SOWING THE SEEDS OF CONTROVERSY: WHAT THE DICAMBA DEBACLE REVEALS ABOUT THE MODERN PESTICIDE REGISTRATION PROCESS AND WHY THE EPA MUST ACT

BY

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The American farmer has long been the worldwide leader in agricultural management practices leading to increased yields. Innovation in agriculture, like any other industry, is a vital component to sustaining progress and viability in future seasons. The United States relies upon formulations of pesticides and herbicides as a method of controlling and reducing threats to priority crops. The usage of these substances led to the natural development of a resistance trait in some weeds. Advances in chemical technology now seek to leverage genetic engineering of seeds to counter this resistance.

This process of agricultural innovation and development has taken place for decades with little, if any, interest from the general public. That changed dramatically in 2015 when new blends of an old herbicide went into use before it was fully tested and vetted for safety, igniting a firestorm that would soon engulf farmers, chemical manufacturers, state legislators, and the United States Environmental Protection Agency (EPA). This Article will examine the Dicamba controversy focusing on the registration process that has largely been the source of conflict. This Article asserts that Monsanto's refusal to authorize third-party volatility testing during the Xtendimax registration process and the EPA's silence following efforts at highlighting the potential adverse environmental effects demonstrate a need to amend the regulatory rules regarding herbicide registration. Specifically, 40 C.F.R. § 158.75 should require a party seeking to register, or reregister, a pesticide to

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submit to additional data testing when the EPA or a state environmental agency has determined a threat of unreasonable adverse effect to the environment actually exists.

I. INTRODUCTION

"[A] new type of thinking is essential if mankind is to survive and move to higher levels." - Albert Einstein[1]

"Did you fill up your water jug? It's going to be hot today." These were the words my father asked me as I loaded up in his truck. My dad worked in the agricultural fertilizer and herbicide industry, straddling an area of northwestern Louisiana and southwestern Arkansas. He spent the majority of the spring, summer, and fall working fourteen hours or more each day with farmers to ensure bean fields were looking good, the corn was growing, and cotton was progressing as it should. I was fourteen at the time and full of youthful energy with little practical useful knowledge of my own outside of my schoolwork, which did not interest me much at the time. This turns out to be the perfect combination for a young farm hand, and my destination that morning was a 300-acre soybean field. The farmer that owned the plot was a very generous man that extended an offer for me to dove hunt on his land in the fall. My dad made it clear that I would not take advantage of this generosity and would work my way to earning this opportunity. By work, he meant that I would start at one end of a massive field and chop out pigweed and other unwanted vegetation competing with the knee-high soybean plants. No tractor, no air conditioning, just me, a long-handled hoe with a file to sharpen it as I wore down the edge, and my water jug. My dad would drop me off in the early morning, check on me throughout the day, and finally come to collect me for the ride home as the evening sky began to turn brilliant hues of purple and pink.

[1] *Atomic Education Urged by Einstein*, N.Y. TIMES, May 25, 1946, at L13 (quoting Einstein).

Hot did not begin to accurately describe the sweltering inferno that can be summer in the piney woods of northern Louisiana or southern Arkansas. I was located just far enough north to miss the gulf breezes and afternoon rains, but far enough south to experience incredible humidity coupled with stifling heat that could drive a person mad as they start to cook in the blast furnace-like heat. These conditions do, however, provide great consistency for growing warm weather crops such as cotton and soybeans that enjoy the long days full of sunshine and warmth. American farmers are a tough group, working more hours before the sun rises than most of us work before lunch. The hard work is partnered with incredible risks, as hail storms, droughts, hurricanes, or a plethora of other natural occurrences can spell disaster for a working farm. An ever-present threat, also, are pests and weeds that sought to overtake and choke out young plants as they struggled through the growing season. I was able to witness first-hand the intricate calculus that American farmers go through each year as they select the right seed and fertilizer, assess when pesticides are necessary to stave off infestations, and constantly seek to beat back the legions of pigweed or other weed varieties that spring up seemingly overnight in their fields. So, day after day, weekend after weekend, I worked in my 300-acre battlefield to ensure it was the most pristine agricultural specimen west of the Mississippi River.

Often, I would be frustrated to find a three-foot-tall pigweed plant in the rows I had just cleaned a few days before, so I would backtrack and walk the lengths of the long rows yet again. Looking back now I realize that eliminating weeds was not the point of my farming odyssey over that sweltering summer. It was about teaching me the value of hard work and giving me just a little taste as to how it would be to earn a living through sheer physical labor. Interestingly, I began to take a keener interest in my school work and my grades suddenly improved the following year. My soybean field did well, and I am sure my sweat saved the farmer an application or two of herbicide on that particular field. The reality I then came to understand was that pesticides and herbicides were vital tools for the farmer. It seems finding enough high school boys to dedicate summers to weeding beanfields is a tall order, and in truth, not nearly as effective at reducing weeds and increasing yields.

It seems life often wraps lessons into experiences that we never anticipate. For example, Professor Kevin Bradley, a doctor of weed science at the University of Missouri, never anticipated that he would be a central figure in several full-length articles produced by the New York Times[2] and National Public Radio;[3] or Joe Mencer, a farmer from southeastern Arkansas, also likely never envisioned being called to serve as a member of a high-profile public task force created by the Governor of Arkansas.[4] Yet both

2 Danny Hakim, *Monsanto's Weed Killer, Dicamba, Divides Farmers*, N.Y. TIMES (Sept. 21, 2017), https://perma.cc/KJ4H-S949.

3 Dan Charles, *Monsanto Attacks Scientists After Studies Show Trouble for Weedkiller Dicamba*, NAT'L PUB. RADIO (Oct. 26, 2017), https://perma.cc/R9PR-64JV.

4 Press Release, Ark. Agric. Dep't, Ark. Dicamba Task Force Members Announced (Aug. 7, 2017), https://perma.cc/B6W3-W4GL.

Bradley and Mencer now find themselves on the frontlines of a skirmish turned full-on war, between American farmers, the pesticide industry, and state and federal regulators.

This war involved the development and application of a new blend of an old herbicide known as Dicamba. Dicamba is a "selective herbicide . . . registered for use in agriculture on corn, wheat and other crops."[5] For years Dicamba was sprayed by farmers in attempts to control weeds and to eliminate the competition for sunlight and nutrients that growing crops require.[6] The chemical industry undertook efforts to refine and improve the effectiveness of herbicides such as Dicamba.[7] Eventually, a sophisticated method of genetically modifying the seeds of some crops to be resistant to herbicides such as Dicamba promised to revolutionize the fight against some strains of weeds.[8] Farmers could now spray growing fields with this Dicamba blend and the resistant crops would be unaffected while the weeds and other vegetation would wilt and die.[9] The commercial impacts for farmers and the ag-chemical industry are both impressive and potentially lucrative. The new Dicamba blends were hailed as a breakthrough in agricultural technology.[10]

However, the rush to bring these products to market as quickly as possible was met with caution as some questioned the potential secondary effects Dicamba could have, which could result in devastating, albeit unintended, impacts on traditional seeds not formulated for use in the genetically modified method.[11] This is where the battle lines began to form. Scientists and state regulators began to request additional information and testing opportunities from the chemical manufacturers.[12] These requests were seen by the chemical companies as redundant and unnecessary, failing to consider the millions of dollars and years of development already sunk into these products by the companies, which would further delay bringing the new Dicamba blends to market.[13] Industry titan Monsanto was particularly adamant that any further testing was unnecessary and duplicative to an absurd degree.[14] Baden Aniline and Soda Factory (BASF), another powerhouse of the ag-chemical world, charted a different path, allowing university researchers to further examine and experiment on its

5 *Registration of Dicamba for Use on Genetically Engineered Crops*, U.S. ENVTL. PROTECTION AGENCY, https://perma.cc/A7UZ-F4GU (last visited Nov. 25, 2018).

6 *See* Jacob Bunge, *Arkansas Bans Herbicide as Farmers Blame Neighbors for Crop Damage*, WALL STREET J. (July 11, 2017), https://perma.cc/3LHB-LH8L.

7 *Id.*

8 *Id.*

9 *Registration of Dicamba for Use on Genetically Engineered Crops*, *supra* note 5.

10 *See About Vaporgrip Technology*, ROUNDUP READY XTEND CROP SYSTEMS, https://perma.cc/M4ZF-FCA7 (last visited Nov. 25, 2018).

11 *See* Dan Charles, *Damage from Wayward Weedkiller Keeps Growing*, NAT'L PUB. RADIO (July 6, 2017), https://perma.cc/MGT2-J58P.

12 *See* Kevin Bradley, *Dicamba Injured Crops and Plants Becoming More Evident: June 15th Update*, U. MO. (June 21, 2018), https://perma.cc/FR9M-RXEY.

13 Emily Flitter, *Scant Oversight, Corporate Secrecy Preceded U.S. Weed Killer Crisis*, REUTERS, Aug. 8, 2017, https://perma.cc/EU3A-WG9X.

14 *Id.*

Dicamba blend while still advancing it to market.[15] The United States Environmental Protection Agency (EPA) registered the new Dicamba blends from both, without requiring further testing.[16] The EPA, instead, relied largely on the extensive testing and analysis submitted by Monsanto and BASF, respectively.[17]

However, starting in 2015 and building steadily through the 2016 and 2017 growing seasons, reports of crop damage began appearing, exhibiting the effects of Dicamba application on non-treated and non-targeted fields.[18] Soon these reports began to flood into agricultural offices throughout the Midwest and South, with Arkansas experiencing particularly severe impacts, registering over 1,000 individual crop damage complaints in 2017.[19] Accusations were levied, alternative explanations offered and outright denials were the order of the day between regulators, chemical company representatives, herbicide applicators, farmers, and scientists. By the summer of 2017, the percolating Dicamba drama detonated in the national media. Full exposés in the New York Times,[20] the Wall Street Journal,[21] and National Public Radio[22] documented how the product appeared to have been rushed to market and was now causing widespread damage to neighboring farms not utilizing the new genetically modified regime of seeds and herbicide. It is little wonder the story has become such an attractive scoop for reporters at the national level, it has all the hallmarks of a great story: big, bad chemical corporations interested in maximizing profits, likable underdog farmers working to scratch out a living in the heartland, and scientists pitted against the corporations. There was even a murder mixed into the intrigue as allegations of Dicamba misuse led to a dispute between neighboring farmers to turn violent.[23] By late 2017, the EPA was forced to publicly acknowledge the controversy existed when it added the new Dicamba blends to the list of restricted-use pesticides.[24] As we move towards the 2018 spring planting season, there is much concern over the future of Dicamba and all eyes are focused directly on the chemical industry and the

15 Press Release, BASF, BASF Statement on Arkansas Dicamba Task Force Recommendation, https://perma.cc/2MZQ-PGCL [hereinafter BASF Press Release]; *see also* Flitter, *supra* note 13.

16 *See generally* U.S. ENVTL. PROT. AGENCY, REGISTRATION DECISION FOR THE CONTINUATION OF USES OF DICAMBA ON DICAMBA TOLERANT COTTON AND SOYBEAN (2018), https://perma.cc/ZKC3-DV26 (extending registration until 2020 while relying on the 2016 data) [hereinafter REGISTRATION DECISION].

17 *Id.*

18 Bryce Gray, *Reports of Dicamba Damage to Crops Are Back Again*, ST. LOUIS POST-DISPATCH (July 7, 2018), https://perma.cc/9D56-3KRM.

19 Andrew Demillo, *Monsanto Sues Arkansas Board for Banning Disputed Herbicide*, ASSOCIATED PRESS, Oct. 20, 2017, https://perma.cc/BWM8-JC4A.

20 *See* Hakim, *supra* note 2.

21 *See* Bunge, *supra* note 6.

22 *See* Charles, *supra* note 11.

23 *See* Marianne McCune, *A Pesticide, a Pigweed and a Farmer's Murder*, NAT'L PUB. RADIO (June 14, 2017), https://perma.cc/CJ6T-A4RB.

24 *See* REGISTRATION DECISION, *supra* note 16, at 20 (stating that "[a]ll dicamba OTT applications are already restricted use" in the 2020 registration extension).

EPA to see if the Dicamba experience will pave the way for a review of the pesticide registration process in the United States, particularly concerning modern innovations in genetically modified crop systems.

This Article will examine the process and differing approaches employed by two of the largest chemical companies, Monsanto and BASF, in registering Dicamba with the EPA for public use. Central to this examination will be a review of the pesticide approval process employed by the EPA and the critical role that the EPA plays in evaluating and authorizing the use of various agricultural chemicals in the United States.

It is important to note at the outset that this Article does not intend to take a side, either industry or academia, scientist or farmer, relevant to this debate. Instead the aim of this Article is to provide a dispassionate review of the Dicamba controversy and provide narrow and useful recommendations to apply the lessons learned over the past several years to modernize our pesticide registration process. This Article advances, as will be explored more fully in the following pages, that the Dicamba controversy is actually a reflection of the natural growing pains that the agricultural sector should anticipate as scientific advancements propel the industry forward. To the greatest extent possible, this Article attempts to avoid viewing the Dicamba controversy, and any associated party, through the lens of "good" or "bad," or "right" or "wrong." Genetically modified crops are a controversial and often maligned subject.[25] The simple fact is that, since the mid-1990s, the U.S. agricultural sector has undergone a scientific revolution of massive scale, transforming almost completely toward a reliance upon genetically modified crops that are teamed with specific blends of herbicide and pesticides.[26]

This Article will endeavor to examine the Dicamba controversy in light of this transformation. Further, this Article will conclude that Monsanto's refusal to authorize third-party volatility testing during the XtendiMax registration process, and the EPA's silence as the State of Arkansas highlighted the potential adverse environmental effects, demonstrate a need to clarify and update the rules regarding pesticide registration in the United States, adapting to encompass the industry-wide shift towards genetically engineered crop systems. This Article argues that the EPA should immediately clarify to industry that the requirements under 40 C.F.R. § 158.75, mandate that a party seeking to register, or reregister, a pesticide, must submit to additional data testing when the EPA or a state environmental agency has determined a threat of unreasonable adverse effect to the environment actually exists. If necessary, the EPA should codify this explicitly. A second vital modernization of these regulations should be achieved through the incorporation of a provision to ensure impartial scientific testing of pesticides submitted for registration and use in the United States.

In order to reach these conclusions, this Article will first provide an overview of the history and development of the law regarding pesticide

25 *See* JORGE FERNANDEZ-CORNEJO ET AL., U.S. DEP'T OF AGRIC., GENETICALLY ENGINEERED CROPS IN THE UNITED STATES 2 (2014).

26 *See id.* at 1–2.

registration, focusing primarily on the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).[27] Next, a brief examination of the development of Dicamba will reveal the interplay of the legal regime constructed to regulate agricultural chemicals with modern science. Specifically, this Article will examine how the revolutionary shift to genetically modified crop systems has advanced to a point beyond the reach of the traditional regulatory scheme but that is easily addressable through a cooperative effort between industry and regulators. Finally, this Article will urge industry and regulators to work together to close the scientific gap that the Dicamba controversy highlights.

Genetically modified crop systems are not the future, they are the present. As a nation we must embrace this shift in industry and ensure that our regulatory schemes remain relevant and comprehensive. The scientific advancement of genetically modified crop systems holds powerful potential for farmers throughout the world,[28] and the United States should embrace a leadership role in advancing this technology for the benefit of the world. Dicamba, as we will see in the pages that follow, is not the problem. Dicamba is merely a symptom of an industry that has advanced beyond the scope ever envisioned by those that constructed regulations to ensure its safety. The time has come for the EPA to modernize and adapt those regulations to match the times.

II. OVERVIEW OF THE DEVELOPMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

In order to examine how the Dicamba controversy erupted, it is necessary to review the mechanisms in place to bring new herbicides to market in the United States. FIFRA is the governing body of law providing oversight for the development of chemicals for agricultural applications in the United States.[29] The federal government has regulated pesticides in the United States dating back to the passage of the Federal Insecticide Act of 1910.[30] Counterintuitively, the origins of FIFRA are not found in environmentalists, but rather from manufacturers and industrial sources, such as the National Association of Insecticide and Disinfectant Manufacturers, The American Farm Bureau Federation, and The Farmers Education and Cooperative Union of America.[31] Congress passed FIFRA in the wake of World War II, in 1947.[32] At the time of its initial passage, FIFRA

27 7 U.S.C. §§ 136–136y (2012).

28 *See* INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATION, GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS IN 2017: BIOTECH CROP ADOPTION SURGES AS ECONOMIC BENEFITS ACCUMULATE IN 22 YEARS 8 (2017) (showing the power of genetically modified crops to produce large economic figures around the world in both developing and industrial countries).

29 *See* 7 U.S.C. §§136–136y.

30 LYNN L. BERGESON, FIFRA: FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT 1 (2000).

31 DAVID M. WHITACRE & KRISTIN R. EADS, DEFENDING PESTICIDES IN LITIGATION 10 & n.36 (2012 ed.) (citing H.R. REP. NO. 313, at 6–7 (1947)).

32 *Id.* at 10.

contained two significant provisions that greatly advanced the modern regulatory mechanisms of the statute. First, FIFRA made unlawful any use or sale of pesticides which were not first registered with the United States Department of Agriculture (USDA).[33] The other significant provision mandated specific labeling or packaging information be included with any pesticide sold in the United States.[34] The result was that at the time FIFRA was primarily a labeling statute requiring the registration of pesticides with the USDA.[35] Upon its creation, the EPA assumed the regulatory oversight function for pesticides from the USDA.[36]

Interestingly, the registration provisions of the 1947 Act contained no mention of a requirement for testing, as the modern statute does.[37] A registrant need only file an application containing his or her name and address, identify the pesticide, and attach a copy of the labeling that would be included with the pesticide packaging.[38] As will become evident in the examination of the Dicamba situation, the registration and testing requirements process are currently significantly intertwined under the current law.

Following the passage of the Federal Environmental Pesticide Control Act of 1972,[39] FIFRA was amended and effectively transformed into a comprehensive scheme for regulating the distribution, sale, and use of pesticide products within the United States.[40] Central to this scheme is the requirement that all pesticides be registered with EPA prior to use.[41] Congress has long sought to recognize and protect the valuable investments the agricultural industry propagates through the development of agricultural chemicals. For instance, in 1978, on one of several occasions Congress amended FIFRA, protections for the proprietary rights were carved out to benefit registrants that submit scientific data to the EPA as required to register pesticides.[42] Similarly, in 1988 Congress adopted a detailed process by which a pesticide company could "reregister" all pesticide active ingredients.[43] Active ingredients are defined by FIFRA as those which "will prevent, destroy, repel, or mitigate any pest."[44]

The term "pesticide" as used in FIFRA is expansive in scope and nature. FIFRA defines a pesticide as "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest . . .

33 *Id.* at 10–11.

34 *Id.* at 11.

35 *Id.*

36 *Id.* at 14 (citing Phillip L. Spector, *Regulation of Pesticides by the Environmental Protection Agency*, 5 ECOLOGY L.Q. 233, 233 (1976)).

37 *Id.* at 11 (citing FIFRA, Pub. L. No. 104, 80th Cong., 1st Sess., § 16(4) (1945)).

38 *Id.* (citing FIFRA § 16(4) (1945)).

39 7 U.S.C. §§ 136, 136a, 136c–136y (2012).

40 *See* WHITACRE & EADS, *supra* note 31, at 14–15.

41 Elizabeth C. Brown et al., *A Practitioner's Guide to the Federal Insecticide, Fungicide, and Rodenticide Act*, *in* PESTICIDE REGULATION DESKBOOK 3, 20–22 (2001).

42 BERGESON, *supra* note 30, at 2.

43 *Id.*

44 *Id.* at 129 (citing FIFRA, 7 U.S.C. §136(a)(1) (2012)).

[and] any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant."[45] The EPA, through regulatory language, adds a further varnish to this definition by adding that a pesticide is "any substance (or mixture of substances) intended for a pesticidal purpose, i.e., use for the purpose of preventing, destroying, repelling, or mitigating any pest."[46] Critical to capturing herbicides within this expansive language is FIFRA's broad definition of "pest" as 1) any insect, rodent, nematode, fungus, *weed*, or 2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism on or in living man or other animals.[47]

The inclusion of weeds within the definition of pests is critical to bringing herbicides, such as Dicamba, under the regulatory umbrella of FIFRA. Herbicides developed to target specific weed species as part of agricultural practices fall within the more general designation of "pesticides" and are therefore subject to regulation by the EPA under FIFRA.[48] The regulatory process from lab to agricultural field for any pesticide, to include herbicides such as Dicamba, must first begin with the process of registration with the EPA.[49]

III. FIFRA'S PESTICIDE REGISTRATION PROCESS

As established from the outset of FIFRA, no person in the United States may distribute or sell any pesticide that is not registered pursuant to FIFRA.[50] Initially, Congress acknowledged that the main purpose of the registration process then was simply to aid the USDA in tracking the pesticides brought to market and employed within the United States.[51] Today, following decades of development and multiple amendments to FIFRA, in order for a new chemical to come into widespread use on the commercial farming market, an intensive testing and registration process must also be completed with the EPA.[52] The specific kinds of data and information the EPA requires in order to make regulatory judgments about the risks and benefits of pesticide products consistent with FIFRA are set forth in 40 C.F.R. Part 158.[53] Applicants submitting a product for registration, or to amend a registration, must include the following elements in their application: a completed EPA Form 8570-1 (application), name and address disclosure of applicant, product identity and formula, draft labeling, data requirements, packaging certification, classification request, and a statement concerning tolerances.[54]

45 7 U.S.C. § 136(u); *see also* BERGESON, *supra* note 30, at 3.

46 40 C.F.R. § 152.15 (2017); *see also* BERGESON, *supra* note 30, at 3.

47 *See* 7 U.S.C. §136(t); *see also* 40 C.F.R. § 152.5 (2017); BERGESON, *supra* note 30, at 3.

48 *See* 7 U.S.C. § 136(u)(2).

49 BERGESON, *supra* note 30, at 9 (citing 7 U.S.C. § 136(a)).

50 *Id.* (citing 7 U.S.C. § 136a(a)).

51 *See* WHITACRE & EADS, *supra* note 31, at 11.

52 *See generally* 40 C.F.R. § 158 (2017).

53 40 C.F.R. § 158.1 (2017).

54 Brown et al., *supra* note 41, at 27–28.

Updating these regulations in 2007, the EPA now requires detailed information on product chemistry as well as information specific to seven basic categories: product performance, toxicology, hazards to nontarget organisms, applicator and post-application human exposure, pesticide spray drift evaluation, environmental fate, and residue chemistry.[55] Unquestionably, this marks a significant increase in the data required for the registration process compared to the initial requirements imposed by FIFRA in the 1940s. As previously discussed, industry has played a significant role in bringing regulations forward from the outset of FIFRA,[56] and that role continues today. Chemical companies are able to negotiate with the EPA over the specific testing required for a product and the specific methodologies which must be employed in carrying out such tests.[57] The EPA does require that chemical companies employ "good laboratory practices," however, there are currently no mandated procedures and the EPA retains the authority as to specific testing requirements.[58]

One of the seven broad categories of registration information required by the EPA is the obligation to test or cite test data regarding pesticide aerial spray drift evaluation.[59] As the term is generally used, aerial drift describes the movement of a liquid away from the target organism to non-target areas.[60] Importantly, especially in consideration of discussion involving Dicamba, aerial drift is distinct from volatility, which "measures the tendency of a chemical to vaporize" ("move from the liquid to gaseous state").[61] Volatilized chemicals may also become mobile and result in unintended impacts after application, as recognized by the EPA's specific inclusion of volatility in potential mobility studies that fall under the broad category of "environmental fate"[62] which the EPA may require during the registration process.[63]

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55 WHITACRE & EADS, *supra* note 31, at 25.

56 *Id.* at 10.

57 *Id.* at 26.

58 *Id.* (citing 40 C.F.R. § 160.1(a) (2017)).

59 40 C.F.R. § 158.130(g) (2017)

60 *See* ROBERT L. ZIMDAHL, FUNDAMENTALS OF WEED SCIENCE 378–81 (4th ed., 2013) (discussing spray drift and methods of mitigation).

61 *See id.* at 381.

62 Regulations clarify the EPA's consideration of data regarding environmental fate:

> The data generated by environmental fate studies are used to: Assess the toxicity to man through exposure to humans to pesticide residues remaining after application, either upon reentering treated areas or from consuming inadvertently-contaminated food; assess the presence of widely distributed and persistent pesticides in the environment which may result in loss of usable land, surface water, ground water, and wildlife resources; and, assess the potential environmental exposure of other nontarget organisms, such as fish and wildlife, to pesticides. Another specific purpose of the environmental fate data requirements is to help applicants and the Agency estimate expected environmental concentrations of pesticides in specific habitats where threatened or endangered species or other wildlife populations at risk are found.

40 C.F.R. § 158.130(h)(1) (2017).

63 40 C.F.R. § 158.120.

If a proposed pesticide requires application in a setting which may produce significant aerial drift, testing in the form of droplet size evaluation is typically required along with drift field evaluations.[64] The data that is derived from this testing will form the basis of any subsequent requirement for specific content in precautionary labeling or application instructions to minimize the potential of harm to non-target organisms.[65] Modeling techniques, such as computer generated drift models, are accepted methodologies to predict or reenact a drift event as described under this requirement.[66]

As previously mentioned, the EPA has not yet established specific testing protocols, instead it requires potential registrants to "submit a statement of compliance or non-compliance with Good Laboratory Practice standards in order to have their test data accepted."[67] Each study submitted by a chemical company in support of their application "must have a written protocol that has been approved by the EPA and must follow a specific format established by the EPA."[68] Studies are required to be conducted or supervised by "properly qualified scientists or other professionals."[69] A report is required for each study submitted in support of a product's registration.[70]

While this extensive testing regime captures the bulk of data that may be anticipated as relevant prior to a pesticide's use, there is always the potential for additional and unanticipated negative consequences or issues that may arise some time after a pesticide's use. FIFRA seeks to capture these instances and bring them within the realm of required reporting as well.[71] "FIFRA requires a pesticide registrant to report any information it has regarding unreasonable adverse effects if such information might affect the agency's decision regarding the risks and benefits of the pesticide."[72] The intention is for this continuing obligation to serve as a safeguard measure to ascertain any information which the registrant becomes aware of after obtaining a registration.[73]

Notably, the data requirements mandated by the EPA are most rigorous "for a pesticide containing a new active ingredient as the applicant must generate all required data elements."[74] However, if an applicant is seeking to register a pesticide that is utilizing an active ingredient that has already passed through the registration process, the applicant may be able to rely, at least to some extent, on data previously generated and submitted by

64 WHITACRE & EADS, *supra* note 31, at 37 (citing 40 C.F.R. § 158.1100 (2017)).
65 *Id.*
66 *Id.*
67 *Id.* at 39 (citing 40 C.F.R. § 160.12).
68 *Id.* (citing 40 C.F.R. § 160.120 (2017)).
69 *Id.* (citing 40 C.F.R. § 160.33 (2017)).
70 *Id.* (citing 40 C.F.R. § 160.185 (2017)).
71 *Id.* at 40 (citing 7 U.S.C.A. § 136d(a)(2) (1996)).
72 *Id.*
73 *Id.* at 73 (citing 40 C.F.R. § 159.158(a) (2017)).
74 Brown et al., *supra* note 41, at 28.

previous applicants.[75] In 1988, Congress further streamlined this process to accelerate the reregistration of pesticides.[76] "The purpose of reregistration is to review the approval of pesticides in light of current data and safety standards."[77]

Traveling as a companion to the extensive review of the chemical components of any product submitted to the EPA for registration are the labeling instructions that are intended to accompany the product.[78] The EPA reviews all pesticide product labels and must approve all label language before a pesticide may be sold or distributed in the United States.[79] The EPA intends the label "to provide clear directions for effective product performance while minimizing risks to human health and the environment."[80] Importantly, it is a violation of federal law to use a pesticide in a manner inconsistent with its labeling, and courts do consider labels to be legal documents.[81] Enforcement for pesticide related violations primarily rests with the states, typically in the form of the state's department of agriculture or the environmental department, as they often have responsibility for compliance and monitoring.[82]

Finally, the EPA is provided broad discretion, under 40 C.F.R. Part 158.75, to require a party seeking registration to provide additional scientific data and research in support of their application, if necessary.[83] This section functions as another broad safety net to provide the EPA with flexibility to ensure a potential pesticide is fully evaluated from a scientific standpoint before it is registered for use in the United States. This brief, but important, section of the federal regulation states:

> The data routinely required by this part may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties and effects of the pesticide.[84]

75 *Id.*

76 *Id.* at 34.

77 *Id.*

78 *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities*, U.S. ENVTL. PROTECTION AGENCY, https://perma.cc/L634-VCWV (last updated Jan. 29, 2018).

79 *See About Pesticide Registration*, U.S. ENVTL. PROTECTION AGENCY, https://perma.cc/4RNK-8H7U (last updated July 31, 2018).

80 *Id.*

81 *Id.*; *see also* Press Release, U.S. Dep't of Justice, Pest Control Company and Its Owner Charged with Unlawful Application of Pesticides and Falsification (Sept. 11, 2013), https://perma.cc/G26M-AF2X.

82 *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities*, *supra* note 78.

83 *See* 40 C.F.R. § 158.75 (2017).

84 *Id.*

The pesticide registration process is a complex and rigorous undertaking that is designed to place the burden upon industry to develop and provide sufficient data proving the value and safety of the products they intend to bring to market in the United States.[85] An important consideration that is often overlooked is the overall cost of this process to the applicant, in terms of industry investments in both time and money. Estimates given by Dow AgroSciences' expert Kelly Bennett set forth that from the time Dow identifies a new area of chemistry, it takes a minimum of ten years to approach a successful market launch of a product.[86] Aside from the significant development timeline required to bring a new pesticide to market, another significant barrier exists in terms of cost. Dow estimates that, in 2016, the cost of bringing a new active ingredient to market is typically $250 million.[87] The massive investment costs require chemical companies to place a tremendous value on the success of their product development. As will be demonstrated, this can be a double-edged sword as industry is clearly motivated to efficiently meet and exceed each data requirement, but it may also be negatively motivated to de-emphasize those findings or developments which may arise years down the line in the research and development process. This impetus is even stronger once a product has actually made it through the process, gained registration, and is actively being sold on the market. It is clearly understandable why a chemical company that invests years of research and development into a product may be disinterested in pursuing potential negative effects once it has negotiated the myriad obstacles to gain a long-awaited registration and begin selling the product in order to see a return on its investment.

The pesticide registration process in the United States is a complex scheme of data collection, submission, and review that is largely spearheaded by the industry seeking to bring a new product to market.[88] The EPA provides critical oversight, working in conjunction with state agricultural and environmental agencies not only for the initial registration of a new pesticide, but throughout the lifetime of its usage in an agricultural capacity.[89] Interestingly, the vital oversight and regulatory framework the EPA enforces today is a legacy of agricultural industry recommendations that were incorporated in the initial statutory scheme for agricultural regulation and expanded over time.[90] As the agricultural yield demands have risen, so to have the investment costs for the chemical corporations developing and marketing new and refined blends of pesticides for

85 *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities*, *supra* note 78.

86 Lisa Guenter, *What's It Take To Produce New Pesticides?*, GRAINEWS (Jan. 5, 2016), https://perma.cc/BS64-SSX4.

87 *Id.*

88 *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Federal Facilities*, *supra* note 78.

89 *See Pesticide Registration Manual: Introduction*, U.S. ENVTL. PROTECTION AGENCY, https://perma.cc/8BSD-NDBD (last updated Apr. 2, 2018).

90 *See* WHITACRE & EADS, *supra* note 31, at 10.

agricultural use in the United States.[91] The development of Dicamba, and its more modern usage in conjunction with genetically modified crops, provides a clear case study for the high economic stakes at play in the modern age of agricultural research and development.

IV. A BRIEF HISTORY OF GENETICALLY MODIFIED CROPS AND DICAMBA

To truly understand the controversy surrounding the Dicamba issue, it is important to have a basic understanding of how genetic engineering is used in agricultural operations, and the recent developments that accompany such technological advances. The benefits of the scientific struggle to find effective herbicides that can eliminate certain weeds while simultaneously having no effect on a designated crop plant is self-evident. "If concern about crop selectivity can be eliminated, then a [single] herbicide that killed most weeds could be used without fear of crop injury."[92]

The initial "herbicide-resistant crop appeared [in the markets] in 1996 when canola resistant to atrazine was made available."[93] This initial batch of atrazine-resistant canola was created after researchers in Ontario, Canada, noticed atrazine-resistances in broadleaved weeds in corn.[94] The University of Guelph established a breeding program with the goal of transferring the source of the resistance to canola, with the initial successful genetic modifications taking place in 1984, 1986, and 1987.[95] Since this first foray into the genetic modification of crop seeds, now nearly three decades ago, industry research has spurred significant advancement.[96] While herbicide-resistant crops are largely thought of in the context of developed nations with advanced agricultural practices, it is important to understand the ramifications of genetically modified crops for developing countries. In developing countries, "weeds are the most commonly cited constraint to increasing crop production and expanding" the acreage of land dedicated to farming.[97]

Unfortunately, to date, the adoption of this agricultural technology in developing countries has not been as rapid as in developed countries, likely caused by the lack of clear evidence of production cost reductions and increased yields, as well as the generally higher cost of genetically modified

91 *See* Wen Zhou, *The Patent Landscape of Genetically Modified Organisms*, HARV. (Aug. 10, 2015), https://perma.cc/3JBE-9HJ3 ("The discovery, development, and authorization of a new GMO plant costs $136 million on average, and companies would not have been willing to make such investment without a period of exclusivity and profitability granted." (citations omitted)); *see also* Press Release, BASF, BASF Closes Acquisition of Business and Assets from Bayer (Aug. 1, 2018), https://perma.cc/L2AG-HSWX (announcing BASF's $4.7 billion acquisition of Monsanto and specifically mentioning that Monsanto was acquired to secure the Glyphosate products and genetically modified crops).

92 ZIMDAHL, *supra* note 60, at 470.

93 *Id.*

94 *Id.*

95 *Id.*

96 *See id.* at 470–71 (discussing the industry's expansion to a wide range of other crops).

97 *Id.* at 471.

crop seed and herbicide.[98] It is an unfortunate irony that those that could benefit the most from genetically modified crops and farming practices will likely not be able to use them. As farmers in developing nations continue to struggle with the effects of global climate change and ever-increasing populations, the reliance upon traditional farming methods and mechanisms will continue until they are displaced by proven and economically attainable genetically modified crops and herbicides.

Roughly 60% of the world's genetically modified crops are grown entirely within the United States, a developed country where the adoption of such technology has expanded rapidly.[99] Genetic modifications have focused predominantly on corn, soybeans, and cotton.[100] As may be expected, the United States also showcases more documented cases of resistance than any other country.[101] Over 3.7 million acres of genetically modified crops were grown in the United States in 1996.[102] In 2006 that number exploded to 135 million acres, and in 2010 the number grew to 158 million acres.[103] To provide context, in 2012 the USDA reported that the total acreage of cropland in the United States was roughly 389.7 million acres (of which only 315 million acres were actually harvested).[104]

Genetically modified crops and herbicides in the United States now dominate the market. The USDA, in 2017, reported that 89% of corn, 91% of cotton, and 94% of all soybeans now planted in the United States are genetically modified to contain herbicide-resistant traits.[105] These levels essentially reflect a complete capture of market for these three major crops by those manufacturing genetically modified seeds and herbicides.[106] The magnitude of this shift in farming technique cannot be overstated, as within the span of just twenty years nearly the entire focus of farming for these staple crops in the United States shifted from traditional methods to rely upon genetically modified seed and herbicide varieties.[107]

The dramatic rise and adoption of genetically modified crops and herbicides in the United States indicates that this is likely the future course for crops not only in developed countries, but worldwide. The United States is truly on the cutting edge for the regulation and application of this new technology in the agricultural realm. The lessons learned in the corn, soybean, and cotton fields of Arkansas and Iowa will reverberate to India and Egypt as developing agricultural economies adopt superior farming

98 *Id.*

99 *Id.*

100 *Id.*

101 *Id.*

102 *Id.*

103 *Id.*

104 NAT'L AGRIC. STAT. SERV., U.S. DEP'T OF AGRIC., 2012 CENSUS OF AGRICULTURE HIGHLIGHTS: FARMS AND FARMLAND 2 (2014), https://perma.cc/VF8D-F432.

105 Econ. Research Serv., *Recent Trends in GE Adoption*, U.S. DEP'T AGRIC., https://perma.cc/N2GJ-NDD5 (last updated July 16, 2018).

106 *See id.* (discussing the significant rise in proportion of use of genetic modification for these three major crops).

107 *Id.*

practices and expand their capabilities to increase yields. As with any new endeavor, especially those rooted in science, the effects of our scientific progress and advances often manifest in unanticipated ways. The current controversy surrounding Dicamba is one such manifestation. In many ways this controversy is one of the traditional and necessary growing pains that accompanies scientific advancement. It is a virtual certainty that this controversy will quickly resolve, as all affected parties share a mutual desire to maximize economic crop returns and minimize associated expenses without the complication of additional government scrutiny or regulation.

The more relevant question is what can be learned from this controversy and how the United States, as a developed nation, can effectively transfer those lessons learned to nations that are developing and transitioning from traditional agricultural practices to the adoption of genetically modified crops. The entire shift of the agricultural practice in the United States over the span of twenty years, as discussed above, is a very rapid transition that governments and regulators are not well-suited to quickly internalize and adapt. This new frontier of agriculture is one that largely did not exist just twenty years ago.[108] Therefore, it is critically important that government, through its regulators, observe and understand these developments and ensure that the traditional regulatory mechanisms built for a 1960s agricultural economy remain suitable and protect the population of a 2020 agricultural economy. It is this Author's opinion, that just as industry was vital to the establishment of the initial regulatory framework for the agricultural practices of the United States, so too will that same industry be vital to bringing genetically modified crops under the umbrella of established regulatory practices and requirements.

V. THE DICAMBA CONTROVERSY

Despite the current headlines, one thing about Dicamba is certain: as an active ingredient in an herbicide, it is not new. Dicamba was initially developed by BASF in 1958.[109] Dicamba was initially registered for use as an active ingredient herbicide in 1967.[110] The generic name of Dicamba is "3, 6-dicholoro-o-anisic acid," which was sold for years under a variety of agricultural trade names such as Banvel, Banex, and Brush Buster.[111] BASF is a chemical company headquartered in Germany and is considered the largest chemical producer in the world, operating in over eighty countries.[112]

108 *See* Econ. Research Serv., *supra* note 105 (detailing the increase over time in the use of genetic engineering in agriculture in the United States).

109 Industry Voice by BASF, *The Evolution of Dicamba*, WALLACES FARMER (Jan. 11, 2017), https://perma.cc/Y6P3-DMLY.

110 OFFICE OF PESTICIDE PROGRAMS, U.S. ENVTL. PROT. AGENCY, PESTICIDE FACT SHEET: DICAMBA (1983).

111 *Id.*

112 Alexander H. Tulo, *C&EN's Global Top 50 Chemical Companies of 2017*, CHEMICAL & ENGINEERING NEWS (July 30, 2018), https://perma.cc/2XAV-RU9V; *BASF Headquarters*, BASF, https://perma.cc/BF2E-HTWK (last visited Nov. 25, 2018); *Locations*, BASF, https://perma.cc/4B3T-RKTK (last visited Nov. 25, 2018).

BASF continually modified its Dicamba offering over the years, largely in response to glyphosate resistance,[113] marketing versions spanning nearly fifty years under the trade names Banvel, Marksman, Clarity, Distinct, Status, and most recently, Engenia.[114]

The key to the long-term success of Dicamba, in its various trade name formulations, was its ability to successfully eliminate broad leaf weeds, especially those that grew tolerant over time to the application of Glyphosate (Roundup).[115] In the most basic terms, Dicamba works by "mimicking" a plant hormone, resulting in "uncontrollable growth in the targeted weed," resulting in the destruction of the weed as its growth outpaces available nutrients.[116]

Counter-intuitively, while Dicamba was a competing product with Glyphosate, its long-term success depended, in large part, on the greater success and wider-use of Glyphosate. Glyphosate was particularly useful in that it could be applied to a farmer's field after the crops had emerged and started growing.[117] Glyphosate was also relatively environmentally friendly in that crops were safe from herbicide damage, with no concern over residual effects as Glyphosate was ineffective after it made contact with the soil.[118] The more Glyphosate was used, the more the resistant trait would be exposed in the targeted weeds and result in an ever-increasing resistance.[119] Essentially, when farmers experienced difficulty with weeds resistant to the industry standard application of Glyphosate, they could turn to Dicamba, either alone or applied in combination with Glyphosate, for a one-two punch to eliminate weeds.

Monsanto also understood this dynamic as well. In 2005 Monsanto began to partner with scientists at the University of Nebraska, Lincoln, in the development of a Dicamba resistant soybean, which quickly expanded to cotton and other crop formulations as well.[120] After the widespread usage of Monsanto's Glyphosate was implemented in the United States in 1996, resistance increasingly became an issue just a short time later. In the year

113 Industry Voice by BASF, *supra* note 109. Glyphosate is the active ingredient in a broad-spectrum herbicide developed by Monsanto Chemical Company and brought to market in 1974 under the trade name Roundup, which quickly became the most popular weed-killer in America. *Glyphosate and Roundup Brand Herbicides*, MONSANTO (May 16, 2017), https://perma.cc/JF5C-L8N4.

114 Industry Voice by BASF, *supra* note 109.

115 *Id.*

116 Matthew J. Grassi, *Herbicide Systems 2.0: Life Beyond Dicamba*, CROP LIFE (May 1, 2012), https://perma.cc/3YRF-H8PV.

117 *See* Leah Sandall et al., *The Kochia and Dicamba Story*, PLANT & SOIL SCI. LIBRARY, https://perma.cc/B56B-76EQ (last visited Nov. 25, 2018).

118 *Id.*

119 *See id.*

120 *About: History of Advancement*, ROUNDUP READY XTEND CROP SYS., https://perma.cc/7WJH-D5Q5, (last visited Nov. 25, 2018).

2000, the first Glyphosate resistant weeds were identified in a soybean field located in Delaware.[121]

As successive farming seasons revealed additional data on the ability of weeds to develop a resistance to Glyphosate, weed scientists and the chemical companies began to apply that knowledge to refine follow-on herbicide products, like Dicamba.[122] This set the stage for researchers at the University of Nebraska-Lincoln to partner with Monsanto in order to synthesize a Dicamba-resistant trait that could enable soybeans, and later cotton and other crops, to enjoy the same if not greater success than Glyphosate. It is worth noting as well that Monsanto likely sensed a significant opportunity to defend the significant foothold in the market that Roundup (Glyphosate) and Roundup Ready crops already secured. If Monsanto could provide American farmers with genetically modified options to compliment Roundup when resistance became an issue, based on the proven successful track record of Roundup, then Monsanto would continue to dominate the herbicide market for the foreseeable future.[123] The successful capture of this market would provide billions of dollars to Monsanto as a return on its long-term and expensive scientific investment. Researchers working with Monsanto anticipated that the Dicamba resistant crops would be commercialized and ready for use, if approved by the EPA, in 2014.[124]

Dicamba did have unique difficulties as an herbicide that made its use and performance distinct from Glyphosate. Dicamba was noted as both highly mobile and poorly absorbed in most soil types, especially the clay-based soils that are common in the grain-belt areas of the midwestern United States.[125] BASF also worked throughout the decades to reduce the volatility of Dicamba.[126] Volatility measures a substance's tendency to change from a liquid to gas.[127] A distinct but important related concept is that of spray drift, which describes the movement of airborne liquid spray particles.[128] Spray drift in the context of Dicamba typically describes movement of the herbicide after it is applied over a crop field by a spray plane.[129] Dicamba is unique due to the fact that it is highly mobile, both in the air and on the soil, and that coupled with the toxicity that it poses to a broad range of plants makes its application significantly more complex than that of other herbicides, such as Glyphosate.[130] Essentially, the concern regarding

121 Sandall et al., *supra* note 117 (referencing that this is not the first identification of an herbicide resistance trait in weeds; in 1957 resistance was noted to exist in wild carrots to the herbicide 2, 4-D).

122 *Id.*

123 *See* David Barboza, *The Power of Roundup; A Weed Killer Is a Block for Monsanto to Build On*, N.Y. TIMES (Aug. 2, 2001), https://perma.cc/6J33-WH3L.

124 Sandall et al., *supra* note 117.

125 Grassi, *supra* note 116.

126 *Id.*

127 ZIMDAHL, *supra* note 60, at 444.

128 *Id.* at 441.

129 *See* Grassi, *supra* note 116 (discussing potential effects of spray drift).

130 *See id.*

Dicamba was that minor atmospheric changes, such as shifts in wind, could cause Dicamba applications to veer off target and into areas not intended for their use.[131] Even worse was the concern that even after a successful application, Dicamba could volatize and move from the correctly applied field to other areas.[132] However, BASF and its scientists were confident in the research dedicated to reducing Dicamba's volatility over the decades, with the latest iteration, Engenia, touted as being "the lowest volatility formulation of [D]icamba on the market."[133]

Bringing the Dicamba research and development investment to fruition required a two-pronged effort. First, the genetically modified Dicamba-resistant crop strains must be approved for use in the United States by the USDA, and, second, the new herbicide formulations developed to complement the resistant seeds must be registered for use by the EPA. The first requirement was satisfied on January 20, 2015, when the USDA cleared the way for the deregulation of soybean and cotton seeds that were genetically modified to be resistant to Dicamba.[134] This announcement cleared the way for the transportation, processing, packaging, and distribution of Dicamba-resistant cotton and soybean seeds.[135] With genetically modified Dicamba-resistant seeds readily available to farmers on the market, the last remaining step was to secure EPA registration for the new formulations of Dicamba that would be authorized for use in conjunction with the new seeds.[136] The wait would not be long.

On March 31, 2016, the EPA proposed approving the registration amendment for Monsanto's XtendiMax with VaporGrip and opened the public comment period.[137] Several months later, the EPA issued the registration for the new uses of Monsanto's Dicamba products M1691 and M1768.[138] The EPA actually registered two herbicide products presented by Monsanto in this action. The currently registered formulation of Dicamba that Monsanto submitted for evaluation for a new use with Dicamba-resistant soybeans and cotton was M1691, and a short time later Monsanto also sought the EPA to include M1768, which references XtendiMax with

131 *See id.*

132 *See id.* (discussing concerns regarding off-site movement of dicamba).

133 *Id.*

134 *See* Monsanto Co.; Determination of Nonregulated Status of Herbicide Resistant Soybean and Cotton, 80 Fed. Reg. 2,675, 2,675 (Jan. 20, 2015) ("We are advising the public of our determination that soybean and cotton genetically engineered for herbicide resistance by the Monsanto Company are no longer considered regulated articles under our regulations governing the introduction of certain genetically engineered organisms.").

135 Forrest Laws, *USDA Announces Deregulation of Dicamba-Tolerant Trait in Cotton and Soybeans*, DELTA FARMPRESS (Jan. 18, 2015), https://perma.cc/WE78-HW35.

136 *See id.*

137 Memorandum from Dan Kenny, Branch Chief, Herbicide Branch, Registration Division US EPA/OSCPP/OPP, to Susan Lewis, Director, Registration Division US EPA/OSCPP/OPP (Mar. 31, 2016), https://perma.cc/T4FC-ZFZ5; *see also* U.S. ENVTL. PROT. AGENCY, FINAL REGISTRATION OF DICAMBA ON DICAMBA-TOLERANT COTTON AND SOYBEAN 2 (Nov. 9, 2016), https://perma.cc/8T2N-EBEM [hereinafter FINAL REGISTRATION OF DICAMBA].

138 FINAL REGISTRATION OF DICAMBA, *supra* note 137, at 2, 29.

VaporGrip, in its evaluation as well.[139] The basis for evaluating the products together was the fact that both products contained the same active ingredient, diglycolamine (DGA) salt of dicamba, which, as discussed above, is the focus of the registration under FIFRA.[140] Monsanto presented data to support the assertion that XtendiMax with VaporGrip was the same product, albeit enhanced to even further reduce potential volatility, and the EPA concurred and agreed to include a combined evaluation and amended registration for both formulations.[141] The "New Uses" portion of the registration encompassed post-emergence application.[142]

BASF followed closely behind Monsanto, with the EPA registration of Engenia taking place on December 20, 2016.[143] Both of the new registrations granted to BASF and Monsanto by the EPA contained extensive conditions, detailing precise application requirements down to the size of the spray nozzle and acceptable application wind speed ranges.[144] These conditional requirements are captured in the label instructions that the company provides to the EPA as part of the registration process.[145]

The sequence of events, described above, is an important aspect of this Dicamba controversy as even prior to the issuance of these registrations, alarm bells were already sounding in regard to Dicamba usage. As described above, the USDA authorized the commercialization of Dicamba-resistant soybean and cotton seeds in January of 2015.[146] Yet the second prong in this crop package, the new formulations of herbicide, were not registered and authorized until late 2016.[147] In the eighteen-month gap between the two events, an unusually high number of crop damage reports were filed with the EPA and various state agricultural agencies—indicating the potential usage of Dicamba applied over the top of growing cotton or soybean plants, including those genetically modified to tolerate dicamba.[148] The sheer volume and broad range of complaints forced the EPA to publicly acknowledge what was likely taking place through the issuance of a Compliancy Advisory in August of 2016.[149] In essence, some farmers were likely conducting an end-run around the regulatory process and obtaining the new genetically modified soybean and cotton seeds and were applying the existing Dicamba

139 *Id.* at 2–3.

140 *Id.* at 2.

141 *Id.*

142 *Id.* at 3–4 (referencing cotton and soybean new use, respectively).

143 *See* U.S. ENVTL. PROT. AGENCY, NOTICE OF PESTICIDE REGISTRATION 1 (Dec. 20, 2016), https://perma.cc/QS4R-7EWK [hereinafter NOTICE OF PESTICIDE REGISTRATION].

144 *See id.* at 7.

145 *Id.* at 13–16 (BASF proposed label is stamped "Accepted 12/20/2016" by the EPA).

146 Monsanto Co.; Determination of Nonregulated Status of Herbicide Resistant Soybean and Cotton, 80 Fed. Reg. 2,675, 2,675 (Jan. 20, 2015).

147 FINAL REGISTRATION OF DICAMBA, *supra* note 137, at 2; *see also* NOTICE OF PESTICIDE REGISTRATION, *supra* note 143, at 1.

148 *See* U.S. ENVTL. PROT. AGENCY, COMPLIANCE ADVISORY: HIGH NUMBER OF COMPLAINTS RELATED TO ALLEGED MISUSE OF DICAMBA RAISES CONCERNS (2016), https://perma.cc/6PX8-S8X8 [hereinafter COMPLIANCE ADVISORY].

149 *See id.*

formulations over the top of the growing crops, in clear violation of FIFRA.[150] The genetically modified crops would perform well, with no ill-effects shown, but if the Dicamba applications volatized or drifted due to incorrect application, then severe consequences could affect neighboring fields that were planted with crops lacking any Dicamba resistance.[151] It was a high-risk calculation that some farmers likely employed when they felt the likelihood of harm, or more cynically their discovery in the unlikely event of harm, was low in comparison to the perceived financial gains of higher yields and lower herbicide costs.

This was not an exercise in mere conjecture on the part of the EPA. On October 27, 2016, Allan Curtis Jones, a twenty-six-year-old farmer from Arbyrd, Missouri, had a heated argument over the phone with a neighboring farmer, fifty-five-year-old Mike Wallace, whose farm was located just over the state line in Monette, Arkansas.[152] The dispute centered on Wallace's allegations that Jones was illegally applying Dicamba over the top of his crops and it drifted onto Wallace's soybeans, killing them.[153] Wallace had already reported his suspicions to the state Plant Board.[154] The two agreed to meet in person to discuss the allegations, and when they met along a rural Arkansas road the dispute intensified and Wallace allegedly grabbed Jones, and Jones responded by pulling a gun and shooting the older farmer to death.[155] Jones was later convicted of second-degree murder and sentenced to twenty-four years in prison.[156] While this was an isolated and extreme example, it underscores the significant tension that simmered below the surface in regards to the use of Dicamba and genetically modified crops in the American farmlands at the end of 2016 when the EPA was registering the new formulations of Dicamba for use. Unfortunately, those tensions would not subside with the newly granted pesticide registrations, but instead they detonated on the national stage during the 2017 growing season.

In its Compliance Advisory issued in August of 2016, the EPA cited concerns founded upon 117 complaints of Dicamba misuse affecting approximately 42,000 acres of cotton, soybeans, and other crops in nine different states.[157] By September of 2017, the Arkansas State Plant Board reported that, in Arkansas alone, there were 963 Dicamba misuse complaints

150 *Id.* (clarifying that, "[u]nder FIFRA, the label on a pesticide package or container and the accompanying instructions are a key part of pesticide regulation. . . . [T]he use of a pesticide in a manner that is inconsistent with the use directions on the label (i.e. a 'misuse' of the pesticide) is a violation of FIFRA").

151 *Id.*

152 Andrew Amelinckx, *Pesticide Drift Leads to Alleged Murder*, MODERN FARMER (Nov. 4, 2016), https://perma.cc/CD6M-C9GP; *see also* McCune, *supra*, note 23.

153 Amelinckx, *supra* note 152.

154 *Id.*

155 *Id.*

156 Kenneth Heard, *Jury Finds Arkansas Man Guilty in Killing of Farmer During Dispute Over Dicamba*, ARK. ONLINE (Dec. 14, 2017), https://perma.cc/P2GJ-EBPR.

157 COMPLIANCE ADVISORY, *supra* note 148 (listing reports of alleged misuse of Dicamba from Alabama, Arkansas, Illinois, Kentucky, Minnesota, Mississippi, North Carolina, Tennessee, and Texas).

spread over twenty-six separate counties.[158] This unprecedented number of complaints prompted the formation of an emergency rule approved by the Governor and state legislature banning the sale and use of Dicamba in Arkansas for 120 days and forming a state task force to evaluate usage of Dicamba in the 2018 growing season and beyond.[159] Arkansas was not alone. Dicamba injury complaints flooded into state regulatory offices nationwide, with over 2,610 complaints lodged in twenty-four different states.[160] Estimates of the crop damage caused by Dicamba at the end of the summer of 2017 ranged as high as 3.1 million acres.[161] Dicamba had become a nationwide agricultural controversy, the size and scope of which had never before been seen in American farming history.[162]

The battle lines were quickly drawn following the 2017 growing season. Monsanto was quick to point to improper applications of traditional Dicamba formulations over the top of newly released Dicamba-resistant crops, in contravention to Monsanto's own explicit warnings against engaging in such practice.[163] While weed scientists and agricultural experts were openly critical of Monsanto's release of Dicamba-resistant seeds ahead of the release of EPA-approved herbicides that were required to be used in conjunction, others raised additional concerns that the real problem may actually lie in the volatility of the new Dicamba formulations that Monsanto refused to allow scientists to fully evaluate.[164]

The EPA was caught in a precarious position moving into the fall of 2017. With the debate over Dicamba ranging from state legislatures to the national media, the EPA broke its silence on October 13, 2017, when it issued a press release announcing that the new Dicamba formulations were to be classified as "restricted use," meaning that only certified applicators that fulfilled specialized training were authorized to apply Dicamba.[165] Importantly, while the press release did indicate that the EPA was actively working with Monsanto and BASF (as well as DuPont) on additional mitigation measures that would be published in revised labels, the EPA made clear that Dicamba usage for the 2018 season was authorized.[166]

The registration process and, later, the response to the Dicamba crisis were handled by BASF and Monsanto in very distinct ways. In the following Part, this Article will compare the responses of each company and examine the EPA's response in order to identify areas of key concern and conflict

158 WINTHROP ROCKEFELLER INST., REPORT OF THE 2017 STATE OF ARKANSAS DICAMBA TASK FORCE MEETINGS 7 (2017), https://perma.cc/2SWW-JFNY.

159 *Id.*

160 Emily Unglesbee, *Dicamba: Pesticide Agencies Overwhelmed; EPA Promises Action for 2018 Season—DTN*, AGFAX (Sept. 21, 2017), https://perma.cc/FP5N-5AZQ.

161 Charles, *supra* note 3.

162 *See* Unglesbee, *supra* note 160.

163 Emily Flitter & Tom Polansek, *U.S. Experts Doubt EPA Curbs on Monsanto, BASF Herbicides Will Halt Crop Damage*, REUTERS, Oct. 13, 2017, https://perma.cc/WW55-5EHC.

164 *Id.*; *see also* Charles, *supra* note 3.

165 Press Release, Envtl. Prot. Agency, EPA and States' Collective Efforts Lead to Regulatory Action on Dicamba (Oct. 13, 2017), https://perma.cc/YK3U-G4LG.

166 *Id.*

between all interested parties. This examination will include how the companies approached the dispute and how the minimal oversight of the EPA, as the neutral regulatory body tasked with oversight of the process implementing pesticide usage in the United States, further contributed to the crises. Finally, this Article will conclude by identifying and recommending discrete actions that may be implemented to mitigate the current controversy, focusing primarily on the inherent regulatory power of the EPA under FIFRA. By implementing such actions, it is hoped that future controversies will be prevented from spiraling out of control in such a dramatic fashion as the Dicamba controversy.

VI. MONSANTO'S RESPONSE

As discussed above, under the regulatory regime of FIFRA, when a company seeks to register a new pesticide for use in the United States, it typically provides a complete scientific package consisting of scientific testing, proposed labeling, and various reports to the EPA for review.[167] A critical point must be understood at this juncture. When Monsanto moved forward with the registration of XtendiMax with VaporGrip, it was not registering a new active ingredient, but was rather seeking to amend the registration of its current Dicamba formulation for use in a new way: application over the top of growing crops that were genetically modified to be resistant to Dicamba.[168] The two substances contained the same active ingredient, and thus under FIFRA, Monsanto was authorized to pursue an abridged registration process.[169] The EPA acknowledged and accepted this logic completely in granting the amended registration:

> The M1768 product contains the same active ingredient as the M1691, diglycolamine (DGA) salt of dicamba, and is to be used with equivalent application rates and the same application techniques. Because the two products *contain the same active ingredient* used at the same rates with the same methods, all of the environmental and human health assessments completed and made public in connection with the proposed registration of decision from the M1691 apply to M1768. After *assessing volatility studies conducted on the M1768 formulation* (discussed later in this document), the EPA has determined that the new lower volatility formulation of M1768 offers the user a product with less potential to volatilize and move off the target area. The volatility analysis is included in the docket for this final decision. Therefore, the new uses were granted for the M1768 formulation.[170]

The abridged registration process that Monsanto utilized, while authorized under FIFRA, relied upon another, more significant irregularity. The volatility studies submitted by Monsanto in support of M1768 (XtendiMax with VaporGrip) were critical to this analysis. In fact, as the

167 Brown et al., *supra* note 41, at 27–28 (discussing the registration requirements).

168 *See* FINAL REGISTRATION OF DICAMBA, *supra* note 137, at 2.

169 *Id.*; *see also* Brown et al., *supra* note 41, at 28.

170 *See* FINAL REGISTRATION OF DICAMBA, *supra* note 137, at 2 (emphasis added).

EPA acknowledges in the amended registration, the reduced volatility was the key distinguishing feature of XtendiMax with VaporGrip.[171]

However, several university weed scientists quickly pointed out that Monsanto, in conducting its scientific studies to accompany the registration package for XtendiMax with VaporGrip, provided them test samples but the samples included a contract that "explicitly forbade" them from conducting any testing relating to volatility.[172] Importantly, these were not just any university scientists, but included prominent weed scientists such as Dr. Jason Norsworthy at the University of Arkansas, Dr. Kevin Bradley at the University of Missouri, and Dr. Aaron Hager at the University of Illinois, all states that were essentially ground zero for the Dicamba controversy.[173] In a statement to Reuters, Dr. Jason Norsworthy noted, "[t]his is the first time I'm aware of any herbicide ever brought to market for which there were strict guidelines on what you could and could not do."[174]

For context, in a typical product evaluation scenario, a company, such as Monsanto, owns the proprietary products that are being submitted for registration with the EPA and potentially evaluated by independent third-parties, such as university researchers.[175] The company has complete control over who is authorized to research the product, what type of research can be done, and how it is carried out.[176] In the university setting, this arrangement is controlled by written contracts that are negotiated between the legal representatives of the university and the company long before the product is actually placed into the hands of scientists for the actual testing.[177] Under current operating procedures, this clearly places the company at a significant advantage in terms of determining the extent and method of scientific evaluation that is actually performed on its proprietary product. General confidentiality concerns of intellectual property rights and trade secrets are clearly at stake and may likewise be addressed in such contractual agreements.

Monsanto's vice president of global strategy, Scott Partridge, responded to this firestorm by stating that additional testing was not necessary, because XtendiMax with VaporGrip was less volatile than the previous formulation of Dicamba that was already registered with the EPA.[178] Monsanto stressed that the data collection process is time intensive and "this product needed to get into the hands of growers."[179] This issue soon turned even more contentious when the Arkansas Plant Board refused to license XtendiMax with VaporGrip for use in the state until volatility testing was allowed to be conducted at the University of Arkansas. In response,

171 *Id.*
172 Flitter, *supra* note 13.
173 *Id.*
174 *Id.*
175 *Id.*
176 *Id.*
177 *Id.*
178 *Id.*
179 *Id.*

Monsanto sued the Arkansas State Plant Board.[180] The lawsuit was dismissed on sovereign immunity grounds in February of 2018.[181]

In the face of the Dicamba firestorm, Monsanto appears to push full-speed ahead. In December of 2017, Monsanto announced a cash-back incentive program for farmers who purchase and apply XtendiMax with VaporGrip, refunding them nearly half the sticker price of the product for the upcoming 2018 growing season.[182] Based upon the actions of Monsanto to date, particularly as highlighted in its lawsuit against the Arkansas Plant Board, the company is demonstrating it is absolutely dedicated to its Dicamba technology and process and will aggressively defend them against any criticism.

The rationale behind this position may have been partially revealed by a Monsanto employee, Agronomist Boyd Carey, during a hearing at the Arkansas Plant Board's Pesticide Committee in the summer of 2016.[183] Carey is on record as stating that neither "the University of Arkansas nor any other university was given the opportunity to test XtendiMax with VaporGrip out of a fear that the results may jeopardize the federal label."[184] Both Monsanto and Carey declined to further clarify this statement.[185] Monsanto's purported concern, as reflected in this statement, would appear to be well-founded. Monsanto has dedicated a tremendous investment in time, resources, and effort in developing its Roundup Ready line of technology and products, to include XtendiMax with VaporGrip.[186] The fact that the EPA's registration of XtendiMax with VaporGrip was granted as an amendment to the existing Dicamba formulation already approved would potentially expose Monsanto's entire Dicamba technology system to be called into question if additional testing were to reveal issues not previously disclosed.[187] The safest path for Monsanto is to tightly control the scientific testing surrounding the Dicamba product line in order to reduce or eliminate the possibility of scientific studies that conflict with the company's own finished testing already presented to the EPA. Thus, it is a perfectly logical course of action for Monsanto to preclude any additional testing as reported by researchers at the University of Arkansas, University of Missouri, and the University of

180 Andrew Demillo, *Monsanto Sues Arkansas Board for Banning Disputed Herbicide*, YAHOO FIN. (Oct. 20, 2017), https://perma.cc/VKL7-T32L. For a copy of the complaint filed, see Compl., Monsanto Co. v. Ark. State Plant Board et al., No. 60CV-17-5964, (D. Ark. Oct. 20, 2017), https://perma.cc/2JAR-ZCQC.

181 *See* Sonja Begeman, *Judge Tosses Monsanto Lawsuit Against State Plant Board*, AGRIC. PROF. (Feb. 16, 2018), https://perma.cc/98EU-Q5Y6.

182 Tom Polansek, *Monsanto Offers Cash to U.S. Farmers Who Use Dicamba*, REUTERS, Dec. 11, 2017, https://perma.cc/5VDD-ZCUE.

183 *See* Flitter, *supra* note 13.

184 *Id.*

185 *Id.*

186 *See id.*; Carey Gillam, *Monsanto to Invest More Than $1 Bln in Dicamba Herbicide Production*, REUTERS, June 24, 2015, https://perma.cc/KCJ4-HUFE.

187 *See* FINAL REGISTRATION OF DICAMBA, *supra* note 137, at 2–3 (showing that XtendiMax with VaporGrip was registered with the EPA as an amendment to the existing Dicamba formula); *see also* Flitter, *supra* note 13.

Illinois.[188] For Monsanto to do otherwise could place in jeopardy millions, if not billions, of dollars and years of research dedicated to the development of the Dicamba-resistant traits and overall crop strategy.

There are many questions that remain unanswered in terms of Monsanto's response to the Dicamba crisis. What is clear is that the company intends to fully press forward with placing its XtendiMax with VaporGrip and associated Dicamba-resistant seeds into the hands of as many farmers as possible in the 2018 growing season.[189] Monsanto representatives are vocal about the company's anticipation that over 40 million acres of soybeans in the United States will be planted using the Xtend technology, doubling the amount planted in 2017.[190] As it stands now, both Monsanto and the EPA appear to have hedged their bets that the additional labeling instructions and intensive training requirements will be sufficient to resolve the Dicamba issues.[191] Recent history makes clear that these issues have grown increasingly impactful over the past three years, in spite of additional scrutiny from agricultural regulators and the public.[192] It is fair to question what, if any, effect these latest requirements will produce for the 2018 planting season and beyond.

VII. THE BASF RESPONSE

Like Monsanto, BASF is struggling to mitigate the impacts of the Dicamba controversy on its own new to market formulation, Engenia.[193] However, BASF is able to point to one significant difference in its research and registration process that Monsanto cannot.[194] BASF allowed, at least to some extent, for scientific testing of Engenia's volatility by outside scientists, such as researchers at the University of Arkansas.[195] The additional volatility research to validate BASF's studies did confirm that Engenia had a lower volatility than previous Dicamba formulations.[196] Dr. Kevin Norsworthy at the University of Arkansas, who was not permitted to study volatility by Monsanto, confirmed that he had been permitted by BASF

188 *See* Flitter, *supra* note 13 (discussing the denial of university researchers' requests to study XtendiMax with VaporGrip).

189 *See* Polansek, *supra* note 182.

190 Kurt Lawton, *Monsanto, Climate Corp 2018 R&D Update*, CORN & SOYBEAN DIG. (Jan. 5, 2018), https://perma.cc/3LQV-MRGQ.

191 *See* Flitter, *supra* note 13.

192 *See Revised Certification Standards for Pesticide Applicators*, U.S. ENVTL. PROTECTION AGENCY, https://perma.cc/DY4P-FP7Z (last updated July 24, 2018) (providing "stronger standards for people who apply restricted use pesticides," with the intent to "reduce the likelihood of harm from the misapplication of toxic pesticides").

193 Gil Gullickson, *Volatility Highlights 2018 Dicamba Concerns*, SUCCESSFUL FARMING (Mar. 2, 2018), https://perma.cc/6QKR-QEEG (reporting that scientists were disconcerted by the injury from XtendiMax and Engenia mixes); *BASF Reports End of Season Dicamba Results*, BASF (Nov. 17, 2017), https://perma.cc/7TPU-76HT (BASF investigating 787 soybean symptomology claims).

194 Flitter, *supra* note 13.

195 *See* BASF Press Release, *supra* note 15; *see also* Flitter, *supra* note 13.

196 Flitter, *supra* note 13.

to study Engenia for its volatility, and he was able to confirm BASF's findings that Engenia did have a lower volatility than previous Dicamba formulations.[197] While not conclusive at this point, the mere fact that BASF allowed additional scientific testing provides a level transparency to BASF's operations that is not present in Monsanto's approach.[198] This is a point that BASF readily points out, even though it acknowledges that investigation into the Dicamba controversy remains underway.[199]

BASF has postured itself as a partner to individual farmers and state agricultural agencies in the investigation of purported Dicamba issues.[200] Like Monsanto, BASF is vocal in their belief that Engenia is an effective and safe product, and BASF points out that the EPA approved the registration of Engenia.[201] BASF is also in a slightly different position as it is the original developer of Dicamba for use as an herbicide, and Engenia is simply the latest in a series of its refined proprietary formulations.[202] BASF is focused exclusively on a single herbicide formulation, whereas Monsanto is in the position of defending an entire crop strategy relying upon genetically engineered traits of resistances to Dicamba. One can readily see why Monsanto would be much more aggressive in terms of defending its product line when viewed in this light.

BASF has traditionally remained focused on the chemical aspect of its agricultural operations and has not forayed into seed production or genetic modification of seeds traits.[203] This stance altered significantly in late 2017, when BASF invested over $7 billion in the acquisition of Bayer AG's agricultural products business, including Bayer's lines of cotton and soybean seeds.[204] Economic analysts point to this acquisition as an acknowledgement of the dissolution of the traditional paradigm of chemical businesses being separate from seed businesses.[205] Modern science and advancements in genetic engineering of seeds now harness seeds and chemicals together, so that today's farmer will employ a unified crop system designed to work in complimentary fashion, rather than a mixture of various individual products.[206] BASF avoided the full weight of the Dicamba controversy in light

197 *Id.*

198 *See id.* (stating "Arkansas blocked Monsanto's product because of the lack of extra volatility testing by universities, but approved BASF's because it had not limited such testing and the results were acceptable").

199 *See* BASF Press Release, *supra* note 15.

200 *See, e.g.*, *Engenia Herbicide Stewardship Portal*, BASF, https://perma.cc/S47G-CSN7 (last visited Dec. 20, 2018) (providing resources to farmers for training and compliance with EPA and state agency regulations).

201 *See BASF Has Created a Better Dicamba from the Molecule Up: Engenia Herbicide*, BASF, https://perma.cc/85AW-W4X3 (last visited Dec. 20, 2018).

202 *See id.*

203 Andrew Marc Noel & Phil Serafino, *BASF Starts Pricey Journey into Seeds with $7 Billon Bayer Deal*, BLOOMBERG (Oct. 13, 2017), https://perma.cc/SU4C-24FP.

204 *Id.*

205 *See id.*

206 *See* BASF Press Release, *supra* note 15.

of its much more recent unification of its agricultural seed and chemical programs.[207]

In simplistic terms, BASF had much less at risk in the Dicamba controversy when compared to Monsanto. This is an important fact and reinforces that we should not misinterpret BASF's actions in response to the crisis as "better" than Monsanto's. The truth is that BASF and Monsanto are not truly comparable when evaluating the Dicamba controversy due to the fundamentally different levels of economic importance to the corporations. Monsanto is an American chemical company focused directly on agricultural chemical and seed development, whereas BASF-SE is a the single-largest chemical company in the world with a diverse mix of chemical programs outside of the agricultural realm. As a result, it is logical that BASF is able to approach the Dicamba controversy from a more neutral position; Engenia is merely one herbicide formulation in a massive company. Monsanto occupies the opposite position, as the company is heavily invested in the Roundup Ready product line, and a threat to that product line could spell disaster for the viability of the company.[208]

While BASF and Monsanto were clearly motivated by their own internal factors in responding to the Dicamba crisis, their actions worked in concert to bring to light a significant gap in the FIFRA pesticide registration process. In the next Part, this Article will examine the gap highlighted by the responses of BASF and Monsanto to the increasing controversy associated with Dicamba's usage. This Article will examine why this gap should not be considered an isolated occurrence, but rather is a clear marker of a change signaling a seismic significant shift in modern agriculture. Finally, this Article will contend that this fundamental transformation of the agricultural sector must be acknowledged and addressed by the EPA. The traditional method of farming in the United States has undergone a revolution over the past twenty years to incorporate and rely upon genetically modified crop systems instead of the traditional single component farming approach. It is vital that FIFRA, and the EPA, adapt. The tools and framework for effective EPA oversight are already in place, but the EPA must actually make use of them in order to prevent future controversies such as Dicamba.

VIII. THE REGULATORY GAP

As previously discussed in this Article's brief review of FIFRA's history, FIFRA was constructed with the input of industry in order to effectively provide oversight for the usage of pesticides within the United States.[209] Amendments were incorporated over the decades to adapt with the modernization of large-scale farming in the United States. However, since 1996, FIFRA has largely remained unchanged, and largely overlooked from a statutory standpoint, as the U.S. agricultural sector has undergone the most

207 *See* Noel & Serafino, *supra* note 203.

208 *See supra* notes 186–187 and accompanying text.

209 *See* WHITACRE & EADS, *supra* note 31, at 10.

dramatic revolution since the industrial revolution.[210] The development and incredible success of genetically modifying herbicide resistance in crops led to the near nationwide adoption of these new seed and herbicide systems as the new industry standard.[211]

FIFRA, and more specifically the pesticide registration mechanisms, were designed to focus on a single active ingredient that was anticipated to be used in a single product in a very traditional way.[212] Dicamba captured headlines in increasing numbers each year starting in 2015.[213] However, Dicamba is not really the problem, or the real story—it is merely a visible manifestation of a more significant issue. Dicamba's controversy is a symptom of a larger underlying problem. That problem is the failure of both industry and the U.S. regulatory scheme to account for, or change to accommodate, genetically modified crop systems during the pesticide registration process.

In 1996, Monsanto truly revolutionized the farming industry in the United States with the implementation of Glyphosate and its Roundup system of genetically engineered soybean and cotton.[214] From 1996 forward, the farming industry in the United States has no longer relied upon the traditional approach of using one herbicide for one purpose, as envisioned in the structure of FIFRA's pesticide registration process.[215] Today's farmer is far more scientifically advanced, relying on genetically modified seeds, which are regulated by the USDA and used in conjunction with specially formulated herbicide blends regulated by the EPA.[216] While the EPA may be long familiar with the active ingredient in a registered herbicide, the Dicamba controversy makes it clear that this simplistic view of pesticides may no longer be valid.

The EPA, and more specifically the pesticide regulators within the EPA, rely upon the scientific data and evaluations provided by industry as the foundation for an effective and responsive regulatory process.[217] It is simply unrealistic to expect the EPA to have the capabilities, resources, and expertise to perform a full scientific evaluation of each and every pesticide brought to market year after year in the United States. FIFRA's design quite elegantly provides a solution by allowing industry to invest in the research and development and then essentially show their work to the EPA in order to obtain registration for their pesticide formulation.[218] However, Dicamba has shown us that this process is not foolproof, and that there are shortcuts

210 *See supra* note 26 and accompanying text.

211 *See* Econ. Research Serv., *supra* note 105 (reporting that 89% of corn, 91% of cotton, and 94% of all soybeans now planted in the United States are genetically modified to contain herbicide-resistant traits).

212 *See About Pesticide Registration*, *supra* note 79.

213 *See, e.g.*, Hakim, *supra* note 2; Charles, *supra* note 3; Laws, *supra* note 135.

214 *See* Charles, *supra* note 3.

215 *See* Grassi, *supra* note 116.

216 *See supra* Part II.

217 *See* 40 C.F.R. § 152.50(c) (2017); Brown et al., *supra* note 41, at 28.

218 *See* 40 C.F.R. § 152.50(c) (2017); Brown et al., *supra* note 41, at 28.

that exist today that can result in potentially catastrophic consequences tomorrow.[219]

As discussed, Monsanto brought XtendiMax with VaporGrip to market, seeking registration and presenting its supporting scientific data to the EPA.[220] Monsanto precluded scientific review of the volatility of XtendiMax with VaporGrip from third parties, such as the University of Arkansas and the University of Missouri.[221] There is no legal prohibition against such a preclusion. XtendiMax with VaporGrip is a proprietary product of Monsanto, and it is not volatility that was then being registered with the EPA, but rather the active ingredient alone.[222] However, the EPA understood that XtendiMax with VaporGrip (as well as BASF's Engenia) were not simply an amendment to a previously registered herbicide, but they were truly new formulations, regardless of the existence of the same active ingredient, and that they were designed to work in conjunction with genetically modified crops only.[223] The stakes were raised even higher considering that these new formulations would be highly toxic to traditional crops and plant species with no genetic traits of resistance to Dicamba.[224] The hesitancy of the EPA in these murky and uncharted waters was readily apparent in that the grants of registration to both Monsanto and BASF were limited to two years, rather than the more common twenty year registration life for pesticides.[225]

The Dicamba controversy highlights two flaws within the current pesticide registration. One flaw is a global flaw affecting regulation of the agricultural sector as a whole, while the second is a more limited flaw that is more readily captured within specific regulatory confines and may potentially be readily resolved. While this Article briefly discusses the more complex, global flaw, the Article primarily focuses on the specific regulatory flaw in the Dicamba controversy to provide concrete recommendations for resolution. The proposed regulatory solution should serve as a starting point to address the more complex issue of regulation of the agriculture section as a whole.

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219 Flitter, *supra* note 13.

220 Ty Vaughn, *Historic Testing of Our Dicamba Formulation, XtendiMax with VaporGrip Technology*, MONSANTO (Aug. 23, 2017), https://perma.cc/X6T3-28U7.

221 Flitter, *supra* note 13.

222 Letter from Kathryn Montague, Product Manager 23, Herbicide Branch, Registration Div., Office of Pesticide Programs, to Thomas Marvin, Dir., Federal Regulatory Affairs, Monsanto Co., (Oct. 12, 2017), https://perma.cc/7FP9-BCHU (containing an enclosure that provides the proposed master label and active ingredient).

223 *See BASF Has Created a Better Dicamba from the Ground up: Engenia Herbicide*, *supra* note 201 (stating that "BASF wiped the slate clean and built a new dicamba from the molecule up" when creating Engenia).

224 Emily Monaco, *Dicamba Might Be Even More Dangerous Than Glyphosate*, ORGANIC AUTHORITY (Oct. 2, 2017), https://perma.cc/VD8A-C22K. Ironically, the exact opposite effect would also hold true, in that the repeated exposure of plants to even the newer Dicamba formulations will perpetuate the development of a naturally-occurring genetic trait of resistance over time.

225 FINAL REGISTRATION OF DICAMBA, *supra* note 137, at 35; NOTICE OF PESTICIDE REGISTRATION, *supra* note 143; *see also* Flitter, *supra* note 13.

First, the EPA-governed process focuses exclusively on the active ingredient and fails to actually consider other aspects, such as the new uses of traditional pesticides as a component of genetically engineered crop systems.[226] The EPA is focused on a singular component rather than the overall crop system that is now employed, of which the pesticide is but one component. The USDA controls the regulation of the genetically engineered seed component, while the EPA controls the regulation of the herbicide component, and the Dicamba controversy highlights that the two systems are not closely coordinated.[227] To describe this problem as a complex regulatory issue would be a significant understatement, and the analysis of recommendations to resolve this issue exceed the limited scope of this Article. What is clear is that industry, in the past twenty years, has combined agriculture and pesticides together in a discrete system, and in order to provide effective regulatory oversight the USDA and EPA will need to likewise evolve.

The second flaw presents a more discrete problem. The Dicamba registration process demonstrated that the EPA can potentially be a rubber stamp of approval if it conditions registration solely upon a review of the scientific data provided to it by the party seeking registration.[228] Reliance solely founded upon industry-provided data raises a facially evident issue: companies could selectively structure their scientific data, cherry-picking only the data that supports registration while censoring data that indicates problems. This would reverse the scientific data burden, placing it on the EPA to decipher whether the scientific data presents a comprehensive picture of the proposed product. This accurately describes the situation presented in the context of Dicamba where Monsanto precluded third-party scientific volatility testing.[229] While investigations are still underway to discover whether it was illegal or improper applications, drift issues, volatility, or some combination of these factors that caused widespread Dicamba damage, it cannot be said that the EPA rendered its registration decision with full scientific transparency, at least in relation to Monsanto's XtendiMax with VaporGrip. The Dicamba controversy, if anything, has shown that the EPA, as the regulatory oversight body tasked with environmental protection in the United States, should be far more cautious about accepting the self-validating data of companies seeking to register new pesticide products on the market.

The ramifications of this regulatory issue extend far beyond Dicamba. Our world is modernizing at an exponential pace, driven by scientific innovations in pharmaceuticals, energy production, genetics, and myriad

226 *See* Caroline Cox & Michael Surgan, *Unidentified Inert Ingredients in Pesticides: Implications for Human and Environmental Health*, 114 ENVTL. HEALTH PERSPECTIVES 1803, 1803 (2006) (stating that the tests required to register a pesticide focus only on the active ingredient alone).

227 Interview with Dr. Kevin Bradley, Professor, Div. of Plant Sciences and State Extension Weed Scientist, Univ. of Missouri. (Mar. 8, 2018) (notes on file with author).

228 *See* Flitter, *supra* note 13 (explaining that Dicamba was approved by EPA based on Monsanto's research alone, despite external researcher's requests to analyze the product).

229 *Id.*

other sectors. Underpinning the regulation of this incredible expansion of knowledge is a reliance upon unbiased scientific data and evaluation. Regardless of the industry being regulated, problems will inevitably arise if regulatory decisions are premised on incomplete or partial data.[230]

The Dicamba controversy is an example of a regulatory action premised on such insufficient data. While the Dicamba controversy is important standing alone, it reveals a larger, systemic regulatory issue: genetically modified crops were not envisioned at the time the mechanisms of FIFRA were created and implemented. In the next Part, this Article will address specific recommendations that the agricultural industry and EPA, together, may quickly implement in order to remedy this issue in the context of Dicamba. Ironically, just as FIFRA was largely dependent upon industry for its initial development and structure, the following recommendations are also largely based upon the path charted by BASF's recent approach in registering Engenia with the EPA.[231] The agricultural sector has undergone a massive transition over the past twenty years and regulatory requirements need a very slight modification in order to bring them closer to modern realities.[232]

IX. WHY THE EPA SHOULD REQUIRE THE BASF APPROACH IN FUTURE PESTICIDE REGISTRATIONS

In this Article we have reviewed the history of FIFRA and examined the Dicamba controversy in the context of the revolutionary changes taking place in the agricultural industry of the United States over the past two decades. This Part will provide discrete recommendations to improve the pesticide registration process in the United States. These recommendations are composed of three unique aspects: first, the anticipation that the agribusiness sector will be strongly motivated to self-correct the perceived deficiencies in the registration process in the wake of the Dicamba controversy without additional government regulation; second, that even if industry implements such practical changes, the EPA should publicly interpret that additional data requirements under 40 C.F.R. Part 158 to include unrestricted third-party testing of pesticides seeking registration; and finally, the EPA should permanently codify the requirement to submit to independent third-party testing by incorporating a sunshine provision in the federal regulations at 40 C.F.R. Part 158.

The requirements of the pesticide registration process in the United States are set forth in regulations found at 40 C.F.R. Part 158, discussed previously.[233] The EPA is specifically empowered in the regulatory language

230 *See* Holly Doremus & A. Dan Tarlock, *Science, Judgment, and Controversy in Natural Resource Regulation*, 26 PUB. LAND & RESOURCES L. REV. 1, 3 (2005).

231 *See* Pam Smith, *EPA Registers BASF's Engenia, Dicamba-Tolerant Herbicide—DTN*, AGFAX (Dec. 23, 2016), https://perma.cc/Z6B6-8DZJ.

232 *See* Kevin M. Hogan, *Inert Ingredients and Pesticide Registration Data Requirements: EPA's Complacency Compounds FIFRA's Inadequacies*, 15 VT. L. REV. 265, 284 (1990).

233 *See* 40 C.F.R. § 158.1(a) (2017).

to require a party seeking to register a pesticide to submit to additional data requirements if, in the EPA's discretion, the explicitly required data does not sufficiently provide for a full evaluation of the pesticide's safety to either man or the environment.[234] The independent evaluation of scientific tests and data submitted by a party seeking to register a pesticide in the United States falls squarely within the confines of additional data.[235] The EPA may, and as the Dicamba controversy now makes abundantly clear, *should* require a company to comply with independent testing and verification of its scientific data submitted in support of pesticide registration.

BASF allowed for independent volatility testing of Engenia in support of its application for registration, and this independent testing confirmed the company's data.[236] This transparent approach is more consistent with the traditional view of scientific methods requiring rigorous, open testing and evaluation than the approach utilized by Monsanto in precluding such independent volatility testing in support of the registration of XtendiMax with VaporGrip.[237] However, this should not be mistaken for the implication that Monsanto acted improperly, even in a scientific sense. Monstanto's registration for XtendiMax With Vapor Grip was required to focus, per FIFRA, on the active ingredient, not volatility.[238] Yet, the EPA could have required additional information from Monsanto, when there was a need for additional data to capture the full picture of a product's environmental safety.[239]

The EPA should have required such open evaluation as an additional data requirement. The EPA is the gatekeeper responsible for ensuring that pesticides permitted onto the market in the United States are safe, both for man and the environment.[240] Dicamba is not a new pesticide, and its toxic effects to plant species are well documented in the over fifty years of its formulation and refinement.[241] The mere fact that drift and volatility issues, today, remain suspects under investigation in the Dicamba controversy are facial evidence of a potential threat to the environment which require the EPA's full scientific evaluation.[242] The EPA's lone reliance upon company-generated scientific data tends to create the appearance of a non-scientific method and, instead, generates the perception of the EPA as simply a

234 40 C.F.R. § 158.75 (2017).

235 *See id.*; 40 C.F.R. § 158.70 (2017).

236 *See* BASF Press Release, *supra* note 15; *see also* Flitter, *supra* note 13.

237 *See* Flitter, *supra* note 13.

238 *See* FIFRA, 7 U.S.C. § 136a (2012).

239 40 C.F.R. § 158.75 (2013); *see supra* notes 83–84 and accompanying text.

240 *Cf. Basic Information About Pesticide Ingredients*, ENVTL. PROTECTION AGENCY, https://perma.cc/YHT9-V9BL (last visited Dec. 20, 2018) (stating that "[b]efore manufacturers can sell pesticides in the United States, EPA must evaluate them thoroughly to ensure that they meet federal safety standards to protect human health and the environment").

241 *See* Kevin Folta & Cameron English, *Lessons Learned from the 2017 Monsanto Dicamba Herbicide Fiasco*, GENETIC LITERACY PROJECT (Jan. 25, 2018), https://perma.cc/R9PT-JNE8.

242 *See* Tyne Morgan, *Dicamba Debate: Is It Drift or Volatility?*, AGWEB (July 24, 2017, 10:21 AM), https://perma.cc/29JW-GJZB.

regulatory rubber stamp for industry. This threat to public confidence is one that the EPA should rightly guard against.

Interestingly, the authority of the EPA to mandate this additional data requirement appears to be quietly acknowledged in Monsanto's own lawsuit against the Arkansas State Plant Board. In its original complaint, Monsanto argues that Arkansas's requirement that Monsanto submit to volatility testing conducted by researchers at the University of Arkansas was outside the state's statutory authority, and further was a violation of the dormant commerce clause as it favored in-state researchers over out-of-state researchers.[243]

While Monsanto's argument that Arkansas's own statutes preclude any requirement that would force the company to submit to independent third-party scientific testing, the same analysis would yield a different conclusion when analyzed under FIFRA.[244] Federal regulations under 40 C.F.R. § 158.75, explicitly authorize the EPA's ability to set forth just such a requirement with the full weight of federal law and regulation.[245] While Monsanto may have won the battle in state court with this argument, it would likely lose the war in the federal context, given the expansive regulatory powers given to the EPA under FIFRA and that traditional deference that courts apply to discretionary decisions that involve complex questions of specific expertise.[246]

As a corollary to this analysis, it is a fair assumption to consider that industry actors, such as Monsanto and BASF, are rationally motivated to seek to minimize the regulatory scrutiny of the EPA in the registration process. Conflicts, especially high-profile incidents like the Dicamba controversy, will necessarily result in additional expenditures in time and capital, regardless of the eventual regulatory outcome, to address and mitigate public perceptions. Therefore, it is likely that, in the future, companies will be self-motivated to submit to independent third-party testing and evaluation as part of the registration process, without the formal requirement of such action by the EPA. This is the tact taken by BASF, and it yielded a positive result in two ways.[247] First, it allowed BASF to confidently express that their product, Engenia, was rigorously tested for volatility by independent scientific researchers, an argument that Monsanto could not make.[248] Second, the independent findings actually confirmed BASF's data.[249] This better reflects the intended marriage of scientific data and regulation that FIFRA sought by placing the onus for supporting data on the private party seeking to register a pesticide in the United States. The industry

243 *See* Compl. At 6–7, Monsanto Co. v. Ark. State Plant Board et al., No. 60CV-17-5964, (D. Ark. Oct. 20, 2017), https://perma.cc/5QKV-DKVU.

244 *See* 40 C.F.R. § 158.75; *supra* notes 83–84 and accompanying text.

245 *Id.*

246 *See* Baltimore Gas and Electric Co. v. Nat. Res. Def. Council, 462 U.S. 87, 103 (1983) (deferring to agencies' scientific determinations); Chevron U.S.A., Inc. v. Nat. Res. Def. Council, 467 U.S. 837, 844 (1984) (deferring to agency interpretations of ambiguous statutes).

247 Flitter, *supra* note 13.

248 *Id.*

249 *Id.*

response will likely take into account the controversy and associated stigma generated in associations with the Dicamba registrations and will attempt to self-correct. The most effective way for industry to contribute to a resolution will be to secure independent, third-party testing to bolster its registration submission to the EPA as well as generate positive public perception through transparency.

However, the past several years has indicated that the EPA cannot solely rely upon a naked trust of the responsible practices of industry in submitting new pesticide products for review and registration. The EPA must trust the data submitted by these companies, but it must be able to independently verify such data as well. This analysis will only become more vital as the technological complexity of such products submitted for registration grows over time.

As discussed above, this Article advances the idea that the EPA holds solid footing to immediately require unrestricted and independent third-party scientific evaluation of a pesticide seeking registration.[250] However, it would be advisable to codify this position within the federal regulations in order to provide clear and concise guidance, eliminating any ambiguity moving forward. The incorporation of such a provision would operate with the same intent as other "sunshine provisions" familiar in many areas of under federal law.[251] Significant concern should be focused on the protection of intellectual property rights of the industry actors in such a scheme. To be clear, this Article does not advocate for unfettered public access and scientific review of a proposed product, but rather an elimination of the absolute embargo placed upon new products seeking registration which forecloses opportunities for those experts in the agricultural sciences to review and validate the data which the company itself derives and submits to the EPA.

The use of contracts to limit the scientific scope of review of potential products pending before the EPA is already an industry standard practice.[252] This Article advocates for the EPA to actively engage itself within that industry practice and eliminate the ability of a company to selectively manipulate what data may or may not be evaluated by independent scientists in a potentially circular process of self-validation.

The incorporation of a sunshine provision into the data requirement listing of 40 C.F.R. § 158.75 would be a simple and effective mechanism by which to correct the larger issue highlighted in the Dicamba controversy.[253] A proposed draft version of such a provision is attached to this Article and is offered merely as a starting point for consideration.[254] The complexity of pesticides submitted for registration within the United States is only

250 *See supra* notes 233–35 and accompanying text.

251 *See, e.g.*, Government in the Sunshine Act of 1976, 5 U.S.C. § 552b (2012); National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321–4270h (2012); Freedom of Information Act of 1967, 5 U.S.C. § 552 (2012).

252 *See* Flitter, *supra* note 13.

253 *See infra*, Attachment 1.

254 *Id.*

anticipated to increase, as the genetic and chemical components of agribusiness become more closely interdependent.[255] The EPA must adjust to this new reality and change its frame of reference from the traditional role of data validator in the registration process. It is imperative that a full and open scientific review is completed on substances submitted for registration under FIFRA. In order to maintain its role of gatekeeper under FIFRA, the EPA must either undertake the massive effort of securing scientific expertise that will enable it to effectively evaluate and review industry submitted data, or it must require industry to allow for unfettered and independent scientific evaluation of products for which registration is sought. The latter of these is the far more economical and realistic answer.

The Dicamba controversy forces a close look at the regime of pesticide regulation in a new way. Pesticide registration can no longer be viewed in the traditional monolithic fashion envisioned under FIFRA, examining a single specific product. Today, pesticide registration must be seen as one component of a complex process of evaluating crop systems designed to work together and spanning across multiple regulatory agencies. While this may appear to require a significant adaptation to the current FIFRA regulatory scheme, in reality it requires relatively little energy and can largely be accomplished by incorporating industry into the solution. The primary focus of a modern pesticide registration process regime must be to fully capture scientific knowledge in an impartial manner in order to validate the performance and safety aspects of a product. The EPA is the agency to which Congress delegated the power to ensure pesticides are registered in a safe, methodical manner, and, as a result, the EPA retains the discretion to require applicants to comply with unrestricted scientific testing procedures.[256]

As highlighted throughout this Article, industry has long been the driving factor in the development and implementation of FIFRA.[257] The Dicamba controversy provides a similar opportunity for industry to continue charting their own regulatory destiny by establishing and incorporating unrestricted scientific testing as the industry standard for products submitted for FIFRA registration. The EPA can, and this Article argues should, codify such a requirement into FIFRA, but it is industry that can immediately incorporate such action and largely resolve similar issues in the future. This is the course that BASF followed when it allowed for third-party volatility testing, and it is a practice that industry should recognize as the reasonable and responsible standard for the future, eliminating the foundation for criticism that Monsanto continues to endure based upon a refusal to allow open scientific volatility testing.

Harnessing the potential of genetically modified crop systems promises incredible benefits. While herbicide resistance remains an issue that scientists continue to study, the ability to significantly reduce the overall

255 Elizabeth S. Dennis et al., *Genetic Contributions to Agricultural Sustainability*, 363 PHIL. TRANSACTIONS ROYAL SOC'Y 591, 604–05 (2008).

256 FIFRA, 7 U.S.C. § 136a (a), (c)(7) (2012).

257 *See* WHITACRE & EADS, *supra* note 31, at 10.

number of pesticides and herbicides applied on the ground in favor of one or two more effective alternatives provides a clear environmental benefit as well as achieving a significant economic boost for farmers.[258] In the future, the transfer of this technology to farmers plagued by similar problems in less developed nations could yield benefits on a far magnified scale. Employing genetically modified crop systems is no longer a future problem that one day needs to be addressed, it is the present state of American agriculture, and the world will follow down the path we are currently charting.

The controversy surrounding Dicamba merely highlights the culmination of a generational shift in farming techniques that started in the mid-1990s with the development and complete market domination of Roundup (Glyphosate) ready seeds.[259] Monsanto and BASF have both invested significantly in the research and development of the new agricultural technology and technique.[260] Of course, the impetus for this investment is the ability to generate a significant return, to make a profit as any business would seek to do. It is both misguided and counterproductive to sustain attacks against Monsanto, BASF, or the agricultural industry as a whole when difficulties and obstacles manifest, such as the Dicamba controversy, while the development and employment of advanced new technology is underway. Continually pushing the technological frontier forward is exactly what will ensure the American agricultural sector retains its preeminence in the future. A significant byproduct of this process that cannot be ignored is that more effective farming techniques are developed and shared throughout the world to meet the needs of an expanding population, which may play a critical role in mitigating the effects of climate change that impact farming capabilities worldwide.

However, as necessary and laudable as these advancements in agricultural science and technology are, the industry is not free from regulatory oversight in the development and application of these products, or even free from criticisms that are aimed at improving the regulatory process. Modern industry recognizes the important role of registration and regulation of pesticides.[261] Even more, industry now understands that there are significant advantages and protections that accompany being the first to the marketplace with an innovative technology.[262] The astounding success of Roundup, as a genetically modified crop system, kicked off a technological

258 *See* Dennis et al., *supra* note 255, at 604 (detailing a cases where use of a genetically modified cotton reduced pesticide usage by 80%).

259 Michael Mascarenhas & Lawrence Bush, *Seeds of Change: Intellectual Property Rights, Genetically Modified Soybeans and Seed Saving in the United States*, 46 J. EUROPEAN SOC'Y RURAL SOC. 122, 129–30 (2006) (discussing the "technology treadmill" and suggesting that "[w]hen confronted with the rapidly expanding technologies of nature's production farmers are left with few options: loyalty to the technology treadmill or exiting the industry all together, the latter being an option few are willing to consider").

260 Peter Mitchell, *GM Giants Pair up to do Battle*, 25 NATURE BIOTECHNOLOGY 695, 695–96 (2007).

261 *See, e.g.*, *Glyphosate and Roundup Brand Herbicides*, MONSANTO (May 16, 2017), https://perma.cc/7PSG-HMX3.

262 *See* Mascarenhas & Busch, *supra* note 259, at 127–28.

arms race between the major chemical companies to adapt and apply the same principles to major cash crops such as soybeans, cotton, and corn.[263] The Dicamba controversy is a physical manifestation of the turbulence we can expect as we push the very ragged edge of the technological frontier forward. Scientific advancement has outpaced regulatory oversight, albeit temporarily, in the Dicamba situation and highlighted gaps within the regulatory framework that must be incorporated as part of the natural progression and development of science and technology in the agricultural realm.

This Article attempted to do just that, reviewing the history of the pesticide registration process in the United States and juxtaposing that regulatory system against the recent rise and reliance upon genetically modified crop systems. Through this analysis several gaps were identified, including the detrimental impacts of the EPA relying solely upon industry-generated data in support of pesticide registrations.

Understanding that genetically modified crop systems require cross-agency cooperation with industry and mandate unfettered scientific testing to validate the performance and safety of these crop systems is critical to solving this modern problem. Industry and the EPA must understand and acknowledge that the days of putting on blinders and only reviewing a single active ingredient for registration purposes are gone. Today, the single active ingredient is but a minor component of an overall crop system that may have significant and wide-ranging impacts that must be considered comprehensively.

Innovation is an imperfect process, and the lesson that I believe the industry will take from the Dicamba controversy is that public perception of transparency and scientific credibility will demand product development be undertaken with allowance for full and fair scientific testing to validate claims of product performance and safety. Companies such as Monsanto and BASF are already rising to meet this challenge in order to ensure they continue the legacy of cooperation between industry and government that led to the development and implementation of FIFRA's regulatory framework.[264]

X. CONCLUSION

As I worked my way through that soybean field clearing weeds one by one many years ago, I quickly learned that no amount of individual effort that I could muster could staunch the seemingly endless growth of weeds that appeared overnight. Today, it is easy for me to imagine the frustration and despair that many farmers must confront as they face the same problem magnified across several tens or hundreds of thousands of acres. The

263 *See* Press Release, Future Mkt. Insights, Dicamba Market: North America Set to Outpace the Largest Market Europe (Jan. 11, 2017), https://perma.cc/WV38-9KBE.

264 *See* Press Release, Envtl. Prot. Agency, *EPA and States' Collective Efforts Lead to Regulatory Action on Dicamba* (Oct. 13, 2017), https://perma.cc/YK3U-G4LG (stating Monsanto, BASF, and DuPont's agreement to cooperate with EPA).

traditional application of herbicides that we collectively relied upon year after year worked to our detriment as each application provided another opportunity for weeds to develop resistant traits and pass them to future generations. Today, for a farmer facing weed strains imbued with powerful resistant traits, the ability to leverage a genetically modified crop system, employing seeds modified to tolerate exposure to various herbicides is an incredibly powerful tool. The ultimate goal of such technology could lead to the employment of a rotation of such products that largely breaks the resistance cycle of weeds and perpetuates larger sustained crop yields.

This is the broader promise of science that provides the context for the development of the new forms of Dicamba that are currently under scrutiny. The easy action is to point to the chemical company and criticize the immediate effects. The more difficult effort is to pause and evaluate the performance of the process that developed the new Dicamba systems and identify those areas that can be iteratively improved upon each growing season.

While the growing pains associated with Dicamba today may be difficult, it is my belief that the end result will be a far stronger body of scientific knowledge and agricultural capabilities. As the spring planting seasons get underway throughout the United States, one thing is certain, Dicamba will continue to be a national news story and only time will tell whether industry and the government will once again come together to weed out the flaws in the process and sustain a much greater scientific yield in the end.

Attachment 1

§ 158.75 Requirements for additional data.

The data routinely required by this part may not be sufficient to permit EPA to evaluate every pesticide product. If the information required under this part is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed. However, EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties and effects of the pesticide.[265]

Recommended revision incorporating a sunshine provision:

§ 158.75 Requirements for additional data and evaluation.

The data routinely required by this part may not be sufficient to permit EPA to evaluate every pesticide product. *To ensure the information required under this part is sufficient to fully evaluate a product, parties shall identify and include within their submission the procurement of unrestricted scientific testing and evaluation of a product and all associated results. This requirement shall not prevent a party from asserting protections over trade secrets, or the like, through contractual or other methods.* EPA expects that the information required by this part will be adequate in most cases for an assessment of the properties and effects of a pesticide *but reserves the right to require a registrant to submit to additional scientific testing at any time when the EPA determines a threat of unreasonable adverse effect to man or the environment exists.*

265 40 C.F.R. § 158.75 (2017).