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### Longstanding Regulatory Loophole Leaves Minority Pesticide **Applicators Unprotected**

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## LONGSTANDING REGULATORY LOOPHOLE LEAVES MINORITY PESTICIDE APPLICATORS UNPROTECTED

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#### **ABSTRACT**

The evolution of U.S. pesticide regulation has been driven by technological advancements in agriculture and our social desire to protect the environment and people from any consequential unintended harms. Each milestone regulation can be traced back to a triggering event. As a result, today's regulations offer robust protections. Nevertheless, there is one group of people who are still at risk. That is, pesticides applicators. Today, pesticide applicators work in both agricultural and other commercial settings, but historically, they were primarily farm workers. Farming in the U.S. is tied to the sinister institution of slavery, and it is difficult, if not impossible, to view farming without this lens. Because of this history, and the remaining racial prejudices still felt today, it comes as no surprise that farm workers and pesticide applicators were largely excluded when regulatory reforms were enacted. These gaps in the Environmental Protection Agency's (EPA) regulatory enforcement of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) have created unjust health risks to pesticide applicators.

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Nevertheless, another triggering event has occurred. In a recent California case, a Black school groundskeeper was awarded \$289 million on a claim that RoundUp® was mislabeled as safe, despite the herbicide causing the groundskeeper's cancer. Although the verdict has been reduced post-trial to \$78 million, thousands of other plaintiffs have since filed lawsuits alleging that exposure to RoundUp® caused them or their relative cancer. An examination of this case is illustrative of where the regulations have failed pesticide applicators. The critical failing is in the exposure assessments used for pesticide applicators during the EPA's risk assessment. The EPA's methodology for pesticide applicator's risk assessments are outdated, confusing, and do not align even with the USDA's policies. This inferior methodology results in an unacceptable level of error in the risk assessments for pesticide applicators. As a consequence, products can be mislabeled, and applicators, such as the California groundskeeper, are unaware of the need to take precautions.

Under FIFRA, the EPA has the mandate to protect humans and the environment. By not conducting appropriate risk assessments for pesticide applicators, EPA has subjected these individuals to unreasonable risks. Because pesticide applicators are primarily minorities, a remedy under the Equal Protection Clause should be available to demand equal enforcement of FIFRA.

The topics covered in this article include: (i) a historical view of racism in agriculture, (ii) an overview of pesticide regulations, (iii) the specific regulations relating to safety assessments for pesticide applicators, and (iv) potential legal remedies under the Equal Protection Clause or state common law tort claims.

### 2019] MINORITY PESTICIDE APPLICATORS UNPROTECTED 39

I. PESTICIDE APPLICATORS AND RACE, A HISTORICAL VIEW 41

40

Crisis of the New Deal 43

Introduction

B.	Current Status: Same Story, Different Minority 45	
C.	Lack of Protection Under Occupational Safety and Healt	th
Administration 45		
II. H	istorical Milestones in Pesticide Regulations 46	
A.	Insecticide Act of 1910 46	
B.	FIFRA 1947 and the Delaney Report 46	
C.	Miller and Food Additive Amendments to the FFDCA 47	
D.	Silent Spring and the Federal Environmental Pesticide Control A	ct
of 1972 48		
E.	FIFRA '88, the Food Quality Protection Act of 1996, and Beyon	ıd
	49	
III. CURRENT PESTICIDE REGULATIONS 50		
A.	EPA's Risk Based Approach to Protect Human Health 51	
1.	Dietary Risk Assessment 52	
2.	Risk Assessment for Pesticide Applicators 53	
a)	Exposure Assessment for Pesticide Applicators 53	
b)	Increased Cancer Risk for Pesticide Applicators 55	
B. <i>E.</i>	PA's Agricultural Worker Protection Standard Falls Short 5	6
IV. 0	CONSEQUENCES FOR PESTICIDE APPLICATORS – A CASE STUDY 5	7
A.	Implications of Johnson 58	
B.	No Preemption by FIFRA for Johnson's Common Law Claim 6	0
V. P	OTENTIAL LEGAL REMEDIES 61	
Con	CLUSIONS 61	

"Change happens when the pain of staying the same is greater than the pain of change."

-Tony Robbins

#### Introduction

The regulation of pesticides in the U.S. has evolved over time in response to changes in agriculture as well as a growing awareness of the need to protect the environment and people from unintended harm. Today, the pillar statute for pesticide regulations is FIFRA.<sup>4</sup> The purpose of FIFRA is to ensure pesticides used in the U.S. will not pose "any unreasonable risk to man or the environment." The regulations promulgated primarily by the EPA under FIFRA are fairly robust. For instance, significant protections from the hazards of dietary exposure are provided for the general public, with additional safety margins required for infants and children. In addition, the regulations require adequate protection of the environment. As an example, the impact on endangered species is evaluated as part of the pre-market approval process.

Nevertheless, there is one demographic that is to date still vulnerable; that is pesticide applicators. Historically, pesticide applicators in the U.S. have been Black or another racial minority. <sup>8,9</sup> Unfortunately, it is a painful reality that many of today's laws are grounded in a history of racism. As a consequence, while pesticide regulations have advanced in many areas, the law has failed to offer the same protection to pesticide applicators as is enjoyed by the general population.

A recent California case illustrates the unfortunate consequences of this failure. In this case, Dewayne Johnson, a Black pesticide applicator, brought a products liability action against Monsanto for its failure to include a cancer

<sup>4.</sup> U.S. EPA, Laws and Regulations, Summary of the Federal Insecticide, Fungicide, and Rodenticide Act, https://www.epa.gov/laws-regulations/summary-federal-insecticide-fungicide-and-rodenticide-act (last visited Dec. 29, 2018) ("The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) provides for federal regulation of pesticide distribution, sale, and use. All pesticides distributed or sold in the U.S. must be registered (licensed) by the EPA. Before the EPA may register a pesticide under FIFRA, the applicant must show, among other things, that using the pesticide according to specifications "will not generally cause unreasonable adverse effects on the environment.")

<sup>5.</sup> *Id*.

<sup>6.</sup> *Id*.

<sup>7.</sup> *Id*.

<sup>8.</sup> National Agricultural Workers Survey, *Agricultural Worker Tables*, https://naws.jbsinternational.com/table/2 (last visited Dec. 30, 2018).

<sup>9.</sup> Juan F. Perea, *The Echoes of Slavery: Recognizing the Racist Origins of the Agricultural and Domestic Worker Exclusion from the National Labor Relations Act.*, 72 LOY. U. CHI., SCH. OF LAW, LAW ECOMMONS, 95-138 (2011), https://lawecommons.luc.edu/cgi/viewcontent.cgi?article=1150&context=facpubs (last visited Dec 18, 2018).

warning on the label of the common herbicide glyphosate (trade name Roundup®). Dohnson claimed that because of this lack of warning, his exposure to glyphosate during his daily work as a school groundskeeper caused him to develop cancer. He jury agreed with Johnson, and awarded him \$289 million in damages. Although the damages have been reduced to \$78 million post-trial, thousands of others have filled similar lawsuits since this verdict. To date, more than 18,400 other plaintiffs have filed suits complaining that Round Up® caused cancer while Monsanto claimed it was safe. So

Given the magnitude of this award and number of new plaintiffs, perhaps the time has finally come to trigger new legislation that will address the needs of pesticide applicators and remove the scar of racism from the FIFRA.

### I. PESTICIDE APPLICATORS AND RACE, A HISTORICAL VIEW

The U.S. agricultural industry was built, and ultimately thrived, on the labor provided by indentured servants and slaves, throughout the seventeenth, eighteenth, nineteenth and early-twentieth centuries. In the 1600s, immigrants from Europe came to America looking for new opportunities. However, what immigrants found oftentimes was indentured servitude masqueraded as agricultural opportunity. Indentured servitude provided the European immigrants with food and shelter, but little else. As the demand for more workers rose, and with European immigrant numbers dwindling, the plantation owners turned to slave labor as the preferred alternative. From the

<sup>10.</sup> Johnson v. Monsanto Co., No. CGC-16-550128, 2018 WL 2324413 (Cal. Super. Ct. May 17, 2018) and Johnson v. Monsanto Co., No. CGC-16-550128, 2018 WL 2324413 (Cal. Super. Ct. Aug. 10, 2018). (Judge denied Monsanto's motion for summary judgement; held a reasonable jury could find that Monsanto sought to influence scientific literature, suppress internal concern over risks, and prevent the public from learning of risks to avoid liability. Jury verdict found by clear and convincing evidence that Monsanto acted with "malice or oppression" and awarded damages, including punitive, for claims of design defect, strict liability with failure to warn, and negligent failure to warn.)

<sup>11.</sup> *Id*.

<sup>12.</sup> *Johnson*, 2018 WL 2324413 (Real damages awarded were past economic loss at \$819,882, future economic loss at \$1,433,327, past noneconomic loss at \$4,000,00, future noneconomic loss at \$33,000,00. Punitive damages awarded at \$250,000,000.)

<sup>13.</sup> Daniel Siegal, *The Verdicts That Left A Mark In 2018*, Law360 (December 17, 2018, 5:51 PM EST), https://www.law360.com/articles/1109456/the-verdicts-that-left-a-mark-in-2018. (The punitive damages awarded in the trial were reduced from \$250 million to \$39.25 million).

<sup>14.</sup> Tina Bellon, *U.S. judge selects first case in federal Monsanto weed-killer litigation*, https://www.reuters.com/article/us-bayer-glyphosate-lawsuit/u-s-judge-selects-first-case-in-federal-monsanto-weed-killer-litigation-idUSKCN1NP2HZ (last visited Dec. 29, 2018).

<sup>15.</sup> Monsanto Papers, Roundup (Glyphosate) Cancer Cases: Key Documents & Analysis, U.S. Right to Know, Https://Usrtk.Org/Monsanto-papers/(Last Visited Aug. 13, 2019).

<sup>16.</sup> Marc Linder, Farm Workers and the Fair Labor Standards Act: Racial Discrimination in the New Deal, 65 TEXAS LAW REVIEW, 1335-1393 (1987).

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

<sup>18.</sup> Id.

eighteenth century until the abolition of slavery, the agricultural industry was a source of tremendous wealth generation for plantation owners, fueled by the free labor that the barbaric practice of slavery provided. It is this foundation of free labor and extreme cruelty that the house of racism in U.S. agriculture is built upon.

At its core, agriculture is a very labor-intensive industry and slavery provided an unmistakable financial advantage by which slaveholders could amass wealth in an incredibly short period of time. <sup>19</sup> It is with that purpose in mind, and the nature of competition, that plantation owners everywhere sought to also gain the same competitive advantage. <sup>20</sup> With such a direct relationship established between racial cruelty and profit, it is safe to say racism became deeply ingrained and intertwined with the agricultural industry. Slaves were forced to work long hours in the blistering heat with no consideration for their well-being. Slaves were viewed as property, not people. Similar to a wagon, a hammer, or a shovel, as property slaves were not afforded any human rights. Harvesting crops became synonymous with slave labor, and that really did not matter at all. The work of a plantation or farm laborers was looked down upon and thought to be the type of work reserved for people that did not matter. If someone worked in the fields, then they were viewed as beneath others.

There is a very similar view held today regarding migrants who are primarily employed as seasonal workers in the agriculture industry.<sup>21</sup> While slavery is on a completely different magnitude than the mistreatment of migrant farmers, there is a common thread between both marked by the power relationship between the laborer and the one who owns the fruits of those labors.<sup>22</sup> Even in today's agriculture industry, benefits are largely reaped by the owners of the crops, fueled by a labor force that is oft-regarded as being sub-human or, at the very least, of lesser importance.<sup>23</sup> This relationship is seen by some as an exploitation of a vulnerable group of people meant to generate profit, forming a common thread between slaves of the past and migrant workers of today.<sup>24</sup>

It is with this context in mind that we consider the modern version of institutional racism in agriculture. Today, similar to slave labor used in the eighteenth and nineteenth centuries, those who are working in the fields are

<sup>19.</sup> See Juan F. Perea supra note 6.

<sup>20.</sup> *Id*.

<sup>21.</sup> Id.

<sup>22.</sup> Id.

<sup>23.</sup> Id.

<sup>24.</sup> Id.

the most vulnerable. There is inadequate consideration given with respect to protecting field workers from the dangerous chemicals used to protect crops.

The use of pesticides and insecticides in the agricultural industry is not new.<sup>25</sup> Archaic methods of the application of pesticides have been used for thousands of years.<sup>26</sup> However, the proliferation of pesticide use exploded after World War II. Consider that most farms are family owned and the success of crops could very well mean the difference between life and death; there are clear motivations in finding solutions to protect crops against insects and various weed infestations.

The question is, what is the cost of the use of these dangerous pesticides? Historically, the answer has been looked at from the standpoint of the consumer. However, in this instance, the goal is to examine the danger from the point of view of the workers who are handling the chemicals on a daily basis. What is the cost to them?

### A. Crisis of the New Deal

The New Deal was a series of programs enacted by Franklin Delano Roosevelt, between 1933 and 1938, as a way to stabilize the economy and move the U.S. out of the Great Depression.<sup>27</sup> It included several programs that implemented social service mechanisms throughout the country.<sup>28</sup> Specifically, the National Labor Relations Act (NLRA) and the Fair Labor Standards Act (FLSA) were key programs designed to help industry by providing much needed funding to jump-start the economy.<sup>29</sup> The Acts also provided assistance to those in poverty and those that were unemployed.<sup>30</sup> However, to get the legislation passed, there were a series of compromises made that stripped away protections for the very group of people that the legislation was designed to help.<sup>31</sup> These compromises were very similar to the Three-Fifths Compromise made during the Constitutional Convention of 1787, when the legislature decided that slaves would count as three-fifths of a person for the purpose of determining state populations.<sup>32</sup> Because of the huge disparity in the number of slaves dispersed between the North and the South, the southern states had the advantage of far more representation in Congress.<sup>33</sup> The

<sup>25.</sup> See Linder, supra note 13.

<sup>26.</sup> Id

<sup>27.</sup> Juan Perea, Destined for Servitude, 44 U. of S. F. L. REV., 245-252 (2010).

<sup>28.</sup> Id.

<sup>29.</sup> *Id*.

<sup>30.</sup> Id.

<sup>31.</sup> *Id*.

<sup>32.</sup> Id.

<sup>33.</sup> Id.

unequal representation remained present through the Great Depression.<sup>34</sup> Because of this advantage, southern politicians possessed the power to force more compromises in laws that affected them. Specifically, both the NLRA and the FLSA provided protections for "employees" in the original version of the legislation.<sup>35</sup> However, following an outcry from the southern politicians, the term "employee" was defined to exclude agricultural workers.<sup>36</sup>

Considering that at the time of the New Deal over fifty percent of farm workers in the South were Black and that eighty-seven percent of all Black agriculture workers resided in the former Confederate States, the impact of the exclusion was clear and dramatic.<sup>37</sup> By 1940, that percentage rose to ninety-two percent.<sup>38</sup> This meant that agriculture workers, who worked in some of the harshest conditions, received very few protections.<sup>39</sup> This also meant that the White landowners would legally have the ability to force the workers to work longer hours for lower pay with no possible recourse.

More specific to the FLSA, given the number of Black agriculture workers in the South vastly outnumbered those in the North, any changes to the minimum wage would have a much larger impact in the South than the North. <sup>40</sup> As such, the Southern politicians fought to ensure that agriculture workers were not considered in any discussions concerning minimum wage increases for workers. For example, Representative J. Mark Wilcox of Florida stated:

[T]here is another matter of great importance in the South, and that is the problem of our Negro labor. There has always been a difference in the wage scale of white and colored labor. . . . You cannot put the Negro and the white man on the same basis and get away with it. Not only would such a situation result in grave social and racial conflicts but it would also result in throwing the Negro out of employment and in making him a public charge. 41

Consequently, agricultural workers were excluded from enjoying any benefits of the FLSA.

<sup>34.</sup> Howard A Ohline, *Republicanism and Slavery: Origins of the Three-Fifths Clause in the U.S. Constitution*, 28 THE WILLIAM AND MARY QUARTERLY, 563–584 (1971).

<sup>35.</sup> *Id* 

<sup>36.</sup> *Id*.

<sup>37.</sup> *Id*.

<sup>38.</sup> *Id*.

<sup>40.</sup> Delaplane, K., *Pesticide usage in the U.S.: History, benefits, risks, and trends* (1996), http://people.forestry.oregonstate.edu/steve-strauss/sites/people.forestry.oregonstate.edu/steve-strauss/files/PestUse1996.pdf.

<sup>41.</sup> Perea, supra note 24.

### B. Current Status: Same Story, Different Minority

Today the vast majority of agriculture workers are Hispanic.<sup>42</sup> According to the National Agricultural Workers Survey, seventy percent of hired and ninety-seven percent of contract farm workers are foreign born, and seventy-five percent of hired and ninety-nine percent of contract workers are Hispanic/Latino.<sup>43</sup> With the shift in time and demographics, the NLRA and the FLSA have not yet been updated to include agriculture workers as "employees."<sup>44</sup> As such, this new population of immigrant agricultural workers routinely face some of the same hostile work environments as the agriculture workers of the past and earn far below minimum wage.

### C. Lack of Protection Under Occupational Safety and Health Administration

The Occupational Safety and Health Administration (OSHA) was the source of a landmark piece of legislation that provided oversight for workplace safety in 1970.<sup>45</sup> However, in 1976 after opposition that arose from its passage, there was an exemption put into place for farms that had fewer than ten workers.<sup>46</sup> This meant these farms were exempted from any of the safety standards required by the Act.<sup>47</sup> It also meant that these farms were not subject to any penalties for unsafe work conditions. This exemption was still passed in light of testimony that revealed farm work had some of the highest numbers of injuries and deaths for employees in any modern industry.<sup>48</sup>

Many saw this exemption as a solely financially motivated policy. However, given the nationalities of those who work the farms, the history of labor rights in agriculture, and the historic disparity of racial groups in the U.S., it is easy to show how race might have an impact in these legislative decisions. Because farm workers are historically poor or considered unworthy, this demographic has lacked the power and social capital to motivate the same legislative protections that today are enjoyed by the rest of society.

<sup>42.</sup> Id. at 251.

<sup>43.</sup> NATIONAL AGRICULTURAL WORKERS SURVEY, AGRICULTURAL WORKER TABLES, https://naws.jbsinternational.com/table/2 (last visited Dec. 30, 2018) (Contributors are Department of Labor's Employment and Training Administration, the National Institute for Occupational Safety and Health, and the Health Resources and Services Administration to serving migrant and seasonal agricultural workers).

<sup>44.</sup> See Juan F. Perea supra note 6.

<sup>45.</sup> Timothy W Kelsey, *The Agrarian Myth and Policy Responses to Farm Safety*, 84 AM. J. OF PUB. HEALTH, 1171-1177 (1994).

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

<sup>47.</sup> Id.

<sup>48.</sup> Id.

### II. HISTORICAL MILESTONES IN PESTICIDE REGULATIONS

The first law to regulate pesticides in the U.S. was limited to protecting the economic needs of farmers and cattlemen, and the U.S. Department of Agriculture (USDA) was the sole agency responsible for pesticide regulations. Over time, the scope and complexity of the regulations increased as awareness of risks grew, and at each regulatory milestone a new risk was addressed. Today, the EPA has the primary accountability, while the Food and Drug Administration (FDA), the USDA, and OSHA all share some regulatory oversight. Currently, regulations provide environmental as well as many human health protections, alongside addressing the economic needs of growers.

### A. Insecticide Act of 1910

The first milestone in pesticide regulation was the passage of Insecticide Act of 1910. This law referred to pesticides as "economic poisons." The law, for the purpose of protecting the grower, prohibited the manufacture, sale, and transportation of insecticides that were adulterated or misbranded. The law centered on labelling requirements, and was meant to prevent chemical manufacturers from selling products that caused inadvertent injury to the farmers' crops. <sup>51</sup>

### B. FIFRA 1947 and the Delaney Report

The next milestone occurred in 1947, when Congress passed FIFRA. This law amended and took the place of the Insecticide Act of 1910.<sup>52</sup> The 1947 FIFRA expanded the economic poisons to include herbicides and rodenticides.<sup>53</sup> The primary focus of this early version of FIFRA remained on labelling requirements, and the purpose was to eliminate "puffing" by the manufacturers.<sup>54</sup> However, in this post World War II era, new technologies, such as synthetic pesticides and the use of antibiotics in livestock, was driving a

<sup>49.</sup> Frank P. Grad, Treatise on Environmental Law, § 8.02 (Matthew Bender, 2018).

<sup>50.</sup> FEDERAL INSECTICIDE ACT OF 1910, PUB. L. No. 61-152, 36 STAT. 331, 332-335 (1910) (*repealed by FIFRA* 1947). (Adulterated articles were prohibited from distribution and sale, where "adulterated" referred to product strength and purity which might "reduce, lower, or injuriously" affect the quality of the product.)

<sup>51.</sup> *Id*.

<sup>52</sup>. Federal Insecticide, Fungicide, and Rodenticide act of 1947, Pub. L. No. 80-104, 61 Stat. 163, 164-173 (1947).

<sup>53.</sup> *Id*.

<sup>54.</sup> See GRAD, supra note 46 at § 8.03 (Although FIFRA 1947 took into consideration risks to the public, and not just economic harm to the grower, sanctions for mislabeled products were limited to "puffing" or exaggerated claims by the manufacturers).

reorganization of agriculture.<sup>55</sup> Because of these changes, there was growing concern of harms caused by chemicals unintentionally added to foods.<sup>56</sup> As a result, in 1950 a Congressional committee, led by Congressman James Delaney of New York, was created to investigate the effects of using chemicals in food production.<sup>57</sup>

The Delaney Report generated by this committee concluded that although the farmers' economic interests were protected by the labelling requirements under FIFRA 1947, protection for public safety was insufficient.<sup>58</sup> The report pointed out that the FDA, who under the Federal Food Drug and Cosmetic Act (FFDCA) was responsible for safeguarding the food supply, had no input to assess the safety of pesticide residues on foods.<sup>59</sup> Consequently, the USDA could approve a chemical for market release under FIFRA, without any safety assessment for the food consumer.<sup>60</sup> The Delaney Report recommended to expand the FFDCA by requiring safety data for pesticide residues on foods.<sup>61</sup> These data would be similar to that required for new drugs, whereby a full safety assessment would be required prior to market launch.<sup>62</sup> However, there was concern that the recommendations were too cumbersome, and new legislation was not immediately enacted.<sup>63</sup>

### C. Miller and Food Additive Amendments to the FFDCA

Nevertheless, the Delaney Report triggered a series of hearings, in which Congress addressed the varied concerns of growers, chemical manufacturers, consumers, and state and federal regulators to draft new legislation.<sup>64</sup> As a result, in 1954 Congress passed the Miller Amendment of the FFDCA.<sup>65</sup> This amendment gave the U.S. government the authority to set tolerances for

<sup>55.</sup> See Kendra Smith-Howard, Antibiotics and Agricultural Change: Purifying Milk and Protecting Health in the Postwar Era, 84 AGR. HIST. 327, 327-346 (2010) (As a result of a "technological reorganization of agriculture" in the post-World War II era Americans were faced with confronting what constitutes pure food).

<sup>56.</sup> *Id.* at 329-30 (After World War II, developing nuclear technology as well as pharmaceutical and chemical industries "gave rise to disquieting unease about the place of modern technology in human life" with the purity of food a primary concern. "Technologies once glorified as modern marvels became anxiety inducing. The ubiquity of synthetic chemicals stirred misgivings about a poisoned world.").

<sup>57.</sup> House of Representatives Select Committee to Investigate the Use of Chemicals in Food Products, H. Rep. No. 323, 81st Cong., 1st Sess. (1950).

<sup>58.</sup> Delaney Report, H. Rep. No. 2356, 82nd Cong., 2d Sess. (1952).

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

<sup>60.</sup> *Id*.

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

<sup>62.</sup> Id.

<sup>63.</sup> See GRAD, supra note 46.

<sup>64.</sup> Id.

<sup>65.</sup> Federal Food, Drug, and Cosmetic Act, amendment., Pub. L. No. 83-518, 68 Stat. 511 (1954).

residues of pesticides on foods for the first time. <sup>66</sup> In the Miller Amendment, Congress gave this authority to the Secretary of Health, Education and Welfare (i.e., FDA). <sup>67</sup>

The next significant change to the regulations occurred in 1958 when Congress passed the Food Additives Amendment of the FFDCA.<sup>68</sup> This amendment contained a provision which later became determinative in setting the safety standards used today. This provision, referred to as the "Delaney Clause" required a zero-tolerance for carcinogens.<sup>69</sup> That is, the Delaney Clause provided that no food additive, as are pesticides, would be approved if testing determined residues in foods were detectable and the chemical was carcinogenic to people or animals.<sup>70</sup>

# D. Silent Spring and the Federal Environmental Pesticide Control Act of 1972

The 1960's brought new and different concerns with the publication of Rachel Carson's *Silent Spring*. <sup>71</sup> In this seminal work, which has been recognized as the inspiration of the modern environmental movement, Rachel Carson used a literary vehicle of a "fable of tomorrow" to explore the harms resulting from DDT, a popular insecticide in use at the time. <sup>72</sup> Once again, social awareness triggered changes in the law and government oversight. First, the EPA was established by President Nixon on July 9, 1970 under the Reorganization Plan No.3 of 1970. <sup>73</sup> Second, it became clear there were key regulatory shortcomings as no law provided provisions to protect the environment or those who applied pesticides. <sup>74</sup>

To address these issues and other issues, FIFRA was amended again with the passage of the Federal Environmental Pesticide Control Act (FEPCA) on October 21, 1972.<sup>75</sup> Under the 1972 amendment to FIFRA, Congress gave the Administrator of the EPA the authority to regulate the sale, distribution, and application of pesticides.<sup>76</sup> The EPA now had the authority once held by

<sup>66.</sup> Id.

<sup>67.</sup> Id.

 $<sup>68. \ \ \, \</sup>text{Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958)}.$ 

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

<sup>70.</sup> NATIONAL RESEARCH COUNCIL (U.S.) COMMITTEE ON DIET, NUTRITION, AND CANCER, *The Delaney Clause and Other Regulatory Action*, DIET, NUTRITION, AND CANCER (National Academies Press, 1982).

<sup>71.</sup> RACHEL CARSON, SILENT SPRING (Houghton Mifflin Company, 2002) (1962).

<sup>72.</sup> *Id*.

<sup>73.</sup> U.S. EPA, *Reorganization Plan No. 3 of 1970*, https://archive.epa.gov/epa/aboutepa/reorganization-plan-no-3-1970.html (last visited Dec. 29, 2018).

<sup>74.</sup> See GRAD, supra note 46.

<sup>75.</sup> Federal Environmental Pesticide Control Act of 1972, Pub. Law No. 92-516,  $86\,\mathrm{Stat}$ . 973 (1972).

<sup>76.</sup> *Id*.

the USDA and the FDA. Another key provision in this 1972 amendment was the establishment of a certification process for pesticide applicators.<sup>77</sup> Now, "restricted" pesticides could only be applied by or under the direct supervision of a certified applicator.<sup>78</sup> Furthermore, the term economic poison was replaced with "pesticide," which is still in effect today.<sup>79</sup> This reflects the shift in focus of the new law away from the economic concerns of the farmer, and more towards protecting people and the environment.

Originally, the EPA had planned to re-register all pesticides according to the new requirements by 1975. 80 However, it was not until October of 1977 that the EPA promulgated all of the necessary regulations to fully implement the 1972 FEPCA amendment to FIFRA. 81 By the late 1980's it was clear that the EPA's regulatory work was progressing too slowly. 82 The Agency was not resourced adequately for the substantial legislative task. 83

### E. FIFRA '88, the Food Quality Protection Act of 1996, and Beyond

To address the slow pace of re-registration, in 1988 Congress passed the next major milestone revision to the FIFRA (FIFRA '88). A main feature of this amendment was to mandate timelines and increase the EPA's resourcing by establishing a system for the Agency to collect fees from the registrants.

The next major change to the pesticide registration process occurred in 1996, with the passage of the Food Quality Protection Act (FQPA). This act

<sup>77.</sup> *Id*.

<sup>78.</sup> Digest of Federal Resource Laws of Interest to the U.S. Fish and Wildlife Service, *Federal Environmental Pesticide Control Act of 1972*, https://www.fws.gov/laws/lawsdigest/fedenvp.html (last visited Dec. 29, 2018).

<sup>79.</sup> See GRAD, supra note 46.

<sup>80.</sup> Report of the House Committee on Agriculture, H.R.Rep.No.939, 100th Cong., 2d Sess.

<sup>81.</sup> See GRAD, supra note 46. (Although the FEPCA was enacted on Oct. 21, 1972 to amend FIFRA, a five-year delay was included within the Act to delay some provisions and requirements until Oct. 21, 1977)

<sup>82.</sup> Kathleen A. Fagerstone, Roger W. Bullard, and Craig A. Ramey, *Politics and Economics of Maintaining Pesticide Registrations*, Proceedings of the Fourteenth Vertebrate Pest Conference 1990.28 (1990), http://digitalcommons.unl.edu/vpc14/28 (Last visited Dec. 30, 2019) ("The 1972 Amendments to FIFRA mandated that all pesticides must meet registration data requirements (be reregistered) within a 5-year period. Under the process established in 1972 and refined in subsequent amendments, Registration Standards were issued to establish data requirements for individual pesticides. These standards were issued for 194 pesticides of greatest concern to EPA. In addition, Data Call-Ins were issued for other pesticides of concern including vertebrate pesticides like strychnine and 1080. By 1987, despite submission of reams of data by registrants, fewer than 5 chemicals (out of 611 active ingredients) had been reregistered (all data provided, and all registration and tolerance decisions completed). As a consequence, public pressure to speed up the reregistration process prompted Congress to pass the 1988 Amendments to FIFRA, which were signed into law on October 25, 1988, and became effective December 24, 1988. This version of FIFRA is frequently called "FIFRA 88" or "FIFRA LITE" (the latter term used by some groups because the final amendment carried fewer provisions than these groups had anticipated).").

<sup>83.</sup> Id.

was passed partially as a result of a lawsuit brought by a coalition of environmental groups who sued the EPA for failing to enforce a zero-tolerance policy for carcinogens as required under the Delaney Clause. The FQPA amended both FIFRA and the FFDCA to revoke Delaney, as it was determined that both were outdated and unreasonable. Nevertheless, environmental advocates were pleased with the passage of the FQPA because it provided modernized, uniform safety requirements for tolerance assessments, and in particular, gave additional protections for infants and children.

In 2003, FIFRA and the FFDCA were amended again under the Pesticide Registration Improvement Act of 2003 (PRIA), which provided some administrative changes to help provide the pesticide registrants a more predictable and timely registration and process.<sup>87</sup> Congress has not passed any major revision to the pesticide statues since the passage of the PRIA.

#### III. CURRENT PESTICIDE REGULATIONS

Today, the EPA regulates pesticides primarily through the enabling legislation of FIFRA and the tolerance setting provisions of the FFDCA. 88 Another supporting statute is the Endangered Species Act (ESA). 9 Under the ESA, the U.S. Fish and Wildlife Service works together with the EPA to protect endangered species and their designated critical habitats. 90 While the EPA is the main driver of pesticide regulation at the national level, several other federal and state agencies play important roles. 91 For example, the EPA sets the tolerance limits for pesticide residues on foods, but it does not conduct the sampling and analysis of foods which is necessary to enforce these limits. 92 This task is shared between the USDA, the FDA, and the state agencies. 93

The first step in the regulatory process is the pre-market approval by the EPA. Before it can be sold, the chemical manufacturer must register the pesticide with the EPA. <sup>94</sup> While the definition of "pesticide" in the statutory

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

<sup>85.</sup> Id.

<sup>86.</sup> Id.

<sup>87</sup>. Pesticide Registration Improvement Act of 2003, Pub. Law. No. 108-199, 118 Stat. 3 (2004).

<sup>88.</sup> U.S. EPA, About Pesticide Registration, Federal Pesticide Laws, https://www.epa.gov/pesticide-registration/about-pesticide-registration (last visited Dec. 29, 2018).

<sup>89.</sup> Id.

<sup>90.</sup> Id

<sup>91.</sup> NATIONAL PESTICIDE INFORMATION CENTER, Other Federal Agencies Regulating Pesticides, http://npic.orst.edu/reg/otherregfed.html (last visited Dec. 29, 2018).

<sup>92.</sup> Id.

<sup>93.</sup> Id.

<sup>94.</sup> FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT 7 U.S.C. § 136a (2017).

language is fairly specific and detailed, it is, in essence, any product that is intended for use in controlling organisms that are considered pests. <sup>95</sup>

The EPA Administrator has the authority, through this regulatory process, to control the use and sale of pesticides to prevent "any unreasonable risk to man or the environment." The registration of pesticides, therefore, involves a scientific, risk-based evaluation of data submitted by the registrant, generated to assess human health and environmental effects. The registration process includes in part, an approval of the pesticide's label. The label is critical to assure that the product is used correctly to optimize effective performance as well as to minimize the risks of use for humans and the environment. The labelling requirements, driven by the EPA's human health and environmental risk assessments, address directions for use as well as appropriate warnings for safe use. 98

### A. EPA's Risk Based Approach to Protect Human Health

To evaluate human health risk assessments, first the EPA determines the hazard of the chemical as well as how sensitive humans are to this hazard.<sup>99</sup> These two steps are referred to by the EPA as the "hazard identification" and the "dose-response assessment" steps. <sup>100</sup> This information is gathered from the submitted toxicity studies generated by the registrants. <sup>101</sup> Next, the EPA estimates how much pesticide a person may come in contact with, given the proposed use of the chemical. <sup>102</sup> This step is called the "exposure

<sup>95.</sup> *Id.* at § 136(u). "The term 'pesticide' means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer,...etc."

<sup>96.</sup> Id. at § 136(bb).

<sup>97.</sup> See U.S. EPA, supra note 85.

<sup>98.</sup> *Id*.

<sup>99.</sup> U.S. EPA, Overview of Risk Assessment in the Pesticide Program, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program, (last visited Dec. 29, 2018); U.S. EPA, Assessing Human Health Risk from Pesticides, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides, (last visited Dec. 29, 2018).

<sup>100.</sup> *Id.* (The EPA uses a four-step processed from the National Research Council for human health risk assessments: "Step 1 – Hazard Identification Examines whether a substance has the potential to cause harm to humans and/or ecological systems, and if so, under what circumstances. Step 2 – Dose-Response Assessment Examines the numerical relationship between exposure and effects. Step 3 – Exposure Assessment Examines what is known about the frequency, timing, and levels of contact with a substance. Step 4 – Risk Characterization Examines how well the data support conclusions about the nature and extent of the risk from exposure to pesticides.").

<sup>101.</sup> *Id.* (Toxicity tests are used to determine potential adverse health effects on adults, infants, and children. Studies submitted by pesticide registrants which are evaluated by EPA include acute, subchronic, chronic, developmental and reproductive, and mutagenicity toxicity testing. *See* also U.S. EPA, *Toxicity Tests for Human Health Assessments for Pesticides*, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/toxicity-tests-human-health-assessments-pesticides (last visited Dec. 30, 2019).

assessment," and it takes into account "what is known about the frequency, timing, and levels of contact with the substance." Last, the EPA characterizes the overall risk. One important outcome of the overall human health risk assessment, for example, is the determination of the chemical's carcinogenicity classification, or potential to cause cancer. 105

There are two main risk areas for humans, which may result from exposure to pesticides. These are exposure to residues of pesticides on food and occupational exposure as a pesticide applicator. Two other risk areas for people which are also evaluated by the EPA, but not considered here, are bystander exposure (i.e., during a pesticide application) and residential risk (exposure to pesticides used within a home). As a result of the overall risk assessment, the EPA sets tolerances and establishes the pesticide labelling requirements.

### 1. Dietary Risk Assessment

For the dietary risk assessment, the "exposure assessment" data is derived from product-specific studies submitted by registrants where they have measured the pesticide residue levels on foods. These data are then combined with national food consumption surveys to determine the anticipated dietary exposure for each pesticide. The "hazard identification" and the "dose-response assessment" are derived from the toxicity studies the registrant

<sup>103.</sup> *Id*.

<sup>104.</sup> *Id*.

<sup>105.</sup> U.S. EPA, Evaluating Pesticides for Carcinogenic Potential, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential (last visited Dec. 29, 2018). (EPA's most recent guidelines for cancer risk assessment was released in 2005 and is available at https://www.epa.gov/sites/production/files/2013-09/documents/cancer\_guidelines\_final\_3-25-05.pdf).

<sup>106.</sup> U.S. EPA, Guidance for Human Health Risk Assessments for Pesticides, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-human-health-risk-assessments-pesticides (last visited Dec. 29, 2018). (See also U.S. EPA, Office of Pesticide Programs, AVAILABLE INFORMATION ON ASSESSING EXPOSURE FROM PESTICIDES IN FOOD, A USER'S GUIDE, (June 21, 2000) available at https://www.regulations.gov/document?D=EPA-HQ-OPP-2007-0780-0001).

<sup>107.</sup> U.S. EPA, Data Requirements for Pesticide Registration, Residue Chemistry, https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration#rc (last visited Dec. 29, 2018); U.S. EPA, Setting Tolerances for Pesticide Residues in Foods, Tolerance Setting Requires Numerous Scientific Studies, https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods#scientific-study (last visited Dec. 29, 2018); 40 C.F.R. § 158.1410 (2018).

<sup>108.</sup> Centers for Disease Control and Prevention, National Center for Health Statistics, National Health and Nutrition Examination Survey, https://www.cdc.gov/nchs/nhanes/wweia.htm (last visited Dec. 29, 2018) (The What We Eat in America (WWEIA) survey is the dietary portion of the National Health and Nutrition Survey Examination (NHANSE) conducted by USDA and DHHS for the years 2003-2004); Food Commodity Intake Database, What We Eat in America, FoodRisk.org, http://fcid.foodrisk.org (last visited Dec. 29, 2018) (The U.S. EPA's Office of Pesticide Programs developed the WWEIA Food Commodity Intake Database (FCID) 2005-10 to improve and update the food consumption data used for their pesticide dietary exposure assessments, conducted for the years 2005-10).

submits.<sup>109</sup> These three assessments (exposure, hazard, and dose-response) are then used to determine the overall dietary risk assessment.<sup>110</sup> The EPA uses this dietary risk assessment to set the safe tolerance limits for a pesticide's residues on foods.<sup>111</sup> Since the passage of the FQPA, the EPA applies a ten-fold safety factor when setting tolerances to account for any potential hazards to infants (including prenatal effects) and children.<sup>112</sup> In summary, when the EPA sets tolerances, the dietary risk assessment uses data from product-specific studies and current food consumption surveys, and then a ten-fold safety factor is applied. Thus, the EPA's dietary risk assessment is well considered and offers substantial protections from dietary exposure to pesticides even for the most vulnerable populations.

### 2. Risk Assessment for Pesticide Applicators

For the pesticide applicator, the process of the risk assessment is similar to the dietary risk assessment, yet there is a key difference which has left pesticide applicators at risk. The major difference is that for pesticide applicators, the exposure assessment piece of the risk assessment is based on generic data from the 1990's along with supplemental data as it has become available, while a dietary risk assessment uses current, product-specific data in the form of the studies submitted by the registrants and updated food consumption surveys. As a result, the risk assessment for pesticide applicators is far more susceptible to error than is the dietary risk assessment. Impacts of this limitation in incorrect risk assessment for the pesticide applicator are far reaching.

### a) Exposure Assessment for Pesticide Applicators

When determining exposure to pesticides for applicators, the EPA uses data from the Pesticide Handler Exposure Database (PHED), the Outdoor Residential Exposure Task Force (ORETF), and the Agricultural Handler Exposure Task Force (AHETF), as well as exposure monitoring studies from

<sup>109.</sup> U.S. EPA, Data Requirements for Pesticide Registration, Data from Studies that Determine Hazard to Humans and Domestic Animals, https://www.epa.gov/pesticide-registration/data-requirements-pesticide-registration#dh; 40 C.F.R. § 158.500 (2018).

<sup>110.</sup> U.S. EPA, *Risk Assessment, conducting a Human Health Risk Assessment*, https://www.epa.gov/risk/conducting-human-health-risk-assessment (last visited Dec. 29, 2018).

<sup>111.</sup> U.S. EPA, Setting Tolerances for Pesticide Residues in Foods, https://www.epa.gov/pesticide-tolerances/setting-tolerances-pesticide-residues-foods (last visited Dec. 29, 2018).

<sup>112.</sup> U.S. EPA, Determination of the Appropriate FQPA Safety Factor(s) in Assessing Pesticide Tolerances, ii, (2002), https://www.epa.gov/sites/production/files/2015-07/documents/determ.pdf.

<sup>113.</sup> See U.S. EPA, supra note 104.

the registrant if available.<sup>114</sup> The PHED and the databases compiled by the ORETF and AHETF provide exposure values that are based on historical data and computer modeling.<sup>115</sup> As a result, these exposure values are not product-specific, and for any given chemical and set of application circumstances, the values could be entirely wrong.

The limitations of the available exposure values used for pesticide applicators is acknowledged by the regulatory authorities. For example, the USDA Forest Service has developed its own risk assessments for their pesticide applicators because the EPA's exposure assessments are inadequate to address the needs of their workers. <sup>116</sup> Furthermore, the PHED database is still used as the basis of most pesticide applicator exposure assessments, even though this database is considered outdated by the EPA. <sup>117</sup> The PHED was initiated by a Task Force in the late 1980's and was designed to provide a generic database for estimating applicator exposure using data collected under actual field conditions, yet almost thirty years later, the system's main weakness is an insufficient amount of data. <sup>118,119</sup>

The EPA intends to eventually replace the PHED with the AHETF and the ORETF databases, along with any other applicable data submitted by the

<sup>114.</sup> U.S. EPA, *Occupational Pesticide Handler Exposure Data*, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data#data-assess (last visited Dec. 29, 2018).

<sup>115.</sup> *Id*.

<sup>116.</sup> Patrick R. Durkin, Preparation of Environmental Documentation and Risk Assessments for the USDA/Forest Service, Syracuse Envt. Res. Assoc., Inc., (2014), https://www.fs.fed.us/foresthealth/pesticide/pdfs/PrepEnvirmentalDoc\_11-2014.pdf; U.S. Forest Service, Pesticide Management & Coordination, Risk Assessments, https://www.fs.fed.us/foresthealth/protecting-forest/integrated-pest-management/pesticide-risk-assessments.shtml (last visited Dec. 29, 2018) (Separate human health risk assessments are performed by the Forest Service. Citing two cases where the courts have held that Forest Service is "required to do an independent assessment of the safety of pesticides rather than relying on FIFRA registration alone." See Save Our Ecosystems v. Clark, 747 F.2d 1240, 1248 (9th Circuit, 1984) and Southern Oregon Citizens v. Clark, 720 F. 2d 1475, 1480 (9th Cir. 1983)).

<sup>117.</sup> U.S. EPA, Occupational Pesticide Handler Exposure Data, Pesticide Handler Exposure Database (PHED), https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data#phed (last visited Dec. 29, 2018). See also https://www.epa.gov/pesticide-registration/prn-2007-3-agricultural-handlers-exposure-task-force-llc#ahetf (lasted vised on Aug. 15, 2019) ("Since the development of PHED, it has become clear that some handler exposure scenarios are not adequately covered in this database. Some of the existing data do not fully represent of current exposure patterns due to changes in work practices, formulations, and equipment. However, these data still represent the best available information for assessing handler exposure. In January 2007, EPA convened a FIFRA Scientific Advisory Panel (SAP) to address the need for a new generation of handler exposure data and to recommend methods for generating them. The Panel confirmed the need for new handler exposure studies and generally supported the methods proposed by the AHETF for conducting these studies.")

<sup>118.</sup> Id.

<sup>119.</sup> Timothy M. Leighton & Alan P. Nielsen, *The U.S. Environmental Protection Agency, Health Canada, and National Agricultural Chemicals Association Pesticide Handlers Exposure Database* 10:4 APPLIED OCCUPATIONAL AND ENVIL. HYGIENE, 270, 270-73 (1995).

registrations.<sup>120</sup> However, the OREFT and the AHETF task forces were initiated in 1994 and 2001, respectively, and the process of updating and replacing PHED remains incomplete.<sup>121</sup> As a result, the EPA is still using this outdated, incomplete data set to conduct risk assessments for pesticide applicators.

### b) Increased Cancer Risk for Pesticide Applicators

Although the EPA is aware of the shortcomings in the exposure assessment, this knowledge has not translated into new regulations. Consequently, it is no surprise that the incidence of some cancers is occurring in increased amounts for pesticide applicators. <sup>122</sup> This troubling finding was the conclusion of Phase I of the Agricultural Health Study (AHS), which occurred between 1993 and 1997. <sup>123</sup> The AHS is a long term epidemiologic study conducted by the EPA, along with the National Cancer Institute, the National Institute of Environmental Health Sciences, and National Institute for Occupational Safety and Health. <sup>124</sup> Phase I of the AHS occurred between 1993 and 1997. <sup>125</sup> In this study the health of more than 89,000 certified pesticide applicators and their spouses from Iowa and North Carolina was evaluated. <sup>126</sup>

Further evaluations of these data have been conducted after Phase I was completed to better understand these results. In one such investigation, the researchers recommended that additional factors not currently evaluated should be used when making exposure assessments for pesticide applicators, such as lifetime days of pesticide use. <sup>127</sup> This conclusion was published in 2005. <sup>128</sup> To date, these findings have not been incorporated fully into the risk assessments for pesticide applicators. Instead, the EPA currently uses the

<sup>120.</sup> See U.S. EPA, supra note 114.

<sup>121.</sup> U.S. EPA, Occupational Pesticide Handler Exposure Data, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data#data-assess (last visited Dec. 29, 2018); U.S. EPA, Occupational Pesticide Handler Exposure Data, Occupational Pesticide Handler Exposure Calculator, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data#calculator (last visited Dec. 29, 2018).

<sup>122.</sup> Alavanja MC, et al., Increased cancer burden among pesticide applicators and others due to pesticide exposure, 63(2) CA CANCER J CLIN. 120-42 (2013).

<sup>123.</sup> U.S. NIH, Agricultural Health Study, https://aghealth.nih.gov/about/index.html (last visited Dec. 29, 2018).

<sup>124.</sup> Id.

<sup>125.</sup> U.S. EPA, Science Inventory, Cancer Incidence in the Agricultural Health Study, https://cfpub.epa.gov/si/si\_public\_record\_report.cfm?dirEntryId=104870&Lab=NERL (last visited Dec. 29, 2018).

<sup>126.</sup> See U.S. NIH, supra note 120.

<sup>127.</sup> C. Samanic et al., Factor analysis of pesticide use patterns among pesticide applicators in the Agricultural Health Study, 15(3) J EXPO ANAL ENVIRON EPIDEMIOL 225-33 (2005). 128. Id.

AHS to "inform regulatory policies and practice." No new regulations have been promulgated as a result of the AHS (and related studies) to provide a comprehensive, accurate exposure assessment for pesticide applicators. 130

### B. EPA's Agricultural Worker Protection Standard Falls Short

The EPA has made some efforts to update the regulations, yet this effort falls short of what is needed. For instance, the EPA has updated the Agricultural Worker Protection Standard (WPS), which is a standard designed to provide protections to pesticide applicators from the hazards associated with using a "restricted use product" (RUP).<sup>131</sup> RUPs cannot be sold or used by the general public.<sup>132</sup> Only certified pesticide applicators, or those working under the direct supervision of a certified pesticide applicator, can use and apply a RUP.<sup>133</sup>

The EPA will determine if the chemical is a RUP based on the risk assessment. <sup>134</sup> Chemicals not classified as a RUP remain unclassified, or for general use. <sup>135</sup> A chemical will be classified as a RUP if the EPA determines that added restrictions are necessary in order to avoid unreasonable adverse effects to the environment or harm to pesticide applicators or bystanders. <sup>136</sup> Therefore, the RUP classification is dependent in part on the risk assessment conducted specifically for pesticide applicators. If there are any errors in this risk assessment, the classification of a chemical will be incorrect.

Certified pesticide applicators must comply with the WPS and must demonstrate a working understanding of how to apply pesticides safely. <sup>137</sup> The recent update to the WPS includes increased competency standards, a nation-wide minimum age limit for pesticide applicators, and a five-year maximum recertification interval. <sup>138</sup> However, the WPS does not address

<sup>129.</sup> U.S. EPA, *How EPA Protects Workers from Pesticide Risk, Risk Assessment*, https://www.epa.gov/pesticide-worker-safety/how-epa-protects-workers-pesticide-risk#risk-assessment (last visited Dec. 29, 2018).

<sup>130.</sup> Id.

<sup>131.</sup> U.S. EPA, *Pesticide Worker Safety, Federal Certification Standards for Pesticide Applicators*, https://www.epa.gov/pesticide-worker-safety/federal-certification-standards-pesticide-applicators(last visited Dec. 29, 2018).

<sup>132.</sup> Id.

<sup>133.</sup> Id.

<sup>134.</sup> *Id*.

<sup>135. 40</sup> C.F.R. §152.160 (2018).

<sup>136.</sup> U.S. EPA, *Pesticide Worker Safety, Restricted Use Products (RUP) Report*, https://www.epa.gov/pesticide-worker-safety/restricted-use-products-rup-report (last visited Dec. 29, 2018).

<sup>137. 40</sup> C.F.R. § 170.130 (2018).

<sup>138. 40</sup> C.F.R. §§ 171.103-105 (2018).

how the exposure or risk assessment for pesticide applications are conducted. 139

Therefore, although the update to the WPS regulation provides protections from chemicals that are already classified as a RUP, there is no safeguard against the use of chemicals which are mislabeled as "general use" due to the shortcomings in the risk assessment. Because the RUP classification is dependent on a correct risk assessment for pesticide applicators, this has created a loophole in the regulations. Furthermore, the EPA has been aware of this issue for more than thirty years. Although the EPA has recognized as early as 1997 that pesticide applicators endure at a higher incidence for some cancers, the EPA has yet to fully address the crux of the issue. That is, how to define the risk in the first place so that appropriate precautions can be taken while using the product.

In summary, the lack of an accurate exposure assessment is a critical gap in the regulations. This information is needed in order to accurately define the overall risk, and accurately classify the pesticide as a RUP. This information is necessary to label the products correctly to identify the risks and allow pesticide applicators to appropriately protect themselves.

### IV. CONSEQUENCES FOR PESTICIDE APPLICATORS – A CASE STUDY

The impact of not accurately addressing risks to pesticide applicators is substantial. An example of this can be found in a California case where Dewayne Johnson, a Black school groundskeeper, brought an action against Monsanto asserting that his occupational exposure to glyphosate as a pesticide applicator caused him to develop cancer. In his complaint, Johnson asserted that Monsanto knew of the human health risks, but the product label did not contain the appropriate warnings. It As a result, Johnson did not take the necessary precautions and was exposed to a toxic chemical. It Johnson supported this claim by referencing the International Agency for Research on Cancer (IRAC) of the World Health Organization classification of glyphosate as a "Group 2A, probable carcinogen."

<sup>139. 40</sup> C.F.R. § 170 (2018).

<sup>140.</sup> Johnson, 2018 WL 2324413.

<sup>141.</sup> Complaint for Damages and Demand for Jury Trial, *Johnson V. Monsanto Co.*, No. 16-550128, 2016 WL 347894, at\*5-6 (Cal. Super. Jan. 28, 2016).

<sup>142.</sup> Id. at 15.

<sup>143.</sup> Id. at 2; International Agency for Research on Cancer, World Health Organization, IARC Monographs Questions and Answers, 2, (2018) https://www.iarc.fr/wp-content/uploads/2018/07/Monographs-QA.pdf ("Group 2A: The agent is probably carcinogenic to humans. This category is used when there is limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals. Limited evidence means that a positive association has been observed between exposure to the agent and cancer but that other explanations for the observations (technically termed chance, bias, or confounding) could not be ruled out.").

However, as recently as 2015, the EPA has classified glyphosate as "Not Likely to be Carcinogenic to Humans," and again in April 2019, EPA reaffirmed that they do not consider glyphosate a carcinogen. Furthermore, glyphosate has been assessed by the EPA several times since its first registration in 1974, and is not currently classified as a RUP. Thus, Johnson's assertion, supported by the IRAC's classification of glyphosate as a carcinogen, was in direct contrast to the EPA's findings.

In its defense, Monsanto argued that the EPA's approval of glyphosate under the FIFRA was conclusive and the product was safe. <sup>147</sup> Nevertheless, the California court ruled that the product's label failed to contain a cancer warning and the jury award was in the high millions. <sup>148</sup>

### A. Implications of Johnson

Glyphosate was originally sold for weed control in soybeans genetically engineered to be tolerant to the chemical. <sup>149</sup> It is now one of the most widely used herbicides in the U.S. <sup>150</sup> In agriculture, glyphosate is used on an array of genetically engineered fruits, vegetables, and row crops. Glyphosate products are also sold to the general public for home use in lawns and gardens. <sup>151</sup> Because glyphosate products are so commonly used, *Johnson* has drawn significant attention. Thousands of new plaintiffs (18,400 at the time of this publication) <sup>152</sup> have filed similar suits claiming that exposure to glyphosate has caused them or their relatives cancer since the *Johnson* ruling. <sup>153</sup>

<sup>144.</sup> EPA's Office of Pesticide Programs, *Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential*, 13, 1-216 (2017), https://cfpub.epa.gov/si/si\_public\_file\_download.cfm?p\_download\_id=534487.

<sup>145.</sup> Tom Polansek, U.S. Environment Agency Says Glyphosate Weed Killer Is Not a Carcinogen, (April 30, 2019, 6:23 PM),

https://www.reuters.com/article/us-usa-epa-glyphosate/us-environment-agency-says-glyphosate-weed-killer-is-not-a-carcinogen-idUSKCN1S62SU.

<sup>146.</sup> Id. at 12; 40 C.F.R. §152.175 (2018).

<sup>147.</sup> Johnson, 2016 WL 2324413, at \*40.

<sup>148.</sup> *Id.* (The original award in *Johnson* was \$289 million in damages, which was later reduced to \$78 million. *See* also Daniel Siegal, *The Verdicts That Left A Mark In 2018*, Law360 (December 17, 2018, 5:51 PM EST), https://www.law360.com/articles/1109456/the-verdicts-that-left-a-mark-in-2018.)

<sup>149.</sup> Maggie Delano, Roundup Ready Crops, Cash Crop or Third World Savior?, Spring 2009, https://web.mit.edu/demoscience/Monsanto/players.html (last visited on Aug. 13, 2019).

<sup>150.</sup> U.S. EPA, *EPA Releases Draft Risk Assessments for* Glyphosate, https://www.epa.gov/pesticides/epa-releases-draft-risk-assessments-glyphosate (last visited Dec. 29, 2018).

<sup>151.</sup> Mass. Inst. of Tech, *Roundup Ready Crops*, http://web.mit.edu/demoscience/Monsanto/about.html (last visited Dec. 29, 2018); U.S. EPA, *Glyphosate*, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate (last visited Dec. 29, 2018); Roundup, *General Weeding, Choosing the Right Roundup*® *Lawn and Garden Products*, Roundup.com, https://www.roundup.com/en-us/library/general-weeding/choosing-right-roundup-lawn-and-garden-products) (last visited Dec. 29, 2018).

<sup>152.</sup> Monsanto Papers, Roundup (Glyphosate) Cancer Cases: Key Documents & Analysis, U.S. Right to Know, Https://Usrtk.Org/Monsanto-papers/(Last Visited Aug. 13, 2019).

<sup>153.</sup> Bellon, supra note 11.

Furthermore, because the EPA has determined that glyphosate is not a carcinogen, the ruling in *Johnson* has focused considerable attention on the carcinogenicity status of glyphosate. Some of the arguments in *Johnson* relating to the cancer causation were focused on epidemiology, toxicology, and genotoxicity/mechanism studies. <sup>154</sup> Nevertheless, the key issue in *Johnson* which can be leveraged to bring about regulatory change is the difference between the EPA and the IRAC's classification system for carcinogens. That is, the primary difference between the EPA and the IRAC is how the exposure element is used in the risk assessment. <sup>155</sup> Because of this fundamental difference in the risk assessment process, the EPA and the IRAC have reached different conclusions. <sup>156</sup>

The IRAC does not use an exposure assessment for determining risks.<sup>157</sup> Instead, the IRAC classification system is based only on an evaluation of whether the chemical can cause cancer (i.e., its "hazard" identification).<sup>158</sup> The EPA's carcinogenicity classification, on the other hand, is based on the exposure assessment.<sup>159</sup> Because the EPA's exposure assessment for pesticide applicators is outdated and prone to error, it is no surprise that the EPA and the IRAC have come up with two different conclusions on the carcinogenicity potential of glyphosate.

If the EPA were to use the IRAC's system of determining risk for glyphosate, a more protective risk assessment would result. Glyphosate, which is currently a general use pesticide, would likely be reclassified as a RUP. <sup>160</sup> This would drastically limit market share as it could no longer be sold to the general public for use in the home. Even though it is possible that glyphosate may actually be safe for home use, the risks to pesticide applicators will

<sup>154.</sup> Johnson v Monsanto Co., No. CGC-16-550128, 2018 WL 2324413, at \*4 (Cal.Super. May 17, 2018).

<sup>155.</sup> Patrick Maxwell, M.S. and Travis Gannon, Ph.D., *EPA Concludes Glyphosate Is Not Likely to Be Carcinogenic to Humans*, N.C. STATE EXTENSION, https://www.turffiles.ncsu.edu/2018/01/epa-concludes-glyphosate-is-not-likely-to-be-carcinogenic-to-humans/ (last visited Dec. 29, 2018).

<sup>156</sup> Id

<sup>157.</sup> See IRAC supra note 140 ("IARC classifies carcinogens in five categories ranging from carcinogenic to humans (Group 1) to probably not carcinogenic to humans (Group 4). The classification indicates the weight of the evidence as to whether an agent is capable of causing cancer (technically called "hazard"), but it does not measure the likelihood that cancer will occur (technically called "risk") as a result of exposure to the agent.").

<sup>158.</sup> Id.

<sup>159.</sup> U.S. EPA, Evaluating Pesticides for Carcinogenic Potential, https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/evaluating-pesticides-carcinogenic-potential#1 (last visited Dec. 29, 2018) ("When assessing possible cancer risk posed by a pesticide, EPA considers how strongly carcinogenic the chemical is (its potency) and the potential for human exposure (emphasis added).").

<sup>160.</sup> Jan Dich, et al., *Pesticides and Cancer. Cancer causes & control*, 8 CCC 420-43 (If the EPA determines a compound is carcinogenic, a range of options are available, including cancelling the registration, requiring a change in the registered use pattern to limit exposure to humans, and reclassifying the chemical as a RUP if it is not currently classified as such.).

necessarily be higher given their routine and prolonged use as part of their normal daily work. Nevertheless, to protect pesticide applicators from serious health risks, a loss of market share for the manufacturer is justifiable and may be necessary.

### B. No Preemption by FIFRA for Johnson's Common Law Claim

In *Johnson*, Monsanto moved for summary judgement on the basis that Johnson's claims were preempted by federal law.<sup>161</sup> Monsanto argued that because the EPA had approved of glyphosate label without a cancer warning under the FIFRA, the State of California could not impose additional labelling requirements and the company was immune from liability.<sup>162</sup> However, the Supreme Court has previously ruled in *Bates v. Dow Agrosciences LLC* that common law claims which impose label changes that are "consistent with" or "equivalent to" the FIFRA can survive preemption challenges.<sup>163</sup> Citing *Bates*, the *Johnson* court held that a state law which requires manufacturers to warn of a risk which is either "known or knowable (in strict liability)" or one that "a reasonably prudent manufacturer would have known or warned about (in negligence)" is no broader than the FIFRA.<sup>164</sup>

The FIFRA contains an express preemption provision and it is limited to requirements "for labelling or packaging" that are "in addition to or different from those required under [FIFRA]." *Bates*, 544 U.S.at 444; 7 U.S.C.§ 136v(b). For example, the state is expressly permitted to ban a pesticide that is approved by the EPA. *Bates*, 544 U.S.at 446; 7 U.S.C.§ 136v(a). Under the express terms of the statute, EPA approval of a pesticide is not a defense for the commission of any offense under FIFRA, it is just *prima facie* evidence that the pesticide and its labelling and packaging are compliant with FIFRA and, accordingly, any state law that imposes labelling requirements consistent with FIFRA is not preempted. <sup>165</sup>

Under this rationale, the *Johnson* court dismissed Monsanto's motion for summary judgement.

<sup>161.</sup> Johnson, 2016 2018 WL 2324413 at \*38.

<sup>162.</sup> Id. at \*40.

<sup>163.</sup> Bates v. Dow Agrosciences L.L.C., 544 U.S. 431 (2005) (Texas peanut farmers claimed Dow's pesticide caused crop damage due to a negligent failure to warn; additional claims of breach of express warranty, fraud, violation of Texas Deceptive Trade Practices Act, strict liability, and negligent testing. S.C.O.T.U.S. held State law was not pre-empted, it even though farmers' claim would induce label change.).

<sup>164.</sup> *Johnson*, 2018 WL 2324413, at \*39 (FIFRA at 7 U.S.C. § 136v(b) provides, "State shall not impose or continue in effect any requirements for labelling or packaging in addition to or different from those required under this subchapter." The Johnson court held that there is no express or implied preemption of the California state law to warn of risk.).

<sup>165.</sup> Id. at \*41-42.

### V. POTENTIAL LEGAL REMEDIES

Two options exist for pesticide applicators who have suffered an injury from exposure to a pesticide, such as glyphosate. First, if the party was personally injured, they can bring a common law claim for products liability against the manufacturer, as in *Johnson*. If proven true, claims such as Johnson's can survive a preemption challenge and have a good chance of success. However, the major drawback to this path is the significant cost in time and money for the individual plaintiff.

As an alternative, a successful suit against the EPA for failure to enforce FIFRA for the protection of pesticide applicators could be brought. Because pesticide applicators are primarily minorities, a remedy under the Equal Protection Clause is available to demand an equal enforcement of FIFRA. This would raise the protection of minority pesticide applicators to the same level that is now enjoyed by the majority. For example, in 1996 Congress passed the FQPA in response to pressures from environmental advocates who sued the EPA for failing to enforce their own stated zero-tolerance policy for carcinogens. However, the focus of FQPA was food consumers, particularly infants and children, and not minority pesticide applicators. Because people of all races consume food, but pesticide applicators are primarily minorities, this demographic was prejudicially excluded, once again, from the benefits of the new legal protections, particularly relating to carcinogens. This is the same pattern of the racially driven exclusion of minority farm workers that was seen in the passage of the NLRA, FLSA, and the OSHA legislations decades earlier.

The EPA has a statutory obligation under FIFRA to protect humans and the environment from the unreasonably adverse effects of pesticides. It is problematic that the individuals who need the greatest protection because they are exposed to the highest levels of the most toxic pesticides, have the least protection under the EPA's current regulations. As discussed herein, the exposure assessments used by the EPA during its risk assessments for pesticide applicators are outdated, confusing, and unaligned, even within the government (i.e., the USDA's Forest Service conducts separate risk assessments for pesticides). The PHED, one of the main databases the EPA relies on, is more than thirty years old. This alone is unreasonable. Finally, it is unconscionable that the progression of regulations protecting minority pesticide applicators have lagged behind other populations.

### **CONCLUSIONS**

The regulations of pesticides in the U.S. have evolved as social awareness for the need to go beyond protecting economic interests has increased. A gap

in the regulations highlighted by *Johnson* points to one area where economic interests still have the upper hand. Pesticide applicators today are still exposed to unreasonable risks.

The time has come for a change, and *Johnson* is the trigger. Equal enforcement of FIFRA for the protection of *all* humans could result in fewer unclassified pesticides, and as a result, lower profits for industry. Even so, it is the right thing to do. It is critical that we finally reverse our history protecting the affluence of the wealthy at the expense of the health and welfare of Blacks and other minorities.