

PRIMARY BARRIERS TO REGULATING POTENTIALLY
CARCINOGENIC PESTICIDES IN THE UNITED STATES:
A CASE STUDY OF GLYPHOSATE

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Executive Summary

Due to the widespread negative health impacts associated with chemical pesticides, the purpose of this study is to explore issues within the EPA's pesticide regulation process and examine whether avenues exist to make pesticide regulation more protective of public health. In examining pesticide regulation in the United States, this paper focuses on glyphosate, as the chemical has demonstrated potential to be a carcinogen through multiple sources of evidence, but is not acknowledged as such by the EPA. The research questions asked are: What are the primary barriers to banning potentially carcinogenic pesticides in the United States, and can the process used by independent agencies in determining glyphosate a probable carcinogen inform the EPA's methods for coming to more sensitive hazard assessment conclusions? The key barriers to stronger restrictions on potentially carcinogenic pesticides are identified by interviews with experts in pesticide regulation in the United States who are knowledgeable about glyphosate. The primary barriers identified include the wide reach of industry influence, in both the formal and informal spheres, systematic issues within the Office of Pesticide Programs, such as program cuts and growing numbers of pesticides to review, considering the benefits of a pesticide during regulatory processes, only examining active ingredients instead of formulations, and giving too much weight to animal studies and not enough to epidemiology studies. Additional barriers specific to glyphosate include minimal low cost alternatives, widespread dependence of farmers on the herbicide, and errors made in the hazard assessment leading the EPA to not recognize its carcinogenic potential, paving the way for less stringent regulation.

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List of Acronyms

IARC – International Agency for Research on Cancer
EPA – Environmental Protection Agency
OPP – Office of Pesticide Programs
GMO – Genetically Modified Organism
FDA – Food and Drug Administration
USDA –United States Department of Agriculture
FIRFA – Federal Insecticide, Rodenticide, and Fungicide Act
FEPCA – Federal Environmental Pest Control Act
FQPA – Food Quality Protection Act
TSCA – Toxic Substances Control Act
FFDCA – Federal Food, Drugs, and Cosmetics Act
EFSA – European Food Safety Authority
GLP – Good Laboratory Practices
SAP – Scientific Advisory Panel
SAB – Scientific Advisory Board
FOIA – Freedom of Information Act
CARC – Cancer Assessment Review Committee
ILSI – International Life Sciences Institute

Introduction

Chemical pesticides have become ubiquitous in our surroundings; as residue on food, on the lawns children play in, in sidewalk cracks, and filling the air those that work in traditional agriculture breathe. Pesticides have even been detected in rainfall in agricultural watersheds across the United States (Pretty and Hine 2005) (J. Vogel, Majewski, and Capel 2008). Pesticide exposure has been associated with cancer, birth defects or miscarriages, damage to key developmental and neurological processes, inhibitions of important enzymes, and further adverse health effects (Cropper et al. 1992). Rising incidence of some cancers can in part be attributed to widespread exposure to chemical pesticides, especially when exposure occurs during developmental years (Wogan et al. 2004) (Wilson and Schwarzman 2009). Chemical pesticides are not only harmful to humans, but also to the ecosystems they inevitably seep into. High levels of pesticide use in the United States further lead to incidences of pesticide poisonings, declining numbers of pollinators, and polluting waterways. Due to the widespread impacts of chemical pesticides, the purpose of this study is to explore issues within the Environmental Protection Agency's pesticide regulation process and examine whether avenues exist to make pesticide regulation more protective of public health.¹ The research questions asked are: What are the primary barriers to strong regulation of potentially carcinogenic pesticides in the United States and can the process used by independent agencies that determined glyphosate to be a probable carcinogen inform the EPA's methods for coming to more sensitive hazard assessment conclusions?²

To address the research question, this paper focuses on the potentially carcinogenic pesticide glyphosate, the most widely used herbicide in the world, that can be found as residue on an increasing variety of food items, both fresh and processed (Gillam 2016e) (Myers et al. 2016) (Samsel and Seneff 2013).³ In 2015, the International Agency for Research on Cancer (IARC) determined glyphosate to be a probable carcinogen. Meanwhile, in 2016 the United States Environmental Protection Agency (EPA) released a draft Hazard Assessment declaring glyphosate "unlikely to be carcinogenic to humans." Examining this discrepancy helps analyze

¹ I define "regulation" broadly to mean policies and actions controlling pesticide use.

² Carcinogen refers to a substance or exposure that can cause cancer.

³ Herbicides are a class of pesticides that are used to kill weeds, distinct from insecticides that target insects, and fungicides used to kill fungi. All can be described as pesticides.

the barriers faced by the EPA in coming to conclusions that support stronger regulation. Because the EPA has only produced the Draft Hazard Assessment of glyphosate, this paper primarily focuses on the barriers to stronger regulation of potentially carcinogenic pesticides that occur in the hazard identification phase.

Strong governmental action on glyphosate alone does not go far enough in reducing negative impacts associated with chemical pesticides in the environment, however determining the barriers to strongly regulating glyphosate is important as they overlap significantly with barriers to stricter limitations on all chemical pesticides. Identifying the factors standing in the way of pesticide regulation leads to an understanding of what needs to change systematically in order to achieve a toxic chemical pesticide-free environment in the future.

Background

Glyphosate Use and Health Effects

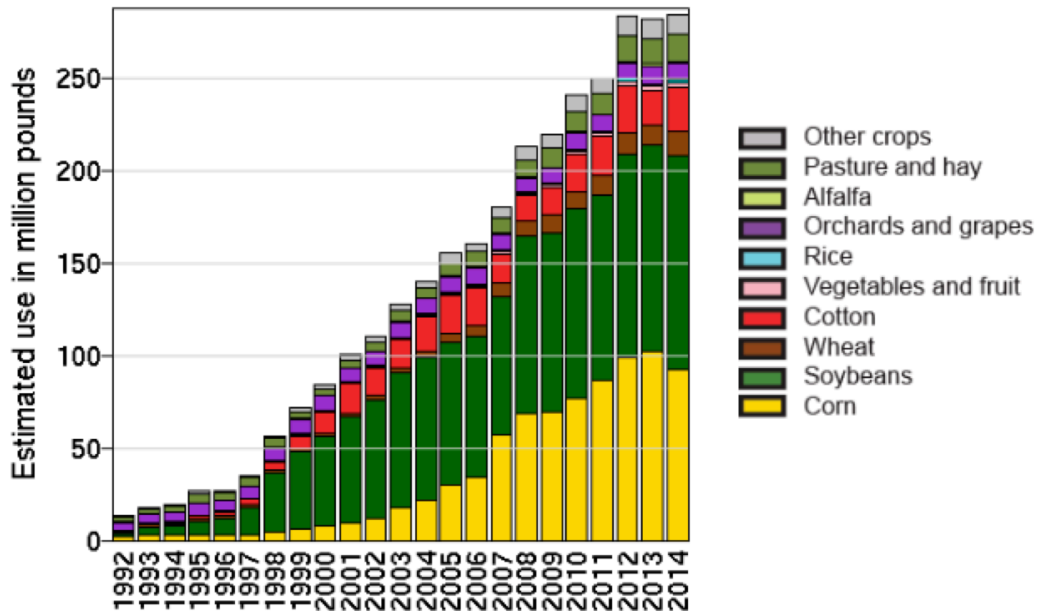
Widespread Use of Glyphosate

The herbicidal potential of glyphosate was discovered by a Monsanto chemist, and in 1974, Monsanto first marketed the widely popular Roundup product (Benbrook 2016). Now, glyphosate is manufactured by 91 producers, more than 750 products contain glyphosate, and it is the most widely used herbicide in the world (IARC 2015). Despite being associated with a wide range of products and producers, glyphosate is still most widely recognized as the main ingredient in the original product, Monsanto's Roundup. Overall, glyphosate is used on more than 150 food and non-food crops (Sass and Hwang 2016). In addition to its use on crops, glyphosate is used for weed control in private yards and public spaces.

Glyphosate is a generalist herbicide, and when applied it will kill most plants on contact through inhibiting a growth enzyme ("IARC Monographs Volume 112: Evaluation of Glyphosate" 2016). This characteristic previously meant glyphosate could only be carefully applied to control weeds in the borders between crops, without making contact with the crop itself. Now, with GMO developments certain crops have been modified to withstand glyphosate, most commonly marketed by Monsanto as "Roundup Ready" seeds. In fact, 45% of glyphosate demand is accounted for by production of genetically modified crops, particularly soybeans,

corn, and cotton (IARC 2015). Figure 1 displays the nearly exponential increases in glyphosate use on corn and soybeans since the 1996 development of GMO crops resistant to glyphosate.

Figure 1: Glyphosate Use by Year and Crop, 2014



Source: USGS Pesticide National Synthesis Project, Pesticide Use Maps (USGS 2014)

Glyphosate use has increased 100-fold since the mid 1970s when it was first introduced by Monsanto (Myers et al. 2016). Now, it is estimated that over 250 million pounds of glyphosate are sprayed annually in the United States alone (USGS 2011). From 1987 to 2007, glyphosate use increased faster and more substantially than that of any other pesticide (Myers et al. 2016). This trend is expected to continue, despite many weeds developing resistance to glyphosate. Potential future increased use of the chemical can be attributed to reformulations combining glyphosate with other herbicides, glyphosate used to replace herbicides identified as more highly toxic, as well as novel uses of the weedkiller, specifically to dry wheat before harvest.

Glyphosate in the Environment

As one would expect, high levels of glyphosate use lead to high levels of glyphosate in the environment. However, it is currently unclear exactly how pervasive glyphosate is in our surroundings, nor exactly how it persists in air and water. Lack of clarity over the amount of glyphosate in the environment, in addition to a minimal monitoring of glyphosate and its

metabolites in the general population, poses a challenge as it means there is not a clear, comprehensive understanding of human exposure to glyphosate (Myers et al. 2016). The FDA recently began testing common products for glyphosate content, but these efforts have proved challenging, and are on pause as of November 2016. Before testing was paused, the FDA found glyphosate in honey advertised as “pure” and “natural”, instant oatmeal, and baby food (Gillam 2016b).

Routes of Exposure

Determining the extent the general population is exposed to glyphosate is important due to the potential health impacts this chemical could have. Pesticide residue on food is often a primary concern, and is an important route to consider as more reports of glyphosate in unexpected foods have been released (Gillam 2016a). Another important source of exposure is Roundup sold in the home and garden market, which can lead consumers to have direct contact with higher volumes of the herbicide. Glyphosate consistently ranks as the second most commonly used home and garden pesticide in the United States (IARC 2015). Farmworkers and chemical manufacturers experience the highest rates of exposure, and can be subjected to high levels of glyphosate on a daily bases, usually additionally combined with other chemicals.

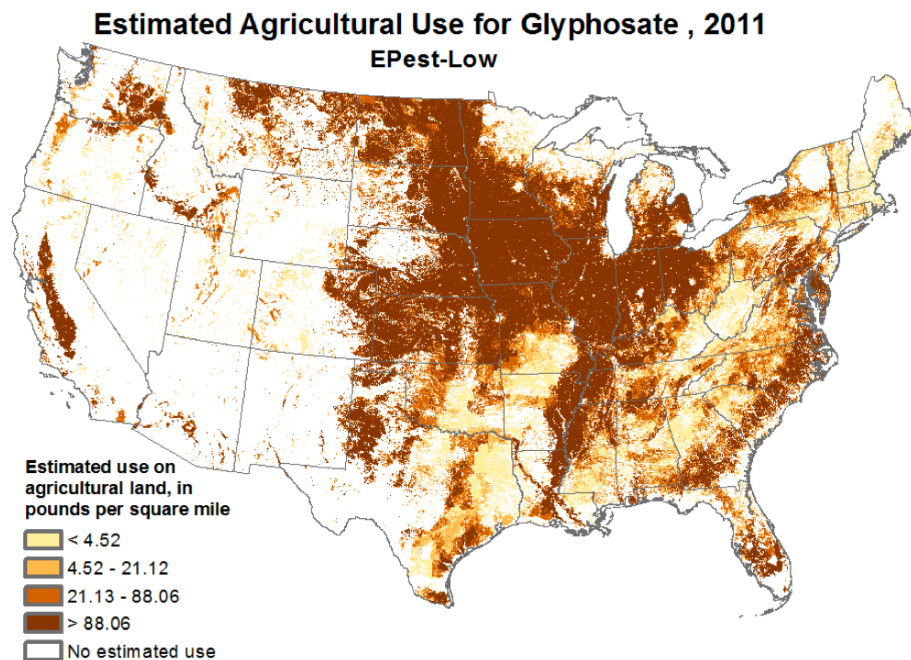


Figure 2: Map of glyphosate use in pounds per square mile for agricultural purposes in the United States. Source: USGS Water Survey 2011

Human Health Effects of Glyphosate

Through multiple sources of evidence, glyphosate has demonstrated potential to be a carcinogen. Occupational exposure studies of glyphosate demonstrate a correlation between glyphosate and non-Hodgkin's Lymphoma, while in-vitro studies ("within the glass"— meaning studies not performed on live animals, but on cells or biological molecules) identify glyphosate's potential to have endocrine disrupting effects in human cell lines (Gasnier et al. 2009).⁴ Endocrine disrupting properties are cause for concern because endocrine disruptors tend to be most damaging with long-term exposure, and especially harmful if exposure occurs during development, even if dosage is low (Myers et al. 2016). Other in-vitro studies have found evidence hinting glyphosate could be a neurotoxin. Scientists even made a connection between glyphosate exposure and gluten intolerance due to glyphosate inhibiting enzyme producing gut bacteria (Samsel and Seneff 2014). According to the IARC monograph, the most direct evidence that glyphosate is a carcinogen comes from animal studies. Numerous studies on lab rats or mice have demonstrated either liver injury, damage to connective tissue, or "tumor promoting activity" influencing the development of renal tubule carcinoma, a type of kidney cancer, hemangiosarcoma, a type of canine cancer, and pancreatic islet-cell adenoma, a type of cancer that occurs in the pancreas (George et al. 2009) (Chang and Delzell 2016). While studies also exist that find glyphosate's potential health effects to be minimal, there is a clear need to further test the carcinogenic potential of glyphosate, especially given the widespread nature of its use, and the potential for it to be toxic at low levels (J. M. Vogel 2004).

IARC's Listing of Glyphosate as a Probable Carcinogen

In March of 2015, the International Agency for Research on Cancer (IARC), a subset of the World Health Organization (WHO), declared glyphosate to be a probable carcinogen. This determination caused a substantial ripple effect, from coverage by the mainstream media such as the New York Times questioning the safety of glyphosate, to individual cities and towns banning or restricting the herbicide, to Monsanto pushing to remove American Cancer Society funding from IARC and attempting to discredit the scientists that worked on the monograph (Pollack 2015) (Gillam 2016c). The highly respected International Agency for Research on Cancer came

⁴ Endocrine disruptors interfere with the body's hormone system and can cause a range of adverse effects. They pose the greatest risk when exposure occurs early on in life (NIH).

to conclusions quite different from those of the EPA, which has glyphosate listed as a Group E chemical, the classification for evidence of non-carcinogenicity in humans (Kasprak 2016). To investigate this discrepancy, this paper focuses on the barriers within and outside of the EPA that lead the agency to less sensitive conclusions on the carcinogenic potential of pesticides than a leading independent agency on cancer research.

Background on the EPA's Regulation of Pesticides

Different Agencies Involved in Pesticide Regulation

The EPA is the main government body responsible for regulating pesticides and does so through setting acceptable residue levels and enforceable tolerances, reviewing safety information, registering pesticides, and monitoring compliance (NPIC 2012). Within the EPA is a special department in charge of pesticide regulation, called the Office of Pesticide Programs (OPP). The OPP implements the main acts and laws relating to pesticides through reviewing studies on the effects of a pesticide that is either being proposed for registration or undergoing a periodic registration review. The Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) play a role in monitoring pesticide residue on food through testing food produced domestically and food that is imported. Additionally, the United States Fish and Wildlife Service (USFWS) works with the EPA in overseeing the impacts pesticides have on threatened and endangered species, and enforcing regulations controlling such impacts (NPIC 2012). States have the ability to impose stricter regulations than those enforced nationally through State Department of Agriculture offices (NPIC 2016). Pesticide use can also be restricted at the city or town level.

Acts and Laws Governing Pesticide Regulation

Before the creation of the EPA in 1970, the USDA and the FDA were the primary governing agencies responsible for regulating chemical pesticides (F. R. Davis 2014). In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FFDCA), marking an important early legislation for pesticides (F. R. Davis 2014). This act introduced setting safe levels of “unavoidable” poisonous substances, like pesticides, on food.

The principle act governing pesticide regulation is the Federal Insecticide, Fungicide, and Rodenticide Act (FIRFA). Passed in 1947, FIRFA requires pesticides to be registered before they

are sold on the market, as well as product labels specifying both content and whether the substance is poisonous. Because of FIRFA, registration is required for all pesticides on the market, and approval for use is granted by the governing agency, pending testing of the proposed active ingredient. While the initial version of the act tended toward leniency for industry, overall, it served as a step towards further development of stronger regulation (F. R. Davis 2014).

FIRFA has been amended numerous times since 1947; notably in 1964 when an amendment increased the authority of the governing agency (not yet the EPA) to remove products from the market based on safety concerns through removing or suspending registration of a pesticide (F. R. Davis 2014). This amendment also changed FIRFA by requiring special consideration of pesticides thought to cause unreasonable adverse effects. The act defines this as, “(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard” (*Federal Insecticide, Fungicide, and Rodenticide Act* 2012). After this update, any pesticide sold or used in the United States must first be approved by the regulating agency based on the determination that it does not cause any unreasonable adverse effects.

The Federal Environmental Pest Control Act (FEPCA) passed in 1972, and amended FIRFA by significantly increasing authority of the newly created EPA in regulating pesticides. It is important to note that this happened after the publication of *Silent Spring*, the influential book by Rachel Carson featuring DDT that widened public awareness and outcry over the environmental disasters pesticides could cause (Griswold 2012). The discourse among regulators was leaning towards the need for stronger regulation, however *Silent Spring* is often credited with substantially increasing awareness and wariness among the American public, especially among environmentalists (F. R. Davis 2014). Important aspects of the 1972 amendments include the reexamination of the safety of pesticides registered in the prior four years, along with the addition of a restricted use classification, which means certain pesticides could only be used by a permitted user.

The Food Quality Protection Act (FQPA), passed in 1996, updates FIRFA as an important asset to stronger regulations of pesticides applied to food products because it mandates that the EPA impose a “safety factor” reduction of chronic reference dose level by three to ten

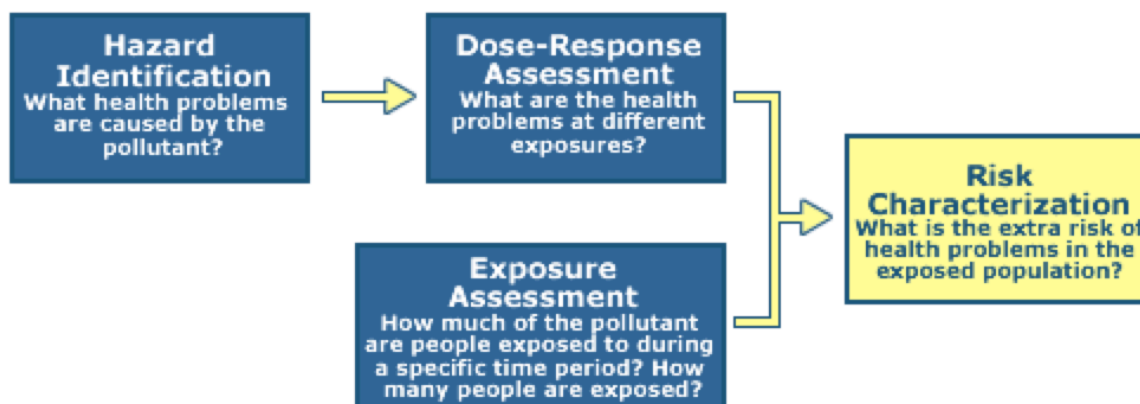
percent if there is any uncertainty about the safety of a chemical (*Public Law 104-170* 1996).⁵ This uncertainty can arise from gaps in data, conflicting studies, or questions over the quality of toxicology data (Myers et al. 2016). The safety factor is intended to protect infants and children, as they are more affected by chemical exposure than adults and are considered a sensitive population (Wilson and Schwarzman 2009). FQPA additionally requires the EPA to reassess pesticide tolerances every 10 years, giving “priority to those that pose the greatest risk to public health” (*Public Law 104-170* 1996). For a further history of important acts relating to pesticides, see Appendix item 1.

Process Behind Regulation

The EPA carries a large responsibility in reviewing the scientific information guiding important decisions in its duty as the main governing agency responsible for upholding the numerous acts regulating pesticides. The 1972 amendment to FIRFA had major implications for how pesticides were approved, and required the EPA to reregister the approximately 40,000 pesticides that were on the market at the time (Cropper et al. 1992). Now, when a new pesticide is developed, the approval process involves a four-step procedure that includes input from industry, EPA reviewers, input from an independent scientific panel, and outside interests. First, the company producing an active ingredient for use as a pesticide is required to submit a proposal to the EPA for registration approval. This proposal must include data on potential risks to human health and the environment, the potential for the pesticide to end up as residues on food, the identity and quantity of all products, labeling, directions for use, and safety information (OECA US EPA 2006). Next, the EPA is directed by FIRFA to complete a special review of any pesticides thought to have particular danger to public health or the environment, as identified by the chemical company in the initial registration proposal. As glyphosate was never identified as posing a danger to public health and the environment, it has never undergone a full review. The goal of the special review is to determine whether the risks associated with the use of the active ingredient outweigh the benefits in a risk benefit assessment. Two separate risk assessments address the impact of the pesticide on human health and the environment.

⁵ Chronic reference dose refers to an estimate of daily exposure to a chemical through ingestion that likely would not cause any risk or deleterious effects during a lifetime (EPA 2011).

Figure 3: The 4 Step Risk Assessment Process



Source: (EPA, 2017)

A risk assessment includes four steps, as illustrated in Figure 3, starting with hazard identification, during which the EPA determines if the chemical has potential to be a hazard to human health or the environment at any dose. In this part of the process, the EPA also reviews open literature, not just data provided by the registrant. While this paper primarily focuses on the barriers to stronger regulation that occur during the hazard assessment phase, it is still important to get a full idea of what comes next, as the forces that affect the hazard identification phase can apply to following steps that inform regulation.

After the hazard identification assessment, a dose-response assessment considers the effects of the pesticide at different doses. Along with the dose-response assessment is an exposure assessment, during which the EPA determines the current levels at which the population is exposed to the pesticide. Finally, the risk assessment concludes by characterizing the risk of the pesticide to the exposed population based on how actual exposure levels compare to dose-response results (OA US EPA 2015). The EPA's proposal based on the full risk assessment is either "(1) cancellation of registration; (2) suspension of registration; (3) continuation of registration, subject to certain restrictions; or (4) unrestricted continuation of registration" (Cropper et al. 1992). This proposal is then open to public comment, where the public can submit comments to the EPA that the agency will consider when coming to a final decision. The EPA's final decision on the regulation of the pesticide could be either an outright ban, or the restriction of certain uses or users.

When regulating pesticides, the EPA solely examines the active ingredient proposed by the registrant, instead of testing the formulated mixture that will make up the marketed product.

The EPA assesses inactive ingredients for safety, however they are not assessed in combination with the active ingredient they are mixed with. This can be problematic because inactive ingredients have been demonstrated to play a role in increasing the toxicity of the active ingredient (Mesnage et al. 2014). This mismatch has specifically been identified with tests of Roundup formulation against pure glyphosate (Mesnage et al. 2014).

History of the EPA's Regulation of Glyphosate

The EPA initially classified glyphosate as a possible carcinogen in 1985, primarily based on a study finding kidney tumors in male rats exposed to glyphosate (EPA 2016c). After a year, the EPA requested that a FIRFA Scientific Advisory Board re-assess the carcinogenicity of glyphosate in response to pressure from Monsanto, who felt glyphosate should be moved to a lower classification. The Scientific Advisory Board determined glyphosate was safe through arguing the data from the study showing tumors in rats could be interpreted as inconclusive. The board recommended moving glyphosate from Group C chemical classification to Group D, “not classifiable as a human carcinogen,” and addressed the need to clear up the ambiguity by recommending the examination and creation of additional rodent studies.

Currently, glyphosate is regulated through labels directing use to ensure minimal exposure, and maximum allowable tolerance levels as residue on and in food. Federal code outlines allowable tolerances for 141 crops, from asparagus and different types of animal feed to sweet potato and wasabi root (*§180.364 Glyphosate; Tolerances for Residues* 1980). Additionally, the EPA imposes a detection limit to the amount of glyphosate in drinking water of 0.006 mg/l, which is among the higher concentrations of the list of chemicals covered by this regulation, likely because glyphosate has long been considered less toxic than other pesticides (*§141.24 Organic Chemicals, Sampling and Analytical Requirements*, n.d.). In general, glyphosate is regulated in terms of how much is allowed in the environment as a toxin, but is not restricted to certain uses or users (EPA 2016b).

In 2009, the EPA began a registration review of glyphosate to “ensure it still performs its intended function without unreasonable adverse effects on human health and the environment” (Environmental Protection Agency 2009). This review was due to be completed in 2015, but due to delays has been pushed back multiple times, and now is expected to be complete by spring of 2017. This review included all relevant glyphosate data available to the EPA, including both

Monsanto studies and studies published in open literature. The Cancer Assessment Review Committee (CARC) of the EPA released their report to the Glyphosate Registration Review Docket in September of 2016, concluding that glyphosate was “not likely to be carcinogenic to humans” (EPA 2016a) The draft of the full review went through the period of public comment in December of 2016 and January 2017. In early March of 2017, the Scientific Advisory Panel reviewing both the draft hazard assessment and all public comments released the results of their deliberations. Ultimately, the panel was divided over whether or not they agree with the EPA’s classification that glyphosate is “not likely carcinogenic.” Some panel members believe a more accurate classification would be “suggestive evidence of carcinogenic potential.” Now the EPA must incorporate the Panel’s remarks in a final hazard assessment.

Influence of the Agrochemical Industry on Pesticide Regulation

While it is important to acknowledge the benefits the agrochemical industry has provided, such as economic growth, contributing billions of dollars to the U.S. GDP, employment (in 2012, there were approximately 36,800 jobs in the pesticide, fertilizer, and other agricultural chemical manufacturing fields), and efficient pest and weed management, it is arguably more important to consider these benefits alongside the immense harm caused by the widespread use of agrochemicals (Henderson 2016). From a monetary perspective, the application of pesticides has been calculated to cost a total of \$10 billion per year in externalities, including \$1.1 billion per year for public health (Pimentel 2005).

While the EPA does put substantial effort into gathering data on pesticides in order to protect public health and the environment, the influence of agrochemical companies in the regulatory process creates a conflict of interest that undermines this ultimate goal.⁶ This conflict of interest is embedded in the very process of pesticide regulation, as corporate-backed science is the main source of information for the EPA when initially registering a pesticide. Another issue with industry providing science used to back regulatory decisions is that this corporate science is generally not available to the public, therefore making this part of the process not transparent. This lack of transparency means independent scientists cannot fully review the data backing the EPA’s initial registration decisions.

⁶ The “agrochemical companies” or “pesticide industry” I refer to in this paper describes the makers of pesticides, a group that has been shrinking into a small number of large corporations, such as Monsanto, Dow Chemical, DuPont, and Syngenta.

Using industry-produced science is not the only avenue for agrochemical companies to influence pesticide regulation. Agrochemical companies partake in significant lobbying for looser pesticide regulation, or expanding the allowed use of chemicals. The agrochemical corporation Monsanto has spent over \$76,700,000 in lobbying since 1998, and \$8,930,000 in 2015 and 2016 (OpenSecrets). In 2016, 75% of Monsanto's donations went to Republican House Representatives and Senators, notably in states with high agriculture production like Iowa, Minnesota, California, Missouri, Illinois, and Idaho (OpenSecrets). Aside from companies lobbying directly, lobbying groups such as the American Chemical Council, Croplife America, and the American Farm Bureau Federation provide additional support for chemical pesticide producer interests in Washington (Pesticide Action Network 2016). Because it is costly for the EPA to constantly have chemical companies fighting regulation decisions with lawsuits, the EPA often ends up working out negotiations with manufacturers, further increasing their power (Pesticide Action Network 2016). Chemical companies have a large incentive to keep up the fight due to the high profits pesticides bring in. For example, glyphosate earned Monsanto \$4.8 billion in revenue in 2015 alone. Agrochemical corporations like Monsanto have been steadily amassing power over the past 10 years through mergers and buyouts, with only a few corporations controlling the entire industry (Yoon 2006).

Along with providing money, chemical companies have a history of providing people to work within the regulatory system despite a clear conflict of interest (Yoon 2006). During the Clinton administration, the CEO of Cargill, Ernest Micek, was appointed as a member of the Presidential Advisory Board charged with finding ways to expand exports (Yoon 2006). This exchange of personnel can occur in reverse as well, with regulators seeking more lucrative employment with the industry they used to regulate. This exchange of personnel across corporate and political bounds is accurately nicknamed the "revolving door" (Yoon 2006). Linda Fisher provides a perfect example of the revolving door. After working for the EPA for 10 years as the Assistant Administrator for Prevention, Pesticides and Toxins, in 1995 she took a position at Monsanto as the VP for Government Affairs. In 2001 Fisher was back at the EPA serving as the Deputy Administrator. Currently (and for the past 12 years) Fisher works for DuPont Chemicals as the VP Safety, Health and Environment and Chief Sustainability Officer ("Linda Fisher" LinkedIn). Overall, through providing the science to back regulatory decisions, high pressure

lobbying, and the crossover of employees, the agrochemical industry is deeply embedded in the EPA’s process for regulating pesticides.

Background on IARC

In March of 2015, the International Agency for Cancer Research (IARC) added glyphosate to its list of probable carcinogens. IARC is a subset of the World Health Organization (WHO) dedicated to cancer research. Over the past 50 years, IARC has evaluated over 1,000 agents that could cause cancer (Portier et al. 2016). These agents are not just chemicals, but include foods such as red meat, fabrics, occupations, and objects such as cell phones (IARC 2016). There are five groups under which IARC classifies carcinogens, listed in Figure 4. These include Group 1, defined as carcinogenic to humans, Group 2A, defined as probably carcinogenic to humans, Group 2B, defined as possibly carcinogenic to humans, Group 3, the largest group with 502 agents defined as not classifiable as carcinogenic to humans, and Group 4, defined as probably not carcinogenic to humans (IARC 2016).

Figure 4: IARC’s Classification of Agents

Group	Classification	Parameter	Number of agents
1	Carcinogenic to humans	Sufficient evidence of carcinogenicity in humans and in experimental animals	118
2A	Probably carcinogenic to humans	Limited evidence of carcinogenicity in humans and sufficient evidence of carcinogenicity in experimental animals	65
2B	Possibly carcinogenic to humans	Limited evidence of carcinogenicity in humans and less than sufficient evidence of carcinogenicity in experimental animals	274
3	The agent is not classifiable as to its carcinogenicity to humans	Inadequate evidence of carcinogenicity in humans and in experimental animals	504
4	The agent is probably not carcinogenic to humans	Evidence suggesting lack of carcinogenicity in humans and in experimental animals	1

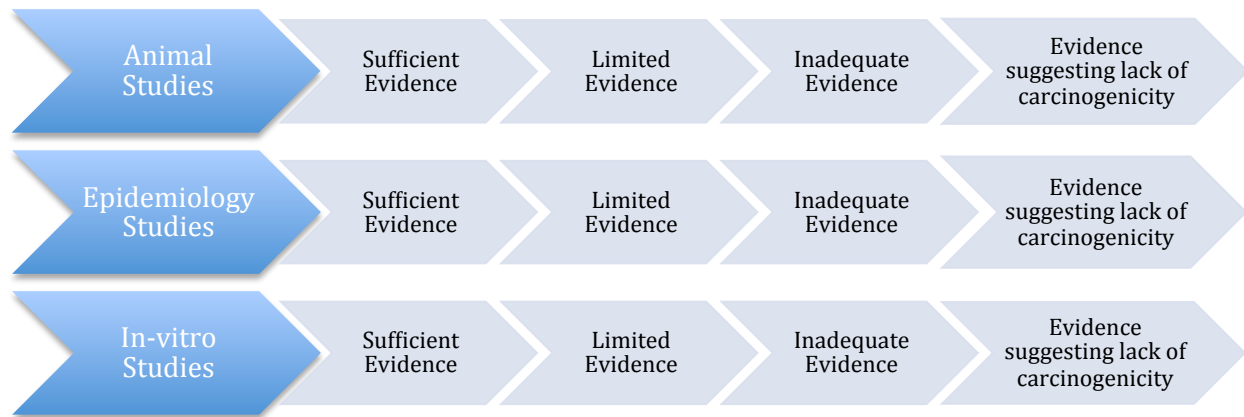
Source: (IARC 2016)

IARC’s Process for Producing Monographs

IARC’s process for producing reports involves gathering a group of ad hoc international scientists with substantial expertise and no conflicts of interest regarding the agent they are recruited to review (IARC 2015). These scientists examine the agent, or agents, in question for 12 months, followed by an eight-day meeting in Lyon, France at the headquarters of the agency

(Portier et al. 2016). When examining the results and validity of studies relating to the agent, IARC scientists have to rule out chance, bias, and confounding factors (Portier et al. 2016). The review solely considers studies and documents that are publicly available, which leads to the exclusion of industry studies that are not made public due to “Confidential Business Information” contained in the studies (Portier et al. 2016). Instead of taking the results of each study they review at face value, the team of scientists makes their own conclusions based on the evidence presented. For example, if the authors of a toxicology study state there is no evidence of carcinogenicity, yet the IARC scientists believe the results do show evidence of carcinogenicity, they will use their own conclusions over the authors (Pollack 2015). When establishing a link to cancer, IARC uses four levels of evidence: sufficient evidence, limited evidence, inadequate evidence, and evidence suggesting lack of carcinogenicity (Cogliano). Finding limited evidence can be a misleading label, because it does not mean there is no evidence, simply that there is room to find additional evidence, perhaps implying the need for additional research.

Figure 5: IARC’s Three Sources of Literature



Source: (IARC, 2015)

IARC’s Conclusion on Glyphosate

The IARC team decided glyphosate is a probable carcinogen, and therefore falls within Group 2A. This result is based on “a small number of epidemiological studies following occupational exposures, rodent studies showing associations between glyphosate and renal tubule carcinoma, haemangiosarcoma, pancreatic islet cell adenoma, and/or skin tumors, and

strong, diverse mechanistic data” (Myers et al. 2016). Putting together the results of a significant number of animal studies, the scientists determined there is sufficient evidence demonstrating the carcinogenic potential of glyphosate. They did not find sufficient evidence for glyphosate’s carcinogenicity in studies involving humans due to the results of the Agricultural Health Study, which did not find a significant enough connection between glyphosate exposure and non-Hodgkin’s lymphoma to draw conclusions of cause and effect (Portier et al. 2016). The Agricultural Health Study is commissioned by the United States government and is a large epidemiologic study designed to observe health effects from working in agriculture. However, it has been faulted for not following glyphosate exposed farmers for long enough to see signs of cancer after exposure. To reiterate, the declaration that glyphosate is a probable carcinogen came from limited evidence of carcinogenicity in humans, but sufficient evidence in experimental animals and strong evidence for two carcinogenic mechanisms (Guyton et al. 2015).⁷

Literature Review

Literature Demonstrating the Effect of Industry on Pesticide Regulation

There is agreement in the literature that the agrochemical industry is motivated to influence regulators to avoid policies that would reduce pesticide use to a specific level, and manage to effectively play an influential role in the regulatory process (Marcoux and Urpelainen 2011) (“Agroecological Approaches to Pest Management in the US” 2005) (van der Wulp and Pretty 2005) (Yoon 2006) (Cropper et al. 1992) This is part of the wider literature addressing how “regulatory failure is politically driven as narrow special interests advance their goals without regard to the societal costs” (Marcoux and Urpelainen 2011). In part as a result of this, for many years U.S. agricultural policy has favored the large-scale industrial model that generally leads to high levels of pesticide use (“Agroecological Approaches to Pest Management in the US” 2005) (Mermarsdeghi and Patel 2003).

In 2011, Christopher Marcoux and Johannes Urpelainen performed a statistical test on the possible influence of the agrochemical industry on regulatory decisions that lead to the overuse of pesticides. Marcoux and others used quantitative data on pesticide use and found that the

⁷ Carcinogenic mechanisms are genetic changes that could lead to cancer

“agrochemical industry is a crucial determinant of pesticides use in nations with low corruption” (Marcoux and Urpelainen 2011). While this study examined agrochemical industries and regulatory systems internationally, it is applicable to whether or not industry is able to sway regulation in general.

While some recognize the use of industry science in pesticide regulation as acceptable, in the article “Association of financial or professional conflict of interest to research outcomes on health risks or nutritional assessment studies of genetically modified products,” Diels and others report, “Over time, associations have repeatedly been observed between study outcomes favoring the industry’s point of view and industry sponsorship, suggesting a publication bias generated through the presence of [conflicts of interest]” (Diels et al. 2010). Study outcomes favoring industry’s point of view have the potential to lead to improper assessments of a pesticide’s safety.

Literature on the Failures of the Toxicology System Informing Pesticide Regulation

As glyphosate has been associated with endocrine disrupting properties and the ability to cause damage at low exposure levels, it is important to consider how the regulatory toxicology system fails to properly address endocrine disruptors, particularly through the use of the traditional dose-response relationship. The dose-response relationship is the idea that as one raises the dose; the response of an organism will increase, in a relationship specific to each chemical. This relationship does not apply to endocrine disruptors because they can be harmful at very low doses. A study by Jason Vogel titled “Tunnel Vision: The Failure of the Regulatory System to Address Endocrine Disruptors” delves into this discrepancy. Vogel conducts a detailed analysis of the EPA’s Endocrine Disruption Screening Program, ultimately deeming it a failure in protecting public health due to the assumptions of the scientific testing (such as the dose-response relationship), and the regulation paradigm. Vogel’s article provides evidence to the failures of regulatory toxicology to properly address endocrine disruptors, calling for a revision of the role of science in making decisions about chemical regulation (J. M. Vogel 2004).

Another important failure of regulatory toxicology is the lack of consideration of inert ingredients when regulating pesticides. Scientists have proven that inert ingredients in pesticide formulas that label glyphosate as the primary active ingredient amplify the potential harm of the chemical in comparison to glyphosate on its own (Cox and Sorgan 2006) (Weinhold 2010)

(Mesnage et al. 2014). Robin Mesnage and others performed such a study in 2014, titled “Major Pesticides Are More Toxic to Human Cells Than Their Declared Active Ingredients.” Their study tested the toxicity of nine different pesticides including glyphosate on key processes in human cells. Of the nine pesticides tested, Roundup was among the most toxic. For eight out of the nine pesticides, the formulations were “up to one thousand times more toxic than their active principles” (Mesnage et al. 2014). This demonstrates a key problem with the toxicology system that solely tests active ingredients when determining acceptable doses. Researchers Cox and Surgan additionally call for the assessment of formulations over solely testing the active ingredient when regulating pesticides in the article “Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health.” While they do not conduct a study comparing the toxicity of formulations against the toxicity of just the active ingredient, their article covers the history and process of testing, as well as the implications of not testing inactive ingredients (Cox and Surgan 2006).

Literature on Glyphosate and Human Health

Whether or not glyphosate has carcinogenic potential has been debated since the herbicide was initially registered for use in 1985, and changed from the classification “possibly carcinogenic to humans” to “evidence of non-carcinogenicity in humans” (Williams, Kroes, and Munro 2000). Generally, glyphosate was considered safe partially because it does not pass easily through the skin, and it is thought most of the chemical will exit the body following exposure (National Pesticide Information Center 2015). However, a significant number of studies demonstrating harm caused by glyphosate bring this assumption into question. Over the years, questions over glyphosate’s safety are periodically raised. Prior to the IARC conclusions about the probable carcinogenicity of glyphosate, in 2011 there was an outbreak of public concern after glyphosate was linked to birth defects in low dosage animal studies in a comprehensive review published by Earth Open Source (Graves 2011) (Antonioni et al. 2011).

Overall, the conclusion a study comes to about the carcinogenicity of glyphosate is influenced by where the study came from and how it was funded. Generally, studies following strict laboratory guidelines that are funded or collected by industry deny glyphosate’s carcinogenic potential. Studies produced by academic sources or independent agencies tend to observe mid to high potential for glyphosate to be carcinogenic, with some exceptions. Reports

from independent agencies reviewing the literature on glyphosate have generally come to the conclusion that glyphosate has a high potential for harm, and there is a need for additional studies testing its carcinogenic potential in humans (IARC 2015) (Myers et al. 2016).

Glyphosate as a Human Carcinogen

Empirical data on glyphosate and human health has primarily been gathered from the Agricultural Health Study. This study is the primary (but not sole) cohort study to publish findings on exposure to glyphosate and cancer risk at many different sites, and was used by both IARC and the EPA in considerations regarding glyphosate. The Agricultural Health Study is conducted in North Carolina and Iowa and follows licensed pesticide applicators, which includes a high number of participants working in agriculture. The study methods include multiple questionnaires about farming, personal pesticide use, and other lifestyle factors, like smoking habits. The study also collects buccal DNA samples by mail from cheek swabs (“About the Study” 2016). While the Agricultural Health Study did find some correlation between glyphosate and non-Hodgkin’s lymphoma (NHL), ultimately the researchers declared a null finding due to the relationship not reaching statistical significance. This study’s evaluation of glyphosate has been criticized for only having a follow up time six to seven years, which is likely not long enough for people to actually develop cancer (Portier et al. 2016).

Other occupational case-control studies in the United States, Canada, and Sweden found glyphosate exposure does in fact increase one’s likelihood of getting non-Hodgkin’s Lymphoma (De Roos et al. 2003) (McDuffie et al. 2001) (Eriksson et al. 2008). A study titled “Integrative assessment of multiple pesticides as risk factors for non-Hodgkin’s lymphoma among men” by De Roos and others pooled the data from three different case-control studies done in Nebraska, Iowa, and Minnesota on non-Hodgkin’s Lymphoma. In analyzing the presented data, the researchers conclude there is a link between glyphosate exposure and non-Hodgkin’s Lymphoma (De Roos et al. 2003).

In June of 2015, researchers Ellen Chang and Elizabeth Dezell completed a meta-analysis and systematic review on the literature of glyphosate and non-Hodgkin’s Lymphoma. They came to the conclusion that there is a statistically significant association between any glyphosate use and non-Hodgkin’s Lymphoma. This study reviews original scientific articles in the field of epidemiology that include a numerical ratio between individual level glyphosate exposure and

likelihood of having non-Hodgkin's Lymphoma, Hodgkin's Lymphoma, Multiple Myeloma, or Leukemia, leading them to examine 19 articles in total (Chang and Delzell 2016).

Glyphosate and Tissue Damage

Numerous studies on the effects of glyphosate on lab rats and mice have demonstrated glyphosate's ability to cause deleterious effects. A study performed by Aloísio Benedetti and others titled, "The effects of sub-chronic exposure of Wistar rats to the herbicide Glyphosate-Biocarb®," was reviewed by both IARC and the EPA (Benedetti et al. 2004). When exposing rats to low levels of glyphosate, Benedetti and others observed minor liver injury as well as effects on connective tissue and enhanced amounts of reticulin, a structural protein that is found in connective tissue and around nerve and muscle fibers (Benedetti et al. 2004). Seeing effects from such tests indicate the chemical is changing key functions in the body. These effects are seen in response to low levels of glyphosate, indicating the need to clarify the amount of harm glyphosate can cause at very real exposure levels and re-examine chronic reference doses that are high in the U.S. compared to other countries (Myers et al. 2016). Other animal studies have found glyphosate exposure positively associated with renal tubule carcinoma, a type of kidney cancer, hemangiosarcoma, a type of canine cancer, and pancreatic islet-cell adenoma, a type of cancer that occurs in the pancreas (Chang and Delzell 2016).

Glyphosate as an Endocrine Disruptor

In-vitro studies ("within the glass"— meaning studies not performed on live animals, but on cells or biological molecules) have indicated that glyphosate can be an endocrine disruptor, specifically through disrupting numerous steroidal hormones, which has consequences in development for vertebrates. These effects can occur at low levels, similar to levels the pesticide could be found in the environment and people could plausibly be exposed to (Myers et al. 2016). Other in-vitro studies testing the potential for glyphosate to be an endocrine disruptor have come to similar conclusions, that low levels of glyphosate can be harmful to human cells (Gasnier et al. 2009). Additionally, a number of studies have implicated that glyphosate can be a neurotoxin at low levels, however this connection requires additional research in order to be fully determined (Myers et al. 2016).

Need For Additional Data

Fully understanding the impacts of glyphosate on human health is imperative at a time when use of the weedkiller is skyrocketing. Now that there is a heightened level of concern about glyphosate people are starting to test for it in products in which one would not expect to find glyphosate. For example, glyphosate was recently detected in the MMRII child vaccine, which is highly concerning as glyphosate has not been tested for safety as an injectable, not to mention the danger of exposing developing children to a potential endocrine disruptor through such a direct route (Honeycutt 2016).⁸ Additionally, assigning cancer as a health impact of a chemical is difficult, given the delayed response that is the nature of the disease. Also, because cancer can be the result of an accumulation of exposures an individual receives throughout their lifetime, it is difficult to come to clear proof of the carcinogenic potential of a single agent. To enhance the literature on glyphosate's carcinogenic potential, further occupational studies on human glyphosate exposure are needed, especially studies looking at chemical manufacturers that work with glyphosate. Currently, there are no epidemiological occupational studies on chemical manufacture workers who receive a high dose of glyphosate in performing their occupational duties. This population would provide a clear examination of the health effects of glyphosate at a high dose, higher than that faced by agriculture workers, with fewer confounding factors.

Literature Comparing IARC's Process With the Regulatory Process

An article by Chris Portier and others written in response to the IARC conclusion breaks down why the methods of IARC are superior to those of the European Food Safety Authority (EFSA), which concluded glyphosate was not carcinogenic after conducting a review of registration in late 2015. Portier's study compared direct wording from each report, to examine the differences in conclusion. Portier and other scientists draw comparisons to how IARC and EFSA evaluated the data, and conclude EFSA incorrectly dismissed important evidence of glyphosate's carcinogenic potential. The authors also stress the need for EFSA to be more

⁸ Glyphosate has been detected in vaccines likely because some vaccine agents are grown on pig fat. Allowable tolerances for glyphosate on animal feed are almost four hundred times more than is allowed on other crops, which means there is a chance these pigs have ingested glyphosate, and it is showing up in their fat, and then in the vaccines (Honeycutt 2016).

transparent by citing where they got their information for the report, given the drastic potential health impacts of glyphosate.

The first comparison this article draws is over both agencies' conclusions on glyphosate and Non-Hodgkin's Lymphoma. IARC found evidence of correlation between glyphosate and Non-Hodgkin's Lymphoma based on available human evidence, while EFSA "classified the available evidence as limited and then dismissed any association of glyphosate with cancer without justification or explanation" (Portier et al. 2016). The next differing conclusion is over the significance of animal studies. The IARC working group found sufficient evidence for carcinogenicity in lab animals based on the studies it evaluated, while EFSA dismissed three studies showing renal tumors in mice, malignant lymphoma in two mice studies, and hemangiosarcoma (a fast growing cancer found almost exclusively in dogs, horses, and cats) in a move that went against the established guidelines cited in their report, discarding the studies as "chance occurrences" (Portier et al. 2016). Finally, in addition to being carcinogenic, the IARC working group also concluded that glyphosate has genotoxicity and can induce oxidative stress based on publicly available DNA studies on exposed humans. EFSA came to this same conclusion, however dismissed it as well stating "oxidative stress alone is not sufficient for carcinogenic labeling" (Portier et al. 2016). Overall, EFSA "ignored important laboratory and human mechanistic evidence of genotoxicity" important for linking glyphosate to serious harm (Portier et al. 2016).

Literature Gap

Overall, many sources of literature touch on the challenges that exist in banning pesticides in the United States, as well as barriers in changing chemical policy as a whole. However, this study is the first to combine these primary barriers, and contrast the methods of the EPA with those of a highly respected independent international agency. This study fills a gap in the literature as an in-depth look at structural failures limiting the EPA's action on pesticide regulation, specific to glyphosate.

Methodology

Participants

In order to determine the primary barriers to banning potentially carcinogenic pesticides, this study gathered participants including six experts knowledgeable about glyphosate, pesticide regulation in the United States, and IARC's process. Experts were identified through having written recent publications on glyphosate. The experts included two employees at nonprofits who have worked on campaigns surrounding glyphosate, a scientist who was in the IARC working group that determined glyphosate to be a probable carcinogen, a reporter who is writing a book on glyphosate and the policy debate surrounding the chemical, and an expert on GMO's and Monsanto. All participants in this study were recruited over email.

Materials

Informed consent forms were collected from each interviewee. Forms provided the subject information about the purpose of the project, the voluntary nature of participation, and the risks and benefits of participating. Interviewees also received a copy of the interview questions over email prior to the interview.

Design and Procedure

This research was qualitative and slightly structured. Questions were standardized to enhance the rigor of the study, however to capture additional information individual interviewees could offer, some interviews extended beyond these core questions. Interviews were conducted over the phone, lasted 30 minutes to an hour, and were audio recorded with permission of the participant. Examples of interview questions include, "Do you believe it is important for the EPA to strengthen regulation of glyphosate? (To what extent, and why?)," "What do you believe are the key barriers affecting the EPA's decision to ban potentially carcinogenic pesticides?" and "What is your opinion on the role of the agrochemical industry in the pesticide regulation process?" A full list of questions is included in the appendix.

Findings & Analysis

There is currently an overreliance on chemical pesticides in the United States, and subsequent widespread negative public health and environmental impacts stemming from high levels of chemical pesticide use. The danger posed by widespread chemical pesticides to public health has been identified in the literature, and has been an ongoing issue since chemical pesticides were used on a broad scale, initiated after WWII (Myers et al. 2016). While there is a system in place designed to regulate pesticides and protect public health and the environment, this system is seriously flawed. Understanding the barriers to more stringent pesticide can ultimately guide how to break them down.

The following section presents the barriers to increased regulation on chemical pesticides. Findings are based in interviews with five experts knowledgeable about pesticide regulation in the United States and the current issues surrounding glyphosate. These experts include Dr. Christopher Portier, a senior scientist who has served on multiple Scientific Advisory Boards for the EPA, and was a member of the IARC Review Board for glyphosate, Emily Marquez, a staff scientist at the Pesticide Action Network of North America, Carey Gillam, a veteran journalist and research director for U.S. Right to Know, Jennifer Sass, a senior scientist in the Health Department of the NRDC, and Bill Freese, a Science Policy Analyst at the Center for Food Safety. Monsanto was reached for interview, but declined, not wanting to speak on behalf of the entire industry. CropLife America was also reached for interview, but declined, not wanting to speak about a specific agent, and referred the researcher to Monsanto. Additional online research further contributed to the following findings and analysis on the key barriers to stronger regulation of carcinogenic pesticides, specifically glyphosate.

Summary of Key Findings

The key barriers to stronger restrictions on potentially carcinogenic pesticides were identified by interviews with experts in pesticide regulation in the United States with knowledge about glyphosate. Barriers include the wide reach of industry influence in both the formal and informal spheres, considering the benefits of pesticides during regulatory processes, systemic issues within the Office of Pesticide Programs such as program cuts and growing numbers of pesticides to review, only examining active ingredients instead of formulations, and giving too much weight to animal studies and not enough to epidemiology studies. Additional barriers

specific to glyphosate include minimal low cost alternatives, widespread dependence of farmers on the herbicide, and errors made in the hazard assessment leading the EPA to not recognize its carcinogenic potential paving the way for less stringent regulation.

Systematic Barriers Within the OPP of the EPA

The Office of Pesticide Programs (OPP) is the department within the EPA responsible for overseeing pesticide regulation. As reported by Carey Gillam, a veteran journalist and research director for U.S. Right to Know, recently the OPP has been limited in its abilities due to a declining workforce paired with an increase in the number of pesticides to review. A restrained budget (of \$8 to \$10 billion) also makes stronger regulation challenging as the office is stretched thin, and more thorough regulation requires additional resources. In addition to these systematic issues, the OPP is heavily influenced by industry. All interviewees described both formal and informal means by which the agrochemical industry influences the OPP of the EPA, described in detail below. Additionally, Christopher Portier, senior scientist who was on the IARC glyphosate review board, identified the barrier that the OPP knows that if they regulate a pesticide strictly they will receive “significant pushback” from corporations in the form of costly lawsuits, whereas unless there is public attention on the specific pesticide (as there is with glyphosate), there is no need for the office to “stick their neck out unnecessarily” (Portier 2017).

Problems with the way the OPP Assesses Data

Experts interviewed in the data collection phase identified numerous problems with the way the OPP assesses data, especially in the case of glyphosate. Portier mentioned the incorrect use of statistics by the OPP when analyzing data and the related observation that the EPA does not have enough statisticians. Perhaps because of this lack of statisticians, the agency has “limited procedures in evaluating data” (Portier 2017). As an example, Portier brought up the incorrect use of historical control data that leads to conclusions that undermine the hazard posed by glyphosate. Historical control data provides scientists with a tool to compare current studies with past studies to see if the study results are exceptionally unusual, but these data need to be used very carefully to be sure studies are actually comparable, because if they are not it is invalid to draw conclusions from statistical tests using historical controls. Generally, historical controls should be used only if there is significant reason to disregard controls from the same study.

Along with the need for more statisticians, Emily Marquez of the Pesticide Action Network of North America (PANNA) brought up the need for additional epidemiologists in the Office of Pesticide Programs (OPP), or at least one. While there are epidemiologists in the EPA, none are permanent staff in the OPP. Three other experts mentioned this point as well. Marquez described how having scientists of different disciplines helps the agency come to a more complete understanding of the meaning of each study and therefore get the best results, as scientists with different backgrounds have specialized training and can interpret results differently.

Another issue within data assessment methods of the EPA identified by experts is when the EPA does not follow its own guidelines when conducting hazard assessments. The cancer assessment guidelines that exist are valuable and help ensure the stringency and consistency of reports. The guidelines cover both how lab animals should be tested to ensure the examination only covers properly performed studies, as well as how the EPA should analyze study results, such as the types of statistical tests to perform and most importantly how they should decide whether they will classify an agent they are reviewing as “unlikely,” “possible,” “probable,” or “likely” to cause cancer. In the case of glyphosate, the EPA did not follow some of the guidelines in a way that led them to dismiss key studies linking glyphosate to carcinogenic effects. Bill Freese of the Center for Food Safety asserts that if the EPA were to follow its own guidelines it would find glyphosate to be probably carcinogenic.

Only Examine Active Ingredients

As mentioned previously, when regulating pesticides, the EPA only takes the active ingredient proposed by the chemical company into account. Three different experts interviewed discussed how only examining the active ingredient is a barrier to stronger regulation because inactive ingredients play a substantial role in determining the toxicity of a formulation. Multiple sources of evidence demonstrate that inactive ingredients can make solvents more toxic. Freese mentioned that it is possible the EPA may not have the resources to test all formulations and mixtures of chemicals, but doing so is an important aspect of determining the hazards associated with exposure to a pesticide. The difference in toxicity between active ingredients and formulations has been demonstrated in studies comparing glyphosate with Roundup (Mesnage et al. 2014). This exclusion is an important barrier because if the OPP were to examine Roundup as

a formulation, the results of a thorough risk assessment would likely find a higher level of risk than is posed by glyphosate alone, which would ideally lead to further regulation (observed through a lower acceptable dose level and restricted usage). When regulators test glyphosate alone it does not go far enough in considering the impacts the chemical has on public health.

Not Enough Input From Independent Agencies

Four out of five interviewees mentioned the need for further incorporation of input from independent agencies in the determination of the health effects of a pesticide, as well as additional research performed by independent agencies. Numerous interviewees suggested corporations need to contract research that is independent and not concerned with pleasing industry interests, as is often the case now. Gillam mentioned the need for more independent research overall and the need for additional grants that support chemical safety research. Independent research would supply the EPA with further studies to review aside from those produced by industry, which make up the clear majority when it comes to animal studies.

The incorporation of independent research is especially important due to the conflicts of interest created by the fact that the majority of animal studies considered in developing human safety standards come from industry or industry sponsored scientists. Toxicology study standards that are widely accepted by regulatory agencies are set up in a way that exclude peer reviewed academic studies from consideration. These studies are required to follow strict guidelines (different from cancer assessment guidelines). While the guidelines do help promote responsible data collection and replicable tests, Sass mentioned the role of Good Laboratory Practices (GLP) guidelines in blocking academic studies from consideration in certain phases of the regulatory process. Excluding academia is problematic because numerous studies have demonstrated that following study methods other than those laid out by GLP can actually lead to more sensitive toxicity testing (Buonsante et al. 2014). Analyzing studies that are more sensitive to detecting toxicity could lead to stricter human safety standards if a chemical is thought to be more of a risk or hazard.

Improper Weighting of Animal Studies over Epidemiological Studies

As part of the hazard assessment process, the EPA gives greater weight to “high quality and well documented studies and those findings confirmed by multiple sources” and takes this weight into account when analyzing the available data (OECA US EPA 2006). Portier and

Freese stress that the EPA gives too much relative weight to animal studies when analyzing available data during a hazard assessment. Freese mentioned the conflict of interest posed by the heavy reliance on animal studies produced by the registrant or contracted firms. Freese, Portier, and Marquez all spoke to the subsequent need to give more weight to epidemiology studies. Epidemiology studies deserve more weight because they encompass the actual human response instead of the response of rats or mice, which involves making “fairly wide extrapolations” (Freese 2017). Additionally, epidemiology studies inherently look at the actual pesticide formulation instead of solely the active ingredient. Finally, epidemiology studies are important because they are generally produced by independent scientists instead of industry-contracted scientists like most of the animal studies. In 2014, the National Research Council created a report detailing recommendations on how the EPA could improve the risk assessment process, and incorporating epidemiology studies was one of their suggestions (Samet 2014). In the current draft hazard assessment of glyphosate, the EPA considers epidemiology studies, however multiple interviewees believe they dismissed important results too readily, supposedly due to the inability to rule out confounding factors.

OPP Aligns With Industry Interests

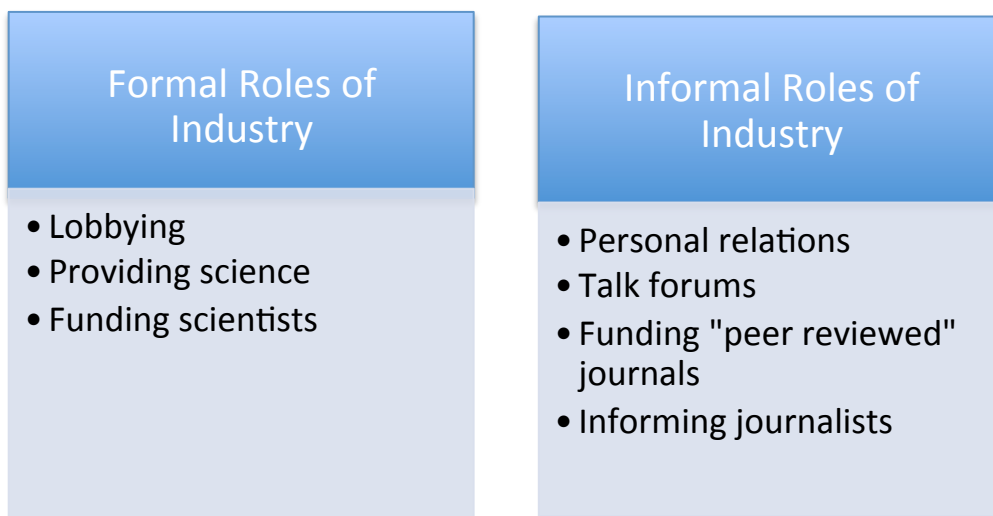
Three out of five experts brought up the inherently conservative nature of the Office of Pesticide Programs in relation to the rest of the EPA as a barrier to stricter pesticide regulation. Portier mentioned how the OPP leans towards industry influence, and Marquez talked about the attitude of the OPP being more about processing and registering as many products as possible if they don't find a negative effect because each chemical agent primarily represents a “job to get done” (Marquez 2017). Similarly, Jennifer Sass, senior scientist in the health program of the NRDC, talked about how OPP has been known to express pride over the speedy approval of pesticides. Sass considered the possibility the OPP office could be more tolerant to industry because of its history as the USDA before the EPA was created, which could lead to an ingrained connection with agriculture interests.

Industry Barriers

Industry poses the greatest barrier to stronger pesticide regulation, according to the experts interviewed. Industry influence comes from a mix of formal and informal roles the industry plays in nearly every stage of the pesticide regulation process (summarized in Figure 4).

Overall, as Sass explained, “the EPA treats industry as an honest broker,” but they need to recognize that it is the EPA’s job to regulate, not Monsanto’s (Sass 2017). The industry is doing what we would expect them to do, which generally translates to trying to maximize profits (Yoon 2006).

Figure 4: Roles of Industry in the Pesticide Regulation Process



Formal Industry Role as a Barrier

Providing background science and lobbying are the primary formal roles the agrochemical industry plays in the regulatory process. The Federal Insecticide, Rodenticide, and Fungicide Act (FIRFA) calls for the EPA to retrieve initial information on the safety of a chemical from the company registering the pesticide for use, therefore setting up the use of industry science to guide the regulatory process (as the results of this initial review determine whether or not a pesticide requires further testing). Interviewees acknowledged this as a sensible step for the preliminary review as public dollars shouldn’t fund the testing of private companies products for safety. However, in terms of using industry science in other periods of the regulation process, both Gillam and Marquez discussed the bias that is implicit when studies come from industry, because they are apt to come out in favor of whatever is being tested. Marquez and Sass both mentioned the impact of strict requirements that determine what studies are eligible to be examined, that ultimately lead to the exclusion of academic and independent studies. Portier and Freese felt differently. They felt that the guidelines help keep studies more accurate and stringent. Portier pointed out that while the studies commissioned by industry are

generally quite rigorous, and follow impossibly strict guidelines that do help keep the studies very controlled, academic studies that are not as rigorous should not be dismissed entirely or given less weight in regulatory considerations.

In addition to toxicology studies that follow strict guidelines, industry contracts additional studies by paying independent scientists. When corporations in the agrochemical industry contract scientists to produce studies from them, they ultimately impact the scientists' results through working with the researchers directly and suggesting method and data analysis strategies. Multiple interviewees mentioned the need for industry-sponsored science to be more independent from industry influence. According to Dr. Cresswell, a scientist who worked for Syngenta and was interviewed in depth by the New York Times in an article about industry influence on scientific results, "It wasn't conniving on my part, but absolutely [Syngenta] influenced what I ended up doing on the project" (Hakim 2016). Dr. Cresswell also said that while Syngenta was not necessarily blatant in asking him to come up with specific results, they "Syngenta clearly has got an agenda" (Hakim 2016). Dr. Cresswell reported initially coming to results that did not support the conclusions Syngenta was looking for, and in emails they asked him to redo the study considering different data and using a new approach. When he did this, Dr. Cresswell came to results that backed Syngenta's desired outcome.

Through having the scientists sign nondisclosure agreements and confidentiality agreements, the corporation essentially owns all rights to the data produced with industry funding, and the scientists are not allowed to release the results independently. This essentially means the corporation controls what data they fund gets released to regulatory agencies and to the public, since scientists doing research for them would be breaking their contract by doing so. Industry controlled science imposes a significant barrier to stricter pesticide regulation, because when regulatory agencies are reviewing scientific data in order to make regulatory decisions, if there are not as many studies showing harm as there are showing lack of harm, it is ultimately going to influence how pesticides are regulated. This clear influence over scientific results supports the literature on the subject, specifically the 2010 study by Diels and others, that observes a trend in industry funding and results that favor industry interests (Diels et al. 2010). As a large portion of the science reviewed by the EPA and the Scientific Advisory Panel is affected by industry influence, any decision they come to based on this scientific evidence will be too.

Lobbying the EPA is another way the agrochemical industry gets involved officially in the pesticide regulation process. Two important lobbying groups that represent agrochemical interests include CropLife America and the American Chemical Council. Portier, Marquez, Gillam, and Freese all mentioned heavy lobbying by industry to the EPA as a factor that gives industry too much influence in the regulatory process. In late 2016, CropLife America lobbied the EPA and successfully influenced the membership of the Scientific Advisory Panel (SAP) for glyphosate through requesting the removal of a key epidemiologist, even though he did not have any financial conflicts of interest or seemingly valid reason to be removed. CropLife argued that he should be removed because he had made prior statements about his belief that glyphosate was a dangerous chemical, which threatened Monsanto's hope that the SAP would agree with the EPA's draft assessment that glyphosate is not a probable carcinogen. This recent event demonstrates the direct influence industry lobbying can have on important regulatory processes.

Informal Industry Role as a Barrier

In addition to formal influences, the agrochemical industry also influences the EPA, and specifically the OPP, through informal means. Marquez described that through working closely, scientists from agrochemical companies, or firms contracted by them, develop relationships with regulatory scientists. Portier mentioned the potential impact of talk forums on industry's scientific influence, specifically those put on three times a year by International Life Sciences Institute. On the International Life Sciences Institute website, one can find the quote, "Membership in ILSI North America provides the opportunity to develop new research knowledge and to interpret and assess the status of current scientific issues through the large network of academia, industry, and government experts in diverse areas of food science, nutrition, safety, and risk assessment" ("Membership" 2017). Portier, however, noted that these meetings are attended primarily by regulators, regulatory scientists, and scientists from the food industry. A quick scroll through a list of the members of ILSI confirms this statement ("Membership" 2017). Events like these tri-annual talk forums further strengthen relationships and foster the sharing of ideas between industry and regulatory scientists. Such a connection between regulators and independent or academic scientists is more limited, according to Portier. Additionally, Sass mentioned that when visiting the EPA headquarters, the sign-in sheet alone displays the disproportionate presence of industry representatives.

Freese and Portier identified the difficulty in establishing a clear link between the agrochemical industry and the influence corporations exert, because the trail of funding and power can get complicated when accounting for NGO's that are funded by industry or lobbying groups like the American Chemical Council, scientists who get paid off by industry, and personal relationships that are not easy or even possible to track. Additionally, according to Portier, industry even can contribute to forming how the press talks about scientific issues through providing courses and forums to "help" journalists describe scientific issues when they come up, such as IARC's listing of glyphosate as a probable carcinogen that made headlines worldwide.

The role of informal EPA-industry relations in influencing pesticide regulation outcomes is exemplified in recent drama over Jess Rowland, a senior OPP official who recently stepped down, and his relations with Monsanto. Evidence of potential conflicts of interest came forth during the ongoing lawsuits against Monsanto brought on by more than 60 people with Non-Hodgkin's Lymphoma who are suing Monsanto for covering up evidence that glyphosate could cause cancer. Thirty different cases were combined in a federal trial based in San Francisco. Documents from this case have been made public, and bring into scrutiny the relationship between EPA staff and Monsanto in regards to covering up glyphosate's potential to cause harm.

As Carey Gillam states in a Huffington Post article, "Mr. Rowland operated under Monsanto's influence to cause EPA's position and publications to support Monsanto's business" (Gillam 2017c). Email correspondence between Rowland and a former longtime EPA employee suggest staff at the agency were aware of glyphosate's carcinogenic properties in 2013, with the other employee telling Rowland, "It is almost certain glyphosate causes cancer... the CARC category [for glyphosate] should be changed to 'probable human carcinogen'" (Gillam 2017c). However, Rowland was the chair of the CARC committee that reviewed glyphosate and declared it "unlikely to be a carcinogen." Plaintiffs in the lawsuit are arguing that Rowland had a "highly suspicious" relationship with Monsanto. Court records also show that Rowland warned Monsanto about the IARC conclusion on glyphosate months before it was released to the public, which meant Monsanto was able to prepare a "public relations assault" (Hakim 2017). In further details released during this case, the vice president of Monsanto's global strategy reportedly said during a phone conversation, "It's not an effort to manipulate the system" (Rosenblatt, Mulvany, and Waldman 2017). After the release of these documents, the courts are putting further investigation into Monsanto's influence in the regulatory process (Gillam 2017a).

Consideration of Benefits as a Barrier

When regulating pesticides, the EPA is required by the Federal Insecticide, Rodenticide, and Fungicide Act (FIRFA) and the Toxic Substances Control Act (TSCA) to consider the benefits of a pesticide and the costs of removing it from the market. This requirement differs from the guidelines of other environmental acts, such as the Clean Air Act, which prohibits the consideration of benefits in coming to regulatory decisions (Cropper et al. 1992). Consideration of benefits includes the monetary cost to consumers and producers of banning a pesticide from use on a particular crop. The consideration of benefits in the review and registration process for pesticides can lead to skewed considerations towards industry interests, especially now that the entire system of agriculture is heavily reliant on chemical fertilizers and pesticides, which increases the benefits to keeping them on the market. Based on the literature, the required consideration of benefits by the EPA when registering a pesticide for use poses an important barrier to stricter pesticide regulation. The consideration of benefits embedded in pesticide regulation leads to decisions that can place higher importance on monetary costs of removing a pesticide from the market than the potentially devastating public health implications of allowing widespread exposure (Cropper et al. 1992).

Lack of Alternatives as a Barrier

An additional barrier to removing chemical pesticides from the market is the lack of development and research on, or attempts to integrate nontoxic alternatives (Wilson and Schwarzman 2009). Gillam pointed out this barrier, and called for the need to develop a space for safe alternatives. There is a need for additional investment in cleaner and safer chemical alternatives and technologies, the field known as “green chemistry” (Wilson and Schwarzman 2009). Currently, there is significant difficulty associated with changing a well-established, complex system that is engrained in this country’s system of food production. The lack of safe, effective, and inexpensive alternatives to chemical pesticides is a significant barrier, because without them, farmer demand for pesticides will remain high, and removing chemical pesticides from the market will continue to have a high associated cost if there is not a cheap alternative to replace said chemical.

Barriers Specific to Glyphosate

Glyphosate is different from other pesticides because of the high market demand for the chemical and the centralized nature of the profits glyphosate brings to Monsanto. According to Gillam, farmers loved glyphosate when it was first introduced because it was cheap and easy, but now due to more and more crops developing glyphosate resistance they “still feel like glyphosate is important and don’t want to lose it, but they wished they had something better” (Gillam 2017b). Glyphosate resistance does not necessarily mean pesticide users will voluntarily phase out glyphosate, but so far is leading to glyphosate being combined with other chemicals increasing the strength and potential toxicity of the widely used herbicide. Companies are coming up with new mixtures of herbicides, such as Dow Chemical’s EnlistDuo that combines glyphosate combined with 2,4-D, a chemical that was a component of the infamous Agent Orange used during the Vietnam War.

As Gillam mentioned, glyphosate is the “bread and butter” for Monsanto, especially because of their popular Roundup Ready seeds, which bring in the highest profits (Gillam 2017b). Due to the high profits Monsanto receives from glyphosate products, the corporation is putting high levels of pressure on the EPA. The lawsuits brought on by people with NHL increase Monsanto’s determination to ensure glyphosate is regarded as safe, because they are concerned that they will not only lose their key product, but also that these lawsuits will, according to Portier, “continue to pile on” (Portier 2017). If Monsanto can get the hazard assessment to say glyphosate is not a carcinogen, they will be able to influence how glyphosate is considered in the full risk assessment due to be published in the upcoming year.

As the results of the draft hazard assessment are important for informing the full risk assessment, it is troubling that Portier, Sass, and Freese all feel strongly that the EPA did not perform the draft hazard assessment of glyphosate correctly, particularly because they did not follow their own cancer assessment guidelines. The Scientific Advisory Panel (SAP) did not come to a consensus about the status of glyphosate as a carcinogen, however they concluded that the EPA failed to properly separate hazard and risk. As described by multiple experts, EPA guidelines state that a hazard assessment solely should assess whether or not a chemical has the potential to cause unreasonable harm, which differs from a risk assessment that considers the hazard potential along with potential exposure levels. Sass called the current assessment “bologna” and said it was “basically negotiated with Monsanto” (Sass 2017). Freese sees this

assessment as a key problem blocking stricter regulation of glyphosate, as determining the chemical is harmful is the first step along the path to stronger regulation. Industry influence at this step (removing key epidemiologist from the panel, delaying the process by months over multiple issues) has the potential to lead to poor outcomes for public health.

Gillam believes while stricter regulation of glyphosate is important, “there’s not a chance in hell they’re going to ban glyphosate in the United States” (Gillam 2017b). Gillam sees more of a possibility for a glyphosate ban in Europe, especially because regulatory guidelines are different and when an agent is identified as a carcinogen it is required to be phased out, because carcinogens have no threshold for causing harm. Lack of optimism about the fate of glyphosate regulation in the United States can stem from the culture and political history surrounding pesticides in this country.

Figure 5: Themes Addressed by Interviewees

Most common themes identified	Interviewees who spoke to theme
Industry plays too big of a role and influences regulatory processes	All
The EPA is not conducting a proper risk assessment with glyphosate because of the failure to separate hazard from risk	Sass, Gillam, Portier, Freese
Important that glyphosate undergoes a full risk assessment because its use is so widespread	Marquez, Gillam, Sass
OPP has always been more in touch with industry interests than public health interests	Sass, Gillam, Marquez
Only testing the active ingredient does not present the full picture	Sass, Freese
Epidemiology studies are not given enough weight	Sass, Freese, Marquez
EPA assessment shouldn’t differ so significantly from that of an independent agency (IARC)	Freese, Sass
EPA assessment relies too heavily on animal studies (which produces a conflict of interest)	Sass, Marquez, Freese
Studies informing regulatory decisions should be done by independent firms	Freese, Gillam, Sass

IARC's Listing of Glyphosate Demonstrating Barriers in OPP Process

IARC's Process For Determining Carcinogens

As mentioned previously, IARC's process for producing reports involves gathering a group of ad hoc international scientists that have substantial expertise and no conflicts of interest (IARC 2015). The review considers studies and documents that are publicly available, which leads to the exclusion of industry studies that are not made public due to "Confidential Business Information" (Portier et al. 2016). Instead of taking the results of each study they review at face value, the selected team of scientists makes their own conclusions based on the evidence presented. For example, if the authors of a toxicology study state there is no evidence of carcinogenicity, yet the IARC scientists believe the results do show evidence of carcinogenicity, they will use their own conclusions over the authors (Pollack 2015). When establishing a link to cancer, IARC uses four levels of evidence: sufficient evidence, limited evidence, inadequate evidence, and evidence suggesting lack of carcinogenicity (Cogliano).

IARC Process Contrasted With EPA Process

The process of a hazard assessment is similar to IARC's process, in that both agencies consider a wide range of studies, give them different weights for how strongly they will consider the studies in the analysis, and after reviewing all the studies they come to a conclusion about whether or not the agent is a carcinogen. As hazard assessments are fundamentally similar to IARC's monographs determining carcinogenic potential, it is confusing that regulatory agencies are coming to different conclusions about glyphosate from independent agencies. The independent IARC review of glyphosate can help point out where the OPP was perhaps too conservative in their analysis of the data. Comparing the two processes is a useful tool in determining the barriers within the OPP to coming to hazard assessment conclusions (that an agent is harmful) that would lead to stronger regulation. Multiple experts pointed to this discrepancy as a sign the OPP is overly captured by industry, as the main difference is how the agencies weight the studies (the EPA gives more weight to industry produced animal studies than IARC) and the EPA dismissed multiple important studies demonstrating glyphosate's harm on bases experts feel is incorrect.

A key difference between the two agencies originates from the actual data they review. As mentioned previously, IARC scientists look at publicly available research, which excludes

industry studies, while in assessing animal studies, the OPP additionally considers a high volume of industry studies. While there are many scientific studies examining the safety of glyphosate, few meet the requirements for strong consideration from both agencies, therefore many of the studies reviewed by IARC were also reviewed by the OPP. However, the OPP dismissed many of the key studies incriminating glyphosate that IARC examined. This dismissal is an important point of contention, because some experts feel OPP dismissed studies unreasonably, without evaluating the potentially important information the studies contained (Portier et al. 2016). Studies dismissed by the OPP include animal studies with doses higher than 1,000 mg/kg/day, on the basis that it is not reflective of realistic human doses. Additional studies were dismissed that did not show a dose response curve that correlated with increased dose increasing the adverse health impact (known as a monotonic dose response relationship). Epidemiology study results were dismissed due to the inability to rule out recall bias. Experts believe there were valuable points in the epidemiology studies that were too readily discounted. In contrast, IARC scientists looked at all of the available data, evaluating the strengths and weaknesses of each study they analyzed, so they did not miss important indicators of the danger of glyphosate. An additional difference includes OPP's use of historical control data, which according to Freese seems to be used to discount studies that otherwise would have presented significance supporting the carcinogenic potential of glyphosate. In summary, IARC differs from the OPP through considering only publicly available literature and not industry produced studies, not considering dose, dismissing fewer studies, using historical controls differently, and evaluating strengths and weaknesses of all available data.

Response to the IARC study

The IARC monograph sparked a wide global response, from regulating agencies of countries, states, and cities, the media, agrochemical companies, and individuals using it as grounds to sue. IARC's conclusion opened up the conversation about glyphosate's safety in a worldwide setting.

Industry interests, namely Monsanto, responded to the IARC conclusion with outrage. Soon after the IARC report was released, Monsanto released a statement reading, "Based on the overwhelming weight of evidence, Monsanto strongly disagrees with IARC's classification of glyphosate" ("IARC's Report on Glyphosate" 2015). Monsanto representatives further claim the

IARC study is inconsistent with the determination of regulatory agencies around the world, and argue the IARC study should not be “sound basis” for regulatory action (“IARC’s Report on Glyphosate” 2016). Throughout 2016, Monsanto undertook efforts to discredit IARC scientists, and even seeking to pull American Cancer Society funding from IARC in response to the monograph (Gillam 2016c). This strong reaction came as a surprise to many involved in the report, who are not used to having their highly distinguished credentials questioned (Gillam 2016c).

Numerous regulatory agencies, including the European Food Safety Authority and Canada’s Pest Management Agency, reviewed the safety of glyphosate after the IARC listing. While the regulatory agency of the European Union came to the conclusion that glyphosate is safe, they set the safe dose to a level much lower than it currently is in the United States (Myers et al. 2016). While previously citing glyphosate’s safety as a reason for not testing its presence on food products, the FDA responded to the IARC conclusion and subsequent increased concern over glyphosate by starting to test common food items for glyphosate content (Gillam 2016). The FDA found glyphosate in products like SueBee honey and Quaker Oats, but the process has been put on pause since November of 2016 (Gillam 2016d). According to Gillam, Freedom of Information Act (FOIA) documents show that Monsanto suspiciously called the FDA just before testing of glyphosate was paused, in a possible demonstration of industry influence in federal processes. Independent groups, however, continued to test foods for glyphosate content, and found glyphosate in Ritz crackers, General Mills’ Cheerios, Kellogg’s Special K cereal, and Kashi oatmeal cookies (Gillam 2016a) (Gillam 2016c).

The California Office of Environmental Health Hazards Assessment (OEHHA) responded to the IARC monograph by listing glyphosate as a carcinogen to be labeled under Prop 65, the state law requiring warning signs when there is risked exposure to potentially carcinogenic chemicals (Plume 2016). Since the IARC report came out, several countries, cities, and towns have banned or severely restricted the use of glyphosate or Roundup. Individual countries including France, Belgium, Sweden, El Salvador, Bermuda, and the Netherlands, are moving to ban glyphosate based on the IARC determination. Cities and towns restricting glyphosate use include Malibu, Richmond, and Fairfax in California, Reno, Nevada, Boulder, Colorado, and Glastonbury in the UK (“Glyphosate and Pesticide Bans around the World as of July 2016” 2016).

Recommendations

Given the environmental health problems associated with high levels of chemical pesticide use, including cancer, birth defects, developmental delays and more, the need exists to change U.S. pesticide policy in order to lower levels of chemical pesticides in the environment. In theory, the current system for regulating pesticides is complete and effectively protects human health while encouraging development in the field of pest and weed management. However, significant flaws in the system impact the decisions made by the EPA (particularly the OPP within the EPA) and lead to lapses in regulation in ways that support industry and fail public health and the environment. The following recommendations propose a step in the direction of human and environmental health protection, however ultimately the removal of toxic pesticides from use as a pest management strategy is the only way to have an agricultural system that is sustainable in the long term.

Many of the following recommendations will be difficult to accomplish with the Trump administration's emphasis on limiting regulations within the EPA. This is exemplified in the recent decision made by Scott Pruitt, the current EPA administrator appointed by Trump, to reject a petition to ban chlorpyrifos, an organophosphate insecticide identified as a developmental neurotoxin (US EPA Media Relations 2017). Particularly, amending the Federal Insecticide, Rodenticide, and Fungicide Act (FIRFA) in ways that will put further restrictions on industry will be unlikely to pass in Congress with the current Republican majority, due to patterns of industry-friendly behavior (Sneed 2017) (Dennis and Mufson 2017). The proposed 43% cut to the EPA budget and laying off of 25% of the agency's employees is a significant barrier posed by the new administration in terms of accomplishing the following recommendations, especially in terms expanding funding programs and hiring additional staffers (Eilperin, Mooney, and Mufson 2017). Nonetheless, the following recommendations are important for drafting proposed changes in legislation, planning for funding changes, and incorporating practices for nonprofits.

Amend FIRFA to Decrease Chemical Industry Influence

As a long-term goal, FIRFA must be amended in order to ensure fair and complete examinations of the carcinogenic potential of chemical pesticides. Such amendments should work to cut industry control over the science informing regulatory decisions. Members of the

House and Senate who support decisions based on unbiased science guiding regulation of potentially harmful pesticides should support amending FIRFA. FIRFA requires every pesticide distributed, sold, and used in the United States to first be approved for use by the EPA, based on the determination that it does not cause any unreasonable adverse effects, and lays out directions for this registration process (EPA).

In order to lessen the influence of industry, FIRFA must be amended to require the results of studies examining an agent they regulate to be sent directly to the EPA, and contracted with entirely independent firms. While it is necessary for chemical companies to fund the science backing initial pesticide registration requests (because using public funds for this would be using public funds to help companies get chemical products registered for use), the client based relationship of such studies can be changed by shifting the EPA to the group contracting the science, while industry is funding it. This way, industry will have less of an influence on the results of independent scientists' studies than they do currently, as exemplified by the New York Times expose on the scientist in England working for Syngenta discussed in the Findings section of this paper.

Further amending FIRFA could modify the current system to allow for the consideration of formulations, instead of only examining the active ingredients, as FIRFA sets the basic guidelines for how regulatory testing proceeds. As there are thousands of different formulations on the market and testing all formulations would present too heavy a burden for the OPP, this adjustment could start by requiring only the consideration of the top ten most applied pesticide formulations currently on the market (adjusted over the years to account for market shifts). This adjustment to FIRFA would help solve the barrier to stronger pesticide regulation posed by the limitations of only testing the active ingredient alone, instead of as a mixture with the inert ingredients it is used with. Only testing an active ingredient doesn't tell the EPA enough about a pesticide to fully understand it's potential effects, because when humans and the environment are exposed to a pesticide, they are exposed to the formulation. Testing formulations has demonstrated higher levels of toxicity than tests of just the active ingredient in the formulation, and higher demonstrated toxicity ideally would lead to stronger regulation.

Amending FIRFA will be difficult given the anticipated strong pushback from the agrochemical industry and its substantial lobbying power. However, FIRFA has been amended to

be more protective of public health in the past, therefore there is hope that in the future it is plausible the act could be revised for the better.

Control Industry Influence Through Limiting Lobbying Spending

In order to limit the overblown power of the agrochemical industry, one of the biggest factors inhibiting stronger pesticide regulation, it is necessary to impose spending limits on lobbying. Lobbying allows money to equate to power, and gives billion dollar corporations huge amounts of influence political decisions that affect public health. This imbalance is reflected in the fact that “of the 100 organizations that spend the most on lobbying, 95 consistently represent business” (Drutman 2015). Along with spending limits, stronger lobbying regulation would decrease the ability of industry to play an influential role in regulatory processes. As Lee Drutman, a senior fellow at New American working for political reform says, “The problem isn’t that corrupt politicians are breaking the law. The problem is that we don’t even have laws for them to break” (Drutman 2015). Having conversations about the possibilities of limiting lobbying spending to the EPA is important given how entrenched corporate lobbying has become in today’s political system.

Block the Honest and Open New EPA Science Treatment Act and the EPA Science Advisory Board Reform Act

In 2017, Republicans reintroduced two bills, the Honest and Open New EPA Science Treatment Act (previously known as the Secret Science Reform Act), and the EPA Science Advisory Board Reform Act, under the guise of improving transparency and science within the EPA. However, together these acts would ultimately undermine the EPA’s ability to act independently and use quality science to back regulatory decisions while posing a significant threat to the scientific integrity of Scientific Advisory Boards. Moving forward, these bills should be shut down by members of the House and Congress who support Scientific Advisory Boards made up of unbiased highly qualified academic experts, and science-backed decisions that prioritize public health and the environment over industry profits. Organizations concerned about environmental health must fight these two bills and others like them to prevent them from passing in the Senate, as they have both already passed in the House. Representative Eddie Bernice Johnson (D–Texas) states, “Those bills were constructed to hamstring the ability of EPA to do about anything to protect the American public” (Cama 2017).

As Dr. Andrew Rosenberg of the Union of Concerned Scientists writes, these two bills “introduce unreasonable requirements, new delays and added levels of bureaucracy, and increase the power of corporations to interfere with laws meant to protect us.” (Andrew Rosenberg 2015). The Honest and Open New EPA Science Treatment Act only allows the EPA to use studies that are entirely reproducible and “transparent” which would have the effect of making it more difficult for the EPA to impose new regulations and “craft them based on the best available science” (Sneed 2017). Only allowing the use of studies that are replicable opens the door to the exclusion of epidemiology and other long-term health studies if opponents can argue they are not entirely “replicable.” Additionally, requiring the EPA to release all data used to back regulatory decisions could be limiting if the data involves confidential health information.

The EPA Scientific Advisory Board Reform Act revises the process for selecting members for the Scientific Advisory Board and changes the guidelines for participation on the board as well as the terms of office (A Rosenberg 2015). Through allowing industry experts to sit on boards, limiting the number of state, local, and tribal officials that can serve on a board, and barring independent scientists from serving if they have received a grant from the EPA in the past three years, this act opens the door for increased industry influence.

As “the bills employ insidious, albeit creative, approaches to weaken the ability of science to inform federal rule-making,” it is important to keep them from going into effect (A Rosenberg 2015) If passed, these bills would accomplish the exact opposite of what this paper suggests, through increasing industry influence in the regulatory process and increasing systematic barriers by requiring unnecessary steps that inhibit the EPA’s processes while not providing a sufficient budget. As it is, through informal influences the agrochemical industry has too much power in influencing membership of Scientific Advisory Boards, as demonstrated by Monsanto impacting the removal of an epidemiologist from the board reviewing the EPA’s assessment of glyphosate.

Additional Funding for Development of Chemical Pesticide Alternatives

Increasing the availability of chemical pesticide alternatives requires adequate generation of science focused on developing safe non-chemical pesticides. A grant program offered by the EPA currently funds scientists to develop safer chemicals, and additional funding directed to this program is recommended. In order to expand funding for the development of alternatives the

EPA could gain additional funds from a tax on chemical pesticide producers, similar to the tax program on cigarettes established by Prop 56 in California. This program allocates a portion of the high tax on cigarettes to low-income health care and tobacco-related disease medical research (Legislative Analyst's Office 2016). One issue with this taxation model applied to chemical pesticides, specifically glyphosate, is that it pushes the cost on farmers who have a dependence on inexpensive pest and weed control. Increased costs for farmers would likely get passed down the supply chain to consumers, and result in higher food costs. However, as part of the fund established by this tax goes towards the development of safe and affordable alternative methods of pest and weed reduction, hypothetically these products could become widespread and the cost of food would go down as alternative pesticides became more affordable. Increasing available funding to expand the current EPA grant program is important because it helps sponsor scientists working to develop alternatives, which would help advance existing technologies and widen options available to farmers.

Existing alternatives have been developed from substances such as microbial biopesticides, insect pheromes, and plant-based products such as garlic spray. Further development of alternative pesticides could be aided by the encouragement of farmer/researcher partnerships. If more industrial-scale farmers supported using alternative pesticides, that would help reduce the demand for chemical pesticides and increase demand for alternatives.

When considering the benefits of a pesticide, regulatory agencies take into account the cost of removing the agent in consideration, as well as the availability of replacements. If there are not a wide variety of inexpensive alternatives, the relative weight of benefits (of allowing continued use) increases, whereas if inexpensive and safe alternatives are plentiful, the EPA will be more likely to take stronger action. Therefore, funding the development of alternative pesticides directly addresses an important barrier to stronger pesticide regulation.

Additional Funding to the OPP

Additional funding directed to the Office of Pesticide Programs (OPP) could allow the office to hire more statisticians, which presumably would help correct errors Portier identified with the way the OPP analyzed available data on glyphosate (errors that likely occur in the analysis of other pesticides as well). This funding could also be directed to hire additional epidemiologists in the OPP in order to balance out the consideration of epidemiology and animal

studies. Sass, Freese, and Marquez mentioned the need for further incorporation of epidemiology, and hiring a permanent epidemiologist to the OPP is a practical recommendation only hindered by the proposed reduction in funding to the EPA. As mentioned previously, additional funding to the OPP is unlikely, especially in light of a proposed bill to cut funding to the program and replace it with fees paid by corporations or individuals applying to register a pesticide product (R. Davis 2017).

With additional epidemiologists, the OPP would be better rounded, and epidemiological studies would likely receive higher consideration and be analyzed more fully with a trained epidemiologist on staff. Epidemiology studies are important to consider in pesticide regulation because they look at how formulations (as opposed to just active ingredients) affect humans (as opposed to lab rats) based on reported exposure.

Increase Role of Non-Profits in Pesticide Regulation to Balance Corporate Influence

When asked about the role of nonprofits in the pesticide regulation process, experts working for Non-Profit Organizations (NGOs) cited the need for NGOs to stay involved through participating in public meetings, submitting official comments, supporting or proposing good legislation, bringing on public pressure, talking more with the EPA, and performing health impact studies (Sass 2017) (Freese 2017) (Marquez 2017). NGO employees and academic scientists can engage further with regulatory scientists through inviting regulatory scientists to academic forums on pesticides and toxicity on a more frequent basis than is done currently, in order to balance out industry engagement with regulatory scientists. Another role of NGO's that many already undertake (such as PANNA and Food and Water Watch) includes educating consumers about chemical pesticides, in terms of specific effects of eating food with pesticide residue, and in terms of effects faced by farmworkers and ecosystems burdened by excessive pesticide use. Consumer education is important for shifting the market demand towards organic products, as has been seen in the past 10 years with total U.S. organic sales going from below \$19 billion to over \$40 billion between 2006 and 2015 (McNeil 2016). Education surrounding glyphosate is especially important to combat years of industry controlled dialogue pushing the idea that glyphosate is harmless.

NGO's can also help keep information transparent by making Freedom of Information Act (FOIA) requests for information concerning regulatory decisions where there is suspected

industry involvement. Reporting on such information and bringing it to the public can help keep regulators accountable, and discourage under the table dealings with agrochemical producers such as Monsanto. Ultimately, changes need to happen at the federal level to prevent widespread exposure to dangerous chemical pesticides. However in the mean time, nonprofits can act to support minimizing public exposure to potentially carcinogenic pesticides, especially by pushing state and local governments to regulate chemical pesticide use.

Encourage State and Local Level Pesticide Regulation

Given the current administration in the United States and its proposed staff and budget cuts to the EPA, predicted industry-lenient attitude, and decision not to ban chlorpyrifos, the most important area to gain traction for change in pesticide regulation lies at the state and local level. State and local restrictions on pesticide use carried out by state and local governments and encouraged by nonprofits are recommended. States have the power to regulate pesticides, or control factors relating to pesticide use, beyond the level they are regulated at the federal level. At the local level, action is already being taken to ban glyphosate, as can be seen in cities such as Boulder, Malibu, and Richmond. This presents a method to get around the barriers at the federal level to banning potentially carcinogenic pesticides. Difficulties associated with getting states and local governments to ban glyphosate include the limited availability of and education on alternatives, but primarily the higher costs of alternatives deters decision makers from supporting the switch. Such difficulties are surmountable, evident through cities and states that have successfully taken action in support of reducing pesticide exposure.

Successful state action occurred recently in California, when the state won a lawsuit against Monsanto over adding glyphosate to the list of carcinogens requiring label under Prop 65.⁹ This listing is important because California often acts ahead of the trend on environmental health issues, and actions taken in California can influence other states to follow suit through providing a framework (Schmidt 2007). Presumably when an item is labeled as a carcinogen, people will be more wary in choosing a product containing glyphosate, and may opt for a safer option instead. This ultimately could lead to lower levels of glyphosate in the environment, and demonstrates the ability of state action to reduce pesticide use. Another potential example of

⁹ Prop 65 is a California state law requiring warning signs when there is risked exposure to potentially carcinogenic chemicals

state based action is taking place in Hawaii, where state senator Josh Green plans to propose legislation that would ban glyphosate, which, if realized, would make Hawaii the first state to do so (“Newsmakers: What Lawmakers Are Doing and Saying” 2017).

As more cities and towns ban glyphosate, suspicions over the safety of the chemical are likely to increase, which could spur additional local governments to impose stricter regulations on glyphosate use. Such a snowball effect can be observed in plastic bag bans that are occurring in more and more cities, counties, and states across the country. Additional action by individual institutions and municipalities, where large quantities of glyphosate are used, presents an important avenue for changing pesticide use habits. While state and local action does not directly address solving the barriers to regulating potentially carcinogenic pesticides, it provides a way around the barriers to achieve the ultimate goal of stronger regulation on potential carcinogens, which is to remove them from the environment.

Conclusion

Strong pesticide regulation that minimizes future public exposure is incredibly important given the widespread use of glyphosate and the potential harm this could implicate due to IARC’s finding that glyphosate is a probable carcinogen. The agency regulating pesticides must be able to come to conclusions over the danger of an agent without overt influence from the industry that will profit from loose regulation. This paper asks the question; What are the primary barriers to banning potentially carcinogenic pesticides, and can IARC’s methods for determining glyphosate a probable carcinogen inform the EPA’s hazard assessment process? The answer to this question can be applied more broadly to encompass other pesticides beyond those that are potentially carcinogenic, and identifies aspects of the EPA that can be changed to make the system for regulating pesticides more protective of public health.

The key barriers to stronger restrictions on potentially carcinogenic pesticides are identified by interviews with experts in pesticide regulation in the United States with knowledge about glyphosate, as well as the literature. Barriers include the wide reach of industry influence, in both the formal and informal spheres, systematic issues within the Office of Pesticide Programs, such as program cuts and growing numbers of pesticides to review, considering the benefits of a pesticide during regulatory processes, only examining active ingredients instead of

formulations, and giving too much weight to animal studies and not enough to epidemiology studies. Additional barriers specific to glyphosate include minimal low cost alternatives, widespread dependence of farmers on the herbicide, and errors made in the hazard assessment leading the EPA to not recognize its carcinogenic potential paving the way for less stringent regulation.

IARC provides an independent standard against which to examine the EPA's hazard assessment of the carcinogenic potential of glyphosate. Understanding how they differ helps point out areas in which the EPA is influenced by industry, as this is an important difference between the two assessments. Barriers to the EPA determining pesticides are carcinogenic exist, as when they are removed, as in the IARC report on glyphosate, a more sensitive conclusion is reached. This has broad implications, because if the EPA fails to find a pesticide carcinogenic when in reality it is, such a pesticide would then be approved for use at levels that, unacknowledged by the EPA, cause cancer in the population. With cancer being a leading cause for death in America today, the public health implications of a regulatory failure such as refusing to properly regulate a carcinogen are enormous.

In order to expand on this research, areas for potential future study include an in depth analysis of Enlist Duo (the formulation proposed by Dow Chemical that combines glyphosate with 2,4-D and was approved for use by the EPA), a feasibility study on the ability of the EPA to test the top 20 pesticide formulations given available resources and trade secret laws, and a study on the best methods for nonprofits to use in order to effectively engage with the EPA to further balance the influence of agrochemical companies. A study mapping glyphosate use and overlaying it with incidence of Non-Hodgkin's Lymphoma would provide an interesting addition to the literature. Expanding this analysis further could look at the barriers to banning glyphosate in developing countries. This could be a compelling topic because multiple developing countries have banned glyphosate, which would provide a comparison to assist with the analysis. Additionally, while research into the effectiveness of pesticide enforcement efforts in supporting the regulations that are so tedious to develop exists, creating an in depth analysis of this issue would be a valuable contribution.

The results of the 2016 election represent a significant step backwards for stricter chemical policy and protecting public health and the environment from the effects of toxic pesticides. Most of the barriers mentioned in this paper will likely be exacerbated to new levels

under the current EPA leadership and Republican majority. Pruitt's decision not to ban chlorpyrifos demonstrates an unwillingness to prioritize public health when it comes to chemical pesticide exposure. Nonetheless, through preparing to draft amendments to FIRFA, expand funding for pesticide alternatives, direct funding to the OPP to hire more statisticians and epidemiologists, and encouraging state-level pesticide regulation while increasing independent scientists' involvement with regulatory scientists, pesticide regulation can feasibly escape undue industry influence and be more protective of public health and the environment in the future.

Appendix

1. History of Acts and Laws Relating to Pesticides

Before the creation of the EPA in 1970, the USDA and the FDA were the primary governing agencies responsible for regulating chemical pesticides (F. R. Davis 2014). In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FFDCA), marking an important early legislation for pesticides (F. R. Davis 2014). This act introduced setting safe levels of “unavoidable” poisonous substances, like pesticides, on food. As the name implies, the Federal Food, Drug, and Cosmetic Act (FFDCA) had implications wider reaching than just pesticides, but this paper focuses only on the impacts these acts had on chemical pesticide regulation.

In the years following the passage of FFDCA, regulators began to realize the limitations of this act in regards to controlling the use of pesticides derived from organic chemistry, such as DDT and organophosphates, which were growing in popularity at the time (F. R. Davis 2014).¹⁰ The inability to set stronger regulations influenced the drafting and passage of the 1947 Federal Insecticide, Fungicide, and Rodenticide Act (FIRFA) (F. R. Davis 2014). FIRFA is regarded as key pesticide legislation, as it required pesticides to be registered before sale and product labels to specify content and whether the substance was poisonous. Post FIRFA, registration is required for all pesticides on the market, and approval for use is granted by the governing agency, pending testing of the proposed active ingredient. While the initial version of the act tended toward leniency for industry, overall, it served as a step towards further development of stronger regulation (F. R. Davis 2014).

FIRFA has been amended numerous times since 1947; notably in 1964, when an amendment increased the authority of the governing agency (not yet the EPA) to remove products from the market based on safety concerns by removing or suspending registration of a pesticide (F. R. Davis 2014). This amendment changed FIRFA to require special consideration of pesticides thought to cause unreasonable adverse effects on the environment. The act defines this as, “(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard” (*Federal Insecticide, Fungicide, and Rodenticide Act* 2012). After this update, any

¹⁰ Organophosphate pesticides have strong evidence of neurological damage, and can be acutely toxic in high doses (“Organophosphate Insecticides” 1996).

pesticide sold or used in the United States must first be approved by the regulating agency based on the determination that it does not cause any unreasonable adverse effects.

In 1970, the EPA was created and assumed responsibility for regulating pesticides, partially in order to lessen the influence of agricultural special interests groups on the regulatory process that existed when the USDA and FDA were in charge, and increase the influence of consumer and environmental groups (Cropper et al. 1992). Within the EPA, the Office of Pesticide Programs (OPP) reviews approved studies on the effects of a pesticide that is either being proposed for registration or undergoing a periodic registration review.

The Federal Environmental Pest Control Act (FEPCA) passed in 1972, and amended FIRFA by significantly increasing authority of the newly created EPA in regulating pesticides. It is important to note that this happened after the publication of *Silent Spring*, the influential book by Rachel Carson featuring DDT that widened public awareness and outcry over the environmental disasters pesticides could cause (Griswold 2012). The discourse among regulators was leaning towards the need for stronger regulation, however *Silent Spring* is credited with creating a substantial ripple effect as far as increasing awareness and wariness among the American public, especially among environmentalists (F. R. Davis 2014). An important aspect of FEPCA includes the reexamination of the safety of pesticides registered in the prior four years.

In 1976, the Toxic Substances Control Act was passed, requiring the government to ensure that “chemicals are properly tested and regulated before they reach the market, and don’t pose any unreasonable risk to human and environmental health” (Black 2005). TSCA was an important step in controlling the use of pesticides, but concerns still existed after its passage over chemical safety and the adequacy of the legislation (Black 2005). Recent updates to TSCA help address these concerns, and hopefully will lead to improvements in speeding up the risk assessment process, prioritizing chemicals to assess, and increasing funding for costs of new chemical reviews and TSCA implementation activities (OCSP US EPA 2016).

The Food Quality Protection Act (FQPA), passed in 1996, updates FIRFA as an important asset to stronger regulations of pesticides applied to food products because it mandates that the EPA impose a “safety factor” reduction of chronic reference dose level by three to ten percent if there is any uncertainty about the safety of a chemical (*Public Law 104-170* 1996).¹¹

¹¹ Chronic reference dose refers to an estimate of daily exposure to a chemical through ingestion that likely would not cause any risk or deleterious effects during a lifetime (EPA 2011).

This uncertainty can arise from gaps in data, conflicting studies, or questions over the quality of toxicology data (Myers et al. 2016). The safety factor is intended to protect infants and children, as they are more affected by chemical exposure than adults and are considered a sensitive population (Wilson and Schwarzman 2009). FQPA additionally requires the EPA to reassess pesticide tolerances every 10 years, giving “priority to those that pose the greatest risk to public health” (*Public Law 104-170* 1996). Another important aspect of this act is the limitation of the consideration of benefits in setting new tolerances, so that such considerations only apply to non-threshold effects of pesticides (such as carcinogenicity, which does not have a threshold). However, benefits still play a role in consideration of existing tolerances, which applies to all pesticides on the market prior to 1996, a large group that includes glyphosate (F. R. Davis 2014).

2. Full List of Interview Questions

1. Do you believe the EPA should impose stricter regulations on potentially carcinogenic pesticides?
2. Do you believe it is important for the EPA to restrict the use of/ strengthen regulation of glyphosate? (To what extent, and why?)
3. What do you believe are the key barriers affecting the EPA’s decision to ban potentially carcinogenic pesticides?
 - a. Specific barriers in the risk assessment process?
 - b. Specific barriers with glyphosate?
4. What is your opinion on the role of the agrochemical industry in the pesticide regulation process?
5. How do you see the role of NGOs in the pesticide regulation process?
6. Do you think the EPA’s process (*just the hazard identification phase*) could benefit from becoming more like that of IARC?
7. Is there anything fundamentally wrong with the risk assessment process itself (*ie how acceptable daily intake level is calculated or only looking at active ingredients instead of marketed formulations*), or do you see the main barrier to stricter regulation as industry involvement? (or both?)

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