Elizabeth Vogel et al., *Bioenergy Maize and Soil Erosion – Risk Assessment and Erosion Control Concepts*, 261 GEODERMA 80, 81 (2016) (interpreting data that show no-tillage and conservation tillage reducing erosion on maize by up to 90% to 100%).

199 *See* John R. Teasdale & Michael A. Cavigelli, *Subplots Facilitate Assessment of Corn Yield Losses from Weed Competition in a Long-Term Systems Experiment*, 30 AGRONOMY SUSTAINABLE DEV. 445, 452 (2010) (reporting that yield increases due to the use of herbicides on corn were related to the nitrogen availability and reduced weed competition). Other research concluded that increased herbicide use over a fifteen-year span commencing in 1964 "accounted for 20% of the increase in corn yields and 62% of the increase in soybean yields" in the United States. Gianessi, *supra* note 196, at 1100.

per acre mean less cropland is needed to grow the same amount of food.[200] In some situations, the use of GBHs as a desiccant allows the harvest of an early season crop and the immediate planting of a second crop, which facilitates the production of two crops a year.[201]A negative feature of GBH use is the evolution of glyphosate-resistant weed species due to the herbicide's use year after year.[202] The International Survey of Herbicide Resistant Weeds lists fifty-one resistant weed species,[203] of which seventeen are a problem in the United States.[204] To control these weeds, producers resort to the use of other herbicides,[205] fallowing land for a year with cover crops,[206] crop rotations,[207] management programs,[208] and mechanical weed control.[209] Resistant weed species are a serious problem, and agricultural scientists continue

200 *See* Brookes, Taheripour & Tyner, *supra* note 31, at 225 (calculating that the cessation of glyphosate-resistant crops would require 762,000 hectares of additional cropland).

201 *See* Brookes & Barfoot 2018, *supra* note 194, at 65 (identifying farms in South America that can grow wheat and soybeans in the same year).

202 *See* John Peterson Myers et al., *Concerns over Use of Glyphosate-Based Herbicides and Risks Associated with Exposures: A Consensus Statement*, 15 ENV'T. HEALTH 1, 5 (2016) (noting that resistant weeds have increased total herbicide use in soybeans and cotton); Brookes, *supra* note 190, at 323 (noting management decisions to control resistant weeds).

203 I. Heap, INT'L HERBICIDE-RESISTANT WEED DATABASE, http://www.weedscience .org (last visited Sept. 20, 2020).

204 Heap & Duke, *supra* note 191 (noting the weed resistance to GBHs started in 2000 with *Amaranthus palmeri* causing the greatest damage).

205 *See* Debalin Sarangi & Amit J. Jhala, *Comparison of a Premix of Atrazine, Bicyclopyrone, Mesotrione, and Smetolachlor with Other Preemergence Herbicides for Weed Control and Corn Yield in No-Tillage and Reduced-Tillage Production Systems in Nebraska, USA*, 178 SOIL & TILLAGE RSCH. 82, 82–90 (2018) (discussing the premix of herbicides for weed control on corn).

206 *See* E.E. Burns, *You Cannot Fight Fire with Fire: A Demographic Model Suggests Alternative Approaches to Manage Multiple Herbicide-Resistant Avena Fatua*, 58 WEED RSCH. 357, 366 (2018) (discussing using a fallow year followed by cover crops to control weeds).

207 *See* R. Gerhards et al., *An Approach to Investigate the Costs of Herbicide-Resistant Alopecurus Myosuroides*, 56 WEED RSCH. 407, 413 (2016) (showing benefits from using crop rotations and cover crops).

208 *See* Jason K. Norsworthy et al., *Reducing the Risks of Herbicide Resistance: Best Management Practices and Recommendations*, 60 WEED SCI. 31, 53 (2011) (recommending a diversified weed management program to minimize weed seed production).

209 *See* Ballard & Nowak, *supra* note 183, at 123 (suggesting managers need knowledge to make informed decisions on weed management); Heap & Duke, *supra* note 191, at 1047 (advocating for intensive weed management that includes "mechanical and cultural strategies").

with research to identify strategies to manage weeds while maintaining crop production and herbicide use.[210]

B. Health Studies

One of the major concerns involving the use of GBHs is whether they are adversely affecting human health.[211] Chronic diseases have complex origins, and insufficient research exists on whether formulations of GBHs are related to endocrine disruption, birth defects, immune functions, metabolism, brain development, and behavior.[212] Data suggesting GBH chemicals are neurotoxic, promote early puberty, lead to diabetes, and contribute to obesity raise questions of whether the use of GBHs should be curtailed or eliminated.[213]

As might be expected of a substance that has been on the market for more than four decades and is the most widely used herbicide in the world,[214] a plethora of studies has examined glyphosate's potential for adversely affecting humans.[215] The EPA examined the literature and evaluated twenty-four epidemiological studies to conclude that "[t]here was no evidence of an association between glyphosate exposure and solid tumors . . . [, and] no evidence of an association between glyphosate exposure and leukemia, or [Hodgkin's lymphoma]."[216] However, the studies suggested a possible exposure-response relationship for multiple myeloma.[217] For non-Hodgkin's lymphoma, the EPA concluded that the data were insufficient to determine whether

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210 *See* Ballard & Nowak, *supra* note 183, at 118 (using mechanical and chemical methods to control weeds).

211 *See* Myers et al., *supra* note 202, at 6–8 (reporting research studies that suggest adverse effects on human health).

212 *See* Linda S. Birnbaum, Paul Jung & Sheila A. Newton, *Environmental Health Science for Regulatory Decisionmaking*, 21 DUKE ENV'T. L. & POL'Y F. 259, 277 (2011) (raising issues about the lack of knowledge on the health effects of toxic chemicals).

213 *See id.* at 278.

214 *See* Benbrook, *supra* note 3, at 1.

215 *See* EUROPEAN FOOD SAFETY AUTHORITY, CONCLUSION ON THE PEER REVIEW OF THE PESTICIDE RISK ASSESSMENT OF THE ACTIVE SUBSTANCE GLYPHOSATE 1, 2 (2015) (concluding "that glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential") [hereinafter EFSA CONCLUSION]; EPA GLYPHOSATE ISSUE PAPER, *supra* note 120, at 12; ASSESSMENT OF IARC MONOGRAPHS, RENEWAL ASSESSMENT REPORT: GLYPHOSATE ADDENDUM 1 TO RAR (2015) [hereinafter RENEWAL ASSESSMENT REPORT]; WHO, SOME ORGANOPHOSPHATE INSECTICIDES AND HERBICIDES, IARC MONOGRAMS (2017) [hereinafter WHO ORGANOPHOSPHATE].

216 EPA GLYPHOSATE ISSUE PAPER, *supra* note 120, at 63.

217 *Id.*

there was an association between glyphosate exposure and risk for this medical condition.[218] Moreover, the EPA noted that a complete human health risk assessment was needed,[219] although the agency remains years away from codifying "tests capable of identifying the risk of low-dose, endocrine-disruption driven effects."[220] While the EPA did not conclusively establish that glyphosate use was harming humans, the agency did not establish that GBH uses are safe.[221] In 2020, the EPA decided that the benefits from glyphosate use outweigh potential ecological risks that justify registrations.[222]

The European Food Safety Authority [Authority] concluded that there was inadequate evidence to preclude the use of GBHs.[223] Despite public antagonism for the production of genetically modified plants using glyphosate, the Authority inferred that the use of plant protection products containing glyphosate would not lead to an unacceptable impact on the natural environment and groundwater if applications were "accompanied by appropriate risk mitigation measures."[224] Because glyphosate is unlikely to pose a carcinogenic hazard to humans, it was not classified as carcinogenic by the Authority.[225]

The United Nations Food and Agriculture Organization and the World Health Organization worked together at a Joint Meeting on Pesticide Residues to evaluate the safety of glyphosate and concluded it was not carcinogenic.[226] Conversely, after analyzing similar data as investigated by the foregoing groups, the International Agency for Research on Cancer concluded glyphosate was probably carcinogenic to humans.[227]

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218 *Id.* at 68. The agency felt that chance and/or bias might serve as an explanation for observed associations. *Id.*

219 *Id.* at 12.

220 Myers et al., *supra* note 202, at 11.

221 EPA GLYPHOSATE ISSUE PAPER, *supra* note 120, at 68 (deciding a decision cannot be made). *See* Li, *supra* note 130, at 206 (explaining what is missing from exposures that only consider glyphosate); Vandenberg et al., *supra* note 171, at 616 (concluding that safety standards for GBHs "may fail to protect public health").

222 EPA DECISION 0178, *supra* note 56, at 15.

223 *See* EFSA CONCLUSION, *supra* note 215, at 1.

224 RENEWAL ASSESSMENT REPORT, *supra* note 215, at 37.

225 EFSA CONCLUSION, *supra* note 215, at 1.

226 FAO/WHO, JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES pt. 1.2 (2016) (concluding "that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet").

227 WHO ORGANOPHOSPHATE, *supra* note 215, at 398 (finding "strong evidence that exposure to glyphosate or glyphosate-based formulations is genotoxic").

The above studies ignored cumulative exposure. In the EPA's analysis, glyphosate was tested using an array of cell assays and rodent bioassays.[228] Most pesticide products containing glyphosate, however, also contain a co-formulant to increase their effectiveness.[229] If a co-formulant is classified as inert, it is exempt from toxicity testing even though it may have toxic qualities.[230] Therefore, studies reporting health problems related to the active ingredient that fail to evaluate co-formulants may not accurately project the dangers of GBH use.[231] A common co-formulant is polyoxyethylene tallow amine, and research suggests this co-formulant is more toxic than glyphosate as it can cause an antagonistic interaction toward the activity of gastrointestinal smooth muscles.[232] Considerable research suggests that the toxicity of GBHs containing co-formulants exceeds the toxicity of the active ingredient glyphosate.[233] Many of the risk assessment statements for glyphosate are untenable for establishing hazard and exposure levels because they did not assess co-formulants.[234]

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228 *See* Mesnage, *Surfactant Co-Formulants*, *supra* note 176, at 138.

229 *See* Claudia N. Martini et al., *Glyphosate-Based Herbicides with Different Adjuvants Are More Potent Inhibitors of 3T3-L1 Fibroblast Proliferation and Differentiation to Adipocytes than Glyphosate Alone* 25 COMPAR. CLINICAL PATHOLOGY 607, 613 (2016) (noting the importance of evaluating the cytotoxic effects of formulations rather than just the active ingredient); Mesnage, *Surfactant Co-Formulants*, *supra* note 176, at 137 (noting the distinction between active ingredients that are governed by FIFRA's registration provisions and co-formulants that are inert); András Székács & Béla Darvas, *Re-registration Challenges of Glyphosate in the European Union*, 6 FRONTIERS ENV'T. SCI. 1, 1 (2008) (identifying the distinction between active and inert ingredients).

230 *See* Mesnage, *Surfactant Co-Formulants*, *supr*a note 176, at 138.

231 *See* Martini et al., *supra* note 229, at 613 (advocating that formulations rather than glyphosate be evaluated); Chłopecka et al., *supra* note 182, at 161 (enumerating the need to distinguish between the active ingredient and its use with a co-formulant).

232 *See* Chłopecka et al., *supra* note 182, at 156–57; Youwu Hao et al., *Roundup-Induced AMPK/mTOR-Mediated Autophagy in Human A549 Cells*, 67 FOOD CHEM. 11364, 11371 (2019) (finding that co-formulant polyethoxylated tallow amine caused Roundup to be more toxic).

233 *See* Chłopecka et al., *supra* note 182, at 156; Mesnage, *Surfactant Co-Formulants*, *supra* note 176, at 144; Székács & Darvas, *supra* note 229, at 22.

234 *See* Székács & Darvas, *supra* note 229, at 22 (discounting an earlier study); Takács et al., *supra* note 178, at 897 (generalizing that the evaluation of an active ingredient of an agrochemical does not predict its effects on ecosystems).

C. Health Concerns

Research reveals a plethora of concerns about potential adverse health effects related to GBH exposure.[235] Three areas may be highlighted: non-Hodgkin's lymphoma, gastrointestinal changes, and reproduction. Most of the concerns are raised by animal studies in which animals were given doses far greater than exposures expected to be experienced by humans, yet the identified effects warrant further research.[236]A vast majority of the lawsuits against Monsanto are based on claims that glyphosate caused non-Hodgkin's lymphoma, a type of cancer originating in a person's lymphatic system.[237] Although the lack of sufficient data precluded determination that glyphosate exposure was related to non-Hodgkin's lymphoma, a number of researchers and medical experts feel there is a relationship.[238] In a Swedish population-based case-control study of exposure to pesticides, the relationship of glyphosate with non-Hodgkin's lymphoma was found to be statistically significant.[239] A study conducted in the United States showed an association of pesticide uses and non-Hodgkin's lymphoma leading to a recommendation for further investigation.[240] Other research studies suggest a compelling link between exposures to GBHs and increased risk for non-Hodgkin's lymphoma,[241] although some failed to show a

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235 *See, e.g.*, Barnett-Rose, *supra* note 10, at 74–83 (highlighting potential health and environmental effects).

236 *See* Robin Mesnage et al., *Multiomics Reveal Non-Alcoholic Fatty Liver Disease in Rats Following Chronic Exposure to an Ultra-Low Dose of Roundup Herbicide*, 7:39328 NATURE SCI. REPS. 1, at 10 (2017) [hereinafter Mesnage, *Multiomics*] (finding low levels of Roundup were "associated with . . . alterations of the liver proteome and metabolome").

237 *See Monsanto Papers*: *Roundup (Glyphosate) Cancer Cases: Key Documents & Analysis*, U.S. RIGHT TO KNOW, https://usrtk.org/monsanto-papers/ (last visited Sept. 20, 2020) [hereinafter U.S. RIGHT TO KNOW] [https://perma.cc/27CN-J7SY] (providing an accounting of the litigation); Hilary Brueck, *The EPA Says a Chemical in Monsanto's Weed-Killer Doesn't Cause Cancer – But There's Compelling Evidence the Agency Is Wrong*, BUS. INSIDER (June 1, 2019, 8:02 AM), https://www.businessinsider.com /glyphosate-cancer-dangers-roundup-epa-2019-5 [https://perma.cc/JNV4-PKHV].

238 EPA GLYPHOSATE ISSUE PAPER, *supra* note 120, at 68.

239 Mikael Eriksson et al., *Pesticide Exposure as Risk Factor for Non-Hodgkin Lymphoma Including Histopathological Subgroup Analysis*, 123 INT'L J. CANCER 1657, 1662 (2008).

240 A.J. De Roos et al., *Integrative Assessment of Multiple Pesticides as Risk Factors for Non-Hodgkin's Lymphoma Among Men*, 60 OCCUPATIONAL ENV'T. MED. E1, E7 (2003).

241 *See id.*; Eriksson et al., *supra* note 239, at 1662; Myers et al., *supra* note 202, at 6; Luoping Zhang et al., *Exposure to Glyphosate-Based Herbicides and Risk for Non-Hodgkin Lymphoma: A Meta-Analysis and Supporting Evidence*, 781 MUTATION RSCH.-REVS. MUTATION RSCH. 186, 203–04 (2019) (observing that the alterations to the gut might promote chronic inflammation and susceptibility to invading pathogens).

relationship.[242] The litigation against Monsanto included testimony by experts that the plaintiffs' non-Hodgkin's lymphoma was caused by their exposure to glyphosate.[243]

A second group of research studies acknowledges that the microbial community in human gastrointestinal tracts may be adversely affected by glyphosate.[244] Glyphosate functions as an antibiotic in the gut and can inhibit beneficial bacteria.[245] Since glyphosate acts as an antibiotic, it may augment the development of resistant bacteria.[246] Glyphosate's detrimental health effect on the microbial community in humans cannot be ruled out.[247] Furthermore, the potential health effect of glyphosate

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242 *See* Maria 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. EPIDEMIOLOGY 1, 11 (2019) (failing to observe a risk of non-Hodgkin's lymphoma with use of glyphosate). Moreover, research with statistically null associations between glyphosate and non-Hodgkin's lymphoma are probably underreported. *See* Ellen T. Chang & Elizabeth Delzell, *Systematic Review and Meta-Analysis of Glyphosate Exposure and Risk of Lymphohematopoietic Cancers*, 51 J. ENV'T. SCI. & HEALTH 402, 418 (2016) (reporting on research of glyphosate exposure and lymphohematopoietic cancers).

243 *See* Proceedings at 2023, Johnson v. Monsanto, No. CGC-16-550128 (Cal. Super. Ct., S.F. Cnty. July 13, 2018), https://www.baumhedlundlaw.com/pdf/monsanto-documents/johnson-trial/Johnson-Day-Four-A-7-13-18.pdf [https://perma.cc/382C-CEL8] (maintaining that it was "highly probable that glyphosate causes cancer in humans"); Transcript at 1219, Hardeman v. Monsanto, No. 16-cv-00525-VC (N.D. Cal. Mar. 2, 2019) https://usrtk.org/wp-content/uploads/2019/03/Trial-Transcript-for-March-6-2019.pdf [https://perma.cc/9DLE-RXMC] (testimony that Roundup was "the substantial factor in causing Mr. Hardeman's non-Hodgkin's lymphoma"); Reporter's Transcript of Proceedings at 2179, Pilliod v. Monsanto, No. RG17862702 (Cal. Super. Ct. Apr. 4, 2019) https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/04/Pilliod-Trial-Transcript-April-4-2019.pdf [https://perma.cc/Q3TW-J2U9] (claiming "the data is very strong that glyphosate causes non-Hodgkin's lymphoma in exposed workers").

244 *See* Anthony Samsel & Stephanie Seneff, *Glyphosate's Suppression of Cytochrome P450 Enzymes and Amino Acid Biosynthesis by the Gut Microbiome: Pathways to Modern Diseases*, 15 ENTROPY 1416, 1417–18 (2013) (finding clear evidence that glyphosate disrupts gut bacteria); Gesine Schütte et al., *Herbicide Resistance and Biodiversity: Agronomic and Environmental Aspects of Genetically Modified Herbicide-Resistant Plants*, 29 ENV'T. SCI. EUR. 1, 4 (2017) (reporting the suppression of microorganisms in the human gastrointestinal tract).

245 *See* Michael J. Davoren & Robert H. Schiestl, *Glyphosate-Based Herbicides and Cancer Risk: A Post-IARC Decision Review of Potential Mechanisms, Policy and Avenues of Research*, 39 CARCINOGENESIS 1207, 1210 (2018) (raising this concern).

246 *See* A.H.C. Van Bruggen et al., *Environmental and Health Effects of the Herbicide Glyphosate*, 616–17 SCI. TOTAL ENV'T 255, 264 (2018) (raising the question of whether glyphosate usage might confer resistance to other herbicides).

247 *See* Lene Nørby Nielsen et al., *Glyphosate Has Limited Short-Term Effects on Commensal Bacterial Community Composition in the Gut Environment Due to Sufficient Aromatic Amino Acid Levels*, 233 ENV'T. POLLUTION 364, 375 (2018) (observing no

on young children is not known, although a rodent model suggests it might modify gut microbiota.[248]

A third area of concern consists of research studies suggesting that GBHs affect animal reproduction. For males, a human study found that glyphosate exerted negative effects on sperm motility.[249] Studies analyzing glyphosate and GBH exposure of male rats disclosed DNA damage,[250] molecular changes in the reproductive function,[251] decreased testosterone levels,[252] a delay in the beginning of puberty,[253] and a disruption in the normal testicular cellular architecture.[254] An experiment involving the administration of water containing GBH to mice showed an increase in the sperm deformity rate and morphological changes to the testis.[255] For females, a human study sampling drinking water sources of pregnant women found exposure levels of glyphosate "correlated significantly with shortened pregnancy

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adverse effects but expressing concern for persons on low protein diets that lack sufficient amino acids).

248 *See* Qixing Mao et al., *The Ramazzini Institute 13-Week Pilot Study on Glyphosate and Roundup Administered at Human-Equivalent Dose to Sprague Dawley Rats: Effects on the Microbiome*, 17 ENV'T. HEALTH 1, 9 (2019) (reporting an experiment on rat pups that raises concerns about gut bacteria influencing the brain and behavior).

249 George Anifandis et al., *The Effect of Glyphosate on Human Sperm Motility and Sperm DNA Fragmentation*, 15 INT'L J. ENV'T. RES. & PUB. HEALTH 1, 6 (2018) (finding that glyphosate exerted negative effects on human sperm motility).

250 F. Avdatek et al., *Ameliorative Effect of Resveratrol on Testicular Oxidative Stress, Spermatological Parameters and DNA Damage in Glyphosate-Based Herbicide-Exposed Rats*, 50 ANDROLOGIA e13036, e13037 (2018); María-Aránzazu Martínez et al., *Neurotransmitter Changes in Rat Brain Regions Following Glyphosate Exposure*, 161 ENV'T. RES. 212, 218 (2018).

251 Estelle Cassault-Meyer et al., *An Acute Exposure to Glyphosate-Based Herbicide Alters Aromatase Levels in Testis and Sperm Nuclear Quality*, 38 ENV'T. TOXICOLOGY & PHARMACOLOGY 131, 138 (2014); Fabiana Manservisi 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*, 18 ENV'T. HEALTH 1, 9 (2019).

252 Davoren & Schiestl, *supra* note 245, at 1210; Jessica Nardi et al., *Prepubertal Subchronic Exposure to Soy Milk and Glyphosate Leads to Endocrine Disruption*, 100 FOOD & CHEM. TOXICOLOGY 247, 250 (2017).

253 Davoren & Schiestl, *supra* note 245, at 1210; Nardi et al., *supra* note 252, at 250.

254 Anifandis et al., *supra* note 249, at 5; Folarin O. Owagboriaye et al., *Reproductive Toxicity of Roundup Herbicide Exposure in Male Albino Rat*, 69 EXPERIMENTAL & TOXICOLOGIC PATHOLOGY 461, 467 (2017).

255 Xiao Jiang et al., *A Commercial Roundup® Formulation Induced Male Germ Cell Apoptosis by Promoting the Expression of XAF1 in Adult Mice*, 296 TOXICOLOGY LETTERS 163, 170 (2018) (concluding that GBH exposure to mice signals potential male reproductive toxicity).

lengths."[256] In a study on female rats, exposure to low levels of GBH led researchers to conclude that the pesticide might be associated with pregnancy loss in humans and animals.[257] Three studies on fish showed glyphosate exposure induced behavioral and morphological changes, reduced fertility rates hindering reproductive success, and may result in changes in the expression of reproductive genes.[258]

Various research studies on GBHs raises other concerns,[259] including a number of studies showing that GBH is related to DNA damage.[260] At least three studies have identified potential damage

256 S. Parvez et al., *Glyphosate Exposure in Pregnancy and Shortened Gestational Length: A Prospective Indiana Birth Cohort Study*, 17 ENV'T. HEALTH 1, 1 (2018).

257 Paola I. Ingaramo et al., *Effects of Neonatal Exposure to a Glyphosate-Based Herbicide on Female Rat Reproduction*, 152 REPRODUCTION 403, 413 (2016).

258 Daiane Bridi et al., *Glyphosate and Roundup® Alter Morphology and Behavior in Zebrafish*, 392 TOXICOLOGY 32, 37 (2017); Fernanda Moreira Lopes et al., *Effect of Glyphosate on the Sperm Quality of Zebrafish Danio rerio*, 155 AQUATIC TOXICOLOGY 322, 326 (2014); Chelsea M. Smith, Madeline K.M. Vera & Ramji K. Bhandarit, *Developmental and Epigenetic Effects of Roundup and Glyphosate Exposure on Japanese Medaka* (*Oryzias latipes*), 210 AQUATIC TOXICOLOGY 215, 224 (2019).

259 *See* Samsel & Seneff, *supra* note 244, at 1445 (surmising that glyphosate may contribute to health issues related to "obesity, depression, ADHD, autism, Alzheimer's disease, Parkinson's disease, ALS, multiple sclerosis, cancer, cachexia, infertility, and developmental malformations.").

260 *See, e.g.*, Marta Kwiatkowska et al., *DNA Damage and Methylation Induced by Glyphosate in Human Peripheral Blood Mononuclear Cells (in Vitro Study)*, 105 FOOD & CHEM. TOXICOLOGY 93, 97 (2017) (observing that glyphosate may induce DNA damage in human leucocytes); F. Mañas et al., *Genotoxicity of AMPA, the Environmental Metabolite of Glyphosate, Assessed by the Comet Assay and Cytogenetic Tests*, 72 ECOTOXICOLOGY & ENV'T. SAFETY 834, 836 (2009) (interpreting assay data to show DNA damage); César Paz-y-Miño et al., *Evaluation of DNA Damage in an Ecuadorian Population Exposed to Glyphosate*, 30 GENETICS & MOLECULAR BIOLOGY 456, 560 (2007) (finding greater DNA damage in persons exposed to GBH aerial spraying); Ewelina Woźniak 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 & CHEM. TOXICOLOGY 510, 521 (2018) (concluding that a GBH caused DNA damage indirectly through reactive oxygen species-mediated effects).

to the liver.[261] Several researchers concluded that GBH exposure exacerbates the risk of Parkinson's disease.[262]

IV
CHALLENGING REGISTRATIONS AND USES

Although FIFRA does not allow for private rights of action, known as citizen suits, as provided in several environmental statutes,[263] its provisions allow environmental groups and competitors to challenge GBH registrations.[264] Opponents of pesticides for which new information and scientific studies disclose additional risks of harm to humans have traditionally focused on registrations. The most common challenge is a request for the cancellation of a registration,[265] and the second is an emergency suspension of a registration due to an imminent

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261 *See, e.g.*, Nathalle 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*, PLOS ONE, June 20, 2018, at 14–15 (observing that glyphosate increased fat and cholesteryl ester levels in the liver of mice); Mesnage, *Multiomics*, *supra* note 236, at 2 (finding consumption of GBHs are associated with liver functional dysfunction); Paul J. Mills, Cyrille Caussy & Rohit Loomba, *Glyphosate Excretion Is Associated with Steatohepatitis and Advanced Liver Fibrosis in Patients with Fatty Liver Disease*, 18 CLINICAL GASTROENTEROLOGY & HEPATOLOGY 741, 742 (2019) (finding glyphosate excretion to be higher in patients with a severe form of nonalcoholic fatty liver disease than others).

262 *See, e.g.*, Carlos Javier Baier et al., *Behavioral Impairments Following Repeated Intranasal Glyphosate-Based Herbicide Administration in Mice*, 64 NEUROTOXICOLOGY & TERATOLOGY 63, 69 (2017) (arguing that their data showing impairments related to Parkinson's disease corresponded with glyphosate exposure); Mariah Caballero et al., *Estimated Residential Exposure to Agricultural Chemicals and Premature Mortality by Parkinson's Disease in Washington State*, 15 INT'L J. ENV'T. RES. PUB. HEALTH 1, 9 (2018) (concluding that glyphosate exposure is associated with the odds of premature mortality from Parkinson's disease); Gang Wang et al., *Parkinsonism After Chronic Occupational Exposure to Glyphosate*, 17 PARKINSONISM & RELATED DISORDERS 486, 486 (2011) (reporting chronic occupational exposure to glyphosate was connected with Parkinson's disease).

263 To help effectuate cancellation efforts, in 1972 a citizen suit provision similar to that included in the Clean Air Act amendments was proposed. S. REP. NO. 92-970, at 4106 (1972). This proposal was not adopted, and FIFRA does not contain a private right of action. *See* No Spray Coal. v. City of New York, 351 F.3d 602, 603 (2d Cir. 2003). However, violations of the Clean Water Act involving pesticides may be challenged by citizen groups. *Id.* Furthermore, states can adopt laws regarding pesticides that provide citizens the ability to file actions for violations of state law. *See* Lowe v. Sporicidin Int'l, 47 F.3d 124, 128 (4th Cir. 1995) (interpreting FIFRA as not preempting a state's authority to enact state remedies).

264 *See* Syngenta Crop Prot., Inc. v. EPA, No. 1:02CV00334 (M.D.N.C. Aug. 9, 2011) (examining petitions to deny the me-too registrations to competing firms).

265 7 U.S.C. § 136d(b) (2018). *See, e.g.*, Defs. Wildlife v. EPA, 882 F.2d 1294 (8th Cir. 1989).

hazard.[266] These mechanisms are provided by FIFRA. A third challenge involves the revocation of a tolerance for a pesticide residue in or on food products that is accompanied by a need to alter or cancel an existing registration.[267]

Alternatively, persons wanting to decrease pesticide usage may recommend mitigation measures.[268] These measures might be incorporated into a product's registration or might be suggestions available for pesticide applicators.[269] A fifth category of challenges is litigation for health damages from pesticide use that imposes liability on sellers and manufacturers.[270] If sellers or manufacturers are held liable for health damages, they may take actions to curtail uses, thereby reducing pesticide usage.

After a registrant submits documentation for registration, it becomes public information. The EPA's proceedings can be reviewed to discern whether registration requirements were met, including the requirement that the product cannot cause an unreasonable adverse effect on the environment.[271] The EPA proceeds to make a determination whether the pesticide qualifies for unconditional or conditional registration. A registration decision can be contested by a registrant or by others,[272] and registrants and environmental groups have challenged registration decisions with varying results.[273]

Once pesticides are registered, challenging registrations and uses becomes more difficult. Because agency actions are presumed to be

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266 7. U.S.C. § 136d(c). *See, e.g.*, Ellis v. Housenger, 252 F. Supp. 3d, 800 (N.D. Cal. 2017).

267 21 U.S.C. § 346a(b) (2018).

268 *See* 40 C.F.R. §§ 155.56, 155.58 (2019) (allowing the EPA to identify and require risk mitigation measures).

269 *See, e.g.*, Pollinator Stewardship Council v. EPA, 806 F.3d 520, 522 (9th Cir. 2015).

270 *See* BAYER, *supra* note 1 (reporting payment of more than $10 billion).

271 40 C.F.R. § 155.53(c) (2019) (allowing public participation).

272 *See* 5 U.S.C. § 706(2)(a) (2018) (providing that courts shall set aside agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.").

273 *See, e.g.*, Nat'l Fam. Farm Coal. v. EPA, 747 F. App'x 646 (9th Cir. 2019) (unsuccessful challenge); Ctr. for Biological Diversity v. EPA, 861 F.3d 174 (D.C. Cir. 2017) (remanded action); NRDC v. EPA, 857 F.3d 1030 (9th Cir. 2017) (successful challenge); NRDC v. EPA, 735 F.3d 873 (9th Cir. 2013) (successful challenge); *Pollinator Stewardship Council*, 806 F.3d 520 (successful challenge); Wash. Toxics Coal. v. EPA, 413 F.3d 1024 (9th Cir. 2005) (successful challenge).

correct, any person who objects to a decision will need to show error.[274] The scope of a reviewing court is narrow: it cannot "substitute its judgment for that of the agency."[275] If there is evidence supporting the registration decision, even if it is weak, the appellate tribunal will give deference to the agency and uphold the decision.[276] In cases requiring a high level of technical expertise, a high degree of deference is accorded to the agency's analysis.[277]

A. Cancellation and Suspension

The EPA should cancel a pesticide's registration whenever the pesticide no longer meets its qualifications.[278] Cancellation, the first mechanism for reducing pesticide usage, is often based on new information of additional health and environmental risks becoming available after the pesticide's initial registration.[279] For situations in which an imminent hazard exists, the agency may employ a second mechanism, a suspension proceeding, to immediately terminate pesticide use.[280] The EPA can commence a cancellation or suspension proceeding by issuing a notice of intent to cancel the registration or by holding a hearing to determine whether the registration should be canceled.[281] Cancellation or suspension proceedings may be initiated at any time.[282]

In addition, any person who feels a pesticide registration no longer meets the requirements of federal law may bring an action for

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274 *See, e.g.*, Env't. Def. Fund, Inc. v. Costle, 657 F.2d 275, 283 (D.D.C 1981) (observing that an agency action is presumed to be valid and the arbitrary and capricious standard of review is highly differential).

275 Citizens of Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971).

276 Ctr. for Biological Diversity v. U.S. Fish & Wildlife Serv., 807 F.3d 1031, 1048 (9th Cir. 2015) (noting that as long as the agency does not ignore available studies and complies with the best available science, a reviewing court should defer to its decision).

277 Marsh v. Or. Nat. Res. Council, 490 U.S. 360, 372 (1989) (deferring to the informed discretion of the agency).

278 7 U.S.C. § 136d(b) (2018) (requiring cancellation or a change in registration if the pesticide, labeling, or materials do not comply with the requirements of FIFRA).

279 *See* Angelo, *The Killing Fields*, *supra* note 122, at 109 (observing cancellation is warranted if new information demonstrates risks outweigh benefits).

280 7 U.S.C. § 136d(c)(1) (2018). *See* Nat'l Coal. Against the Misuse of Pesticides v. EPA, 867 F.2d 636, 638 (D.C. Cir. 1989) (observing that an emergency may support immediate cancellation after a hearing or even without a hearing).

281 7 U.S.C. § 136d (2018); 40 C.F.R. § 164.20 (2019). *See* Woodstream Corp. v. Jackson, 845 F. Supp. 2d 174, 177 (D.D.C. 2012) (highlighting the EPA's options concerning cancellation of a pesticide registration).

282 *See Nat'l Coal. Against the Misuse of Pesticides*, 867 F.2d at 638.

cancellation or suspension of the registration.[283] Once evidence has been presented that supports cancellation, the burden shifts to the registrant to produce additional evidence in defense of registration.[284] After a pesticide's registration is canceled, registrants can no longer sell the product and producers have to find an alternative pest control.[285] Because registrants and users have financial interests linked to pesticide use, they often oppose cancellations.[286]

Registrants receiving a notice of intent from the EPA to cancel a registration are able to demand a hearing.[287] Cancellation under this mechanism must consider impacts "on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy."[288] This provision was intended to protect the economic interests of farmers and consumers.[289] The EPA also considers mandatory restrictions on usage and the availability of an alternative pesticide.[290] To assist producers facing hardship, federal regulations allow a canceled or an unregistered pesticide to be

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283 7 U.S.C. § 136n (2018). *See, e.g.*, Reckitt Benckiser Inc. v. EPA, 613 F.3d 1131, 1134 (D.C. Cir. 2010) (opining that parties secure district court review of the EPA's refusal to cancel a registration).

284 Defs. Wildlife v. Jackson, 791 F. Supp. 2d 96, 101 (D.D.C. 2011). The "'proponent of cancellation or change in classification' must present an 'affirmative case for the cancellation or change in the classification of the registration.'" *Id.* (citing 40 C.F.R. § 164.80(a)). "[T]he ultimate burden of persuasion shall rest with the proponent of the registration." 40 C.F.R. § 164.80(b) (2019). Courts have noted a strong presumption in favor of judicial review of administrative actions regarding registrations of pesticides. *See* New York v. EPA, 350 F. Supp. 2d 429, 434 (S.D.N.Y. 2004) (citing the Administrative Procedure Act's presumption favoring judicial review); *Woodstream Corp.*, 845 F. Supp. 2d at 177 (observing that a court does not substitute its construction of a statutory provision for an interpretation made by the agency).

285 *See* EPA AZINPHOS-METHYL INTERIM DECISION, *supra* note 47, at vii (noting that the termination of azinphos-methyl uses would lead producers to use alternative products in some cases).

286 *See* Pollinator Stewardship Council v. EPA, 806 F.3d 520, 531 (9th Cir. 2015) (showing the manufacturer arguing to continue with its registration); Nat'l Corn Growers Ass'n v. EPA, 613 F.3d 266, 269 (D.C. Cir. 2010) (concerning producer groups opposing the revocation of tolerances); Ellis v. Housenger, 252 F. Supp. 3d, 800, 805 (showing four intervenors opposing suspension of registrations).

287 7 U.S.C. § 136d(b)–(d) (2018); 40 C.F.R. § 164.20 (2019).

288 7 U.S.C. § 136d(b) (2018).

289 *See* McGill v. EPA, 593 F.2d 631, 635 (5th Cir. 1979).

290 *See* Timothy F. Malloy, *Principled Prevention*, 46 ARIZ. STATE L.J. 105, 115–16 (2008) (observing that the existence of a significantly safer alternative pesticide may mean a pesticide no longer qualifies for registration).

distributed or sold under an emergency exemption.[291] Emergency exemptions are rather common.[292]

For the initial registration of glyphosate in 1974, Monsanto submitted four studies conducted by the Industrial Bio-Test Laboratory to justify qualification.[293] Subsequently, it was discovered that the lab had misrepresented data to support the use of hundreds of pesticides it had tested,[294] and the lab was convicted of falsifying product-safety tests.[295] Monsanto's Roundup was one of the products registered based on the laboratory's invalid tests.[296] Despite learning that the lab's studies were fraudulent, Monsanto's glyphosate products remained on the market,[297] although subsequent tests were conducted.[298] Cancellation under federal law required proof that the risks were greater than the benefits, which was not available.[299]

Petitioners applying for cancellation of a pesticide's registration often argue its use is causing "unreasonable adverse effects on the environment" in violation of federal law.[300] Unreasonable adverse effects on the environment involve an unreasonable risk to humans accounting for "economic, social, and environmental costs and benefits."[301] The EPA conducts a detailed cost-benefit analysis that takes into account the costs related to anticipated harm compared to the

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291 40 C.F.R. § 152.30 (2019).

292 *See, e.g.*, *Pesticide Registration: Emergency Exemption Database: Section 18 Database: Apple*, EPA, https://iaspub.epa.gov/apex/pesticides/f?p=SECTION18:3:::NO::: (last visited Nov. 3, 2020) (listing 49 emergency exemptions requested since 2010 for apples, with most exemptions allowing applications of a pesticide for a few months).

293 Testimony of Charles Benbrook, Day 11 at 3523–27, Pilliod v. Monsanto, No. RG17862702 (Cal. Super. Ct. Apr. 4, 2019) [hereinafter *Pilliod* Benbrook Testimony] (testifying that the laboratory submitted four studies used to justify glyphosate's registration and they were all subsequently found to be invalid because they were not supported by the raw data).

294 Nathaniel Sheppard Jr., *Fraud in Toxicology Studies Charged to Big Laboratory*, N.Y. TIMES, Apr. 13, 1983, at A18 (reporting of jury selection for a trial involving the misrepresentation of data that was used to justify health safety studies).

295 *See* Dow Jones & Co., *Three Convicted of Falsifying Data at Nalco's IBT Unit*, WALL ST. J., Oct. 24, 1983 (noting that the EPA declared the laboratory had conducted invalid tests on over 200 pesticides); *see also Pilliod* Benbrook Testimony, *supra* note 293, at 3529 (testifying that the laboratory studies used to justify registration were by a laboratory engaged in fraud).

296 *See* Mary Thornton, *EPA Review Finds Flawed Tests Made by Research Firm*, WASH. POST, May 13, 1983, at. A3.

297 *Pilliod* Benbrook Testimony, *supra* note 293, at 3529.

298 *See* Thornton, *supra* note 296.

299 7 U.S.C. § 136d(b) (2018). *See Pilliod* Benbrook Testimony, *supra* note 293, at 3533.

300 7 U.S.C. § 136d. *See* Defs. Wildlife v. Jackson, 791 F. Supp. 2d 96 (D.D.C. 2011).

301 7 U.S.C. § 136(bb)(1).

benefits of allowing a pesticide product to be used.[302] Costs include both direct and indirect costs as well as explicit and implicit costs.[303] A registration may be canceled when credible evidence shows there is an unreasonable adverse effect on the environment[304] and the pesticide's costs outweigh its benefits.[305] The EPA may require several years to complete its analysis of whether a registration needs to be canceled.[306]

For glyphosate, considerable data and analyses show that the costs and benefits employed for registrations have changed.[307] Yields and prices are different, so they need to be reconsidered.[308] The evolution of glyphosate-resistant weeds probably means that benefits calculated at registration involving higher yields were overestimated.[309] Simultaneously, GBH use has lowered the prices of food products[310] and contributes to food security for many persons who lack sufficient

302 EPA GUIDELINES, *supra* note 94, at pt. 7.4. *See* Li, *supra* note 122, at 1424 (noting the balancing of potential risks and benefits).

303 EPA GUIDELINES, *supra* note 94, at pts. 5.12, 7.3, 8.7.

304 7 U.S.C. § 136d(b). *See* Ciby-Geigy Corp. v. EPA, 874 F.2d 277, 279 (5th Cir. 1989) (noting that only a significant probability of adverse effects is needed to justify cancellation); Nat'l Coal. Against the Misuse of Pesticides v. EPA, 867 F.2d 636, 643 (D.C. Cir. 1989) (noting that a notice to cancel may be issued if it appears that a pesticide "generally causes unreasonable adverse effects on the environment").

305 *See Nat'l Coal. Against the Misuse of Pesticides*, 867 F.2d at 639 (observing that the EPA intended to cancel a pesticide registration as the risks outweighed the benefits); Ctr. for Biological Diversity v. EPA, 847 F.3d 1075, 1085 n.9 (9th Cir. 2017) (noting the possibility of not reregistering a pesticide if the costs outweigh the benefits).

306 *See* EPA AZINPHOS-METHYL FINAL DECISIONS, *supra* note 47, at 1. The cancellation proceeding for azinphos-methyl shows time is needed. Because the pesticide was providing significant economic benefits for a small group of uses, the agency granted producers more time to adopt alternative pest control measures. Some pesticide stocks were used more than a decade after the findings that azinphos-methyl failed to meet registration requirements. *Azinphos-Methyl Phase-Out*, *supra* note 126.

307 *See* Centner, Russell & Mays, *supra* note 31, at 614–15 (identifying preferred strategies for allowing uses of glyphosate dependent upon the magnitude of adverse effects on human health and food insecurity).

308 *See* MICHAEL LIVINGSTON ET AL., THE ECONOMICS OF GLYPHOSATE RESISTANCE MANAGEMENT IN CORN AND SOYBEAN PRODUCTION 24 (USDA 2015) (surmising benefits from using a GBH in conjunction with another herbicide); C.L. Keene & W.S. Curran, *Optimizing High-Residue Cultivation Timing and Frequency in Reduced-Tillage Soybean and Corn*, 108 AGRONOMY J. 1897, 1897 (2016) (advocating "new integrated weed management approaches" given weed resistance that developed since registration of GBHs).

309 *See* Heap & Duke, *supra* note 191, at 1042 (noting that resistant weeds can devastate corn and soybean yields).

310 *See* Brookes, Taheripour & Tyner, *supra* note 31, at 224 (projecting a 5.4% increase in soybean prices if glyphosate use was discontinued).

financial resources to buy food.[311] These benefits may not have been included in a registrant's registration materials. For many registrations, insufficient numbers of studies on potential health costs were conducted, and only later were health issues identified.[312] If subsequent significant health costs related to exposure to glyphosate are known, a new cost-benefit analysis is needed.[313]

Numerous new risks have been identified concerning adverse health effects from uses of GBHs.[314] Yet, a majority of the results of reported studies acknowledge that the risks do not definitively show adverse effects to human health.[315] Rather, many of the studies analyzed nonhuman animals to show changes without defining their expected toxicity or the degree of risk for human health.[316] Others involved case studies with results that were not statistically significant.[317] Until more definitive data exist, it is unclear that health costs justify canceling GBH registrations. However, the expenses and damage awards from litigation against manufacturers such as Monsanto might alter a registration's cost-benefit analysis to support its cancellation.[318]

B. Revocation of Tolerances

Exceeding tolerances established for pesticide residues on or in food products provides a justification for ending a pesticide registration, and

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311 *See* Christian A. Gregory & Alisha Coleman-Jensen, *Do High Food Prices Increase Food Insecurity in the United States?* 35 APPLIED ECON. PERSPS. & POL'Y 679, 679 (2013) (observing that food prices affect food security).

312 *See, e.g.*, Notice of Receipt of Requests to Voluntarily Cancel Certain Pesticide Registrations, 68 Fed. Reg. 36,786 (June 19, 2003) (delineating 45 cancellations of pesticides); EPA Chlorpyrifos Human Health, *supra* note 119 (reporting new epidemiological studies providing evidence that uses of chlorpyrifos were associated with neurodevelopmental effects).

313 *See* EPA DECISION 0178, *supra* note 56, at 10 (acknowledging new studies on non-Hodgkin's lymphoma but concluding they did not affect the agency's assessment).

314 *See supra* notes 237–62 and accompanying text.

315 *E.g.*, Anneclaire J. De Roos et al., *Cancer Incidence Among Glyphosate-Exposed Pesticide Applicators in the Agricultural Health Study*, 113 ENV'T. HEALTH PERSP. 49, 52 (2005) (finding no association between glyphosate exposure and non-Hodgkin's lymphoma); Leon et al., *supra* note 242, at 1533 (failing to observe a risk); Davoren & Schiestl, *supra* note 245, at 1210 (raising a concern); Nielsen et al., *supra* note 247, at 375 (observing no adverse effects but expressing a concern).

316 *See supra* notes 250–58 and accompanying text (discussing studies involving animal reproduction).

317 *See* De Roos et al., *supra* note 240, at E7 (reporting a Swedish study finding an association involved a small case-control study); Chang & Delzell, *supra* note 242 (summarizing studies looking at the relationship of glyphosate and non-Hodgkin's lymphoma and noting limitations of the researchers' findings).

318 *See infra* notes 345–81 and accompanying text.

revocation of tolerances is a third mechanism for reducing pesticide usage.[319] FIFRA incorporates the FFDCA's provisions on food safety to make it illegal to sell food products with unsafe pesticide residues.[320] For residues that are safe, tolerances delineate the maximum amount of the residue permitted.[321] A residue in or on a food product "shall be deemed unsafe" unless a tolerance has been approved.[322] If new information shows harm will result from residues on a product with a tolerance, the tolerance should be revoked.[323] For situations where pesticide use results in unsafe residues in or on food products, the revocation of a tolerance would require the cancellation of a registration.[324] The EPA or others may initiate a revocation proceeding.[325]

Numerous tolerances have been established for residues of glyphosate and its metabolite, aminomethylphosphonic acid, in or on a wide variety of crops and processed foods.[326] The tolerances were calculated by determining that the combined exposure from drinking water and residential exposure was below a safe level so that people could be exposed to low amounts of residues in or on food products and continue to be safe.[327] If evidence shows the possibility of harm from residues in or on a food product, the tolerance needs to be lowered or revoked.[328]

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319 *See* League of United Latin Am. Citizens v. Wheeler, 899 F.3d 814, 829 (9th Cir. 2018), *rev'd en banc* 922 F.3d 443 (9th Cir. 2019) (noting that failing to meet tolerances mandated by the FFDCA can lead to the cancellation of registrations).

320 *Id.*; 21 U.S.C. § 346a(b) (2019).

321 21 U.S.C. § 346a(b)(2)(A)(ii) (2019); *see* 40 C.F.R. pt. 180.1 (2016) for specific tolerances.

322 21 U.S.C. § 346a(a)(1) (2019).

323 *Id.* § 346a(b)(2)(A)(i). "The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id. See* NRDC v. Johnson, 461 F.3d 164, 167–68 (2d Cir. 2006) (noting that an unsafe tolerance must be modified or revoked).

324 *See Johnson*, 461 F.3d at 171 (challenging registrations due to changes in allowable tolerances).

325 21 U.S.C. § 346a(d)(1) (2019). Often, it is other parties. *See* Petition To Modify the Tolerance and Product Labels for Glyphosate With Regard to Oats; Notice of Filing, 84 Fed. Reg. 19,783, 19,784 (May 6, 2019) (lowering tolerances and preventing preharvest use of glyphosate on oats at the request of private vendors) [hereinafter EPA Oats Tolerance Petition]; *see also* NRDC v. EPA, 658 F.3d 200, 204 (2d Cir. 2011) (challenging tolerances established for numerous dichlorvos products).

326 40 C.F.R. § 180.364 (2013).

327 Office of Pesticide Programs, *General Principles for Performing Aggregate Exposure and Risk Assessments* 12–22, EPA (Nov. 28, 2001), https://www.epa.gov/sites/production/files/2015-07/documents/aggregate.pdf [https://perma.cc/4TPH-K8VB].

328 *Id.*

When existing tolerances were established, fewer quantities of GBHs were being used for agricultural production.[329] With increased usage of GBHs, dietary exposure has increased.[330] Research has shown that there are glyphosate residues in ground water, human and animal urine, and farmed-animal meat products.[331] Glyphosate tolerances may need to be reevaluated to determine whether total exposure meets the safety requirements prescribed by FIFRA. Given glyphosate's ubiquitous presence, the combined exposure from residential and drinking water sources may be so great that no residues should be allowed in or on food products.[332]

C. Mitigation Measures

During interactions with registrants and others, while considering a registration application, the EPA has opportunities for incorporating mitigation measures into registrations to reduce risks and safeguard public welfare.[333] Mitigation measures are a fourth mechanism for lowering amounts of exposure that contribute to health costs and

329 *See* U.S. Department of the Interior, *Estimated Annual Agricultural Pesticide Use*, U.S. GEOLOGICAL SURVEY (June 18, 2020), https://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2016&map=GLYPHOSATE&hilo=L (showing increased amounts being used over the past 24 years).

330 Marek Cuhra, Thomas Bøhn & Petr Cuhra, *Glyphosate: Too Much of a Good Thing?*, 4 FRONTIERS ENV'T. SCI. 1, 1 (2016), https://www.frontiersin.org/articles/10.3389/fenvs.2016.00028/full (noting that consumers are ingesting more glyphosate residues in the foods they eat).

331 *See* Vincenzo Torretta et al., *Critical Review of the Effects of Glyphosate Exposure to the Environment and Humans Through the Food Supply Chain*, 10(4) SUSTAINABILITY 1, 13 (2018), https://www.mdpi.com/2071-1050/10/4/950/htm [https://perma.cc/C2KF-ETQP] (reporting various exposures to humans).

332 A recent petition to reduce glyphosate tolerances in oats due to residues in various granola, breakfast cereal, snack commodities, and instant oats shows new residues in food and expresses concern that children need more protection from residue exposure. EPA Oats Tolerance Petition, *supra* note 325, at 19,784. In 2018, the European Food Safety Authority lowered tolerances on many food products. European Food Safety Auth., *Review of the Existing Maximum Residue Levels for Glyphosate According to Article 12 of Regulation (EC) No 396/2005*, 16 EFSA J. 1,1 (2018).

333 40 C.F.R. §§ 155.53(c), 155.56, 155.58(B)(2) (2019). This may occur in an interim registration review or the registration review.

environmental damages.[334] Mitigation measures that reduce health costs may enable a pesticide to qualify for registration.[335]

Several voluntary or regulatory mitigation measures may be identified to reduce some of the adverse effects of GBH usage. Requiring a pesticide protection plan is a logical starting point.[336] By preparing a protection plan, producers can learn how to reduce the impacts of pesticide use on human health and the environment, avoid inappropriate uses of pesticides, and improve spray delivery.[337] For especially problematic pesticides, governments can provide training to applicators to prevent situations where improper use may lead to problems.[338] Governments may also adopt policies that offer producers greater encouragement in adopting integrated pest management practices and crop rotations to address problems of counterproductive

334 *See, e.g.*, EPA, OFF. OF PESTICIDE PROGRAMS, NOTICE OF PESTICIDE REGISTRATION, EPA REG. NO. 62719-623, at 9 (2016) (considering the registration of Dow's Closer SC containing sulfoxaflor with precautions including an integrated pest management program and insecticide resistance management); EPA, OFF. OF PESTICIDE PROGRAMS, NOTICE OF PESTICIDE REGISTRATION, EPA REG. NO. 62719-625, at 10 (2016) (considering the registration of Dow's Transform WG containing sulfoxaflor with precautions including an integrated pest management program and insecticide resistance management).

335 *See* Memorandum from Debra Edwards, Special Rev. & Registration Div., Off. of Pesticide Programs, Dir., to Jim Jones, EPA Off. of Pesticide Programs, Dir. Finalization of Interim Reregistration Eligibility Decisions (IREDs) and Interim Tolerance Reassessment and Risk Management Decisions (TREDs) for the Organophosphate Pesticides, and Completion of the Tolerance Reassessment and Reregistration Eligibility Process for the Organophosphate Pesticides (July 31, 2006) (reporting that with mitigation measures, worker risks from chlorpyrifos exposure will be below levels of concern facilitating registration).

336 *See* WHITE HOUSE POLLINATOR HEALTH TASK FORCE, NATIONAL STRATEGY TO PROMOTE THE HEALTH OF HONEY BEES AND OTHER POLLINATORS (2015) (developing a strategy to protect pollinators).

337 Juan J. Villaverde et al., *Biopesticides in the Framework of the European Pesticide Regulation (EC) No. 1107/2009*, 70 PEST MGMT. SCI. 2, 5 (2013) (commenting on how to reduce pesticide damages for European producers).

338 *See* EPA, REGISTRATION DECISION FOR THE CONTINUATION OF USES OF DICAMBA ON DICAMBA TOLERANT COTTON AND SOYBEAN 20 (2018) (limiting application to certified applicators); *Using Pesticides Wisely: Required Training to Use Auxin Pesticides, GA. DEP'T AGRIC.*, http://agr.georgia.gov/24c.aspx (last visited Nov. 3, 2020) [https://perma.cc/9X5C-PJ44]; *Pesticide Control: Dicamba Facts*, MO. DEP'T AGRIC., http://agriculture.mo.gov/plants/pesticides/dicamba-facts.php (last visited Nov. 3, 2020) [https://perma.cc/L7WU-K9P6].

pesticide applications.[339] Another measure might prohibit tank mixing with other products to reduce risks of harmful mixtures.[340]

For spray drift that damages neighboring properties, the requirement of a buffer area may be inserted into a registration.[341] The buffer area would reduce the likelihood of drift onto others' properties to reduce the risks of damages.[342] The adoption of drift reduction technology might lower the number of spray applications required to achieve pest control or might keep more spray on target.[343] This could reduce overall usage to lower concentrations in the environment. Drift problems can also be reduced by delineating limitations on nozzle size and sprayer heights in a registration.[344] The limitations established by one or more of these mitigation measures could reduce risks that spray drift will be transported to other properties and cause damages.

D. Litigation for Health Damages

A fifth mechanism that might lead to reductions in GBH use is litigation. Approximately 125,000 plaintiffs have filed lawsuits against Monsanto Company and/or its parent company Bayer AG.[345] Most of these lawsuits were filed by persons who applied Monsanto's Roundup

339 Craig D. Osteen & Jorge Fernandez-Cornejo, *Economic and Policy Issues of U.S. Agricultural Pesticide Use Trends*, 69 PEST MGMT. SCI. 1001, 1018 (2013) (urging management policies to avoid pesticide applications that destroy beneficial organisms and pests' natural enemies).

340 *See, e.g.*, EPA, REGISTRATION OF SULFOXAFLOR FOR USE ON AGRICULTURAL CROPS, ORNAMENTALS AND TURF 10 (2016) (delineating a prohibition of mixing with other products).

341 *See, e.g.*, Letter from Stephanie M. Parent, Ctr. for Biological Diversity, to the Off. of Pesticide Programs, EPA Comments on EPA's Proposed Registration of Sulfoxaflor for Use on Agric. Crops, Ornamentals and Turf (June 17, 2016) (observing the need for buffer areas to minimize damages).

342 *See* F.M. Fishel & J.A. Ferrell, *Managing Pesticide Drift*, UNIV. FLA. IFAS EXTENSION PUBL'N PI232, http://edis.ifas.ufl.edu/pi232 (last visited Nov. 3, 2020) [https://perma.cc/3AZ4-UYXA] (noting that after pesticide applications, volatilization may be a problem).

343 EPA, SUPPORTING STATEMENT FOR AN INFORMATION COLLECTION REQUEST (ICR), EPA ICR NO. 2472.01 (2012) (recommending a program to encourage the use of drift reduction technologies to reduce drift of pesticide spray droplets to nontarget areas).

344 *See* J. Franklin Egan et al., *Herbicide Drift Can Affect Plant and Arthropod Communities*, 85 AGRIC. ECOSYSTEMS & ENV'T 77, 86 (2014) (noting that off-target pesticide "movement can be effectively reduced by using drift-reducing spray nozzles"); Nathan Palardy & Terence J. Centner, *Improvements in Pesticide Drift Reduction Technology (DRT) Call for Improving Liability Provisions to Offer Incentives for Adoption*, 69 LAND USE POL'Y 439, 440 (2017) (discussing spray-drift reduction technologies that consider nozzle size).

345 *See* BAYER, *supra* note 1.

spray to control weeds and developed non-Hodgkin's lymphoma, a type of cancer.[346] The plaintiffs allege that their exposure to Roundup was a substantial cause of their cancer.[347] In addition, the cases include evidence that Monsanto engaged "in conduct with malice, oppression, or fraud committed by one or more officers, directors, or managing agents of Monsanto."[348] This evidence justified punitive damages.[349]

Juries in three lawsuits have awarded damages: *Johnson v. Monsanto Company*,[350] *Hardeman v. Monsanto Company*,[351] and *Pilliod v. Monsanto Company*.[352] These lawsuits may be referred to as the *Monsanto* cases.[353] In *Johnson v. Monsanto Co.*, a school groundskeeper brought a lawsuit with causes of action based on strict liability for a design defect, strict liability for failure to warn, negligence, breach of implied warranties, and punitive damages.[354] After being successful at trial court, the plaintiff accepted a reduction in punitive damages and was awarded $78,506,418.70.[355] This has been appealed.[356]

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

347 *See* Leora Friedman, *Litigating the Alleged Carcinogenicity of Glyphosate in Monsanto's Roundup: The Fairness (and Unfairness) of Deciding Causation Independent of Liability*, GEO. ENV'T. L. REV. ONLINE, Jan. 17, 2019 (summarizing the initial claims for health damages from glyphosate exposure).

348 Transcript of Proceedings at 5748, Pilliod v. Monsanto, No. RG17862702 (Cal. Super. Ct. Alameda Cnty. May 13, 2019) https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/05/Trial-Transcript-Pilliod-Verdict.pdf [https://perma.cc/E9HZ-USN2].

349 *Id.* at 5750–51.

350 *Johnson*, *supra* note 53.

351 *Hardeman*, *supra* note 53.

352 *Pilliod*, *supra* note 53, at 5748, 5750–51; *see also* Jeff Davis, *The Next Asbestos? What Do the Monsanto Trials Mean for the Future of Roundup*, AUSTRALIAN BROAD. CORP. NEWS (May 31, 2019), https://www.abc.net.au/news/2019-06-01/is-roundup-the-next-asbestos/11167866 [https://perma.cc/RRF8-SCPQ].

353 The term "*Monsanto* cases" distinguishes the three cases from other litigation against Monsanto including *In re* Roundup Product Liability Litigation. *See supra* notes 347–53 and accompanying text; *infra* notes 355–64 and accompanying text.

354 Summons and Complaint at 1, Johnson v. Monsanto Co., No. CGC-16-550128 (Cal. Super. Ct., S.F. Cnty. Jan. 28, 2016), https://usrtk.org/wp-content/uploads/2016/09/Dewayne-Johnson-lawsuit.pdf [https://perma.cc/59YX-HXDF].

355 Plaintiff's Notice of Acceptance of Remittitur at 1, Johnson v. Monsanto Co., No. CGC-16-550128 (Cal. Super. Ct., S.F. Cnty. Oct. 26, 2018), https://usrtk.org/wp-content/uploads/2018/12/Johnsons-acceptance-of-reduced-award.pdf [https://perma.cc/X8HE-TZM3].

356 Defendant Monsanto Company's Notice of Appeal at 1, Johnson v. Monsanto Co., No. CGC-16-550128 (Cal. Super. Ct., S.F. Cnty. Nov. 20, 2018).

A second case, *Hardeman v. Monsanto Co.*, was filed in the federal district court in the Northern District of California.[357] This court also has more than thirty filed glyphosate cases against Monsanto, which were consolidated into *In re Roundup Products Liability Litigation*.[358] Mr. Hardeman alleged negligence, defective product design, defective warnings, and breach of implied warranties.[359] The jury returned a verdict for more than $5 million in compensatory damages and $75 million for punitive damages.[360] The punitive damage award was reduced to $20 million.[361] Subsequently, the *Hardeman* court noted it was the design defect that supported the verdict.[362] The consolidated cases are being referred to their home districts with the direction that *Daubert* motions[363] will be governed by Ninth Circuit law.[364]

A third lawsuit, *Pilliod v. Monsanto*, was heard by a California court in 2019 with causes of action based on design defect, strict liability-failure to warn, negligence, and negligent failure to warn.[365] The plaintiffs introduced considerable evidence questioning the quality of studies justifying the registration of Roundup and Monsanto's activities, thereby casting doubt on whether glyphosate was

357 First Amended Complaint, Hardeman v. Monsanto Co., No. 16-cv-00525-DMR (N.D. Cal. Feb. 12, 2016) [hereinafter *Hardeman* First Amended Complaint].

358 *In re* Roundup Prod. Liab. Litig., Transfer Order, Case No. 16-md-02741-VC (N.D. Cal. Oct. 4, 2016), https://www.cand.uscourts.gov/filelibrary/2886/JPML-transfer-order.pdf [https://perma.cc/TN8Y-BTW7].

359 First Amended Complaint at 18–28, *Hardeman*, No. 16-cv-00525-VC (N.D. Cal. Feb. 12, 2016).

360 *Hardeman*, *supra* note 53, at 2.

361 Pretrial Order No. 160 at 8, Hardeman v. Monsanto Co., No. 16-cv-00525-VC (N.D. Cal. July 15, 2019).

362 Pretrial Order No. 159 at 3, Hardeman v. Monsanto Co., No. 16-cv-00525-VC (N.D. Cal. July 12, 2019). The court found that the failure-to-warn claim merged with the defective design claim. *Id.* at 4. The design defect was the absence of a warning. *Id.*

363 Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993) (deciding whether expert witnesses or evidence qualifies for introduction at trial). *See* Barrera v. Monsanto Co., No. N15C-10-118 VLM, 2019 WL 2331090 (Del. Super. Ct. May 31, 2019) (discussing the application of *Daubert* to testimony by experts on evidence that glyphosate causes health problems).

364 The *Daubert* hearings in 2018 involved screening potential expert witnesses to determine whether testimony is sufficiently reliable to be admissible. Pretrial Order No. 147: Tentative Remand Plan, *In re* Roundup Prod. Liab. Litig., No. 16-md-02741-VC (N.D. Cal. May 21, 2019), https://www.cand.uscourts.gov/filelibrary/3694/PTO147.pdf [https://perma.cc/WUP5-2FJD].

365 Proceedings held on Friday, July 13, 2018, at 5745–50, Pilliod v. Monsanto, No. CGC-16-550128 (Cal. Super. Ct., S.F. Cnty. July 13, 2018), https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/05/Trial-Transcript-Pilliod-Verdict.pdf [https://perma.cc/T2W5-XCYJ].

carcinogenic.[366] The jury found economic losses of more than $52 million and awarded punitive damages of $2 billion.[367] Monsanto has entered a settlement agreement.[368]

For the *Monsanto* cases, the defendants have appealed the verdicts and have presented courts with several arguments. An initial argument concerns sufficient causation.[369] Defendants claim the testimony of the expert witnesses did not establish a cause of action.[370] In the *Johnson* lawsuit, when the plaintiff developed non-Hodgkin's lymphoma from exposure to Roundup, glyphosate was not considered to be toxic.[371] The International Agency for Research on Cancer reached its conclusion in 2017 that glyphosate was probably carcinogenic to humans.[372] Thus, prior to 2017, there was no substantial evidence that glyphosate presented a potential cancer risk, so manufacturers may not have had a duty to warn.[373] In the absence of a duty, plaintiffs cannot establish a negligence cause of action. The absence of evidence of carcinogenicity at the time of the plaintiffs' exposure may mean Roundup's design was not defective and did not violate minimum safety requirements.[374] Thus, it may be argued that there is no substantial evidence supporting a failure-to-warn claim and the defective design cause of action.[375]

The verdicts in the *Monsanto* cases show plaintiffs being effective in convincing the juries that Monsanto knew glyphosate was dangerous and could cause health damages. The juries also believed that Monsanto had neglected to provide adequate warnings on the dangers of pesticide use and should pay large sums of punitive damages.[376] The

366 Proceedings held on April 2, 3, 4, 7, 16, 17, 2019 at 1533–3654, Pilliod v. Monsanto, No. RG17862702.

367 Proceedings held on Friday, July 13, 2018 at 5647, 5751, Pilliod v. Monsanto, No. CGC-16-550128 (Cal. Super. Ct., S.F. Cnty July 13, 2018), https://usrtk.org/wp-content/uploads/bsk-pdf-manager/2019/05/Trial-Transcript-Pilliod-Verdict.pdf [https://perma.cc/T2W5-XCYJ].

368 *See* BAYER, *supra* note 1.

369 Monsanto Company's Notice of Motions and Motions for Judgment as a Matter of Law or, in the Alternative, For a New Trial at 1, *In re* Roundup Prods. Liab. Litig., No. 16-cv-0525-VC (N.D. Cal. July 31, 2019) [hereinafter Monsanto Motions].

370 *Id.*

371 Appellant's Opening Brief at 25–26, Johnson v. Monsanto Co., No. A155940 & A156706 (Cal. 1st Dist. Ct. App. Apr. 23, 2019) [hereinafter *Johnson* Opening Brief].

372 WHO ORGANOPHOSPHATE, *supra* note 215, at 398.

373 *Johnson* Opening Brief, *supra* note 371, at 15.

374 *Id.* at 16.

375 *Id.* at 39.

376 *See Johnson*, *supra* note 53; *Hardeman*, *supra* note 53; *Pilliod*, *supra* note 53 (citing the verdicts from the three cases).

verdicts indicate that the jurors did not find Monsanto's defenses credible.

For the three *Monsanto* cases, issues about the impropriety of admitting some of plaintiffs' evidence and the statements made in the plaintiffs' closing arguments are being appealed. The judge in the *Johnson* case circumscribed the evidence admitted to counter the plaintiff's evidence on carcinogenicity.[377] In *Hardeman*, the trial court precluded the admission of significant EPA documents on registrations.[378] In the *Pilliod* lawsuit, plaintiffs' counsel highlighted a deficiency of Monsanto's warnings on product labels, but an earlier court ruling had determined that issue should not be discussed.[379] It is possible that statements by plaintiffs' counsel could be found to be improper and prejudicial.

V
NEW DIRECTIONS FOR PESTICIDE LIABILITY

The verdicts of the *Monsanto* cases suggest that people feel they should be protected from pesticides that injure their health. Due to FIFRA's undervaluation of human health and approval of pesticide registrations without sufficient mitigation measures, too many people may be injured by pesticide exposure. For several decades, FIFRA was interpreted as precluding many pesticide liability claims because it included a preemption provision.[380] The provision provided that states could not impose "any requirements for labeling or packaging in addition to or different from those required under" FIFRA.[381]

In *Bates v. Dow Agrisciences, LLC*, the Supreme Court clarified the meaning of the preemption provision: preemption only applies to labeling and packaging requirements.[382] Claims based on pesticide

377 *Johnson*, *supra* note 53, at 68.

378 Monsanto Motions, *supra* note 369, at 25.

379 Reporter's Transcript of Proceedings at 5612, Pilliod v. Monsanto Co., No. RG17862702 (Cal. Super. Ct., Alameda Cnty. May 8, 2019).

380 7 U.S.C. § 136v (2018). *See* Joseph Frueh, *Pesticides, Preemption, and the Return of Tort Protection*: Bates v. Dow Agrosciences LLC, *125 S. Ct. 1788 (2005)*, 23 YALE J. REG. 299, 308 (2006) (noting the valuable counterbalance to the profit motive served by tort law that is not preempted by FIFRA).

381 7 U.S.C. § 136v (2018).

382 Bates v. Dow Agrosciences LLC., 544 U.S. 431, 444 (2005). *See* Mortellite v. Novartis Crop Prot., Inc., 460 F.3d 483, 489 (3rd Cir. 2006) (observing that an event inducing a registrant to change a label is not preempted).

use,[383] design defect,[384] manufacturing defect,[385] negligent testing,[386] negligent misrepresentation,[387] and fraud[388] are not preempted. The causes of action alleged in the *Monsanto* cases disclose that FIFRA's preemption provision is not as broad as manufacturers had envisioned.[389] The trial courts' rulings on liability for health-related damages were based on causes of action that did not involve labeling and packaging. The verdicts show that liability causes of action against manufacturers may lead to significant awards of damages.

The *Monsanto* cases herald a jurisprudential evolution under which courts are finding pesticide manufacturers have responsibilities for the safety of their consumers. These responsibilities are consistent with other jurisprudence on hazardous materials,[390] products liability,[391] and unsafe conditions.[392] Liability is based on the justification that

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383 *See* Schoenhofer v. McClaskey, 861 F.3d 1170, 1174 (10th Cir. 2017) (finding a state application requirement was not preempted).

384 *See Bates*, 544 U.S. at 444.

385 *See id.*

386 *See id.*

387 *See Mortellite*, 460 F.3d at 486.

388 *See id.*

389 *See Bates*, 544 U.S. at 444 (interpreting the preemption of 7 U.S.C. § 136v(b) to acknowledge that FIFRA allows consistent state-law labeling requirements to meet special local needs); *see also* Terence J. Centner, *Damages from Pesticide Spray Drift Under Trespass Law*, 41 ECOLOGY L. CURRENTS 1 (2014) (discussing the nonapplicability of federal preemption to pesticide spray drift claims).

390 42 U.S.C. § 9607 (2018) (establishing strict liability for hazardous materials in section 107 of the Comprehensive Environmental Response and Compensation Act). Persons that caused the harm should be responsible for the costs of damages. The common law causes of action used in the *Monsanto* cases support the premise that liability for damages should be placed on parties responsible for creating the hazard. *See* NCR Corp. v. George A. Whiting Paper Co., 768 F.3d. 682, 689 (7th Cir. 2014) (noting that Congress wanted to shift the costs for the cleanup of hazardous substances to "parties responsible for creating the hazard").

391 RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965) imposes strict liability on manufacturers of defective products. *See, e.g.*, Berrier v. Simplicity Mfg., Inc., 563 F.3d 38, 59 (3rd Cir. 2007) (finding manufacturers guarantee safety for all foreseeable users and others).

392 *See, e.g.*, Rodriguez v. Kroger Co., 422 P.3d 815, 823 (Utah 2018) (noting liability for the creation of an unsafe condition by an independent contractor under the state's "nondelegable duty to keep its premises . . . safe); QBE Ins. Corp. v. Brown & Mitchell, Inc., 591 F.3d 439 (5th Cir. 2009) (finding that a firm breached its professional responsibilities when it failed to stop an unsafe act causing an injury); Nelson v. United States, 915 F.3d 1243, 1256 (10th Cir. 2019) (finding a landowner was liable for failing to warn of a dangerous condition on its property). In many cases, liability is pursuant to statute. *See, e.g.*, Mut. Pharm. Co. v. Bartlett, 133 U.S. 472, 475 (2013) (observing that state law imposed a duty on manufacturers to only market safe drugs).

manufacturers should pay for social costs associated with their products.[393] Pursuant to the judgments in the *Monsanto* cases, persons negatively afflicted by pesticide exposure can seek recompense from manufacturers for negligence, defective design, and inadequate warnings.[394] Similarly, persons with properties damaged by pesticides might maintain actions for compensation.[395] Moreover, it might be advisable for owners of lands receiving applications of pesticides to add indemnity provisions in their contracts with renters and applicators.[396]

Looking at the *Monsanto* verdicts from a public policy perspective, the preservation of tort law may be appropriate due to the information asymmetries of pesticide registration.[397] Not only have some registrants withheld important scientific data, but some have also engaged in activities to discredit credible scientific information.[398] Some pesticides including glyphosate were approved based on fraudulent data.[399] The adversarial system of tort law may be less susceptible to data manipulation by pesticide registrants than registration.[400]

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393 *See* Sam F. Halabi, *The Scope of Preemption Under the 2009 Family Smoking Prevention and Tobacco Control Act*, 71 FOOD & DRUG L.J. 300, 307 (2016) (discussing payments by tobacco companies for damages related to their products).

394 *See supra* Part IVD.

395 For example, persons experiencing crop damages from their neighbors' use of the herbicide dicamba have advanced claims based on a design defect, failure to warn, and negligent training in the manufacturing of dicamba. *See* Bader Farms, Inc. v. Monsanto, 431 F. Supp. 3d 1084 (E.D. Mo. 2019) (advancing damage claims for injury to peach trees from dicamba applications on nearby crops and declining to grant the defendants summary judgment).

396 *See, e.g.*, Plourde v. Gladstone, 190 F. Supp. 2d 708 (D. Vt. 2002), aff'd 69 F. App'x. 485 (2d Cir. 2003) (holding that a plaintiff had presented evidence of harm from pesticide spray drift that precluded summary judgment on nuisance and negligence causes of action against a landowner who had hired the pesticide applicator spraying the pesticide).

397 *See* Adam D.K. Abelkop, *Tort Law as an Environmental Policy Instrument*, 92 OR. L. REV. 381, 468 (2013) (noting that "strength of the tort system is its capacity to incorporate privately held information from both injured parties and risk-taking firms").

398 *Id.* This has occurred with registrations of GBHs. *See supra* notes 293–99 and accompanying text. *See also* Katherine Drabiak, *Roundup Litigation: Using Discovery to Dissolve Doubt*, 31 GEO. INT'L ENV'T. L. REV. 697, 704 (2019) (discussing Monsanto's efforts to discredit the finding by the International Agency for Research on Cancer that glyphosate should be classified as a Group 2A carcinogen).

399 *See Pilliod* Benbrook Testimony, *supra* note 293, at 3519–26 (disclosing that the research study supporting the registration of glyphosate was fraudulent).

400 Evidence in the *Pilliod* case claimed that Monsanto knew in 1976 that the only study supporting the safety of glyphosate had been found to be fraudulent but waited until 1982 to conduct another study. Closing Arguments Day 21 at 5501, Pilliod v. Monsanto Co., No. RG17862702 (Cal. Super. Ct., Alameda Cnty. May 13, 2019). After a dubious Knezevich and Hogan study, all subsequent mice studies showed malignant lymphoma. *Id.* at 2106–13.

A. Undervaluing Human Health

FIFRA undervalues human health by failing to consider the problems with co-formulant use and cumulative exposure. By only considering the health effects of active ingredients, FIFRA fails to account for situations where co-formulants exacerbate the negative effects of pesticide exposure.[401] Active ingredients are substances that "prevent, destroy, repel or mitigate any pest, or that functions as a plant regulator, desiccant, or defoliant."[402] Active ingredients include any group of structurally similar substances specified by the EPA.[403] Inert ingredients are those "intentionally included in a pesticide product" that are not active ingredients.[404] Research shows that damages from pesticide use are not simply related to active ingredients.[405] This means the registration of a pesticide under FIFRA does not guarantee that ordinary usage is safe.

Situations involving cumulative exposure to other chemicals also mean people may suffer significant health damages from exposure to a registered pesticide.[406] Persons exposed to pesticides may be exposed to other nonpesticide chemicals that harm human tissues, organs, and systems.[407] FIFRA's cost-benefit analysis allows human health to be overshadowed by benefits to producers and consumers. In pursuing more profitable food production, FIFRA fails to protect people from harm.[408] This legislative provision may no longer be consistent with American liability principles.[409]

Given damages occurring from pesticide exposure, requirements to keep people safe might be superior to the existing regulatory regime

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401 *See supra* notes 178–82 & 229–34 and accompanying text.

402 40 C.F.R. § 152.3 (2019).

403 *Id.*

404 *Id.*

405 *See supra* notes 229–34 and accompanying text.

406 *See supra* Part IIB.

407 *See supra* notes 129–31 and accompanying text.

408 *See* Keating, *supra* note 77, at 242, 258 (acknowledging that although we allow people to pursue many activities accompanied by risks, the cost-benefit analysis conflicts with moral institutions).

409 Changes in liability law since the enactment of FIFRA place a higher priority on human safety. Through § 402A of the Restatement of Torts, a rule of strict liability applies to manufacturers of products. RESTATEMENT (SECOND) OF TORTS § 402A (AM. L. INST. 1965). A strict liability standard is being projected for autonomous vehicles. *See* Mark A. Geistfeld, *A Roadmap for Autonomous Vehicles: State Tort Liability, Automobile Insurance, and Federal Safety Regulation*, 105 CALIF. L. REV. 1611, 1623 (2017). As sellers of a product, pesticide manufacturers might be held responsible for health damages.

that weighs costs and benefits.[410] In the absence of adequate protection of human health by FIFRA, state governments might consider further action.[411] States might adopt further safety measures so long as they do not offend preemptive federal pesticide labeling requirements.[412] States might decide that individual communities should be able to adopt safeguards to reduce the risks of cancer or other health maladies related to the use of pesticides,[413] preclude the sales and storage of pesticides in inappropriate locations,[414] and offer greater protection for wellhead production and water recharge areas from pesticide contamination.[415]

B. Mitigation Measures

FIFRA's registration requirements may underemphasize the importance of mitigation measures offering alternative solutions to reduce pesticide use.[416] Regulations require the EPA to identify proposed risk mitigation measures that are needed and to describe the basis for requiring mitigation measures.[417] In most cases, the requirement of a measure would be related to securing a favorable cost-benefit analysis.[418] Nevertheless, once a favorable cost-benefit analysis is achieved, further mitigation measures are not required despite

410 Frueh, *supra* note 380, at 309 (noting that manufacturers are not paying the full social costs of products because victims of negligence go uncompensated). *See also* Aceves, *supra* note 131, at 65 (advocating the minimization of partisan influence and bureaucratic bias in calculations of human life).

411 *See, e.g.*, CAL. ENV'T. PROT. AGENCY, AGREEMENT REACHED TO END SALE OF CHLORPYRIFOS IN CALIFORNIA BY FEBRUARY 2020 (Oct. 9, 2019), https://www.cdpr.ca.gov/docs/pressrls/2019/100919.htm [https://perma.cc/8GK7-SHLB] (ending most uses of chlorpyrifos in California); Andrew M. Cuomo, Governor Cuomo Directs DEC to Ban the Use of Chlorpyrifos (Dec. 10, 2019), https://www.governor.ny.gov/news/governor-cuomo-directs-dec-ban-use-chlorpyrifos [https://perma.cc/72MF-H3WZ] (ending chlorpyrifos uses in New York).

412 *See* Bates v. Dow Agrosciences LLC., 544 U.S. 431, 444 (2005) (interpreting the preemption of 7 U.S.C. § 136v(b)).

413 *See* Terence J. Centner & Davis Clarke Heric, *Anti-Community State Pesticide Preemption Laws Prevent Local Governments from Protecting People from Harm*, 17 INT'L J. AGRIC. SUSTAINABILITY 118 (2019) (discussing the benefits from local regulations of pesticides).

414 *See, e.g.*, COLO. REV. STAT. § 35-10-112.5(3)(a)(I) (2018) (recognizing the need for local governments to regulate zoning of sales or storage facilities).

415 *See, e.g.*, FLA. STAT. § 482.242(1)(d) (2018) (recognizing the need for communities to take action to protect water resources).

416 *See* Torretta et al., *supra* note 331, at 16 (advocating implementing funding and resources for alternative weed control solutions).

417 40 C.F.R. §§ 155–58 (2019).

418 *See* Centner, Brewer & Leal, *supra* note 118 (discussing the use of mitigation measures to protect pollinator species from lethal pesticides).

pesticide uses that cause human health damages. Mitigation measures altering existing practices that could lead to reductions in pesticide usage are not required even though they could contribute to reduced environmental and health problems.[419]

For example, would reductions in the use of GBHs as desiccants or defoliants to remove foliage prior to the harvest of oats, dry beans, and lentils be beneficial?[420] Would reductions in applications of GBHs as desiccants on cover crops lead to reductions in health maladies?[421] By discontinuing harvest aid uses, less glyphosate would be released into the environment.[422] Other mitigation approaches might be adopted to reduce the harm caused to the environment and human health by pesticide uses.[423]

CONCLUSION

Americans are using large quantities of synthetic pesticides to manage pests that diminish crop yields, denigrate food quality, impair human health, and detract from general well-being. Despite the many benefits accruing from pesticide usage, negative externalities in the form of adverse human health and environmental effects detract from the benefits. Federal law considers a pesticide's negative externalities and a pesticide can only be registered if it does not cause an "unreasonable adverse effect[] on the environment."[424] However, the absence of a full accounting of co-formulants and cumulative exposure

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419 *Id.*

420 *See, e.g.*, Kristen E. McNaughton et al., *Effect of Application Timing of Glyphosate and Saflufenacil as Desiccants in Dry Edible Bean (*Phaseolus vulgaris L.*)*, 95 CANADIAN J. PLANT SCI. 369, 374 (2015) (noting that glyphosate applied as a desiccant increases residue levels in dry beans); Ti Zhang, Eric N. Johnson & Christian J. Willenborg, *Evaluation of Harvest-Aid Herbicides as Desiccants in Lentil Production*, 30 WEED TECH. 629, 636 (2016) (finding "that using glyphosate as a desiccant can result in unacceptable glyphosate seed residues").

421 GBHs are used to kill the cover crop to enhance subsequent crop germination. *See* Ryan D. Lins et al., *Glyphosate Application Timing and Rate for Annual Ryegrass (*Lolium multiflorum*) Cover Crop Desiccation*, 21 WEED TECH. 602, 603–04 (2007).

422 Some groups are supporting this idea. *See* Alex Formuzis, *More than 100,000 Americans Urge EPA To Restrict Unnecessary Use of Monsanto's Weedkiller on Oats*, ENV'T. WORKING GRP. (June 7, 2019), https://www.ewg.org/release/more-100000-americans-urge-epa-restrict-unnecessary-use-monsanto-s-weedkiller-oats [https://perma.cc/FBE3-7EHN] (urging the EPA to restrict uses of glyphosate on oats).

423 *See* Larsen, Patton & Martin, *supra* note 42, at 828 (discussing "opportunities for crop-specific pest management and region-specific mitigation approaches" to reduce pesticide uses).

424 7 U.S.C. § 136a(a) (2018).

means that some external costs are not considered. Moreover, the lack of sufficient information on long-term chronic health effects at the time of a pesticide's initial registration may understate negative externalities.[425] A pesticide may qualify for registration without considering all its health costs.[426]

Furthermore, when post-registration studies reveal that pesticide use has significant health risks, the costs associated with these risks are not considered unless a registrant agrees to cancel a registration or a cancellation proceeding is initiated.[427]Administrative delays with the cancellation of a registration allow human health costs to be overshadowed for years by production benefits.[428] The application of FIFRA's registration provisions employing a cost-benefit analysis sacrifices human health to foster greater agricultural production. While food safety tolerances safeguard human health from pesticide residues in and on food,[429] the registration of pesticides allows pesticide exposure to harm people.

The jury verdicts of the three *Monsanto* cases holding the glyphosate manufacturer liable for health damages suggest that governments are not providing equitable resolutions to govern the use of pesticides. Persons injured from pesticide exposure should not suffer uncompensated damages while others reap the benefits of profitable pesticide sales and reduced food costs. Pesticide manufacturers and users inflicting health damages on others should provide recompense.[430] This will require manufacturers and users to budget health costs into business practices and prices for their products and services, which may be expected to lead to higher food prices and more expensive public-health pest control measures.[431] In some cases, manufacturers may want to amend or cancel registrations that are

425 *See* Roberts, Karr & Council on Environmental Health, *supra* note 129, at 1773 (noting "a growing body of literature that suggests that pesticides may induce chronic health complications in children, including neurodevelopmental or behavioral problems, birth defects, asthma, and cancer.").

426 7 U.S.C. § 136a(1)(5) (2018) (exceptions allowing residues above current legal provisions).

427 *Id.* § 136d.

428 *See Azinphos-Methyl Phase-Out*, *supra* note 126 (discussing ending azinphos-methyl use); League of United Latin Am. Citizens v. Wheeler, 899 F.3d 814, 817–18 (attempting to cancel registrations of chlorpyrifos over a 12-year timeframe).

429 *See* 21 U.S.C. § 346a (2018).

430 Alternatively, protecting public health may need to ignore costs. *See* Driesen 2, *supra* note 116, at 70 (advancing this idea).

431 *See* Centner, Russell & Mays, *supra* note 31, at 613.

accompanied by significant health damages.[432] In February 2020, Corteva, the leading manufacturer of chlorpyrifos pesticides in the United States, announced it was discontinuing production.[433] While the company cited reduced demand and its agreement with California to end sales in that state, the known health damages presumably contributed to the decision.[434] Manufacturers may cease production of dangerous pesticides to avoid future allegations of health damages.

The judgments of the *Monsanto* cases have been appealed, and Bayer AG, the owner of Monsanto, has agreed to a settlement under which it will pay more than $10 billion for current and future plaintiffs alleging health damages.[435] The placement of health costs on manufacturers may curtail pesticide usage, encourage practices to keep people safe, and reduce health costs related to pesticide exposure. However, the absence of statutory and regulatory provisions aligning pesticide liability with the public's expectations means that persons harmed by pesticide exposure need to pay their own health costs and resort to tort litigation to secure recompense. Until legislatures place greater emphasis on safeguarding human health and the use of mitigation measures, the costs associated with pesticide use will not be factored into production costs. To foster the adoption of greater safety measures and innovation, it may be time to hold manufacturers accountable for damages caused by the use of their products.[436]

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432 *See* Chlorpyrifos Cancellation Order, *supra* note 41 (manufacturers agreeing to cancel multiple uses of chlorpyrifos due to human health risks).

433 Britt E. Erickson, *Corteva to stop producing chlorpyrifos*, CHEM. & ENG'G NEWS (Feb. 7, 2020), https://cen.acs.org/environment/pesticides/Corteva-stop-producing-chlorpyrifos/98/web/2020/02 [https://perma.cc/TQ3E-DASC].

434 *Id. See also* EPA Chlorpyrifos Human Health, *supra* note 119 (discussing human health issues).

435 *See* BAYER, *supra* note 1.

436 *See* Hyundai Motor Co. v. Alvarado, 974 S.W.2d 1, 11 (Tex. 1998) (fostering safety included allowing the imposition of tort liability); Robert E. Litan, *The Safety and Innovation Effects of U. S. Liability Law: The Evidence*, 81 AM. ECON. REV. 59, 63 (1991) (noting that "liability . . . attempts to induce safety-enhancing behavior . . .").