CULTIVATING UNITED STATES PESTICIDE REGULATION: SOWING THE SEEDS OF THE EUROPEAN UNION REACH FRAMEWORK

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ABSTRACT

Pesticides and herbicides are an integral part of the global food supply chain, and they have made their way from our food into our bodies, causing cancer and other harm to the humans who consume them. Agriculture is a critical component of the United States economy, fostered by a notion of "agricultural exceptionalism" by United States lawmakers that has resulted in regulatory policies that are permissive towards the agricultural industry, including pesticide manufacturers. Recent litigation against Monsanto, one of the largest pesticide manufacturers in the world, reveals that the EPA has not acted to protect Americans from harmful pesticides that can cause cancer. While the three landmark cases discussed in this Essay resulted in victories for the plaintiffs, Americans cannot rely solely on state tort law litigation to address a nationwide problem that touches every person who consumes food in the United States.

Exploring this issue, this Essay then compares the regulatory regimes of the United States EPA FIFRA "permissive model" and the European Union REACH "approval model." By adopting more stringent pesticide approval standards that are less permissive towards industry, the EPA can better protect American farmers and consumers. Additionally, expanding the Lautenberg Amendments to FIFRA and embracing new technology along with the practice of agroecology can cultivate a new iteration of agricultural exceptionalism for the 21st century that supports farmers and farm workers, while also ensuring the safety of United States food.

I. INTRODUCTION

Dewayne Johnson had an accident at work.[1] While performing his daily duties as a school groundskeeper, a hose spraying Roundup Pro became lodged in a sidewalk crack and began "shooting fluid everywhere," breaching the full-body protective Tyvek suit he wore when using the herbicide.[2] The chemical soaked his skin, face, neck, and head, and despite cleaning himself as best as he could, he developed a severe rash.[3] Less than three months later, he was diagnosed with non-Hodgkin's lymphoma.[4] A jury found the Roundup had a design defect and its manufacturer, Monsanto, had failed to adequately warn consumers about the dangers of its products.[5] Mr. Johnson was awarded almost $300 million in damages and

1. Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 116 (Ct. App. 2020).
2. *Id.*
3. *Id.*
4. *Id.*
5. *Id.* at 120.

has lived with terminal cancer since its onset in 2014.[6]

Unfortunately, stories like Mr. Johnson's are not unique, and this Essay will discuss two other cases featuring plaintiffs who have suffered devastating consequences from consumer use of Roundup, which is a glyphosate-based herbicide.[7] Pesticides and herbicides (both commercial-grade and consumer-grade) are so pervasive that they are likely to be found in the urine of people who do not live nor work on farms.[8] A 2016 analysis of urine samples submitted by 48 members of the European Parliament found detectable levels of glyphosate in every single sample, each in concentrations more than double the level permitted in European drinking water.[9] If members of the European Parliament have a strong herbicide in their urine, then statistically speaking, readers of this Essay probably do as well, as these chemicals enter the human body via the drinking water and food supply.[10]

Despite the harms they cause, pesticides and herbicides also play an important role in modern global agriculture, enabling farmers to produce a higher crop output than they could without the aid of these chemicals.[11] Pest control measures have been used by humans for centuries, and modern pesticide use accelerated in the United States after World War II when chemicals such as DDT, BHC, endrin, and 2,4-D were introduced into the agricultural industry.[12] A primary benefit of pesticide use is increased crop yield, which allows more food output at lower prices for consumers.[13] The dominance of agriculture in the American economy has been deemed "agricultural exceptionalism"—a position that leads to government policies that are friendly towards agriculture, even when these policies

6. Josh Voorhees, *The Inside Story of the School Groundskeeper Who Took on Monsanto*, MODERN FARMER (Feb. 28, 2021), https://modernfarmer.com/2021/02/the-inside-story-of-the-school-groundskeeper-who-took-on-monsanto/ [https://perma.cc/9NJN-U93Y].

7. *See generally* Hardeman v. Monsanto Co., 997 F.3d 941 (9th Cir. 2021); Pilliod v. Monsanto Co., 282 Cal. Rptr. 3d. 679 (Ct. App. 2021).

8. CAREY A. GILLAM, WHITEWASH 174 (2017). This Essay will refer to pesticides and herbicides interchangeably, as some chemicals target pests (insects) while others target undesirable herbs (weeds).

9. *Id*.

10. *Id.*; *see* Mitchel Cohen, *Foreword by* VANDANA SHIVA, THE FIGHT AGAINST MONSANTO'S ROUNDUP: THE POLITICS OF PESTICIDES, at xvii (2019).

11. *See* Keith S. Delaplane, *Pesticide Usage in the United States: History, Benefits, Risks and Trends*, UNIV. OF GA. 1 (1996), http://people.forestry.oregonstate.edu/steve-strauss/sites/people.forestry.oregonstate.edu.steve-strauss/files/PestUse1996.pdf [https://perma.cc/TY4V-TUBH].

12. *Id.*

13. *Id.*

foster agricultural production that does not match economic demand.[14]

While there are benefits to pesticide use, not every pesticide available *should* be used—there are a number of pesticides that have been deemed too dangerous to use by Brazil, China, and the European Union, but not the United States.[15] These three nations plus the European Union constitute both the largest agricultural producers in the world and the largest consumers of pesticides in the world.[16] Of the four largest agricultural producers, 13 pesticides are still approved for use in the United States but have been banned or are being phased out in at least two of the three compared nations, including 2,4-DB, bensulide, chloropicrin, dichlobenil, dicrotophos, norflurazon, paraquat, phorate, and tribufos.[17] Specifically, in 2016 the United States used 322 million pounds of pesticides that had been banned in the European Union, 26 million pounds of pesticides that had been banned in Brazil, and 40 million pounds of pesticides that had been banned in China.[18] A pesticide of particular concern from this list is paraquat, which is banned or being phased out in China, Brazil, and the European Union, due to its high level of toxicity and widespread usage as an herbicide that controls grasses and weeds.[19] Paraquat has been involved in approximately 100 poisoning incidents in the United States per year, and has resulted in at least one death per year since 2012, most of which were accidental.[20]

The United States Environmental Protection Agency (EPA) has the authority to regulate pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).[21] FIFRA is primarily a licensing and registration statute that gives the EPA the regulatory authority to require pesticide manufacturers to submit data from scientific tests of their products to the EPA for registration approval.[22] All

14. *See* Bradley R. Finney, *Agricultural Law Stifles Innovation and Competition*, 72 ALA. L. REV. 785, 787 (2021).

15. *See* Nathan Donley, *The USA Lags Behind Other Agricultural Nations in Regulating Pesticides*, ENV'T HEALTH, June 2019, at 4.

16. *Id.* at 1.

17. *Id.* at 3.

18. *Id.* at 4.

19. *Id.* at 4, 6; *Paraquat Dichloride*, U.S. ENV'T PROT. AGENCY (July 12, 2022), https://www.epa.gov/ingredients-used-pesticide-products/paraquat-dichloride [https://perma.cc/64F5-XFJC].

20. *See* Donley, *supra* note 15, at 6.

21. *See* 15 U.S.C. §§ 2601–2697; 7 U.S.C. § 136.

22. *See Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities*, U.S. ENV'T PROT. AGENCY (Mar. 28, 2022), https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities [https://perma.cc/R7DB-4NCX] [hereinafter *(FIFRA) and Federal Facilities*].

pesticides must be registered with the EPA to be used in the United States.[23] The standard of review for a pesticide to be registered under FIFRA is that no "unreasonable adverse effects on the environment" will result from use of the pesticide according to specification.[24] The EPA interprets this to include "[a]ny unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."[25] FIFRA operates on what could be deemed a "permissive model," wherein the burden falls on the EPA to demonstrate that a pesticide is *unsafe* before it denies or cancels an existing registration.[26]

FIFRA also includes a misbranding provision, which permits the EPA to cancel a pesticide registration if it is determined to have been misbranded by the manufacturer under FIFRA.[27] A pesticide is misbranded if "labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading"[28] or "the label does not contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment."[29] Pesticide manufacturers must initially register their pesticides with the EPA, and then the misbranding provision is an additional regulatory authority given to the EPA to cancel a pesticide registration if its label is found to be misbranded.[30]

Despite its statutory authority to cancel pesticide registrations for pesticides that do not comply with FIFRA, such as if they are misbranded, the EPA has frequently allowed pesticides to remain on the United States market, even after data accumulates that brings a pesticide's safety into question.[31] The EPA's inaction in the regulation of pesticides leaves Americans injured by pesticides to turn to the

23. 7 U.S.C. § 136(a).

24. *(FIFRA) and Federal Facilities*, *supra* note 22.

25. *Id.*

26. *See Pathways to Pesticide Cancellation Under FIFRA*, THE NAT'L AGRIC. L. CTR. (Oct. 21, 2022, 7:31 PM), https://nationalaglawcenter.org/pathways-to-pesticide-cancellation-under-fifra/ [https://perma.cc/G6BG-P5F4].

27. § 136(q).

28. § 136(q)(1)(A).

29. § 136(q)(1)(G).

30. *See id.*

31. *See, e.g.*, *IARC Monographs Volume 112: Evaluation of Five Organophosphate Insecticides and Herbicides*, WORLD HEALTH ORG. INT'L AGENCY FOR RSCH. ON CANCER 1 (Mar. 20, 2015), https://www.iarc.who.int/wp-content/uploads/2018/07/MonographVolume112-1.pdf [https://perma.cc/J8Z4-5HQ2] [hereinafter *IARC Monographs Volume 112*]; *Glyphosate*, U.S. ENV'T PROT. AGENCY (Sept. 23, 2022), https://www.epa.gov/ingredients-used-pesticide-products/glyphosate [https://perma.cc/G78G-BC2K].

courts, as the plaintiffs in the *Monsanto* cases did.[32] These cases provide some measure of justice for the plaintiffs when they win, but result in protracted trial and appellate proceedings that are costly and all-but-impossible for every person who is injured by a pesticide to undertake. To make matters worse, the injury suffered by most of these plaintiffs is terminal cancer, which they demonstrated via a preponderance of the evidence standard in their jury cases they developed because Roundup is a defective product.[33] These jury findings show that the EPA is not adequately using its legal authority to protect the public from products like Roundup. It is a legal imperative that the EPA act according to its own interpretation of FIFRA, where the "benefits" of any pesticide, economic or otherwise, do not outweigh the "unreasonable risk" to human life or the environment.[34]

The EPA should look to the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) framework to strengthen its standard of review and approval of pesticide registrations. The European Union REACH framework could be considered an *approval model* as it requires the company submit data to demonstrate the pesticide is safe for human use.[35] Shifting the burden from the EPA to industry following the REACH model would result in greater ability (and legal imperative) of the EPA to take action when a pesticide causes human harm, preferably *before* thousands of injured Americans have to rely on state tort law to recover for often fatal harm suffered by a pesticide, as the plaintiffs in the *Monsanto* cases did.[36]

In Part II, this Essay will provide a background on American agricultural exceptionalism's role in creating a regulatory body that operates in a permissive stance towards the agricultural industry and provide an overview of the existing regulatory authority in the United States under FIFRA and in the European Union under REACH. Part III will examine the *Monsanto* cases and the developing patchwork of state regulations regarding pesticide use. Part IV will conduct an analysis of how the EPA can exercise its regulatory authority more assertively to better

32. *See* Hardeman v. Monsanto Co., 997 F.3d 941, 950 (9th Cir. 2021); Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 114–16 (Ct. App. 2020); Pilliod v. Monsanto Co., 282 Cal. Rptr. 3d 679, 679–89 (Ct. App. 2021).

33. *See* Hardeman, 997 F.3d at 950; Johnson, 266 Cal. Rptr. 3d at 114–16; Pilliod, 282 Cal. Rptr. 3d at 679–89.

34. *See (FIFRA) and Federal Facilities*, *supra* note 22.

35. *See* Adam D.K. Abelkop et al., *Regulating Industrial Chemicals: Lessons for U.S. Lawmakers from the European Union's REACH Program*, 42 ENV'T L. REP. 11042, 11044–45 (2012).

36. *See* Hardeman, 997 F.3d at 950; Johnson, 266 Cal. Rptr. 3d at 114–16; Pilliod, 282 Cal. Rptr. 3d at 679–89.

regulate pesticides. Finally, Part V will provide recommendations on how the United States can chart a path forward on future pesticide regulation that accounts for the needs of all stakeholders, including the farmers and farm workers who rely on the pesticides, the individuals who use them frequently as part of their work, and the Americans who ultimately consume the pesticides and pesticide residues within the food supply.

II. BACKGROUND: AMERICAN AGRICULTURAL EXCEPTIONALISM, FIFRA, AND THE EUROPEAN UNION

American pesticide laws have formed in a landscape of agricultural exceptionalism and deep ties between the EPA regulators and the pesticide manufacturers. This convergence of factors has led to pesticide laws that are permissive towards industry and more ambivalent toward human health, resulting in devastating health consequences for people like the plaintiffs in the *Monsanto* cases.[37] American agricultural exceptionalism has created a regulatory environment highly favorable to pesticide manufacturers. In contrast to the permissive rules of the United States, the European Union has established more stringent standards of pesticide approval under its REACH legislation.[38] This section will examine the current EPA rules and European Union REACH to examine the current landscape of American pesticide legislation.

A. Agricultural Exceptionalism Guides United States Pesticide Laws

Agriculture plays a crucial role in the United States economy: the agriculture, food and related industries contributed $1.109 trillion to the United States gross domestic product (GDP) in 2019.[39] An industry of that size would ordinarily be subject to a large array of state and federal environmental laws; however, the United States agricultural industry is largely exempt from environmental laws—including the Clean Water Act (CWA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)—for its own benefit, a phenomenon deemed agricultural exceptionalism.[40] This term captures the "array of government benefits provided to agriculture, specifically regulatory exemptions,

37. *See* Hardeman, 997 F.3d at 950; Johnson, 266 Cal. Rptr. 3d at 114–16; Pilliod, 282 Cal. Rptr. 3d at 679–89.

38. *See* Regulation (EC) No 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), 2006 O.J. (L 396/3).

39. *Ag and Food Sectors and the Economy*, U.S. DEP'T OF AGRIC. (Feb. 24, 2022), https://www.ers.usda.gov/data-products/ag-and-food-statistics-charting-the-essentials/ag-and-food-sectors-and-the-economy/ [https://perma.cc/TZD9-ZA25].

40. *See* Finney, *supra* note 14, at 787.

monetary subsidies, and the permission to externalize pollution costs."[41]

Agricultural exceptionalism developed during the Great Depression in the 1930s, when the economic devastation meant farmers could not afford to harvest their crops, leading crops to rot on the vines while Americans lacked sufficient food.[42] Regulators implemented policies and regulations that highly favored United States agriculture, measures which have continued for almost 100 years and which have not kept up with the pace of technological innovation in the agricultural sector.[43]

Agricultural exceptionalism can be seen in the statutes that govern American agriculture, particularly in FIFRA.[44] FIFRA defines a pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest . . . or . . . intended for use as a plant regulator, defoliant, or desiccant, or any nitrogen stabilizer."[45] For a manufacturer to register a pesticide with the EPA under FIFRA, the applicant must show that using the pesticide "will not generally cause unreasonable adverse effects on the environment," which the EPA interprets to include "any unreasonable risk to man" or "any human dietary risk from residues that result from use of a pesticide in or on any food inconsistent with the standard."[46] A key component of the FIFRA framework is that the burden is on the regulator to prove that a chemical is *unsafe* for human use, with the regulatory scales tipped in favor of bringing pesticides onto the market.[47] FIFRA sets a low pesticide approval threshold, which is essentially a balancing test that incorporates economic benefits into its pesticide approval calculus—meaning that economic benefits can theoretically outweigh potential human harm in approval decisions,

41. *Id.*
42. *Id.*
43. *Id.* at 788.
44. *See* 7 U.S.C. § 136.
45. § 136(u).
46. § 136(bb); *Summary of the Federal Food, Drug, and Cosmetic Act*, U.S. ENV'T PROT. AGENCY (Sept. 12, 2022), https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act [https://perma.cc/A24R-WG5Q]. There is proposed legislation in the House as of April 1, 2021, called the "Farmworker Pesticide Safety Act" which would amend FIFRA to "provide for better protection of workers using registered pesticides. Farmworker Pesticide Safety Act, H.R. 2313, 117th Cong. (2021) (This short amendment does not go very far for such protection and would not preempt an analysis of the case law from the Monsanto cases, nor would it come anywhere close to the European Union REACH Framework.).
47. *See (FIFRA) and Federal Facilities*, *supra* note 22.

so long as the risk to humans is not "unreasonable."[48] Pesticide manufacturers must submit studies and testing data to the EPA when seeking pesticide registration, but those studies are often inadequate and lack peer-review, which allows the industry to effectively create their own scientific results that favor their product.[49]

Complementing the relative ease of pesticide approval to enter the market, it is difficult for the EPA to cancel a pesticide registration to get a pesticide off of the market, which it must do according to the steps established under FIFRA §136d(b).[50]

> First, EPA will be required to issue a Notice of Intent to Cancel ("NOIC"). The notice must consider the effect of cancellation on production, price of agricultural commodities, retail food prices, and the agricultural economy as a whole. Typically, EPA is required to issue the NOIC and an **analysis on the impact of cancellation to the agricultural community** to the United States Department of Agriculture ("USDA") at least 60 days before issuing the NOIC to the pesticide registrant and the public.[51]

After it receives the NOIC, there is a 30-day window in which the USDA can comment, which the EPA must publish, along with its own response, in the Federal Register.[52] When the EPA provides the NOIC to the USDA, it must also submit the NOIC to the FIFRA Science Advisory Panel so it can comment on the effect of the NOIC on human health and the environment.[53] Only after the EPA has completed all of the above steps can it submit the NOIC with the reasons for the action to the pesticide registrant, and publish the documents in the Federal Register for public review.[54] The pesticide registration cancellation will become effective thirty days after the NOIC is published in the Federal Register or the registrant receives the NOIC, but the cancellation date can be delayed if the registrant requests a hearing.[55] Additionally, the EPA is required to consider alternatives to cancellation, like usage restrictions.[56]

In line with agricultural exceptionalism, pesticides are specifically excluded from the primary chemicals management law in the United States—the Toxic

48. *See id.* ("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").

49. *See* GILLAM, *supra* note 8, at 215–34.

50. 7 U.S.C. § 136d(b).

51. *Pathways to Pesticide Cancellation Under FIFRA*, *supra* note 26 (emphasis added).

52. *Id.*

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

Substances Control Act (TSCA).[57] Passed in 1976, the law provides the EPA with the authority to "require reporting, record-keeping and testing requirements, and restrictions relating to chemical substances and/or mixtures."[58] In 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the TSCA, which created a mandatory requirement for the EPA to evaluate existing chemicals with clear and enforceable deadlines, increased transparency for chemical information, and created a consistent source of funding for the EPA to carry out the new law's responsibilities.[59] Pesticides are still excluded from the TSCA under the Lautenberg amendments, a modern result of continued agricultural exceptionalism.[60]

The EPA has the authority to set tolerances (maximum residue limits) on foods under Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA).[61] The EPA can establish a "zero tolerance" for pesticides when the pesticide in question is toxic, carcinogenic, or there is no safe level of the chemical that has been reliably determined—meaning that "no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment."[62] If residues are found above the tolerance level set by the EPA, the commodity is subject to seizure by the government.[63] A "safe" tolerance is defined as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide residue" with a note that some pesticides are exempted from the requirement to have a tolerance when the "pesticide residues do not pose a dietary risk under reasonably foreseeable circumstances."[64]

B. The European Union and REACH

The European Union government structure has seven official institutions, divided into executive, legislative, and judicial functions.[65] On the executive side,

57. 15 U.S.C. § 2601; *see also Summary of the Toxic Substances Control Act*, U.S. ENV'T PROT. AGENCY (Oct. 4, 2022), https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act [https://perma.cc/GS4E-8V4Y].

58. § 2602(B)(ii); *see also Summary of the Toxic Substances Control Act*, *supra* note 57.

59. *The Frank R. Lautenberg Chemical Safety for the 21st Century Act*, U.S. ENV'T PROT. AGENCY (Mar. 24, 2022), https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act [https://perma.cc/LQ9B-85NA] [hereinafter *The Frank R. Lautenberg Chemical Safety*].

60. *Id.*

61. *Summary of the Federal Food, Drug, and Cosmetic Act*, *supra* note 46.

62. 40 C.F.R. § 180.5 (2022).

63. *Summary of the Federal Food, Drug, and Cosmetic Act*, *supra* note 46.

64. *Id.*

65. James McBride, *How does the European Union Work?*, COUNCIL ON FOREIGN REL.

there is the European Commission, which proposes and implements legislation, and the European Council, which sets the policy agenda.[66] On the legislative side, there is the European Parliament and the Council of the European Union, which serve as a bicameral legislature that rejects or approves legislation.[67]

Food safety, including the regulation of pesticides, falls under the purview of the European Commission's Food Safety group, similar to how the EPA is an executive branch agency in the United States.[68] The Farm to Fork initiative, announced in May 2020, aims to reduce the use of chemical pesticides by 50% by 2030.[69] While every European Union Member State retains a great deal of autonomy as an independent country, the food sanitary laws are harmonized in the European Union.[70] Each Member State has the responsibility of implementing and enforcing the harmonized standards, with audits conducted by the European Commission to ensure compliance.[71]

The European Union REACH legislation was enacted in 2007 and is administered by the European Chemicals Agency (ECHA).[72] REACH places the burden of proof on companies, requiring companies to "demonstrate to ECHA how the substance can be safely used, and . . . communicate the risk management measures to the users."[73] A key component of REACH is that it is a "data-generating regulation," which requires that industry register the chemical with the European Union and submit a minimum safety dataset before it can enter the market.[74] Additionally, REACH Article 5 is explicit in stipulating "no data, no market,"[75] meaning that articles cannot be placed on the market in the European Union unless the manufacturers have met the data requirements. This European Union approach could be deemed an "approval model," as companies in an industry must go through a

(Mar. 11, 2022), https://www.cfr.org/backgrounder/how-does-european-union-work#chapter-title-0-2 [https://perma.cc/AZH7-B9DP].

66. *Id.*

67. *Id.*

68. *See Food Safety*, EUR. COMM'N (Oct. 21, 2022, 6:19 PM), https://ec.europa.eu/food/index_en [https://perma.cc/WM8V-EBPX].

69. *From Farm to Fork*, EUR. COUNCIL (Sept. 22, 2022), https://www.consilium.europa.eu/en/policies/from-farm-to-fork/ [https://perma.cc/L8MD-E36Q].

70. *Ensuring Food is Safe: The Veterinary and Phytosanitary System of the European Union Explained*, EUR. COMM'N 5 (2017), https://op.europa.eu/en/publication-detail/-/publication/b70d1b20-499a-11e7-aea8-01aa75ed71a1 [https://perma.cc/L4QT-RVTG].

71. *Id.*

72. *Understanding REACH*, EURO. CHEMS. AGENCY (Oct. 21, 2022, 6:17 PM), https://echa.europa.eu/regulations/reach/understanding-reach [https://perma.cc/Z5TB-SNRM].

73. *Id.*; *see generally* Donley, *supra* note 15.

74. *See* Abelkop et al., *supra* note 35, at 11044.

75. Regulation (EC) No 1907/2006, *supra* note 38, at (L 396/62).

regulatory approval gate to prove to the regulator that their pesticides and herbicides are safe *before* the chemicals can be placed on the market.

C. Genetically Modified Crops, Agricultural Workers & Pesticides in the Food Chain

The rise of genetically modified (GM) crops has created new concerns about pesticide use.[76] Proprietary seeds genetically engineered by large agricultural companies are sold to farmers[77] and are paired with strong pesticides to which the GM seeds have a resistance.[78] The strong pesticide is not a problem for the GM seeds with built-in resistance, but the pesticide spray drift can harm non-GM seeds—both on that farmer's land and neighboring plots.[79] A prominent group of GM herbicide-resistant crops are the "Roundup-resistant" genetically modified organisms (GMOs), which have been modified to tolerate the herbicide glyphosate, the active ingredient in Roundup.[80] Herbicide-resistant GMOs lead to more pesticide use because the crops are unharmed while harmful pests are exterminated.[81] However, the increased volume of herbicides such as Roundup can have harmful effects on human health: in 2015, the World Health Organization's (WHO) International Agency for Cancer Research (IARC) classified glyphosate as "probably carcinogenic to humans" after reviewing approximately 1,000 studies of the chemical.[82] This classification provoked concern, as glyphosate has the highest global production volume of all herbicides.[83]

GM crops are not nearly as pervasive in Europe as they are in the United States, because "Europeans never embraced the new high-tech tinkering with plant DNA."[84] GM crops are banned in several European countries, including Poland, Austria, Greece, Hungary, and Germany, and are primarily only cultivated on a

76. David Freeman, *The Truth About Genetically Modified Crops*, SCI. AM. (Sept. 1, 2013), scientificamerican.com/article/the-truth-about-genetically-modified-food/ [https://perma.cc/GP6N-379W].

77. *See id.*

78. *See id.*

79. *See Introduction to Pesticide Drift*, U.S. ENV'T PROT. AGENCY (Oct. 31, 2022), https://www.epa.gov/reducing-pesticide-drift/introduction-pesticide-drift [https://perma.cc/YH9H-JZ7V].

80. *See* Jennifer Hsaio, *GMOs and Pesticides: Helpful or Harmful*?, HARV. UNIV. (Aug. 10, 2015), https://sitn.hms.harvard.edu/flash/2015/gmos-and-pesticides/ [https://perma.cc/D26W-F8A5].

81. *Id.*

82. *IARC Monographs Volume 112*, *supra* note 31, at 1.

83. *Id.*

84. GILLAM, *supra* note 8, at 171.

small amount of corn acreage in Spain.[85] Despite the lack of GM crops in Europe, Roundup herbicide is still used often on European farmland.[86] This is because glyphosate, the active ingredient in Roundup, is both popular and effective at killing weeds.[87] Glyphosate is "cheap, highly effective, and [was] generally regarded as one of the safest and most environmentally benign herbicides ever discovered."[88]

The pesticides used in the agricultural process can make their way up the food chain to become incorporated in human bloodstreams, even if the individual has never had any direct contact with the pesticide.[89] A particularly well-studied agricultural pesticide is chlorpyrifos, an organophosphate that is in a class of neurotoxins similar to dangerous compounds developed by Nazi Germany before World War II.[90] Heavy use of chlorpyrifos has led to its accumulation in the groundwater of agricultural regions such as California that relied on it for crop production.[91] Chlorpyrifos has been found in the umbilical cords of pregnant women, and prenatal exposure to the chemical has been linked to lower IQ and cognitive function in young children.[92] In a victory for environmentalists and farmworker advocates, California and other states started banning the pesticide in the 2010s, which was then followed by action from the EPA under the Biden Administration in August 2021 that formally revoked all tolerances for chlorpyrifos on food and began the cancellation process.[93] This is a promising start for the Biden

85. *Id.*

86. *Id.*

87. Erik Stokstad, *Why Europe May Ban the Most Popular Weed Killer in the World*, SCI. (June 17, 2016), https://www.science.org/content/article/why-europe-may-ban-most-popular-weed-killer-world [https://perma.cc/DF32-76Y4] (Europe has yet to ban glyphosate, although it is expected to release a decision on the status of glyphosate's European Union registration by December 2022.).

88. *Id.*

89. *See* Aziz Aris & Samuel LeBlanc, *Maternal and Fetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec, Canada*, 31(4) REPROD. TOXICOLOGY 528, 532 (2011).

90. *See* Brian Melley, *California to Ban Pesticide Said to Harm Child Development*, PBS (May 8, 2019, 4:36 PM), https://www.pbs.org/newshour/nation/california-to-ban-pesticide-said-to-harm-child-development [https://perma.cc/9TB8-8YGC].

91. *See id.*

92. Sarah Yang, *Prenatal Exposure Tied to Lower IQ in Children*, UNIV. CAL. BERKELEY RSCH. (Apr. 20, 2011), https://vcresearch.berkeley.edu/news/prenatal-pesticide-exposure-tied-lower-iq-children [https://perma.cc/REY6-MDKG].

93. *EPA Takes Action to Address Risk from Chlorpyrifos and Protect Children's Health*, U.S. ENV'T PROT. AGENCY (Aug. 18, 2021), https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health [https://perma.cc/BWP7-FM4S] [hereinafter *EPA Takes Action to Address Risk from Chlorpyrifos*].

Administration to take action on cancellation of additional pesticides, but decades of inaction suggest that one should be cautiously optimistic at best, as there will need to be further changes to the regulatory enforcement scheme for the United States to adequately protect agricultural workers, consumers, and the food supply chain from harmful pesticides.

Another point of concern for pesticide use regards the humans whom they harm; the people most often poisoned by pesticide use are farmworkers, who are disproportionately Hispanic and low-income.[94] This disproportionate exposure raises environmental justice issues in addition to human health concerns.[95] In conjunction with the health of farmworkers, the needs of the farmers must also be taken into account. Many farmers like using the Roundup products because they are extremely effective at killing weeds without harming the crops—when farmers use patented "Roundup Ready" seeds—and the herbicide reduces labor costs by reducing the amount of tillage farmers must conduct in their fields.[96] Thus, there are many delicate factors at play—economics, health, safety, and a critical societal component: the food supply.

III. PRODUCTS LIABILITY AND THE MONSANTO CASES

In each of the *Johnson, Pilliard,* and *Hardeman* cases, the jury verdict was clear: glyphosate-based herbicide Roundup and RangerPro were sufficiently linked to the plaintiffs' development of non-Hodgkin's lymphoma for the jury to find Monsanto liable and award large amounts of compensatory and punitive damages.[97] This finding was held under three different theories of product liability

94. *See generally* Joan D. Flocks, *The Environmental and Social Injustice of Farmworker Pesticide Exposure*, 19 GEO. J. ON POVERTY L. & POL'Y 255 (2012) (examining the social, economic and political factors that have limited farmworker success in addressing harms from their occupational exposure to pesticides). While beyond the scope of this Essay, there is a strong body of work on the harms caused to farmworkers from pesticides. *See, e.g.*, 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 (2004); *see also* Shannon Adair Tool, *Farmworkers and FIFRA: Laboring Under the Cloud*, 31 SW. U. L. REV. 93 (2001).

95. *See* Flocks, *supra* note 94, at 256.

96. ABC News In-Depth, *The Secret Tactics Monsanto Used to Protect Roundup, Its Star Product*, YOUTUBE, at 12:05 (Oct. 9, 2018), https://www.youtube.com/watch?v=JszHrMZ7dx4&list=WL&index=4&t=1305s&ab_channel=ABCNewsIn-depth [https://perma.cc/L6YA-JVAX].

97. *See* Hardeman v. Monsanto Co., 997 F.3d 941, 950 (9th Cir. 2021); Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 114–16 (Ct. App. 2020); Pilliod v. Monsanto Co., 282 Cal. Rptr. 3d. 679, 679–89 (Ct. App. 2021).

(strict liability for failure to warn, strict liability for defective design, and negligent failure to warn and the consumer expectations test).[98] While these victories for individual plaintiffs are important, protracted litigation for every person harmed by a pesticide is not only impractical but virtually impossible. The plaintiff has the burden of establishing causation between the pesticide and the injury, and even if the plaintiff does have the ongoing and systematic exposure to the pesticide needed to establish the causation, many would-be plaintiffs are farm workers, who are disproportionately low-income and potentially undocumented, making it unlikely that they would bring a claim for recovery.[99]

When pesticides cause harm to human health, plaintiffs can rely on common law strict product liability theory that pesticides are defective products. This can be done by using either the consumer expectations test or the risk-utility test.[100] The consumer expectations test provides that a defendant is strictly liable for products it produces that pose more risk than a reasonable consumer would expect.[101] The risk utility test holds a defendant liable when "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe."[102] The plaintiffs in the *Monsanto* cases relied on these theories when bringing suit against Monsanto, alleging that exposure to glyphosate-based Roundup herbicide caused cancer, specifically non-Hodgkin's lymphoma.[103] To date, there have been approximately 124,000 lawsuits brought against Roundup, of which 96,000 have been settled by Bayer.[104] Below is an examination of just three of these suits, all of which went to a jury that reached a verdict for the plaintiff(s). Promisingly, in response to the Roundup litigation, Bayer has announced that it will change the formula for its Roundup residential

98. *See* Hardeman, 997 F.3d at 955–56; Johnson, 266 Cal. Rptr. 3d at 117; Pilliod, 282 Cal. Rptr. 3d. at 697.

99. Flocks, *supra* note 94, at 255.

100. *See* George S. Smith & Barbara Rasco, *The Dose Makes the Poison: Are Pesticides Defective Products?*, 8 DRAKE J. AGRIC. L. 653, 665 (2003).

101. RESTATEMENT (SECOND) OF TORTS § 402(A) (AM. L. INST. 1965); *see also* Clayton J. Masterman & W. Kip Viscusi, *The Specific Consumer Expectations Test for Product Defects*, 95 INDIANA L. J. 183, 185 (2020).

102. Evans v. Lorillard Tobacco Co., 990 N.E.2d 997, 1010 (Mass. 2013) (quoting RESTATEMENT (THIRD) TORTS: PROD. LIAB. § 2(b) (AM. LAW INST. 1998)); *see also* Masterman & Viscusi, *supra* note at 101.

103. *See infra* Section III, subsections A–C.

104. *Outcomes of Recent Roundup Lawsuits*, THE LEGAL EXAM'R (Dec. 20, 2021), https://www.legalexaminer.com/environment/roundup-lawsuits/outcomes-of-recent-roundup-lawsuits/#:~:text=There%20have%20been%20more%20than, settle%20many%20of%20these%20claims [https://perma.cc/R4KP-YKDV].

products to remove glyphosate, reiterating that the change was only because of the litigation and "not because of any safety concerns."[105]

A. Johnson v. Monsanto Company

The first of these cases was *Johnson v. Monsanto Company*, brought by DeWayne Johnson, the school groundskeeper who developed non-Hodgkin's lymphoma after exposure to Roundup and its stronger, professional counterpart RangerPro, at his job.[106] In *Johnson*, the jury found Monsanto liable for a defective design in its Roundup products, strict liability for failure to warn of the dangerous risks of exposure to Roundup, and that it was negligent for failing to warn of these risks.[107] While Johnson was working, an accident occurred where a hose became lodged in a sidewalk, causing RangerPro to begin spraying uncontrollably, where it penetrated Johnson's protective suit and got onto his skin, including his face.[108] He attempted to clean himself immediately in a sink at the school, and soon thereafter developed a severe rash on his skin, and eventually he was diagnosed with non-Hodgkin's lymphoma.[109] The only warning on the Roundup and RangerPro product label stipulated that the chemicals were an eye irritant—nothing suggested that they could cause cancer, even after the IARC determined that glyphosate was probably carcinogenic to humans.[110] He sued Monsanto, alleging the Roundup products were defectively designed, strict liability applied to the company for failure to warn, and there was a negligent failure to warn.[111] Excerpts of the jury instructions on failure to warn are illustrative of what the court looked to when determining Monsanto's liability (all questions were answered by the jury in the affirmative):[112]

Claim of Strict Liability—Failure to Warn:

- Did Roundup Pro or Ranger Pro have potential risks that were known or knowable in light of the scientific knowledge that was generally accepted in the scientific community at the time of their manufacture, distribution or sale?
- Did the potential risks of Roundup Pro or Ranger Pro present a substantial

105. Purbita Saha, *Roundup is Finally Going to be Made Without Glyphosate in the US*, POPULAR SCI. (Aug. 9, 2021, 4:00 PM), https://www.popsci.com/health/bayer-lawsuit-phase-out-roundup/ [https://perma.cc/SFD8-UMPK].

106. Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111, 115–16 (Cal. Ct. App. 2020).

107. *Id.*

108. *Id.* at 116.

109. *Id.* at 115–16.

110. *Id.* at 116; *IARC Monographs Volume 112*, *supra* note 31, at 1.

111. Johnson, 266 Cal. Rptr. 3d at 120.

112. Johnson v. Monsanto Co., No. CGC16550218, 2018 WL 4261442, at *1–2 (Cal. Super. Aug. 23, 2018).

danger to persons using or misusing Roundup Pro or Ranger Pro in an intended or reasonably foreseeable way?
- Did Monsanto fail to adequately warn of the potential risks?
- Was the lack of sufficient warnings a substantial factor in causing harm to Mr. Johnson?

Claim of Negligent Failure to Warn:
- Did Monsanto know or should it reasonably have known that Roundup Pro or Ranger Pro were dangerous or were likely to be dangerous when used or misused in a reasonably foreseeable manner?
- Did Monsanto fail to adequately warn of the danger or instruct on the safe use of Roundup Pro or Ranger Pro?

The jury instructions demonstrate the high burden of proof a plaintiff must meet in order to recover for an injury caused by a pesticide. The severity of Mr. Johnson's accident and his frequent use of Roundup in his job made it possible for him to prove that Roundup was the but-for cause of his injuries—most plaintiffs do not have such a straightforward case.[113] The jury returned a verdict for Johnson, awarding $39 million in compensatory damages and $250 million in punitive damages.[114] On appeal, the awarded damages were reduced to $4 million and $10.2 million, respectively.[115]

B. Hardeman v. Monsanto Company

The second of the cases is *Hardeman v. Monsanto Company*, in which Edwin Hardeman was awarded $5.2 million in compensatory damages and $75 million in punitive damages by a jury in the United States District Court for the Northern District of California for his failure-to-warn claims on Roundup's labeling.[116] Hardeman alleged that long-term exposure to glyphosate through Roundup caused his non-Hodgkin's lymphoma.[117] This was the first case to go to trial in a consolidated multidistrict litigation proceeding of similar claims against Monsanto, which the court acknowledged as a "bellwether trial with potentially thousands of federal cases to follow."[118] The District Court issued a "substantial factor" jury instruction,

113. *See* Johnson, 266 Cal. Rptr. 3d at 115–116.

114. Johnson, 2018 WL 4261442, at *2.

115. Tina Bellon, *Monsanto Ordered to Pay $239 Million in World's First Roundup Cancer Trial*, REUTERS (Aug. 10, 2018, 5:20 PM), https://www.reuters.com/article/us-monsanto-cancer-lawsuit/monsanto-ordered-to-pay-289-million-in-worlds-first-roundup-cancer-trial-idUSKBN1KV2HB [https://perma.cc/4W6J-KUYH]; Johnson, 266 Cal. Rptr. 3d at 136.

116. Hardeman v. Monsanto Co., 997 F.3d 941, 954 (9th Cir. 2021).

117. *Id.* at 952.

118. *Id.* at 976.

instructing the jury that it must find that glyphosate exposure was a but-for cause of Hardeman's cancer or one of two or more factors that could have caused his cancer.[119] The jury returned a verdict that glyphosate exposure was a substantial factor in the cause of Hardeman's non-Hodgkin's lymphoma, and it found that Monsanto's failure to warn of Roundup's cancer risk entitled Hardeman to punitive damages.[120] The substantial factor test used in *Hardeman* demonstrates Roundup's dangerous qualities, as it was found to be a key cause of Mr. Hardeman's cancer.[121] Extrapolating from this substantiated causation, *Hardeman* is a powerful model of how state tort law can provide for stronger consumer protection than the EPA's current regulatory model, which suggests a major gap in the EPA's threshold for approving chemicals like Roundup for human use.[122]

On appeal, Monsanto argued that Hardeman's claims were preempted by FIFRA's misbranding provision, which requires a pesticide label "contain a warning or caution statement which may be necessary and if complied with . . . is adequate to protect health and the environment."[123] The California common law requires that a manufacturer warn of "known or knowable" health risks or risks that a "reasonably prudent manufacturer would have known and warned about."[124] The Ninth Circuit held that Hardeman's claims were not preempted by FIFRA because FIFRA's requirement of a warning necessary and adequate to protect health is broader than California's requirement under negligence, and is consistent with California's warning requirement under strict liability; therefore, "Hardeman's failure-to-warn claims effectively enforce FIFRA's requirement against misbranding and are thus not expressly preempted."[125] Additionally, the Court found that carcinogenic risk was knowable at the time of Hardeman's exposure because various independent scientific studies linking glyphosate to cancer were released by 2012 (the last time of Hardeman's Roundup exposure).[126] The District Court reduced the $75 million in punitive damages to $20 million, which the Ninth Circuit upheld on appeal.[127]

119. *Id.* at 954.

120. *Id.*

121. *See id.*

122. *See generally id.*

123. *Id.* at 954; 7 U.S.C. § 136.

124. Hardeman v. Monsanto Co., 997 F.3d 941, 955 (9th Cir. 2021) (citing Conte v. Wyeth, Inc., 85 Cal. Rptr. 3d. 299, 310 (Cal. Ct. App. 2008)).

125. *Id.*

126. *Id.* at 970.

127. *Id.*

C. Pilliod v. Monsanto Company

The third in this suite of *Monsanto* cases is *Pilliod v. Monsanto Company*, in which husband and wife plaintiffs both developed non-Hodgkin's lymphoma and brought action against Monsanto under the consumer expectations test for failure to warn and design defects after using Roundup on their property.[128] The Pilliods based their claims on Monsanto's marketing, labeling, and promotion of Roundup, which included no warning about wearing protective gear when using the product nor any warning of cancer risk.[129] The Pilliods testified that Roundup television commercials depicted users spraying Roundup while wearing shorts and a t-shirt, and they wore similar attire while spraying gallons of the chemical on their yard every week because they believed it was safe due to the lack of a warning label and the depictions in the commercials.[130] *Pilliod* also notes that the surfactant[131] in United States Roundup is polyethoxylated tallow amine (POEA), which is banned in Europe, where the use of a less toxic surfactant is permitted.[132] POEA is more dangerous than its European counterpart because it "enhances the absorption of the herbicide through the skin," which makes United States Roundup more dangerous than the Roundup in European markets.[133]

The jury returned a verdict with damages over $2 billion between the couple, which were reduced by the court.[134] The verdict was affirmed on appeal.[135] The court wrote that the consumer expectations test for a design defect is appropriate where "the everyday experience of the product's users permits a conclusion that the product's design violated minimum safety assumptions, and is thus defective regardless of expert opinion about the merits of the design"—*i.e.* Roundup is an inherently dangerous product that violated a consumer's reasonable minimum safety assumptions.[136]

The claims have taken a recent turn, as Bayer acquired Monsanto for $63 billion in June 2018, inheriting the many legal claims made against Roundup.[137]

128. *See* Pilliod v. Monsanto Co., 282 Cal. Rptr. 3d. 679, 688 (Cal. Ct. App. 2021).

129. *Id.* at 693.

130. *Id.* at 692.

131. A surfactant is a compound that enhances the absorption of the chemical through the waxy surface of the plant.

132. Pilliod, 282 Cal. Rptr. 3d. at 690–91.

133. *Id.*

134. *Id.* at 727.

135. *Id.*

136. *Id.* at 702 (citing Soule v. General Motors Corp., 882 P.2d 298 (Cal. 1994)).

137. 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 [https://perma.cc/5YKL-HAMH].

After the *Johnson, Hardeman,* and *Pilliod* victories in court, each for millions in awarded damages, Bayer moved to settle the outstanding claims in an estimated 95,000 cases and also included $1.25 billion for "potential future claims from Roundup customers who may develop" non-Hodgkin's lymphoma cancer.[138] In total, Bayer has factored in $16.1 billion for future claims and settlements from allegations that Roundup causes cancer, all while maintaining the public position that Roundup is safe for human use.[139] The Bayer acquisition of Monsanto has been noted as "one of the worst corporate deals in recent memory" by the Wall Street Journal, due to the accompanying lawsuits.[140]

Despite the jury findings that Roundup is inherently a dangerous and defective product that has caused cancer, the EPA also continues to maintain that glyphosate-based herbicides are safe for human use.[141] The EPA explicitly disagrees with the IARC's determination that glyphosate is probably carcinogenic to humans, noting in a January 2020 interim decision that glyphosate is "not likely to be carcinogenic to humans" and claiming to have reviewed more data and studies than the IARC did to reach this determination.[142] The European Union's glyphosate registration was set to remain active until Dec. 15, 2022,[143] however the registration's validity has been extended while an EU peer review process of glyphosate takes place (results expected July 2023) .[144]

Johnson, *Pilliod*, and *Hardeman* are three landmark cases that resulted in

138. *Id.*

139. *Bayer to Book Extra $4.5 Bln Provision for Roundup Litigation*, REUTERS (July 29, 2021, 6:31 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/bayer-posts-additional-45-billion-provision-roundup-litigation-2021-07-29/ [https://perma.cc/A29L-CVYJ].

140. Ruth Bender, *How Bayer-Monsanto Became One of the Worst Corporate Deals—in 12 Charts*, WALL ST. J. (Aug. 28, 2019, 10:12 AM), https://www.wsj.com/articles/how-bayer-monsanto-became-one-of-the-worst-corporate-dealsin-12-charts-11567001577 [https://perma.cc/3GN8-22DE].

141. *Glyphosate*, *supra* note 31.

142. *Id.*

143. *Glyphosate*, EUR. COMM'N (Oct. 21, 2022, 6:19 PM), https://ec.europa.eu/food/plants/pesticides/approval-active-substances/renewal-approval/glyphosate_en [https://perma.cc/ZPN4-RXKX].

144. *See Glyphosate: Why the EU Needs to Ban the Popular Weedkiller to Protect Health*, HEAL: HEALTH & ENV'T ALL. (Oct. 21, 2022, 6:22 PM), https://www.env-health.org/campaigns/glyphosate-why-the-eu-needs-to-protect-health-ban-the-popular-weedkiller/ [https://perma.cc/5ZB5-G6Q9].

victory for the plaintiffs.[145] However, that victory is bittersweet, as the plaintiff's monetary damages came at the cost of their personal health and is the result of cancer that will eventually take their lives. It is important to examine the *Monsanto* cases because these plaintiffs were able to get some measure of justice, but many thousands more people who are harmed by Roundup and other pesticides will not have that same access to justice. Other plaintiffs do not have as strong of a causal connection between their pesticide exposure and their illness, other plaintiffs might be undocumented agricultural workers, and still others do not have the resources to bring a lawsuit in the first place. This is why the EPA must utilize its regulatory authority to cancel or revoke pesticide registrations when strong evidence emerges that a pesticide is unsafe for human use, rather than leaving plaintiffs to protracted litigation based on state tort law. The EPA has the power to protect millions of people in the United States from suffering pesticide-related harm in the first place, while state tort law claims have so far provided a measure of retroactive justice to only a handful of plaintiffs.

IV. ANALYSIS: HOW THE EPA CAN USE ITS REGULATORY AUTHORITY TO SERVE AS A SAFETY NET FOR AMERICAN FARMERS AND CONSUMERS

As the *Monsanto* case law demonstrates, serious harms occur when dangerous pesticides remain on the market. Part IV will examine how the EPA can better use its powerful regulatory authority to protect both consumers and farmers, arguing that the EPA must shift from its current permissive model that favors industry, and towards the European Union's more rigorous approval model. Specifically, the EPA can exercise its authority to cancel existing pesticide registrations once it becomes apparent that a pesticide is unreasonably dangerous to humans or the environment.[146] Additionally, many pesticides are on the market under conditional registrations, without inquiring further into the requested data.[147] These conditionally registered pesticides should be evaluated and rigorously tested for safety and if there is not sufficient data to support their safety, they should be removed from the market.[148] Finally, the European Union REACH framework serves as an example of strong pesticide safety legislation, components of which can be adopted in the United States to serve as a safety net for farmers, farmworkers, and

145. *See generally* Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111 (Cal. Ct. App. 2020); Pilliod v. Monsanto Co., 282 Cal. Rptr. 3d 679 (Cal. Ct. App. 2021); Hardeman v. Monsanto Co., 997 F.3d 941 (9th Cir. 2021).

146. Donley, *supra* note 15, at 2.

147. JENNIFER SASS & MAE WU, SUPERFICIAL SAFEGUARDS: MOST PESTICIDES ARE APPROVED BY A FLAWED EPA PROCESS, NRDC 2 (2013), https://www.nrdc.org/sites/default/files/flawed-epa-approval-process-IB.pdf [https://perma.cc/ZX4T-YP2U].

148. *See id.*

consumers.[149]

A. Pesticide Cancellations under FIFRA

The EPA permissive model has resulted in a two-decade decline in the number of non-voluntary pesticide cancellations in the United States.[150] This industry-facing permissive approach has meant that most of the recent pesticide phase-outs have been the result of voluntary industry cancellations: only five agricultural pesticides were non-voluntarily cancelled in the United States from 2000-2018.[151] While non-voluntary cancellations and bans dominate the European Union, Brazil, and China, the United States EPA heavily relies on industry to initiate voluntary pesticide cancellations.[152] The involuntary pesticide cancellation requires "considerable agency resources and multiple steps designed, above all, to ensure that the agricultural sector will not experience undue hardship."[153] Throughout the process (including on appeal) the pesticide approval remains in place and it can still be used by the agricultural industry.[154]

Though the EPA has the regulatory power to force the cancelation of pesticides, in practice the EPA has taken years, even decades, to regulate pesticides—even after harm has been scientifically established.[155] The August 2021 decision to revoke all tolerances for chlorpyrifos provides an illustrative example of how the EPA can involuntarily cancel a pesticide, albeit as the culmination of more than a decade of legal proceedings.[156] In 2007, the Pesticide Action Network North America and the Natural Resources Defense Council (NRDC) filed a petition asking the EPA to revoke all tolerances for chlorpyrifos.[157] For ten years, the EPA declined to act on the petition with a final action, until 2017 when the Trump Administration denied the 2007 petition, and then in 2019, it denied all objections to that petition.[158] During the decade of declining to reach a decision on the 2007 Petition, the EPA gathered evidence on the dangerous effects of chlorpyrifos and repeatedly determined that it could not conclude, to the statutorily required level

149. *See generally* Regulation (EC) No 1907/2006, *supra* note 38.
150. Donley, *supra* note 15, at 2, 5.
151. *Id.* at 6.
152. *Id.* at 7.
153. *Id.* at 8.
154. *Id.*
155. *See EPA Takes Action to Address Risk from Chlorpyrifos*, *supra* note 93.
156. *See id.*
157. League of United Latin Am. Citizens v. Regan, 996 F.3d 673, 677 (9th Cir. 2021).
158. *Id.* at 678.

of certainty, that the established tolerance levels caused no harm.[159] The Ninth Circuit held that the EPA had a duty under the FFDCA to not delay issuing a final rule any further, and ordered the EPA "within 60 days after the issuance of the mandate either to modify chlorpyrifos tolerances and concomitantly publish a finding that the modified tolerances are safe, including for infants and children – or to revoke all chlorpyrifos tolerances."[160] This Court order spurred the EPA to revoke all tolerances for chlorpyrifos, and to issue a Notice of Intent to Cancel under FIFRA to cancel the registered food uses of chlorpyrifos.[161] Essentially, the cancellation of *one* pesticide, with extensive evidence of its harmful effects, spanned four Presidential Administrations (Bush, Obama, Trump, Biden) and still required a court order for the EPA to exercise its regulatory authority.[162]

In the face of regulatory inaction by the EPA, some states have enacted greater restrictions on pesticides than the EPA. These regulations, while a step in the right direction, are insufficient to tackle a nationwide issue because they are piecemeal and agriculture frequently flows across state borders. States often regulate the 13 pesticides that are still in use in the United States that are banned or being phased out in at least two out of the other three largest agricultural economies.[163] California "has imposed greater restrictions on chloropicrin, EPTC and norflurazon, including larger buffer zones, reduced acreage that can be treated, additional protective equipment and mitigations to prevent groundwater contamination."[164] New York and Washington state have also enacted additional restrictions on phorate and paraquat, respectively.[165] State action imposing greater regulations on pesticides can spur federal action, or at least bolster it, as evidenced by EPA's citation of California, Hawaii, New York, Maryland, and Oregon's actions restricting chlorpyrifos in its press release announcing the decision to revoke all chlorpyrifos tolerances in August 2021.[166] The press release also noted that Canada and the European Union greatly restrict the use of chlorpyrifos.[167]

159. *Id.*

160. *Id.*

161. *EPA Takes Action to Address Risk from Chlorpyrifos*, *supra* note 93.

162. *See generally id.*; *The Presidents Timeline*, THE WHITE HOUSE HIST. ASS'N (Oct. 21, 2022, 7:47 PM), https://www.whitehousehistory.org/the-presidents-timeline [https://perma.cc/6Z36-3ZN3].

163. Donley, *supra* note 15, at 4.

164. *Id.* at 7.

165. *Id.*

166. *EPA Takes Action to Address Risk from Chlorpyrifos*, *supra* note 93.

167. *Id.*

B. Conditional Registrations and Inadequate Testing

The EPA has ignored many of its pesticide safety and testing responsibilities through the overuse of conditional registrations and overreliance on faulty scientific studies conducted by the pesticide manufacturers.[168] One study by the NRDC revealed that many pesticides are approved under an EPA "conditional registration," in which a pesticide can get approval despite missing testing data required by the EPA.[169] Conditional registration is meant to be a stopgap measure to allow new active ingredients in pesticides to enter the market when it would be in the public interest and there has not been enough time to industry test the new chemical; it also provides that industry must provide testing data to the EPA within an "unspecified period of time."[170] However, rather than serving as an emergency and rare measure, an NRDC analysis confirmed by the EPA revealed that in August 2010, about 65 percent of the 16,000 active pesticide products on the market had been approved by conditional registration and permitted to stay on the market.[171] The EPA's own analysis found that the agency had misused the conditional registration provision 98 percent of the time between 2004 and 2010.[172]

In addition to the misused conditional registration process allowing pesticides onto the market without proper testing, the FDA does not always conduct uniform analyses when testing for pesticide residues on food, as evidenced by its omission of oats and wheat products in a 2018 glyphosate residue test, despite the fact that glyphosate is known to accumulate in oat and wheat products.[173] Pesticide residues on food are so pervasive that environmental group EWG compiles an annual Shopper's Guide to Pesticides in Produce, warning consumers about pesticide residues on various fruits and vegetables.[174]

168. SASS & WU, *supra* note 147, at 4.

169. *Id.* at 2.

170. *See id.*

171. *Id.*

172. *Id.*

173. *FDA Glyphosate Testing Conspicuously Skips Oats, Wheat Products*, ENV'T WORKING GRP. (Oct. 2, 2018), https://www.ewg.org/news-insights/news-release/fda-glyphosate-testing-conspicuously-skips-oats-wheat-products [https://perma.cc/9LV8-KXMJ]; *see* SASS & WU, *supra* note 146, at 1.

174. *See generally* EWG's Science Team, *EWG's 2022 Shopper's Guide to Pesticides in Produce*, EWG (Apr. 7, 2022), https://www.ewg.org/foodnews/summary.php [https://perma.cc/V2FJ-Z7AW].

C. European Union REACH and the United States

The European Union REACH framework[175] could serve as a model for developing more stringent pesticide regulation standards in the United States. REACH uses the concept of "one substance, one registration" and it does not treat already-approved existing chemicals leniently.[176] This contrasts with the United States approach, which "focuses regulatory efforts primarily on new chemicals and 'grandfathers' in existing chemicals, unless EPA takes affirmative action to compel the submission of additional safety data or restricts or prohibits the sale of existing substances for specific uses."[177]

There were some promising results from the REACH implementation in the period evaluated after it was first enacted, such as corporate training efforts on REACH raising "general awareness of chemical hazards, specifically the challenges posed by carcinogens, mutagens, reproductive toxins, and persistent and bioaccumulative substances."[178] Heightened corporate awareness of the risks of the chemicals could help avoid tragic situations like Johnson's, where he was repeatedly assured by Monsanto representatives that the product was not carcinogenic and where the company failed to follow-up with Johnson, despite its promises to do so.[179] Additionally, heightened corporate awareness of the risks of substances removes plausible deniability on the part of the corporations in claiming that it did not know its substances were harmful, or claiming that its products are definitely *not* harmful, as Monsanto repeatedly claimed in the aforementioned cases (a position that Bayer maintains today).[180] And on a more hopeful note, the corporations have the power to change their products (in the face of EPA inaction), removing the veil of ignorance from the corporations, can actually enable the company to produce a safer product for consumers, as Bayer is doing with its revamped Roundup formula that removes glyphosate.[181]

The restriction powers created under REACH have been described as a "safety net" for "substances that pose an unacceptable risk to human health or the environment but that cannot be addressed effectively or promptly through the other

175. *See generally* Regulation (EC) No 1907/2006, *supra* note 38.

176. *See* Abelkop et al., *supra* note 35, at 11045.

177. *Id*.

178. *Id.* at 11047.

179. Johnson v. Monsanto Company, 266 Cal. Rptr. 3d 111, 116 (Cal. Ct. App. 2020).

180. *See id.*; Pilliod v. Monsanto Co., 282 Cal. Rptr. 3d 679, 696 (Cal. Ct. App. 2021); Hardeman v. Monsanto Co., 997 F.3d 941, 954 (9th Cir. 2021); *Answers to Common Questions about Glyphosate*, BAYER (Oct. 21, 2022, 6:02 PM), https://www.bayer.com/en/glyphosate/is-glyphosate-safe [https://perma.cc/9ERH-9YJ7].

181. Saha, *supra* note 104.

provisions of REACH or through procedures in EU legislation."[182] REACH is specific and targeted by focusing more on concerning uses of chemicals, rather than on the substances themselves—this means that chemicals can be approved for certain uses, while restricting more "worrisome" uses.[183] If the current EPA regulatory processes are a "safety net," it is a safety net with some fairly large holes through which harmful chemicals can pass with relative ease to gain regulatory approval, even if the required data is not gathered and provided to the EPA.[184]

A relevant endorsement for the efficacy of REACH is that the United Kingdom chose to keep key provisions of REACH even after it exited the European Union, calling it United Kingdom REACH.[185] Notably, United Kingdom REACH, just like European Union REACH, places the burden of proof on companies, which are required to "identify and manage the risks presented by substances [they] manufacture and place on the market in [Great Britan]. [They] must be able to demonstrate how the substance can be used safely and [they] must communicate the risk management measures to the users."[186]

V. RECOMMENDATIONS

While the plaintiff victories in the *Monsant*o cases examined in this Essay are encouraging, those individuals are still suffering from devastating health outcomes. Plaintiffs should continue to bring cases against chemical manufacturers who have demonstrably caused harm, but not every plaintiff will be able to bring suit (nor will every plaintiff prevail, for that matter). Lack of access to legal services and a person's immigration status can be just two of many factors that might prevent a potential plaintiff from pursuing legal remedies for harms caused by pesticides.[187]

Similarly, state and local-level action to regulate pesticides are positive steps,[188] but non-federal laws can run into federal preemption problems and strong resistance from the pesticide manufacturers. This is a nationwide problem that requires action at the national level. Continuing the status quo is not acceptable for

182. Abelkop, *supra* note 35, at 11061.

183. *See id.* at 11043, 11061.

184. *See* SASS & WU, *supra* note 147, at 2.

185. *UK REACH Explained*, HSE (Oct. 21, 2022, 6:23 PM), https://www.hse.gov.uk/reach/whatisreach.htm [https://perma.cc/726W-FW9P].

186. *Id.*

187. *See* Flocks, *supra* note 94, 255–56.

188. *See generally Which Countries and U.S. States are Banning Roundup?*, CASLON L. FIRM (Feb. 10, 2021), https://www.carlsonattorneys.com/news-and-update/banning-roundup [https://perma.cc/XB33-MVY6].

Americans' health nor the agricultural industry. The United States must look to its own states, European Union REACH, and our existing regulatory bodies to forge a new path of pesticide safety and compliance.

A. FIFRA, REACH, and Scientific Integrity

FIFRA should be amended to capture the most effective parts of European Union REACH, particularly shifting more of the burden to industry to prove that pesticides are safe, rather than putting the burden on the EPA to prove that pesticides are harmful to human health. A particularly effective provision of REACH that could be adopted in the United States is REACH Article 5: "No data, no market."[189] Article 5 stipulates that substances "shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required."[190] It references a number of other Articles of REACH with requirements that are too technical for the scope of this Essay, but the core principle behind Article 5 should be adopted within the United States.[191] To put it simply, if there is not enough data on a pesticide, it should *not* go on the market. This could stem the tide of conditional registrations on pesticides in the market and prevent new products from coming to the market under conditional registrations that lack sufficient data.

One key point about this recommendation is that the safety data submitted by industry *must* be conducted by independent scientists and, ideally, peer-reviewed.[192] This is because of the pesticide industry's demonstrated track record of influencing regulatory decisions by commissioning their own studies that contradict independent scientific review, such as the studies funded by industry in the wake of the 2015 IARC classification of glyphosate as a carcinogen.[193] Those industry-funded studies claimed to review more data than that which was reviewed by the IARC team of independent scientists, but all of the industry studies rather conveniently concluded that glyphosate was completely safe for use on agricultural crops—it really does not matter if those studies looked at "more" data if that data was cumulative junk science done by industry scientists.[194] The scientific integrity of EPA (and other United States Government) scientists should be protected and shielded from industry to ensure that studies yield fruitful results, which is currently not the case at the EPA, according to a study by nonprofit group Union of

189. *See* Regulation (EC) No 1907/2006, *supra* note 38, at (L 396/62).
190. *Id.*
191. *See id.*
192. *See* GILLAM, *supra* note 8, at 216–18, 221.
193. *Id.* at 227.
194. *Id.* at 16.

Concerned Scientists (UCS).[195] The UCS conducted a survey of over 3,400 United States Government scientists, in which hundreds of the surveyed scientists reported that they had "witnessed EPA officials misrepresenting scientific findings" and that they had been "directed to 'inappropriately exclude or alter technical information' in an EPA document."[196] If Americans are to trust the science that comes out of government regulatory agencies, the scientists must be free from external influence and misdirection.

Finally, EPA should implement more rigorous standards in its test requirements of pesticide residues in foods and disallow results that exclude key foods like oats and grains when a pesticide is known to accumulate in those heavily consumed foods. The official European Union European Commission for Food Safety website declares: "Every European citizen has the right to know how the food they eat is produced, processed, packaged, labeled and sold."[197] Americans should enjoy that same right to know what is in their food. The United States should take similar steps to gather data so that American citizens and residents can fully understand what residues might be on the food that they put into their bodies.

B. Statutory Interpretation of the FIFRA Misbranding Provision

The FIFRA misbranding provision, coupled with state action, provides a workable solution to pesticide labeling issues and pesticide manufacturer liability, as demonstrated in *Hardeman*.[198] The Ninth Circuit determined that a pesticide manufacturer can violate the misbranding provision of FIFRA if it does not seek approval from the EPA to amend a label that does not contain all "necessary warnings or cautionary statements."[199] Using the "necessary warnings" standard, California has read a requirement into FIFRA that required companies to update their labels as more information became available.[200] In the case of glyphosate, that included updating the label under Proposition 65 to include a cancer warning on glyphosate-based products after the IARC classified glyphosate as a probable

195. *Id.* at 220–21.

196. *Id.* at 221.

197. *Food Safety*, *supra* note 68.

198. *See* Hardeman v. Monsanto Co., 997 F.3d 941, 950–51, 970 (9th Cir. 2021).

199. *Id.* at 951 (citing Bates v. Dow Agrosciences, LLC, 544 U.S. 431, 438 (2005)).

200. *Id.* at 960 ("Considering the responsibility FIFRA places on manufacturers to update pesticide labels and that EPA has allowed pesticide manufacturers to add cancer warnings to labels throughout the notification process without prior approval, it is not *impossible* for Monsanto to add a cancer warning to Roundup's label.") (citation omitted).

carcinogen in 2017.[201]

Just like California requires chemical manufacturers to update labels as more information becomes available to sell products in the state of California, this could be done at the federal level through statutory interpretation by the courts. Essentially, other federal courts can utilize the Ninth Circuit's interpretation of California's misbranding interpretation and require that labels be updated when significant new studies and classifications are released by entities like the IARC.

C. Expanding the Lautenberg Chemical Safety Act to FIFRA

The Lautenberg Chemical Safety Act amended TSCA to require that EPA evaluate existing chemicals with clear and enforceable deadlines.[202] However, pesticides are excluded from TSCA, which means that they are not subject to review under the Lautenberg Amendments.[203] Expanding the Lautenberg Amendments to FIFRA would require the EPA to conduct a thorough analysis of all registered pesticides, and the expansion could specify that EPA conduct a *de novo* review of all registered pesticides that have been approved through conditional approvals. Conditional approvals are meant to be temporary stopgap measures until the relevant data can be submitted for review, but often conditional approvals simply allow a pesticide to stay on the market even if the data is not submitted in a timely manner.[204]

The Lautenberg Amendments would require that EPA pause or cancel the conditional pesticide registrations if the review concludes that the pesticide is unreasonably harmful to people's health or the environment.[205] Crucially, expanding these amendments to FIFRA would provide a mandatory impetus for EPA to conduct this *de novo* review of the conditionally registered pesticides currently on the United States market.[206] This would be an important step away from the current status quo of conditional approvals that sometimes remain in place for years, by requiring that the EPA conduct a thorough review of the currently registered pesticides.[207] To further bolster this review, more stringent scientific study requirements could be implemented so that the required studies are not merely industry-

201. *Glyphosate*, OEHHA (Oct. 21, 2022, 6:05 PM), https://oehha.ca.gov/ proposition-65/chemicals/glyphosate [https://perma.cc/LX42-VG63].

202. Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, § 2625(l)(5), 130 Stat. 448 (2016).

203. 15 U.S.C. § 2602; *see Summary of the Toxic Substances Control Act*, *supra* note 57.

204. GILLAM, *supra* note 8, at 229.

205. *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, § 2613(g)(2)(C)(i).

206. *See generally id.*

207. *See generally id.*

sponsored junk science, and instead are rigorous and peer-reviewed (as discussed in Part V Subpart A above).

D. Agroecology: Agricultural Exceptionalism for the 21st Century

Agroecology is defined as the effort to move toward more traditional and sustainable farming practices and away from the "resource-intensive, fossil-fueled, and pesticide-dependent practices tied to mass production of a few select crops."[208] Working with farmers to move toward a more diverse crop rotation, along with planting cover crops (crops which are different from the cash crops typically planted by farmers) is a key part of agroecology.[209] Cover crops help to replenish the soil and store carbon and are viewed by farmers and agricultural experts as key to combatting climate change while ensuring sustainable food production for the future.[210] Just as American agricultural exceptionalism has been used to funnel federal subsidies into farming since the Great Depression, it is now time to turn to the future and subsidize agroecological practices. Encouragingly, this is beginning to be a policy priority for the federal government, which announced in January 2022 that the USDA's Natural Resources Conservation Service (NRCS) will spend $38 million for farmers in eleven states (Arkansas, California, Colorado, Georgia, Iowa, Michigan, Mississippi, Ohio, Pennsylvania, South Carolina and South Dakota) to plant cover crops.[211] NRCS plans to expand this program to farmers in more states in the coming years, with the overall goal of planting 30 million acres of cover crops in the United States by 2030.[212] Agroecology is an aspirational solution to a serious problem, and it is worth briefly mentioning in this Essay because it is a practice that individual farmers can use in their fields—and that the government can encourage through subsidies and tax breaks to farmers who engage in safer farming with fewer pesticides. Additionally, the government can give tax incentives to farmers who employ technological innovations on their fields, such as devices that can conduct more targeted spraying of fields. One such innovation

208. GILLAM, *supra* note 8, at 243–44.

209. *See* William S. Eubanks II, *A Rotten System: Subsidizing Environmental Degradation and Poor Public Health with Our Nation's Tax Dollars*, 28 STAN. ENV'T L. J. 213, 301 (2009).

210. *See id.* at 301–02.

211. Karl Plume, *U.S. Aims to Double Cover Crop Planting to Address Climate Change*, REUTERS (Jan. 10, 2022, 12:53 PM), https://www.reuters.com/markets/commodities/us-aims-double-cover-crop-planting-address-climate-change-2022-01-10/ [https://perma.cc/R522-KKGE].

212. *Id.*

comes from Blue River Technology, which was acquired by John Deere in 2017.[213] Blue River's "See & Spray" technology uses cameras and artificial intelligence deep learning to spray herbicides only on weeds, which allows farmers to use an average of seventy-seven percent less herbicide on their fields when compared to conventional broadcast spraying.[214]

VI. CONCLUSION

Pesticides and herbicides are everywhere in the United States. They can be found in our food, our products, and even our urine. To chart a sustainable path for the future of our food supply, action must be taken at both the federal and the local level to regulate these dangerous chemicals. The studies used to evaluate pesticides should be peer-reviewed. When a pesticide is proven to be unsafe for human use, its registration should be cancelled. The Lautenberg Amendments should be expanded to pesticides under FIFRA, with a full *de novo* review conducted of all pesticides that are currently registered under conditional registrations.

As the devastating health outcomes of the plaintiffs in the *Monsanto* cases demonstrate, the time to act is now.[215] People are dying, and the EPA can save countless lives by using its regulatory authority to regulate these chemicals with greater attention and oversight.

213. Louisa Burwood-Taylor, *John Deere Acquires 'See & Spray' Robotics Startup Blue River Technology for $305m*, AGFUNDER NEWS (Sept. 6, 2017), https://agfundernews.com/breaking-exclusive-john-deere-acquires-see-spray-robotics-startup-blue-river-technology-305m.html [https://perma.cc/2G8A-6T63].

214. JOHN DEERE, *+Gain Ground with See & Spray™ Select | John Deere*, YOUTUBE, at 1:35–2:15 (Mar. 2, 2021), https://www.youtube.com/watch?v=L0nGUSPDnUU&t=325s [https://perma.cc/3HS8-GR7F].

215. *See generally* Hardeman v. Monsanto Co., 997 F.3d 941 (9th Cir. 2021); Johnson v. Monsanto Co., 266 Cal. Rptr. 3d 111 (Cal. Ct. App. 2020); Pilliod v. Monsanto Co., 282 Cal. Rptr. 3d 679 (Cal. Ct. App. 2021).