

# COMMENTS

## NOTHING BUT UNCONDITIONAL LOVE FOR CONDITIONAL REGISTRATIONS: THE CONDITIONAL REGISTRATION LOOPHOLE IN THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

BY  
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*This Comment examines the practice of the U.S. Environmental Protection Agency (EPA) of issuing “conditional registration” status to pesticides rather than requiring the pesticide manufacturer to comply with full registration requirements as outlined in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This Comment argues that conditional registration goes against the purpose of FIFRA by allowing potentially harmful pesticides to evade safety requirements and to permeate the environment with effects yet unknown.*

*This Comment analyzes the history of pesticide law in the United States as well as the structure and purpose of FIFRA and its pesticide registration process. This Comment further draws attention to the flaws of the conditional registration process, and finally discusses current litigation that has the potential to change EPA’s conditional registration practices.*

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## I. INTRODUCTION

During the past century, federal law has had a wide and varied relationship with pesticides. As with any evolving area of law, changes in statutes along with developments in case law signal corresponding shifts in societal attitudes. Far removed from its humble beginning as a statute only concerned with pesticide efficacy,<sup>1</sup> federal pesticide law has grown in the last 104 years to include environmental and human safety provisions, supported by the latest reliable scientific data available.<sup>2</sup> The modern Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)<sup>3</sup> focuses on safety by requiring pesticide producers to register all pesticides with the U.S. Environmental Protection Agency (EPA) before entering the market, and to

<sup>1</sup> Insecticide Act of 1910, Pub. L. No. 61-152, 36 Stat. 331, ch. 191 (codified as amended at 7 U.S.C. §§ 135–135k (2012)).

<sup>2</sup> Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136a(a) (2012) requires registration of all pesticides that are sold or distributed and provides that the EPA Administrator may, “[t]o the extent necessary to prevent unreasonable adverse effects on the environment . . . limit the distribution, sale, or use . . . of any pesticide that is not registered . . . and that is not the subject of an environmental use permit . . . or emergency exemption.”

<sup>3</sup> 7 U.S.C. §§ 136–136y.

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prove their pesticides pose no unreasonable adverse effects to human health or the environment.<sup>4</sup>

On its face, FIFRA<sup>5</sup> pesticide registration provisions such as extensive data requirements and the possibility of civil and criminal penalties seem to accurately reflect society's concern for safety.<sup>6</sup> However, delving deeper reveals a significant loophole to the safety requirements Congress contemplated. Specifically, FIFRA's conditional registration provision allows pesticide manufacturers to circumvent a requirement of proving their pesticide is safe by providing a quasi-registration status in the absence of critical data.<sup>7</sup> Moreover, EPA's lax enforcement measures illustrate that EPA has abused the conditional registration exception and has relied on the exception as its main way of allowing pesticides to market.<sup>8</sup>

This Comment argues that the conditional registration provision of FIFRA violates—in theory and in effect—the purpose of FIFRA's pesticide registration requirement, which is to prevent pesticides that pose “unreasonable adverse effects” to human health and the environment from entering the market.<sup>9</sup> Part II describes the evolution of federal pesticide law from the first federal pesticide law in 1910 to the present. Part III outlines the registration process for pesticides and compares full registration requirements with conditional registration requirements. Part IV explores the flaws in the conditional registration process, both in terms of theoretical invalidity and EPA's implementation. Part V discusses the legal effects that result from EPA's granting of conditional registration status, as well as litigation options for adversely affected parties to attain relief. Part VI offers suggestions for EPA to improve the conditional registration program. Part VII describes current case law relating to conditional registrations. This Comment concludes the conditional registration provision is a loophole to FIFRA that poses detrimental implications not intended by Congress, and that even in the absence of Congressional action, litigation is a viable means for ensuring EPA complies with the more stringent requirements for full registration under FIFRA.

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<sup>4</sup> *Id.*; *see, e.g., id.* § 136a(c)(2)(B)(vii) (citing human health and environmental concerns as independent reasons for rejecting registration extension).

<sup>5</sup> Unless otherwise specified in this Comment, “FIFRA” refers to the federal pesticide laws and related amendments currently in force, codified at 7 U.S.C. §§ 121–136y (2012).

<sup>6</sup> *Id.* § 136a(c)(2) (data submission requirements); *see id.* § 136l (civil and criminal penalties); H.R. Rep. No. 1887, at 1–2 (1946) (describing necessity for changes to registration requirements due to potential for injury to persons).

<sup>7</sup> 7 U.S.C. § 136a(c)(7).

<sup>8</sup> JENNIFER SASS & MAE WU, *SUPERFICIAL SAFEGUARDS: MOST PESTICIDES ARE APPROVED BY FLAWED EPA PROCESS 2* (2013), *available at* <http://www.nrdc.org/health/pesticides/files/flawed-epa-approval-process-IB.pdf>; *see id.* at 4 (exemplifying EPA's failure to adequately enforce the requirement that data support product safety prior to registration).

<sup>9</sup> 7 U.S.C. § 136a(a); *see, e.g., id.* § 136a(c)(2)(B)(vii).

## II. FIFRA HISTORY

Throughout its century-long history, pesticide regulation steadily became more comprehensive, culminating in Congress's addition of human health and environmental safety standards in the Federal Environmental Pesticide Control Act of 1972 (FEPCA).<sup>10</sup> FEPCA required EPA to consider whether a pesticide would cause "unreasonable adverse effects on the environment" during the registration process.<sup>11</sup> Just a few years later, however, Congress enacted the Federal Pesticide Act of 1978,<sup>12</sup> which gave the EPA power to grant conditional registrations. The addition of conditional registrations to the pesticide registration process remains controversial and is at the heart of this Comment.

### *A. Insecticide Act of 1910*

National pesticide legislation has only been in place for a little more than one hundred years, and the scope of pesticide law has changed drastically and increased steadily during that time. In 1910, Congress enacted the first pesticide-related law, the Insecticide Act of 1910 (Insecticide Act).<sup>13</sup> The Insecticide Act addressed pesticide labeling and prohibited the sale of fraudulently labeled pesticides.<sup>14</sup> Importantly, the Insecticide Act granted pesticide program oversight powers to the U.S. Department of Agriculture (USDA), by mandating that the USDA "collect[] and examin[e]" pesticides and related products sold or manufactured in the United States.<sup>15</sup> The Insecticide Act neither required pesticide registration nor established specific standards for pesticide efficacy or environmental or human safety.<sup>16</sup>

### *B. Federal Insecticide, Fungicide, and Rodenticide Act of 1947*

In 1947, Congress adopted the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA I),<sup>17</sup> which broadened the scope of national pesticide law by including more types of pesticides than the Insecticide

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<sup>10</sup> Pub. L. No. 92-516, 86 Stat. 973.

<sup>11</sup> *Id.* § 3, 83 Stat. 8081.

<sup>12</sup> Pub. L. No. 95-396, 92 Stat. 819.

<sup>13</sup> Pub. L. No. 61-152, ch. 191, 36 Stat. 331 (1910) (codified as amended at 7 U.S.C. §§ 135-135k (2012)).

<sup>14</sup> *Id.*

<sup>15</sup> *Id.* at 331-32.

<sup>16</sup> Elizabeth C. Brown et al., *A Practitioner's Guide to the Federal Insecticide, Fungicide, and Rodenticide Act*, in PESTICIDE REGULATION DESKBOOK 3, 10 (Env'tl. Law Inst. et al. eds., 2001).

<sup>17</sup> Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 80-104, § 1, 61 Stat. 163 (1947).

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Act,<sup>18</sup> requiring product registration by USDA prior to interstate or international shipment, and mandating warning labels and instructions.<sup>19</sup>

Moreover, FIFRA I required every “economic poison” distributed or sold in the United States to be registered with the Secretary of Agriculture,<sup>20</sup> and authorized the Secretary, after an opportunity for a hearing, to “determine economic poisons, and quantities of substances contained in economic poisons, which are highly toxic to man.”<sup>21</sup> FIFRA I also prescribed criminal penalties for violations of this registration requirement.<sup>22</sup> Like its predecessor the Insecticide Act, however, strikingly absent from FIFRA I registration was any safety requirement.<sup>23</sup>

*C. Federal Environmental Pesticide Control Act of 1972*

After remaining largely unchanged for close to thirty years,<sup>24</sup> Congress drastically amended FIFRA by passing the Federal Environmental Pesticide Control Act of 1972 (FEPCA),<sup>25</sup> “essentially rewr[iting]” it to include human health and environmental safety standards.<sup>26</sup> The impetus for Congress’s overhaul stemmed from increasing public awareness of the dangers of pesticide use in terms of environmental hazards and human safety, coupled with the inadequacy of FIFRA I to address those dangers.<sup>27</sup>

In his presidential signing statement, President Nixon stated that FEPCA:

[R]epresents the most significant legislation in this field since [FIFRA I] was passed in 1947. . . . [T]he Federal Government, for the first time, will be able to exercise adequate control over the use of pesticides. We will now be able to ensure that we can continue to reap the benefits which these substances can contribute to the well-being of America . . . without risking unwanted hazards to our environment and our health.<sup>28</sup>

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<sup>18</sup> The Insecticide Act covered insecticides, fungicides, and a single rodenticide: Paris green. *Id.* § 1, 36 Stat. at 332. FIFRA I covered insecticides, fungicides, as well as herbicides and rodenticides. *Id.* § 2, 61 Stat. at 164.

<sup>19</sup> *Id.* § 3(a), 61 Stat. at 166; Brown et al., *supra* note 16, at 10.

<sup>20</sup> Pub. L. No. 80-104, § 4(a), 61 Stat. at 167.

<sup>21</sup> *Id.* § 6(a), 61 Stat. at 168–69.

<sup>22</sup> *Id.* § 8(b), 61 Stat. at 170.

<sup>23</sup> *Id.* § 3(a), 61 Stat. at 166.

<sup>24</sup> One significant interim development was the 1964 FIFRA amendment, which gave the Secretary of Agriculture the power to refuse to register a new product, cancel an existing registration, and suspend registration if it posed an imminent hazard to the public. Federal Insecticide, Fungicide, and Rodenticide Act of 1964, Pub. L. No. 88-305, § 3, 78 Stat. 190 (1964).

<sup>25</sup> Pub. L. No. 92-516, 86 Stat. 973 (1972).

<sup>26</sup> U.S. Envtl. Prot. Agency, *Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)*, <http://www.epa.gov/agriculture/lfra.html#> (last visited Nov. 22, 2014).

<sup>27</sup> H.R. REP. NO. 92-511, at 4 (1971).

<sup>28</sup> Presidential Statement on Signing the Federal Environmental Pesticide Control Act of 1972, 8 WEEKLY COMP. PRES. DOC. 1550–51 (Oct. 21, 1972).

Indeed, Congress's amendment shifted the focus and purpose of FIFRA from efficacy and consumer deception to consumer and public safety and environmental consequences of pesticide use, in light of up-to-date science.<sup>29</sup> The most significant changes introduced by FEPCA were 1) an environmental health component in the registration process requiring EPA to consider whether a pesticide would cause "unreasonable adverse effects on the environment"<sup>30</sup> and 2) an expansion of EPA's jurisdiction and enforcement powers.<sup>31</sup>

#### *D. Federal Pesticide Act of 1978*

Congress again made major changes to U.S. pesticide law when it enacted the Federal Pesticide Act of 1978 (FPA).<sup>32</sup> Most significantly, the FPA gave the EPA Administrator the power to grant conditional registrations for new pesticides as well as to amend a currently registered pesticide.<sup>33</sup> By allowing pesticide producers to forego full pesticide registration, Congress hoped to streamline pesticide registration without jeopardizing environmental or human health safety.<sup>34</sup> Congress felt that because of the safeguards in place, the allowance of conditional registrations would only enable EPA to "make available more pesticides that are deemed to be basically safe."<sup>35</sup> The current conditional registration provisions remain largely the same as those passed in 1978.<sup>36</sup>

### III. PESTICIDE REGISTRATION PROCESS

FIFRA requires applicants to submit extensive scientific data regarding safety when applying to register a pesticide. The EPA Administrator is charged with granting registration to those pesticides that will not "cause unreasonable adverse effects on the environment." While the FIFRA registration scheme focuses mostly on the full registration process, EPA has in practice registered most pesticides under conditional registration. This practice has resulted in most pesticides reaching the market and the environment while their safety is yet unknown.

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<sup>29</sup> See generally H.R. REP. NO. 92-511, at 1 (1971) ("The thrust of these amendments is to change FIFRA from a labeling law into a comprehensive regulatory statute that will henceforth more carefully control the manufacture, distribution, and use of pesticides.").

<sup>30</sup> Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, § 3(c)(5)(D), 86 Stat. 973 (1972).

<sup>31</sup> *Id.*; see Brown et al., *supra* note 16, at 10 (stating that the 1972 Act expanded EPA's jurisdiction to include intrastate distribution of pesticides, authorized EPA to approve pesticides for "restricted" rather than general use, and established a re-registration process).

<sup>32</sup> Pub. L. No. 95-396, 92 Stat. 819 (1978).

<sup>33</sup> *Id.* § 6, 92 Stat. at 825.

<sup>34</sup> 124 CONG. REC. S29,756-57 (daily ed. Sept. 18, 1978).

<sup>35</sup> *Id.* at S29,760.

<sup>36</sup> Compare 7 U.S.C. §136a(c)(7) (2012) with § 6, 92 Stat. at 825-26 (presenting nearly identical language).

### *A. General Registration*

The current language of FIFRA requires anyone who sells or distributes a pesticide to register the pesticide with EPA.<sup>37</sup> FIFRA outlines a detailed procedure for new pesticide registration,<sup>38</sup> including the important and cumbersome requirement of submitting data pursuant to 7 U.S.C. § 136a(c)(2).<sup>39</sup> Based on submitted data, the EPA Administrator “shall register” a pesticide when the Administrator determines the pesticide “will perform its intended function without unreasonable adverse effects on the environment [and] when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.”<sup>40</sup> If the Administrator determines an applicant fails to meet these requirements after the applicant has had notice and an opportunity to correct the application, the Administrator shall deny the application request and publish notice of, and reasons for, the registration denial in the Federal Register.<sup>41</sup>

The requirement that applicants submit extensive scientific data to support registration of a pesticide goes to the heart of the 1972 FEPCA amendments, which included the additional requirement that an applicant demonstrate no “unreasonable adverse effects on the environment.”<sup>42</sup>

### *B. Conditional Registration Exceptions*

Despite Congress’s safety concerns and FEPCA’s corresponding addition of lengthy, specific, and cumbersome data submission requirements to support a registration, the FPA added the conditional registration provision to FIFRA.<sup>43</sup> This provision allows the Administrator to conditionally register new pesticides and amend registered pesticides under the following circumstances:

**(1) Identical or Substantially Similar Products:** The Administrator may register or amend a pesticide registration when:

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<sup>37</sup> 7 U.S.C. § 136a(a).

<sup>38</sup> *Id.* § 136a(c)(1)–(10). The 10 major components of full registration include: 1) Statement, 2) Data in Support of Registration, 3) Application, 4) Notice of Application, 5) Approval of registration, 6) Denial of Registration, 7) Registration Under Special Circumstances, 8) Interim Administrative Review, 9) Labeling, and 10) Expedited Registration of Pesticides.

<sup>39</sup> LINDA-JO SCHIEROW, CONG. RESEARCH SERV., RL31921, PESTICIDE LAW: A SUMMARY OF THE STATUTES 4 (2008) (“EPA may require data from any combination of more than 100 different tests, depending on the potential toxicity of active and inert ingredients and degree of exposure.”).

<sup>40</sup> 7 U.S.C. § 136a(c)(5)(C)–(D).

<sup>41</sup> *Id.* § 136a(c)(6).

<sup>42</sup> Federal Environmental Pesticide Control Act of 1972, Pub. L. No. 92-516, § 3(c)(5)(C), 86 Stat. 973 (1972). The 1972 Act defined “unreasonable adverse effects” as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.” *Id.* § 2(bb), 86 Stat. at 979.

<sup>43</sup> Federal Insecticide, Fungicide, and Rodenticide Act, Pub. L. No. 95-396, § 6, 92 Stat. 819, 825–26 (1978) (codified at 7 U.S.C. § 136a(c)(7) (1982)).

(i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment.<sup>44</sup>

**(2) New Uses:** The Administrator may amend a pesticide registration:

to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional [full] amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment.<sup>45</sup>

**(3) New Active Ingredients:** The Administrator may register:

a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this subchapter, and on such other conditions as the Administrator may prescribe.<sup>46</sup>

The FIFRA registration scheme focuses mostly on the requirements for the full registration process, and not on the conditional registration exception.<sup>47</sup> Although it is unknown whether Congress contemplated an appropriate volume of conditional registrations, it is arguable that Congress approved the conditional registration exception on the basis that it was just that: an *exception* to the registration process.<sup>48</sup> Thus, the fact that EPA registers most pesticides under this conditional exception is counterintuitive.<sup>49</sup>

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<sup>44</sup> 7 U.S.C. § 136a(c)(7)(A) (2012).

<sup>45</sup> *Id.* § 136a(c)(7)(B).

<sup>46</sup> *Id.* § 136a(c)(7)(C).

<sup>47</sup> *Id.* § 136a(c).

<sup>48</sup> Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1978, Pub. L. No. 95-396, § 6, 92 Stat. 819, 825-26 (1978). Senator Lugar, committee member of the bill, stated in a Senate Hearing, "I... am persuaded by the lengthy [Environmental Protection] Agency testimony... that conditional registrations of new chemicals will be granted only under limited circumstances, and only after a specific finding that the public interest would be served by the registration." 123 CONG. REC. S25,708 (daily ed. July 29, 1977).

<sup>49</sup> Brown et al., *supra* note 16, at 22; CAROLINE COX, NO GUARANTEE OF SAFETY 4 (2002), available at <http://www.pesticide.org/get-the-facts/ncap-publications-and-reports/general-report-s-and-publications/journal-of-pesticide-reform/journal-of-pesticide-reform-articles/eparegis.pdf>



## IV. FLAWS IN THE CONDITIONAL REGISTRATION PROCESS

The conditional registration process is flawed in many respects, including EPA's overreliance on and inaccurate recording of conditional registrations. At a basic level, conditional registration allows pesticide manufacturers to distribute pesticides that have not gone through rigorous human and environmental safety testing. This means people, wildlife, and nutrient systems are exposed to substances that have not been tested for adverse effects.

*A. Problems with Conditional Registrations "In Theory"*

The conditional registration exception for new active ingredients<sup>50</sup> contravenes the purpose of requiring pesticide registration under FIFRA, i.e., assuring that pesticides "will be properly labeled and that, if used in accordance with specifications, they will not cause unreasonable harm to the environment."<sup>51</sup> Because even registered pesticides are not without their risks,<sup>52</sup> it is unreasonable to allow *any* unregistered pesticide into the market; by definition, conditional registrations allow EPA to register pesticides without critical safety data.<sup>53</sup> In regard to risk, EPA assesses only the short-term risks of allowing a conditional registration.<sup>54</sup> This means EPA judges risks for the time period that it expects the applicant should need to complete its unmet data requirements. This time period can be up to fifty months for some tests.<sup>55</sup> EPA's limited focus on only the period for which it expects a pesticide will be conditionally registered is flawed for two reasons.

First, the effects of pesticides in the environment are not limited to the time during which they are actively applied. Instead, pesticides linger in the environment, seep into groundwater, and bioaccumulate in organisms throughout the food chain.<sup>56</sup> Second, by making a risk assessment in the absence of critical data, EPA cannot accurately evaluate risks. Conditional registrations effectively defeat the purpose for requiring data showing "no

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("[Northwest Coalition for Alternatives to Pesticides] surveyed 41 new conventional pesticides between 1997 and 2001; over half were conditionally registered.")

<sup>50</sup> 7 U.S.C. § 136a(c)(7)(C) (2012).

<sup>51</sup> U.S. Envtl. Prot. Agency, *supra* note 26.

<sup>52</sup> Extension Toxicology Network, *Movement of Pesticides in the Environment*, <http://pmep.cce.cornell.edu/profiles/extoxnet/TIB/movement.html> (last visited Nov. 22, 2014) (explaining that high human exposure to persisting pesticides can result in pesticides traveling through organisms up the food chain, a process known as "bioaccumulation").

<sup>53</sup> 7 U.S.C. § 136a(c)(7).

<sup>54</sup> *Id.*

<sup>55</sup> Pesticide Programs; Conditional Registration of New Pesticides, 51 Fed. Reg. 7628, 7630–32 (Mar. 5, 1986) (listing time periods ranging from 6 to 50 months).

<sup>56</sup> Extension Toxicology Network, *supra* note 52 (noting that some pesticides have a half-life of greater than 100 days, meaning it takes more than 100 days for half of a pesticide to break down to its chemical properties in the environment).

adverse environmental effects” *prior* to issuing a registration.<sup>57</sup> Of course, the extent to which this loophole undermines FIFRA safety requirements depends on EPA issuing conditional registrations. However, EPA relies primarily on conditional registrations rather than on general registrations, and most currently registered pesticides are conditionally registered.<sup>58</sup>

### *B. Problems with the “New Active Ingredients” Provision*

All three conditional registration exceptions pose inconsistencies with the safety requirements of FIFRA, in that each exception provides a means for a pesticide—whose environmental and human health effects are unknown—to obtain registration and thus find a way into the environment.<sup>59</sup> However, the first two exceptions—those for pesticides that are “identical or substantially similar” to registered pesticides or that are already registered pesticides with a proposed “additional use”—are less egregious violators of FIFRA’s purpose than is the third exception: pesticides with “an active ingredient not contained in any currently registered pesticide.”<sup>60</sup> The first two exceptions contemplate a situation involving a fully registered pesticide.<sup>61</sup> Under the first two exceptions, EPA can at least extrapolate safety data from the already registered pesticides to an identical or substantially similar pesticide, or to a new use of a fully registered pesticide.<sup>62</sup> Of course, even these two situations are not as comprehensive as full registration of the pesticide. While EPA relies on *some* existing data, the extent to which EPA can accurately predict whether a product is identical or substantially similar in terms of safety and environmental effects is unclear, as is the question of how a new use of an already registered pesticide will affect the environment.<sup>63</sup>

More concerning is the “New Active Ingredient” exception, which allows pesticides with new active ingredients not contained in other registered pesticides to obtain conditional registration even where the pesticide lacks sufficient data required in the registration process.<sup>64</sup> EPA issued a notice on March 5, 1986 explaining its policy behind the “New

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<sup>57</sup> See SASS & WU, *supra* note 8, at 2 (noting that EPA’s “stringent testing requirements” for pesticides are effectively waived during the conditional registration period, and explaining that EPA’s current system for tracking conditional registrations may allow conditional registrations to last “many years” without further investigation).

<sup>58</sup> *Id.* at 2 (stating that a study by Natural Resources Defense Council (NRDC) showed that as of August 2010, more than 11,000 pesticides, or about 65% of currently active pesticide products, had conditional registration status).

<sup>59</sup> 7 U.S.C. § 136a(c)(7)(A)–(C) (2012).

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

<sup>61</sup> *Id.* § 136a(c)(7)(A)–(B).

<sup>62</sup> *Id.* The registration process in 7 U.S.C. § 136a(c)(2)–(6) requires data showing no “unreasonable adverse effects” before the actual registration of the pesticide.

<sup>63</sup> SASS & WU, *supra* note 8, at 2.

<sup>64</sup> 7 U.S.C. §§ 136a(c)(4), (c)(7)(C).

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Active Ingredient” exception.<sup>65</sup> EPA explained that in addition to the “insufficient data” requirement common to all three conditional registration categories,<sup>66</sup> the applicant must also show that 1) the pesticide will not “cause unreasonable adverse effects” during the period of conditional registration and 2) the use of the pesticide is in the public interest.<sup>67</sup>

### 1. *Insufficient Data Requirement*

In 1985, EPA published Pesticide Registration (PR) Notice 85-5, prescribing timeframes “reasonably sufficient to generate required studies.”<sup>68</sup> The timeframes range from six to fifty months for different safety tests, and serve as the basis for whether the “insufficient data” requirement is met.<sup>69</sup> An applicant seeking conditional registration of a new active ingredient must show EPA that the applicant has had insufficient time to generate a particular study at the time of submitting an application.<sup>70</sup> The timeframes also serve as the basis for how long a conditional registration period will be granted: “Conditional registration will be granted to coincide with the timeframe for generation of the longest study conditionally required. If the results of the conditionally required study trigger a requirement for another . . . study, the conditional registration may be extended.”<sup>71</sup>

Despite this explicit agency-issued language describing EPA’s own process for determining how long a conditional registration will last, EPA rarely follows this timeline, and most often allows conditional registrations to remain long after the data submission deadline.<sup>72</sup>

### 2. *Risk Assessment for New Chemicals Requirement*

The second requirement is that the conditionally registered pesticides will not “cause unreasonable adverse effects” during the period of conditional registration.<sup>73</sup> EPA measures this requirement based on “the

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<sup>65</sup> Pesticide Programs; Conditional Registration of New Pesticides, 51 Fed. Reg. 7628, 7628–29 (Mar. 5, 1986).

<sup>66</sup> 7 U.S.C. § 136a(c)(7)(A)–(C).

<sup>67</sup> Pesticide Programs; Conditional Registration of New Pesticides, 51 Fed. Reg. at 7629.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.* at 7631–32.

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> One such example is the subject of current litigation surrounding the pesticide clothianidin (discussed in Part VII(b)). EPA originally issued a conditional registration for clothianidin in May 2003, imposing a condition of a pollinator field study to be completed within three years of conditional registration approval. As of 2013, the field study was not completed, yet EPA has not revoked clothianidin’s conditional registration status. U.S. ENVTL. PROT. AGENCY, PESTICIDE FACT SHEET 16 (2003) [hereinafter PESTICIDE FACT SHEET], *available at* [http://www.epa.gov/opp00001/chem\\_search/reg\\_actions/registration/fs\\_PC-044309\\_30-May-03.pdf](http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-044309_30-May-03.pdf); First Amended Complaint at 3–4, 29, *Ellis v. Bradbury*, No. 3:13-cv-012660-LB, 2013 WL 3063552 at ¶¶ 5, 91 (N.D. Cal. May 31, 2013).

<sup>73</sup> Pesticide Programs; Conditional Registration of New Pesticides, 51 Fed. Reg. at 7629.

limited time period [for which] required studies are being generated.”<sup>74</sup> The applicant must meet the rest of the data requirements at the time of the application and may only lack data for recently imposed requirements. Thus, EPA believed the scope of the risk assessment would be sufficiently limited for it to accurately assess risks.<sup>75</sup> However, this has not been EPA’s practice, as illustrated by recent litigation discussed in Part VIII.<sup>76</sup>

### 3. Public Interest Requirement

The last requirement—that EPA must determine the conditional registration is in the public interest—can be satisfied in two ways.<sup>77</sup> First, in some circumstances EPA presumes a finding of public interest.<sup>78</sup> This presumption raises questions about whether the public interest finding has any weight. For example, EPA presumes a conditional registration is in the public interest where the registration “involves a use against a pest of public health significance.”<sup>79</sup> However, EPA does not define what constitutes a “pest of public health significance” and does not discuss under what circumstances such public interest presumption is appropriate. The broad categories for which EPA presumes a registration to be in the public interest, without requiring the applicant to prove this presumption, raises questions about whether EPA has really adhered to its statutory authority, which requires the Administrator to determine if the use of the pesticide is in the public interest.<sup>80</sup>

In other circumstances, EPA considers factors related to the comparative benefits, risks, and costs of registering a pesticide.<sup>81</sup> EPA stated that although it prescribed specific factors for considering whether the public interest prong is met, these factors are not binding requirements, but rather provide guidance to applicants as factors EPA may consider.<sup>82</sup>

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<sup>74</sup> *Id.* at 7632.

<sup>75</sup> *Id.*

<sup>76</sup> *See infra* Part VII.

<sup>77</sup> EPA will either presume a public interest finding, or find that “1) there is a need for the new pesticide that is not being met by currently registered pesticides; 2) the new pesticide is less risky than currently registered pesticides; [or] 3) the benefits from the new pesticide are greater than those from currently registered pesticides or non-chemical control measures.” Memorandum from Nicole Zinn, Biologist, EPA, to Jim Stone, Prod. Manager, EPA, Evaluation of Public Interest Documentation for the Conditional Registration of Topramezone on Field Corn, Sweet Corn, and Pop Corn 1–2 (May 13, 2005), *available at* [http://www.epa.gov/pesticides/chem\\_search/cleared\\_reviews/csr\\_PC-123009\\_13-May-05\\_a.pdf](http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-123009_13-May-05_a.pdf).

<sup>78</sup> EPA presumes the conditional registration of a pesticide to be in the public interest when: “1) it involves a replacement for another pesticide that is of continuing concern to the Agency; 2) it involves a use for which a Section 18 emergency exemption has been granted, if the basis for the exemption was the lack of a suitable alternative; and 3) involves a use against a pest of public health significance.” *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136a(c)(7)(C) (2012).

<sup>81</sup> Pesticide Programs; Conditional Registration of New Pesticides, 51 Fed. Reg. 7632, 7632–33 (Mar. 5, 1986).

<sup>82</sup> *Id.*

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If an applicant meets these three conditions and EPA grants it a conditional registration, EPA will prescribe specific conditions—e.g., developing the missing data—with which the applicant must comply.<sup>83</sup> An important aspect of the conditional registration process is that if a conditional registration is granted, it is to expire upon the date set by EPA, which corresponds to the length of the longest study required for registration.<sup>84</sup> If the missing data is received by the expiration date, EPA is supposed to extend the conditional registration on a day-by-day basis until it has reviewed the data and determined whether the applicant fulfills the conditions of the registration.<sup>85</sup>

*C. Problems with Conditional Registrations “In Effect”*

Even assuming that conditional registrations sufficiently take risks into account and do not go against the purpose of FIFRA, EPA’s implementation practices illustrate that the exception is unworkable.

In 2010, EPA’s Office of Pesticide Programs (OPP) commenced an internal review of EPA’s use of conditional registrations.<sup>86</sup> For the general Registration Review process, EPA uses a “data call-in”<sup>87</sup> system called the Pesticide Registration Information System (PRISM), which ensures data is collected within a specific timeframe.<sup>88</sup> To track the data submitted during the conditional registration period for the New Active Ingredient exception, EPA uses a much less precise data-tracking program called the Office of Pesticide Programs Information Network (OPPIN).<sup>89</sup> In EPA’s own words, the OPPIN system is “older . . . and . . . not as robust in its features [as the PRISM Registration Review system].”<sup>90</sup> Unlike PRISM, the OPPIN system lacks the ability to automatically track data collection. Instead, when data is submitted, it goes through a lengthy multi-step process of review before reaching reviewers.<sup>91</sup>

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<sup>83</sup> *Id.* at 7634.

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

<sup>85</sup> *Id.*

<sup>86</sup> U.S. Env’tl. Prot. Agency, *Conditional Registration*, <http://organicconnectmag.com/wp-content/uploads/2013/04/conditional-registration.html> (last visited Nov. 22, 2014).

<sup>87</sup> A “data call-in” is “an order issued to a pesticide [applicant or applicants] which requires the submission of scientific data within a specified time frame.” *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> When EPA receives data submissions, the “consumption module” first checks the data for viruses, then transfers the documents to EPA’s tracking system, OPPIN. Next, regulatory division experts are notified of the submission, assign the submission to a PRIA fee category and create a tracking number for the application. If correct payment has been received, the applicant is notified by e-mail. Individuals conducting the 21-day content screen are then notified by e-mail that a document is ready for their review in the document repository. Once this process is complete, the appropriate regulatory manager is informed that documents are ready for the next level of review, an in-depth review which leads to a regulatory decision. PESTICIDE PROGRAM DIALOGUE COMM., U.S. ENVTL. PROT. AGENCY, PESTICIDE PROGRAM DIALOGUE

Prior to EPA's OPPIN study, the Natural Resources Defense Council (NRDC) criticized EPA's overreliance on conditional registration in a comment opposing the conditional registration of nanosilver.<sup>92</sup> NRDC found that over two-thirds of EPA's pesticide registrations were conditional registrations.<sup>93</sup> EPA attempted to dispel this statistic with the results of its conditional registration OPPIN review, in which it determined that EPA was mistakenly using the term "conditional registration" to refer to other agency actions,<sup>94</sup> and that in fact, only 2% of those actions termed as "conditional registration" referred to *actual* conditional registrations.<sup>95</sup> EPA stated, "[t]here are 25,421 registration decisions classified as conditional for the 11,205 Section (c)(7)(B) and (C) conditionally registered products: 1,408 are related to new active ingredients and new uses, and 24,013 are related to other actions (product formulation data, label amendments, 'me-too' registrations, etc.)."<sup>96</sup>

While EPA's OPPIN study may have refuted NRDC's concern that most registered pesticides are conditionally registered,<sup>97</sup> it also raises new questions regarding tracking and classification. For example, if only 2% of the actions EPA previously classified as "conditionally registered" are *actual* "conditional registrations," EPA would need to reclassify 98% of its "registration decisions."<sup>98</sup> More recently, EPA initiated a more in-depth internal analysis and noted that "of the products for which the conditional registrations were examined, no conditional registration caused unreasonable adverse effects on the environment."<sup>99</sup> EPA stated that "[e]ven though the detailed review found that EPA had at times misclassified the

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COMMITTEE PRIA PROCESS IMPROVEMENT WORKGROUP MINUTES OF THE SEPTEMBER 23, 2008, MEETING 3 (2008), *available at* <http://www.epa.gov/pesticides/ppdc/pria/sept08/minutes.pdf>.

<sup>92</sup> SASS & WU, *supra* note 8, at 2 (citing NRDC, COMMENTS FROM THE NATURAL RESOURCES DEFENSE COUNCIL ON THE PROPOSED CONDITIONAL REGISTRATION OF A PESTICIDE PRODUCT HEIQ AGS-20, CONTAINING NANOSILVER 10 (2010), *available at* <http://switchboard.nrdc.org/blogs/mwu/NRDC%20nanosilver%20CR%20Docket%20ID%20EPA-HQ-OPP-2009-1012.pdf>).

<sup>93</sup> *Id.* (discussing NRDC study that showed that as of August 2010, more than 11,000 pesticides, or about 65% of currently active pesticide products, had conditional registration status); NRDC, COMMENTS FROM THE NATURAL RESOURCES DEFENSE COUNCIL ON THE PROPOSED CONDITIONAL REGISTRATION OF A PESTICIDE PRODUCT HEIQ AGS-20, CONTAINING NANOSILVER 10 (2010), *available at* <http://switchboard.nrdc.org/blogs/mwu/NRDC%20nanosilver%20CR%20Docket%20ID%20EPA-HQ-OPP-2009-1012.pdf>.

<sup>94</sup> U.S. Env'tl. Prot. Agency, *Conditional Registration*, <http://www.epa.gov/pesticides/regulating/conditional-registration.html#conditional> (last visited Nov. 22, 2014) (summarizing the EPA's internal review of conditional pesticide registration decisions).

<sup>95</sup> SASS & WU, *supra* note 8, at 2.

<sup>96</sup> Bergeson & Campbell, P.C., *EPA Releases New Website on FIFRA Conditional Registrations*, <http://www.lawbc.com/regulatory-developments/entry/epa-releases-new-website-on-fifra-conditional-registrations/> (last visited Nov. 22, 2014).

<sup>97</sup> EPA stated that the study results "indicate[] that, as statutorily intended, the authority for conditional registrations for registering new uses or new ingredients has been used in narrow circumstances." *Id.*

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

<sup>99</sup> U.S. Env'tl. Prot. Agency, *Conditional Pesticide Registration*, <http://www2.epa.gov/pesticide-registration/conditional-pesticide-registration> (last visited Nov. 22, 2014).

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status of conditionally and unconditionally registered pesticides in its record-keeping, the registration decisions met the statutory standards.”<sup>100</sup>

EPA’s inaccurate recording of conditional registrations is at best sloppy and at worst, severely misleading to the public and pesticide applicants. It is unclear whether EPA’s misrecording of conditional registrations was solely an internal misclassification or whether EPA wrongly represented to pesticide applicants that their registration status was a conditional registration, when in fact it was not. As a result of its OPPIN review study, EPA admits its data tracking for conditional registrations is “out of date and inaccurate.”<sup>101</sup> Although EPA describes the steps it is taking to ensure OPPIN data is not misleading,<sup>102</sup> it appears EPA has no immediate concrete plans for implementing a better, more accurate, data-tracking system for its conditional registrations.<sup>103</sup>

*D. Problems with the National Environmental Policy Act of 1969*

The National Environmental Policy Act of 1969 (NEPA)<sup>104</sup> ensures that federal agencies engage in informed decision making and requires agencies to consider ex ante the effects of any major federal action that may significantly affect the environment.<sup>105</sup> The NEPA process can be extremely time-consuming, sometimes delaying an agency action for years.<sup>106</sup> Actions under FIFRA have traditionally been exempt from NEPA.<sup>107</sup> Some courts have held that processes and safeguards in FIFRA make FIFRA the “functional equivalent” of NEPA.<sup>108</sup> Under the functional equivalence doctrine, statutes that implement environmental assessments “functionally equivalent” to NEPA are exempt from NEPA, as NEPA processes would be redundant to those already required.<sup>109</sup> Other courts, such as the Ninth

<sup>100</sup> *Id.*

<sup>101</sup> Bergeson & Campbell, P.C., *supra* note 96.

<sup>102</sup> *Id.*

<sup>103</sup> EPA generally states that one of its planned steps is “[e]nsuring future system developments include the ability to adequately track conditional registrations.” *Id.*

<sup>104</sup> 42 U.S.C. §§ 4321–4347 (2012).

<sup>105</sup> *Id.* § 4332(C); Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA, 40 C.F.R. 1500.1(c) (2014) (explaining that NEPA procedures are “intended to help public officials make decisions that are based on [an] understanding of environmental consequences”).

<sup>106</sup> The Department of Transportation estimates that for highway projects requiring NEPA review, the “NEPA process alone tak[es] an average of four years.” FED. HIGHWAY ADMIN., EVERY DAY COUNTS: BUILDING A CULTURE OF INNOVATION FOR THE 21ST CENTURY 44 (2013), available at [https://www.fhwa.dot.gov/everydaycounts/pdfs/edc2\\_2013.pdf](https://www.fhwa.dot.gov/everydaycounts/pdfs/edc2_2013.pdf).

<sup>107</sup> *See, e.g.,* *Env'tl. Def. Fund, Inc. v. EPA (EDF)*, 489 F.2d 1247, 1256 (D.C. Cir. 1973) (holding that EPA’s compliance with FIFRA was the functional equivalent of NEPA compliance).

<sup>108</sup> SHEILA R. FOSTER, *THE LAW OF ENVIRONMENTAL JUSTICE* 299 (Michael B. Gerrard & Sheila R. Foster eds., 2d ed. 2009) (explaining that EPA is exempt from going through NEPA processes where other regulations or statutes provide for the same degree of environmental assessment and public participation procedures as NEPA); *EDF*, 489 F.2d at 1256.

<sup>109</sup> *E.g., EDF*, 489 F.2d at 1257 (“[W]here an agency is engaged primarily in an examination of environmental questions, where substantive and procedural standards ensure full and

Circuit, have not firmly adopted the “functional equivalence” doctrine, but nevertheless have opined that Congress did not intend NEPA to apply to FIFRA pesticide registrations.<sup>110</sup>

Even assuming full registrations are the functional equivalent of NEPA because of the extensive environmental safety data requirements, conditional registrations fall short of such equivalency. Specifically, FIFRA’s procedural standards for conditional registration do not “help public officials make decisions that are based on [an] understanding of environmental consequences.”<sup>111</sup> Conditional registrations do the opposite—that is, they exempt the environmental and human health safety data requirements as a prerequisite to gaining registered status.<sup>112</sup> Although EPA sometimes solicits public comment before making a final determination on whether to grant conditional registration status,<sup>113</sup> FIFRA does not require this practice.<sup>114</sup> Thus, while situations involving full registrations may serve as the functional equivalent of NEPA, conditional registrations do not.

#### V. LEGAL EFFECTS OF EPA’S IMPLEMENTATION PRACTICES

EPA has virtually never pursued an enforcement action in court against a conditional registration applicant who is in violation of their application. Parties adversely affected by the conditional registration of pesticides have thus turned to litigation for relief. Parties must show standing to challenge EPA decisions. Even then, they face the burden of having to show the agency’s decision was arbitrary and capricious. This highly deferential standard is difficult for challengers to overcome.

##### *A. Applicants and Users*

FIFRA provides civil and criminal penalties for both pesticide applicants (i.e. manufacturers) and users.<sup>115</sup> However, although EPA has the authority to engage in enforcement actions against applicants and users, EPA rarely uses such measures against individuals of either group. Between 1999 and 2011, EPA brought 203 civil cases and administrative enforcement actions and 7 criminal cases against pesticide manufacturers, sellers, and

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adequate consideration of environmental issues, then formal compliance with NEPA is not necessary, but functional compliance is sufficient.”).

<sup>110</sup> See *Merrell v. Thomas*, 807 F.2d 776, 781 (9th Cir. 1986) (holding that based on FIFRA’s registration procedure, standard, and applicable review processes, Congress did not intend NEPA to apply to EPA’s actions under FIFRA).

<sup>111</sup> Council on Environmental Quality Regulations for Implementing the Procedural Provisions of NEPA, 40 C.F.R. § 1500.1(c) (2014).

<sup>112</sup> See *SASS & WU*, *supra* note 8, at 2.

<sup>113</sup> *E.g.*, Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities, 77 Fed. Reg. 43,562, 43,564 (July 25, 2012) (codified at 40 C.F.R. § 180.668 (2014)).

<sup>114</sup> See Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136a(c)(7) (2012).

<sup>115</sup> *Id.* § 136l.



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users.<sup>116</sup> These cases involved violations of labeling requirements, unauthorized use of restricted pesticides, failure to comply with registration requirements, among other FIFRA violations.<sup>117</sup> None of the cases involved conditional registrations.<sup>118</sup>

That EPA has virtually never pursued an enforcement action in court against a pesticide applicant with a conditional registration raises a serious question as to whether conditional registration allows an applicant to get around the threat of enforcement, in addition to getting around the safety requirements of the pesticide registration process. Of course, the fact that EPA has never used an enforcement measure against a conditional registration applicant could also be due to the fact that EPA can revoke a pesticide's conditional registration status by determining the pesticide is not complying with the timeline for seeking new data or other limitations of the conditional registration.<sup>119</sup> Since EPA has never sought criminal or civil enforcement against users of conditionally registered pesticides, and rarely uses administrative remedies, it remains an open question as to whether their legal responsibilities and liabilities differ from those who are using pesticides with full registration. It likely does not matter whether a pesticide has a full or conditional registration for enforcement purposes, since EPA rarely uses enforcement actions at all.

### *B. Relief for Adversely Affected Parties Through Litigation*

Rather than relying on EPA's inconsistent enforcement policies, individuals who are adversely affected by pesticides with conditional registration status may be more successful in seeking relief through litigation. Several federal statutes provide adversely affected individuals the right to sue EPA for violations of the conditional registration provisions of FIFRA.

For example, the Administrative Procedure Act (APA)<sup>120</sup> provides judicial review for any individual who is "adversely affected or aggrieved by an agency action within the meaning of a relevant statute."<sup>121</sup> Although FIFRA lacks a citizen suit provision,<sup>122</sup> section 16(b) does authorize federal courts of appeals to review final agency actions and omissions when an action is not discretionary, after the adversely affected party has received a

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<sup>116</sup> U.S. Env'tl. Prot. Agency, *FIFRA: Agriculture-Related Enforcement Cases*, <http://www.epa.gov/agriculture/lfraenf.html> (last visited Nov. 22, 2014).

<sup>117</sup> *Id.*

<sup>118</sup> *See id.*

<sup>119</sup> 7 U.S.C. § 136d(e)(1) ("The Administrator shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title [i.e., a conditional registration] if (A) the Administrator, at any time during the [conditional registration period] . . . determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met.").

<sup>120</sup> 5 U.S.C. §§ 551–559, 701–706, 1305, 3105, 3344, 4301, 5335, 5372, 7521 (2012).

<sup>121</sup> *Id.* § 702.

<sup>122</sup> SCHIEROW, *supra* note 39, at 10.

“public hearing.”<sup>123</sup> A public hearing within the meaning of section 16(b) may consist of EPA’s public notice and comment period, in which EPA solicits public comments before making its final decision.<sup>124</sup>

Additionally, if a conditional registration of a pesticide results in violations of the Endangered Species Act of 1973 (ESA),<sup>125</sup> adversely affected parties may seek relief under the ESA.<sup>126</sup> FIFRA’s authorization of the federal court of appeals to review final agency action will likely prove to be a valuable tool for adversely affected parties in attaining relief, since standing requirements are not difficult to meet.<sup>127</sup> Indeed, public interest organizations with representational standing have already used litigation to highlight the inadequacies of EPA’s conditional registration practices.<sup>128</sup>

However, even those who can meet the burden of standing and show they are adversely affected by EPA’s conditional registration of a certain pesticide face a difficult hurdle in having to show that EPA’s action was arbitrary and capricious.<sup>129</sup> Courts use the highly deferential *Chevron* doctrine in evaluating EPA’s actions under FIFRA.<sup>130</sup> Unless an individual can show that EPA granted conditional registration status without “substantial evidence,” courts will defer to the agency’s decision.<sup>131</sup> The substantial evidence standard is difficult to overcome because it does not require the agency to have made the decision the court would have made, or even to have made the decision the agency itself would make in light of evidence that comes to light after the relevant time period.<sup>132</sup> Rather, substantial evidence is “such relevant evidence as a reasonable mind might

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<sup>123</sup> 7 U.S.C. § 136n(b) (stating that the court of appeals has exclusive jurisdiction to affirm or set aside the agency order); see SCHIEROW, *supra* note 39, at 10.

<sup>124</sup> 7 U.S.C. § 136n(b); *United Farm Workers v. EPA*, 592 F.3d 1080 (9th Cir. 2010) (holding that EPA makes a decision following a “public hearing” within the meaning of FIFRA § 16(b) when it provides notice in the Federal Register and an opportunity for public comment).

<sup>125</sup> 16 U.S.C. §§ 1531–1544 (2012).

<sup>126</sup> For example, the ESA contains a citizen suit provision providing that “any person” may sue 1) “any person . . . who is alleged to be in violation” of the ESA, 2) to compel the Secretary of the Interior to apply the ESA, and 3) the Secretary of the Interior for alleged failure to perform required duties under the ESA. 16 U.S.C. § 1540(g)(1)(A)–(C).

<sup>127</sup> See Christopher Warshaw & Gregory E. Wannier, *Business as Usual? Analyzing the Development of Environmental Standing Doctrine Since 1976*, 5 HARV. L. & POL’Y REV. 289, 296–98, 321 (2011) (noting the broad scope of environmental standing and how its relaxed standards should leave environmental groups confident in their ability to obtain standing).

<sup>128</sup> See, e.g., *Natural Res. Def. Council v. EPA*, 735 F.3d 873, 875–78 (9th Cir. 2013). In this case, an environmental advocacy group claimed that EPA’s decision to conditionally register a product resulted in threatened pesticide exposure to the group members’ children, thereby establishing representational standing.

<sup>129</sup> See *Woodstream Corp. v. Jackson*, 845 F. Supp. 2d 174, 182 (D.C. Cir. 2012) (applying the EPA’s arbitrary and capricious standard to conditional registrations).

<sup>130</sup> *Chevron v. Nat’l Res. Def. Council*, 467 U.S. 837, 842–43 (1984) (holding that courts should defer to agency interpretation if the statute the agency administers is “ambiguous with respect to the specific issue” and the agency’s interpretation is “based on a permissible construction of the statute”); e.g., *Woodstream*, 845 F. Supp. 2d at 180 (applying *Chevron* analysis to EPA’s interpretation of FIFRA).

<sup>131</sup> Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136n(b) (2012).

<sup>132</sup> See *Env’tl. Def. Fund, Inc. v. EPA*, 489 F.2d 1247, 1252 (D.C. Cir. 1973).

accept as adequate to support a conclusion.”<sup>133</sup> For statutes like FIFRA that involve a substantial evidence standard of review, the implementing agency—here, EPA—must provide “a reasoned explanation for [its] policy assumptions and conclusions, identify relevant factual evidence, state any assumptions relied on, and present reasons for rejecting significant contrary evidence and argument.”<sup>134</sup> While difficult, it is not impossible to show that EPA acted without any rational basis at the time it made its conditional registration. Especially in light of EPA’s current practice of highly deficient conditional registration decisions, individuals seeking relief may see some success, as highlighted in Part VII.

## VI. SUGGESTIONS AND PREDICTIONS

The conditional registration process would be greatly improved by a better data-tracking system and increased agency enforcement of data submission requirements. Alternatively, if EPA were to get rid of the conditional registration process altogether, it could focus its efforts on making the full registration process more efficient and streamlined, lessening the need for conditional registration status altogether.

### *A. Better Data Tracking and Data Deadline Enforcement*

As previously discussed, one of the biggest problems with conditional registration is the inadequate data-tracking system.<sup>135</sup> EPA has acknowledged that its current data-tracking system, OPPIN, is out of date and provides inaccurate information.<sup>136</sup> After reviewing the results of its OPPIN program evaluation study, EPA stated it would take steps to improve data tracking, including training agency staff and modifying the OPPIN system.<sup>137</sup> A more efficient data-tracking system has the potential to greatly increase the accuracy of tracking conditionally registered pesticides’ outstanding data requirements. The enforcement of data deadlines, however, depends only in part on the accuracy of the data-tracking system. More importantly, data deadline enforcement depends on agency action. EPA did not include any discussion of more aggressive data deadline enforcement in reporting the results of its program evaluation.<sup>138</sup> As recent conditional registration litigation makes clear, even when EPA has been aware of conditional

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<sup>133</sup> *Universal Camera Corp. v. Nat’l Labor Relations Bd.*, 340 U.S. 474, 477 (1951) (citation omitted).

<sup>134</sup> Brief for Petitioner at 15–16, *Natural Res. Def. Council v. EPA*, 735 F.3d 873 (9th. Cir. Apr. 16, 2013) (No. 12-70268), 2012 WL 1423879, at \*15–16 (noting that certain questions are “more naturally and appropriately tested in terms of reasonableness than in terms of evidentiary weight” (citing *Am. Iron & Steel Inst. v. U.S. Occupational Safety & Health Admin.*, 939 F.2d 975, 982 (D.C. Cir. 1991) and *IBP, Inc. v. Herman*, 144 F.3d 861, 866 (D.C. Cir. 1998))).

<sup>135</sup> See *supra* Part IV.C.

<sup>136</sup> Bergeson & Campbell, P.C., *supra* note 96.

<sup>137</sup> U.S. Envtl. Prot. Agency, *supra* note 94.

<sup>138</sup> See *id.*

applicants missing data deadlines, it has failed to revoke a conditional registration status.<sup>139</sup> Therefore, while better data-tracking systems present an opportunity for EPA to increase its accuracy and better maintain conditional registrations, ultimately EPA must be more proactive in enforcing conditional registrations to realize any improvement in the conditional registration program.

### *B. Abandon Conditional Registrations Altogether*

EPA's implementation of the conditional registration program has undoubtedly strayed from the one envisioned by Congress: as a provision for use in rare situations where pesticides "basically deemed safe" may go to market without causing adverse effects.<sup>140</sup> Whether due to inefficient data-tracking methods, ever-increasing federal agency budget cuts, or other reasons, EPA clearly has been unable to use the conditional registration program for its intended purpose.<sup>141</sup> Rather than focusing on why conditional registration has failed to live up to its statutory purpose, it may be more constructive to concentrate on a solution: getting rid of the conditional registration provisions altogether, and improving the full registration process. Since the reason Congress contemplated adding a conditional registration provision was to "streamline" the pesticide registration process,<sup>142</sup> improving the program by increasing the efficiency of the full registration process, rather than registering pesticides through the guise of conditional registration exceptions, may ultimately be a more workable and preferred solution for all stakeholders. Of course, this is far from a realistic or timely solution, given that it would require Congress to amend FIFRA and would likely be opposed by pesticide producers who currently have easy market access through conditional registrations. Given the unlikelihood of either increased EPA enforcement of data deadlines or Congressional amendments to get rid of conditional registrations, the most effective solution to achieving more immediate change is litigation.

## VII. CURRENT CASE LAW DEVELOPMENT

Two recent public interest-led cases illustrate the cumbersome process of challenging EPA's conditional registrations. In both *NRDC v. EPA* and *Ellis v. Bradbury*, public interest group plaintiffs challenged EPA decisions to approve conditional registration status for specific pesticides. The Ninth Circuit ruled in favor of NRDC, affirming that at a minimum EPA must follow its own rules in deciding whether to grant conditional registration to

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<sup>139</sup> First Amended Complaint at 30–32, *Ellis v. Bradbury*, No. 3:13-cv-01266-LB (N.D. Cal. May 31, 2013), 2013 WL 3063552 at \*17–18.

<sup>140</sup> See *supra* note 26.

<sup>141</sup> See *supra* Part IV.

<sup>142</sup> 124 CONG. REC. S29,758–61 (daily ed. Sept. 18, 1978).

a pesticide. The *Ellis* decision remains in litigation, and its outcome will be telling as to the court's tendency for agency deference.

*A. NRDC v. EPA: Conditional Registration of Nanosilver*

On December 1, 2011, EPA approved the conditional registration of the pesticide HeiQ AGS-20 (AGS-20) as a “preservative for textiles,”<sup>143</sup> finding that it met all necessary prerequisites for issuing a conditional registration under the “new active ingredient” provision.<sup>144</sup> EPA determined AGS-20 met the new active ingredient provision because it met all three requirements—insufficient data for granting a full registration,<sup>145</sup> no unreasonable adverse effects on the environment during the conditional registration period, and the issuance of a conditional registration would be in the public interest.<sup>146</sup>

EPA found there would be “no unreasonable adverse effects” from the conditional registration of AGS-20, relying on “limited data submitted by HeiQ and data in the public literature on nanosilver, and use of uncertainty factors and conservative assumptions.”<sup>147</sup> In regard to human health risks from exposure to AGS-20, EPA relied on results from scientific literature involving the washing of AGS-20 treated textiles, and noted there were no existing studies for determining subchronic or chronic oral or dermal toxicity.<sup>148</sup> Thus, EPA estimated risks in that area based on “analogous nanosilvers reported in the literature.”<sup>149</sup> EPA concluded that acute toxicity levels with regard to AGS-20 were low.<sup>150</sup>

EPA found the approval of AGS-20 to be in the public interest because it “may lead to less environmental loading of silver as compared to currently registered products containing silver salts with the same use patterns.”<sup>151</sup> Because no studies existed on long-term health and environmental effects at the time of the conditional registration,<sup>152</sup> EPA required the applicant to

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<sup>143</sup> AGS-20 is a nanosilver powder product proposed for use in textiles “to suppress the growth of bacteria, which cause textile odors, stains, and degradation.” U.S. ENVTL. PROT. AGENCY, DECISION DOCUMENT: CONDITIONAL REGISTRATION OF HEIQ AGS-20 AS A MATERIALS PRESERVATIVE IN TEXTILES iv (2011) [hereinafter DECISION DOCUMENT], *available at* <http://www.regulations.gov/contentStreamer?objectId=0900006480f787d3&disposition=attachment&contentType=pdf>.

<sup>144</sup> *Id.* at 41–42; Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136a(c)(7)(C) (2012).

<sup>145</sup> “[U]ntil today, EPA had not reached a final decision with regard to which types of data would be further required.” DECISION DOCUMENT, *supra* note 143, at 42. Therefore, insufficient time had lapsed for the applicant to conduct the study.

<sup>146</sup> *Id.* at 42–46.

<sup>147</sup> *Id.* at 44–45.

<sup>148</sup> *Id.* at 45.

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Id.* at 2.

<sup>152</sup> *Id.* at iv. (“There are no intermediate- or long-term human or environmental toxicity studies available for AGS-20 or for the nanosilver that might break away from AGS-20. However, there are intermediate-term toxicity studies available in the scientific literature for analogous forms of nanosilver.”).

conduct additional testing on the “long-term or chronic ecotoxicity effects of AGS-20.”<sup>153</sup>

NRDC sued EPA for its conditional registration of AGS-20 on January 26, 2012.<sup>154</sup> NRDC alleged that EPA’s conditional registration decision was not supported by substantial evidence.<sup>155</sup> Specifically, NRDC alleged EPA’s determination of no “unreasonable adverse effect” on human health was not supported by substantial evidence,<sup>156</sup> because EPA failed to evaluate risks to infants, and to consider the risk of aggregate exposures from other nanosilver products already on the market.<sup>157</sup>

In regard to EPA’s alleged failure to evaluate AGS-20’s risks to infants, EPA acknowledged that children were “the likely most vulnerable subpopulation, from chewing on and wearing textiles treated with AGS-20.”<sup>158</sup> NRDC noted that despite this recognition, EPA erroneously calculated infants’ exposure risk assessment or the “margin of exposure” (MOE) by using the body weight of a three-year-old toddler instead of that of an infant.<sup>159</sup> NRDC explained that if EPA had instead properly used the weight of an infant in determining MOE for infants, it would have arrived at an unacceptable MOE level for infants, meaning EPA would have found AGS-20 to be presumptively unsafe.<sup>160</sup> Furthermore, NRDC argued, EPA’s decision to use a toddler’s body weight rather than an infant’s was “an unexplained and arbitrary assumption” *not* supported by substantial evidence.<sup>161</sup>

In regard to EPA’s failure to address aggregate exposures, NRDC alleged that EPA failed to consider the effect of AGS-20 in aggregation with the presence of nanosilver products already on the market.<sup>162</sup> NRDC noted that EPA acknowledged the reasonableness of aggregating exposures in conducting risk assessment, but did not do so because it lacked adequate information.<sup>163</sup>

Several other public interest groups together filed an amicus brief, authored by Center for Food Safety (CFS), in support of NRDC.<sup>164</sup> The amici pointed out two categories of risks that pervade nanotechnology: “increased potential toxicity and unprecedented mobility for a manufactured material.”<sup>165</sup> CFS also discussed that EPA’s conditional registration of AGS-20

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<sup>153</sup> *Id.* at 36.

<sup>154</sup> Pet’rs’ Pet. for Review, *Natural Res. Def. Council v. EPA*, 735 F.3d 873 (9th Cir. 2013) (No. 12-70268).

<sup>155</sup> Brief for Petitioner, *supra* note 134, at \*14–15.

<sup>156</sup> *Id.* at 7; Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136(bb) (2012).

<sup>157</sup> Brief for Petitioner, *supra* note 134, at \*7–8.

<sup>158</sup> DECISION DOCUMENT, *supra* note 143, at 25.

<sup>159</sup> Brief for Petitioner, *supra* note 134, at 16, 19–20.

<sup>160</sup> *Id.* at 19.

<sup>161</sup> *Id.* at 26.

<sup>162</sup> *Id.* at 33–34.

<sup>163</sup> *Id.* at 33. EPA conceded this point in oral argument. Oral Argument at 26:54–27:30, *Natural Res. Def. Council v. EPA*, 735 F.3d 873 (9th Cir. 2013) (No. 12-70268), *available at* [http://www.ca9.uscourts.gov/media/view.php?pk\\_id=0000010249](http://www.ca9.uscourts.gov/media/view.php?pk_id=0000010249).

<sup>164</sup> *See* Brief for Int’l Ctr. for Tech. Assessment et al. as Amici Curiae Supporting Petitioners, *Natural Res. Def. Council v. EPA*, 735 F.3d 873 (9th Cir. 2013) (No. 12-70268), 2012 WL 1548673.

<sup>165</sup> *Id.* at 13.

was different from most other conditional registrations because, as a nanomaterial, AGS-20 is part of a “new class of materials” that are in the beginning stages of scientific understanding.<sup>166</sup>

The Ninth Circuit heard oral arguments on January 16, 2013, and released its opinion on November 7, 2013, granting in part and denying in part NRDC’s petition for review.<sup>167</sup> The court ruled in favor of NRDC, finding that EPA’s decision to grant conditional registration to AGS-20 violated the agency’s own procedures.<sup>168</sup>

The court relied particularly on NRDC’s argument that EPA failed to follow its own risk assessment rules in regard to a margin of exposure in the short or intermediate term.<sup>169</sup> The Court noted that “EPA’s risk assessment sets out a rule whereby there is a risk concern requiring mitigation if the ‘margin of exposure’ to AGS-20 in the short or intermediate term is less than or equal to 1,000.”<sup>170</sup> Since one of the scenarios EPA analyzed had a MOE of 1,000, that scenario presented a “risk concern” which, under EPA’s own rules, required mitigation.<sup>171</sup> Although NRDC lost on its risk to infants claim and its aggregate exposure claims,<sup>172</sup> this decision is nonetheless important for NRDC because the Ninth Circuit vacated EPA’s approval of the conditional registration status of AGS-20 and sent it back to EPA for reevaluation.<sup>173</sup> The Ninth Circuit’s decision reaffirms that EPA must at a minimum follow its own rules in deciding whether to grant a pesticide conditional registration status.<sup>174</sup>

#### *B. CFS Petition and Complaint to EPA: Conditional Registration of Clothianidin*

In May 2003, EPA approved the conditional registration of clothianidin,<sup>175</sup> a neonicotinoid pesticide primarily used for the treatment of

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<sup>166</sup> *Id.* at 31.

<sup>167</sup> Oral Argument, *supra* note 163; *Natural Res. Def. Council v. EPA*, 735 F.3d 873, 886–87 (9th Cir. 2013).

<sup>168</sup> *Natural Res. Def. Council v. EPA*, 735 F.3d at 881 (“We vacate this portion of EPA’s decision and remand to the agency because it did not satisfy its own rule for determining when there is a risk concern requiring mitigation.”).

<sup>169</sup> *Id.* at 876.

<sup>170</sup> *Id.*

<sup>171</sup> *See id.* at 881.

<sup>172</sup> *Id.* at 879–80 (holding that EPA’s decision to use the characteristics of three-year-olds rather than infants in its risk assessment was supported by substantial evidence); *id.* at 885 (“EPA’s decision not to conduct an aggregate risk assessment in this instance is consistent with its regulations.”).

<sup>173</sup> *See supra* Part IV; Press Release, *Natural Res. Def. Council, Court Ruling in NRDC’s Favor Should Limit Pesticide Nanosilver in Textiles* (Nov. 7, 2013), *available at* <http://www.nrdc.org/media/2013/131107.asp>.

<sup>174</sup> *Natural Res. Def. Council v. EPA*, 735 F.3d at 884 (“EPA may wish to revisit its standards in the future, but it cannot ignore them.”).

<sup>175</sup> PESTICIDE FACT SHEET, *supra* note 72, at 1.

corn and canola seeds.<sup>176</sup> As a prerequisite to clothianidin's conditional registration and EPA's finding of no unreasonable adverse effects, EPA required Bayer, the applicant, to conduct a chronic lifecycle study, evaluating the long-term effects of clothianidin to honeybees.<sup>177</sup> At that time, EPA stated the study must be completed by December 2004, yet allowed clothianidin on the market in 2003. In March 2004, EPA extended Bayer's deadline to May 2005.<sup>178</sup> In 2007, EPA reviewed Bayer's field study and determined it to be "acceptable," but in 2010, downgraded the status of the field study from "acceptable" to "supplemental."<sup>179</sup> EPA then required Bayer to conduct a new pollinator study.<sup>180</sup> Although Bayer has not yet completed the necessary field study, clothianidin continues to receive conditional registration status.<sup>181</sup>

As a result of this continued conditional registration status, in March 2012, CFS, representing about twenty-seven commercial beekeepers and honey producers, filed an emergency citizen petition to EPA to suspend the conditional registration of clothianidin.<sup>182</sup> Clothianidin acts as a systemic insecticide, which allows it to move easily within a plant and make the plant poisonous to insects, including bees that pollinate corn.<sup>183</sup> In its emergency petition, CFS alleged that EPA's conditional registration of clothianidin is a likely contributor to Colony Collapse Disorder,<sup>184</sup> and requested EPA take four measures: 1) cure clothianidin's unlawful conditional registration in light of outstanding data requirements, 2) prevent imminent harm to petitioners, 3) recognize clothianidin's inadequate labels, and 4) comply with the ESA.<sup>185</sup>

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<sup>176</sup> *Id.*; Neonicotinoids are pesticides that affect the central nervous system of insects to paralyze and kill them. Neonicotinoids persist in the environment and translocate to residues in pollen and nectar of treated plants, and are a suspected contributor to Colony Collapse Disorder. Beyond Pesticides, *Chemicals Implicated*, <http://www.beyondpesticides.org/pollinators/chemicals.php> (last visited Nov. 22, 2014).

<sup>177</sup> Memorandum from Miachel Rexrode, Senior Aquatic Biologist, EPA, to Meredith F. Law, Chief, Insecticide Branch & Terri Stowe, NAFTA Joint Review Coordinator, EPA, Addendum Referring to EFED's Risk Assessment on Clothianidin Use As a Seed Treatment on Corn and Canola (PC Code 044309;) 1-2 (Apr. 10, 2003), *available at* [http://www.epa.gov/pesticides/chem\\_search/cleared\\_reviews/csr\\_PC-044309\\_10-Apr-03\\_a.pdf](http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-044309_10-Apr-03_a.pdf). EPA formerly stated that it required a lifecycle study prior to registration and also required strong labeling, but revoked that requirement in April 2003 in granting the conditional registration status contingent on the pollinator field study. PESTICIDE ACTION NETWORK, CLOTHIANIDIN CONDITIONAL REGISTRATION TIMELINE 1 (2010) [hereinafter PESTICIDE ACTION NETWORK, NORTH AMERICA], *available at* <http://grist.files.wordpress.com/2010/12/clothianidin-condl-reg-timeline.pdf>.

<sup>178</sup> PESTICIDE ACTION NETWORK, NORTH AMERICA, *supra* note 177, at 2.

<sup>179</sup> *Id.*

<sup>180</sup> *Id.* at 2-3.

<sup>181</sup> First Amended Complaint, *supra* note 72, at 2-3, 29.

<sup>182</sup> *See* CTR. FOR FOOD SAFETY ET AL., EPA-HQ-OPP-2012-0334, EMERGENCY CITIZEN PETITION TO THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY SEEKING SUSPENSION OF REGISTRATION FOR CLOTHIANIDIN 3 (Mar. 20, 2012), *available at* <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0334-0002>.

<sup>183</sup> PESTICIDE FACT SHEET, *supra* note 72, at 15.

<sup>184</sup> *See* CTR. FOR FOOD SAFETY ET AL., *supra* note 182, at 13-16.

<sup>185</sup> *Id.* at 5-7.



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EPA denied petitioner's emergency petition in July 2012.<sup>186</sup> In response, on March 21, 2013, Plaintiffs including individual citizens and public interest and environmental organizations<sup>187</sup> filed suit against EPA, seeking injunctive and declaratory relief.<sup>188</sup> In their amended complaint, Plaintiffs alleged fourteen claims for relief, each involving EPA's "refusal . . . to cancel or suspend a registration or to change a classification not following a hearing, [and] failure to conduct required ESA analysis and consultation," as well as other agency actions outside the Administrator's discretion.<sup>189</sup> Plaintiffs further alleged that EPA violated conditional registration requirements and the APA for conditionally registered products. Plaintiffs alleged that EPA acted arbitrarily and capriciously and in violation of FIFRA's conditional registration provisions which require compliance with conditions imposed within a limited, reasonable period.<sup>190</sup> Specifically, Plaintiffs alleged that EPA violated FIFRA's conditional registration provision by failing to issue a notice of intent to cancel a conditional registration, since the pollinator study requirement was not met,<sup>191</sup> and was instead placed "in reserve."<sup>192</sup>

As of the writing of this Comment, the parties continue to litigate, and the outcome of this case remains uncertain.<sup>193</sup> However, this case may serve as a test case for EPA's conditional registration policy. That Plaintiffs are able to allege in good faith six different substantial claims for relief against EPA's conditional registration policy for clothianidin suggests that EPA's conditional registration policy is unlawful.<sup>194</sup> The extent to which the court determines EPA may stray from its conditional registration requirements or from EPA's statutory duties, will reveal the court's degree of deference.

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<sup>186</sup> Letter from Steven Bradbury, Director, Office of Pesticide Programs, EPA, to Peter T. Jenkins, Attorney, Ctr. for Food Safety & Int'l Ctr. for Tech. Assessment 5 (July 17, 2012), *available at* <http://www.epa.gov/opp00001/about/intheworks/epa-respsns-to-clothianidin-petition-17july12.pdf>.

<sup>187</sup> Plaintiffs include individual beekeepers and honey producers—Mr. Steve Ellis, Mr. Tom Theobald, Mr. Jim Doan, and Mr. Bill Rhodes—as well as public interest groups—Center for Food Safety, Beyond Pesticides, Pesticide Action Network, the Sierra Club, and Center for Environmental Health. First Amended Complaint, *supra* note 72, at 1.

<sup>188</sup> Plaintiffs filed an amended complaint on May 31, 2013, adding six additional claims to their complaint. *See* First Amended Complaint for Declaratory and Injunctive Relief at 44–49, *Ellis v. Bradbury*, No. 3:13-cv-01266-LB (N.D. Cal. 2013).

<sup>189</sup> *Id.* at 5.

<sup>190</sup> *Id.* at 39.

<sup>191</sup> *Id.* at 39–40 (quoting 7 U.S.C. § 136d(e)(1) (2012)).

<sup>192</sup> *Id.* at 40.

<sup>193</sup> EPA moved to dismiss the case on July 31, 2013, which the Court granted in part and denied in part. Order Granting In Part EPA's Motion to Dismiss; Granting In Part And Denying In Part Interveners' Motion To Dismiss And For Judgment On The Pleadings; Affording Plaintiffs Leave To Amend at 1, *Ellis v. Bradbury*, No. C-13-1266-MMC (N.D. Cal. Apr. 18, 2014), 2014 WL 306552 at \*25.

<sup>194</sup> In its April 2014 Order, the court dismissed Plaintiffs' Fifth through Eighth Claims without leave to amend, and partially dismissed Plaintiffs' Third, Fourth, Thirteenth, and Fourteenth Claims with leave to amend. *See* Second Amended Complaint for Declaratory and Injunctive Relief at 2, *Ellis v. Bradbury*, No. 3:13-cv-01266-LB (N.D. Cal. 2014), ECF No. 123.

## VIII. CONCLUSION

The extensive data requirements contemplated by Congress in FIFRA are a testament to the importance of considering pesticides' grave human health and environmental effects before allowing them to enter the market. While this Comment posits that all conditional registrations inherently violate the purpose of FIFRA, the most important legal developments in overturning conditional registrations will likely come not as an overhaul of the entire conditional registration program, but instead, one pesticide at a time, through vigorous litigation by public interest organizations. As recent cases illustrate, EPA's inadequate enforcement of conditional registration data requirement deadlines has the potential to adversely affect everyone from the most vulnerable members of our society, such as infants, to valuable assets of our economy, such as small farmers. While outcomes of the two pending cases challenging EPA conditional registration practices remain to be seen, both cases have the potential to set important legal precedent regarding the rights of parties adversely affected by conditional registrations.