

# IT'S EVERYONE'S BEESWAX: HOW WEAKNESSES IN THE FEDERAL REGULATION OF PESTICIDES ENDANGER THE ENVIRONMENT AND THREATEN THE PUBLIC WELFARE

## I. INTRODUCTION

Mankind and the honeybee have enjoyed a long and fruitful history together.<sup>1</sup> From facilitating the development of ancient civilizations to becoming an indispensable component of modern industrial agriculture, through the centuries the honeybee's existence has become increasingly connected with human activity and its fate somehow inextricably intertwined with that of the human species.<sup>2</sup> However, despite thousands of years of unquestioned reciprocity, the relationship of these strange bedfellows has reached a critical threshold. Honeybee populations are disappearing in a phenomenon known as Colony Collapse Disorder and many in the scientific community are scrambling to determine why.<sup>3</sup> While the exact cause of this calamity is the source of ongoing debate, some scientists and bee keepers around the world believe they know the primary cause—a widely-used class of pesticides known as neonicotinoids.<sup>4</sup> Convinced that the

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<sup>1</sup> See generally Tammy Horn, *Honey Bees: A History*, N.Y. TIMES BLOG (Apr. 11, 2008, 1:05 PM), [http://topics.blogs.nytimes.com/2008/04/11/honey-bees-a-history/?\\_r=0](http://topics.blogs.nytimes.com/2008/04/11/honey-bees-a-history/?_r=0) (providing an overview of the relationship of the honeybee and human being through history).

<sup>2</sup> See MICHAEL SCHACKER, *A SPRING WITHOUT BEES* 26-28 (2008) (describing how the disappearance of the honeybee poses a major threat to the fragile ecosystem and the potential economic crisis that is likely to ensue due to reduced food production and soaring prices).

<sup>3</sup> See generally Myrna E. Watanabe, *Colony Collapse Disorder: Many Suspects, No Smoking Gun*, 58 *BIOSCIENCE* 384, 384-388 (2008), available at <http://www.bioone.org/doi/full/10.1641/B580503#.Ug1YppK1Evo> (describing various scientific efforts to determine the exact cause of Colony Collapse Disorder).

<sup>4</sup> See generally *Clothianidin Pesticide Harms Honeybees and Must Be Banned, Beekeepers Claim*, THE HUFF POST GREEN (Mar. 21, 2012, 6:37 PM), [http://www.huffingtonpost.com/2012/03/22/clothianidin-pesticide-honeybees-banned\\_n\\_1371274.html?view=print&comm\\_ref=false](http://www.huffingtonpost.com/2012/03/22/clothianidin-pesticide-honeybees-banned_n_1371274.html?view=print&comm_ref=false) (describing the concerns of

United States Environmental Protection Agency (“EPA”) has engaged in administrative misconduct in facilitating the registration and harmful use of these pesticides, a combination of environmental groups and apiculturists have filed a lawsuit against the EPA in an attempt to force it to take corrective measures to prohibit the use of these substances and thereby prevent further harm to the honeybee, agriculture, and ultimately mankind.<sup>5</sup>

This Comment will discuss the current threat to the honeybee posed by the neonicotinoid clothianidin and the EPA’s controversial registration of this pesticide, address weaknesses inherent in the current federal pesticide regulatory system, and provide recommendations for improvement of the registration process. Part II will offer background on the relationship between honeybees and humans, discuss the threat posed by Colony Collapse Disorder and the recent lawsuit filed by beekeepers against the EPA, and address the possibility that neonicotinoids are contributing to mass bee die-offs. Part III will scrutinize the EPA’s policies for granting and cancelling conditional pesticide registrations under the statutory framework provided by the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), and will analyze the standard used by the EPA for determining when an active registration suspected of causing harm is subject to an immediate suspension. To highlight the weakness in the current pesticide regulation system, this section will discuss the controversial neonicotinoid registrations. Following this assessment of the efficacy of current federal pesticide regulations, Part IV will make recommendations for improving the process to prevent harmful pesticides from entering the market and to facilitate their removal from the market when new studies indicate they may no longer be safe.

## II. MANKIND, THE HONEYBEE, AND THE THREAT POSED BY COLONY COLLAPSE DISORDER

### *A. The Rise of the Honeybee and Its Role in Modern Agriculture*

The act of beekeeping, or *apiculture*, is believed to have begun as long ago as 20,000 BCE and was critical in helping early civilizations

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scientists and beekeepers that neonicotinoids play a key role in Colony Collapse Disorder).

<sup>5</sup> See First Amended Complaint at 5-12, *Ellis v. Bradbury*, C-13-1266 MMC (N.D. Cal. Filed Mar. 31, 2013) (generalizing claims and describing the plaintiffs) [herein after *Complaint*].

develop and thrive through the pollination of the agricultural enterprises of Neolithic villages, towns, and cities.<sup>6</sup> Greece, Egypt, Israel, and Italy created organized beekeeping locations until the dissolution of the Roman Empire around 400 A.D. at which time Christian monasteries and convents became the stewards of this tiny insect.<sup>7</sup> During the 1620s, European settlers flocking to the New World brought with them the honeybee along with centuries of extensive beekeeping knowledge and skill.<sup>8</sup> This tiny member of the order Hymenoptera was remarkably suited to assist in the development of human society because of its unique tendency to build large hives around a single queen that could be easily transported and utilized to assist in pollination efforts in a variety of locations.<sup>9</sup> During the 19th Century, beekeeping was not spared the modernization and mechanization characteristic of the Industrial Revolution, and a new dynamic between human being and bee emerged.<sup>10</sup> That period marked a transformation in apiculture from small trade craft to commercially viable enterprise.<sup>11</sup>

Today, honeybees pollinate seventy-one of the world's most common crops, which account for ninety percent of global food supply.<sup>12</sup> The United States provides no exception as honeybees account for one of every three bites of food consumed by the average American.<sup>13</sup> While many of the staples consumed in the United States, such as corn, rice, and wheat, are self-pollinating, and therefore only partially dependent on bee pollination, other heavily consumed foods cannot survive without the work of these tiny insects.<sup>14</sup> Without them, American diets would be far less varied and significantly less nutritious, as commonly consumed foods such as apples, asparagus, avocados, broccoli, blueberries, onions, cherries, cucumbers, celery,

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<sup>6</sup> See SCHACKER, *supra* note 2, at 9.

<sup>7</sup> See Horn, *supra* note 1.

<sup>8</sup> See SCHACKER, *supra* note 2, at 9

<sup>9</sup> *Id.*

<sup>10</sup> See Horn, *supra* note 1.

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

<sup>12</sup> Heather Pilatic, PESTICIDE ACTION NETWORK, *Pesticides and Honeybees: State of the Science* 1 (May 2012), available at

<http://www.panna.org/issues/publication/pesticides-and-honey-bees-state-science>.

<sup>13</sup> *Honey Bees and Colony Collapse Disorder*, U.S. DEP'T OF AGRIC., AGRIC. RESEARCH SERV., <http://www.ars.usda.gov/News/docs.htm?docid=15572#public> (last updated Dec. 2, 2013).

<sup>14</sup> Bryan Walsh, *The Plight of the Honeybee*, TIME MAGAZINE, August 19, 2013, at 30-31.

and watermelon are highly dependent on bee pollination.<sup>15</sup> American health and the economy quite literally benefit from the fruit of honeybee labor.<sup>16</sup> In fact, the United States Department of Agriculture (“USDA”) estimated in 2000 that “bee pollination is responsible for more than \$15 billion in increased crop value each year,” most of which is attributable to these bee-dependent specialty crops.<sup>17</sup>

This is particularly true in the case of almonds.<sup>18</sup> The state of California is the sole producer of almonds in the United States and is responsible for seventy-five percent of the world’s almond productions.<sup>19</sup> Almond production accounts for \$2.8 billion dollars in farm value, making almonds California’s third most valuable crop.<sup>20</sup> “The single most important factor determining a good almond yield is pollination during the bloom period,”<sup>21</sup> which requires growers to utilize 1.4 million honeybee colonies every year.<sup>22</sup>

Whether at the state, national, or global level, it is clear that these ancient pollinators are crucial to maintaining a healthy diet, productive agriculture, and a sound economy.<sup>23</sup> This is why the occurrence of

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<sup>15</sup> *Id.* at 30-31.

<sup>16</sup> HANNAH NORDHAUS, THE BEEKEEPER’S LAMENT: HOW ONE MAN AND HALF A BILLION HONEY BEES HELP FEED AMERICA 23 (2009) (“Honeybees are the glue that holds are agricultural system together.”).

<sup>17</sup> *Honey Bees and Colony Collapse Disorder*, *supra* note 13.

<sup>18</sup> See Wendy Lee, *Honey Bee Shortage Could Harm the World’s Almond Supply*, 89.3 KPCC S. CAL. PUB. RADIO (Mar. 14, 2013, 6:08AM), <http://www.scpr.org/news/2013/03/14/36354/honeybee-shortage-could-harm-worlds-almond-supply/>.

<sup>19</sup> Richard Waycott, *Growing Advantage: The California Almond Industry*, ALMOND BD. OF CAL., [http://www.almondboard.com/AboutTheAlmondBoard/Documents/EconomicRoadShow\\_presentation.pdf](http://www.almondboard.com/AboutTheAlmondBoard/Documents/EconomicRoadShow_presentation.pdf) (last visited Jan. 11, 2014).

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

<sup>21</sup> *A Successful Harvest Starts at Bloom*, ALMOND BD. OF CAL., <http://www.almondboard.com/Growers/OrchardManagement/Pollination/Pages/Default.aspx> (last visited Nov. 23, 2013).

<sup>22</sup> See *Honey Bees and Colony Collapse Disorder*, *supra* note 13.

<sup>23</sup> See Walsh, *supra* note 14, at 26 (“You can thank *Apis Mellifera*, better known as the Western honeybee, for 1 in every 3 mouthfuls of food you’ll eat today.”); See SCHACKER, *supra* note 2, at 25-28 (explaining how the global economy and modern civilization are threatened by the potential loss of the honeybee due to an inability to produce enough nutritious food to sustain populations without it).

honeybee die-offs in unprecedented numbers has drawn such focused attention in recent years.<sup>24</sup>

*B. Colony Collapse Disorder: Symptoms, Significance, and Suspects*

In the United States, honeybee populations have seen a steady decline since 1947, with a reduction in their numbers averaging approximately one percent per year.<sup>25</sup> However, the fall of 2004 and fall of 2005 marked a change in this pattern with increased bee disappearances reported in the Midwest and Florida.<sup>26</sup> In November of 2006, the first documented case of the phenomenon now known as Colony Collapse Disorder was reported after a migratory beekeeper in Florida made a routine visit to check on his hives to find that only ten percent remained viable.<sup>27</sup> Unlike other previously documented threats to bees, such as mites and viruses, which caused the health of the hive to deteriorate slowly over time, Colony Collapse Disorder had caused a sudden and unexplainable disappearance of the colony's adult bees, often leaving only an unattended queen, unhatched larvae, and stores of honey and pollen left unfiltered by other scavenging insects.<sup>28</sup> This unique occurrence quickly spread, and by the time beekeepers gathered to discuss the issue during their annual conference in 2007, Colony Collapse Disorder had already been reported found and reported in twenty-two states, with some apiaries suffering up to ninety-five percent in hive losses.<sup>29</sup> Reports indicate that between the winter of 2006 and the winter of 2011, average honeybee losses increased to approximately thirty-three percent each year.<sup>30</sup>

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<sup>24</sup> See generally U.S. DEP'T OF AGRIC., REPORT ON THE NATIONAL STAKEHOLDERS CONFERENCE ON HONEY BEE HEALTH (2012) (Executive Summary describing the creation of the Colony Collapse Disorder Steering Committee in response to the widespread loss of honeybee hives. Report describes how the committee is composed of a number of concerned entities including the Department of Agriculture's Agricultural Research Service, National Institute of Food and Agriculture, Animal Plant Health Inspection Service, Natural Resources Conservation Service, Office of Pest Management Policy, the National Agricultural Statistics Service, and the Environmental Protection Agency).

<sup>25</sup> Pilatic, *supra* note 12, at 2.

<sup>26</sup> See SCHACKER, *supra* note 2, at 15.

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 15-16.

<sup>29</sup> *Id.* at 17.

<sup>30</sup> *Honey Bees and Colony Collapse Disorder*, *supra* note 13.

The USDA warns that continued annual losses at this rate could lead to an agricultural crisis by causing the costs of pollination services to skyrocket and ultimately to higher food costs being passed on to consumers.<sup>31</sup> Periods of food shortages could become longer in duration and severity, until the very foods that contain the bulk of vitamins and minerals necessary to stave off malnutrition become permanently absent from our diets.<sup>32</sup>

In response to this threat, scientists worldwide are working to identify the cause of Colony Collapse Disorder in order to avert an agricultural catastrophe and have developed a lineup of potential suspects which they believe work in concert with one another to weaken honeybee populations.<sup>33</sup> These include nutritional stress caused by loss of habitat and manifested in immune system harm and reduced reproduction capability; pathogens such as mites, viruses, and fungus found in the gut; and pesticides which are beginning to show signs of causing harm to honeybees through both acute toxicity and through their sub-lethal effects.<sup>34</sup> A number of recent studies have yielded data that support the theory that neonicotinoids, a unique group of insecticides registered by the EPA and applied in great quantities throughout the United States, are a primary contributor to the devastation of bee populations.<sup>35</sup> The data connecting honeybee depopulation to an increase in neonicotinoid use has raised broader concerns regarding the reliability of current pesticide risk assessment and regulation in promoting the public welfare.<sup>36</sup> Such concerns include (1) whether the procedure for issuing and monitoring conditional registrations for pesticide use is adequate to prevent harmful products from being sold and used in the United States and (2) whether the standards for determining when a pesticide registration should be cancelled or suspended in the face of new science are effective in protecting the public and the environment.<sup>37</sup> A recent

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

<sup>32</sup> See SCHACKER, *supra* note 2, at 25-26.

<sup>33</sup> Pilatic, *supra* note 12, at 2; See also Watanabe, *supra* note 3, at 388.

<sup>34</sup> Pilatic, *supra* note 12, at 2; See *Honey Bees and Colony Collapse Disorder*, *supra* note 13.

<sup>35</sup> See generally Pilatic, *supra* note 12 (report considering the causes of honeybee decline which focuses on increased pesticide use in the United States).

<sup>36</sup> See *Id.* at 7.

<sup>37</sup> See Jennifer Sass & Mae Wu, NAT'L DEF. RES. COUNCIL, *Superficial Safeguards: Most Pesticides Are Approved by Flawed EPA Process 2* (Mar. 2013), available at <http://www.nrdc.org/health/pesticides/flawed-epa-approval-process.asp>.

lawsuit filed by beekeepers and environmental groups against the EPA addresses these concerns by claiming violations under FIFRA.<sup>38</sup>

### *C. Bee Supporters File Suit*

Recently, a group comprised of beekeepers, honey producers, and environmental public interest organizations filed a lawsuit against the EPA seeking declaratory and injunctive relief in response to what they claim is the agency's continued unlawful registration and labeling of two neonicotinoids—clothianidin and its parent compound thiamethoxam.<sup>39</sup> Plaintiffs' First Amended Complaint in *Ellis v. Bradbury*, No. C-13-1266 MMC (N.D. Cal. filed March 31, 2013) contains fourteen separate claims of alleged EPA violations of FIFRA.<sup>40</sup> One criticism leveled against the EPA by the plaintiffs is that the agency granted the pesticide clothianidin a conditional registration despite serious concerns about the threat it posed to honeybees and other pollinators, and that this conditional registration remained in effect after the registrants missed deadlines on the conditions imposed.<sup>41</sup> The plaintiffs also claim that cancellation and suspension proceedings have not been initiated by the EPA in the face of mounting evidence of their harmful effect on honeybees and other pollinators.<sup>42</sup> Rather than focusing on the particular legal claims in *Ellis*, this Comment will use the conditional registration of clothianidin to draw a spotlight on more general criticisms of EPA's procedures for granting conditional registrations, commencing cancellation of existing registrations, and determining when an active registration poses sufficient harm that it be immediately suspended. A look into the legislative history and current provisions of FIFRA will provide the necessary context for understanding these issues.

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<sup>38</sup> See generally Complaint, *supra* note 5.

<sup>39</sup> See *id.* at 2.

<sup>40</sup> *Id.* at 33-49.

<sup>41</sup> *Id.* at 29-31.

<sup>42</sup> *Id.* at 3.

### III. CONDITIONAL REGISTRATION, CANCELLATION, AND SUSPENSION UNDER FIFRA

#### *A. Legislative History*

FIFRA was first enacted in 1947 as a successor to the Federal Insecticide Act of 1910 and has since undergone a number of revisions.<sup>43</sup> It was initially passed to increase the scope of pesticide regulation by extending coverage to rodenticides and herbicides and required that information regarding ingredients, manufacturer name and address, directions for proper use, warning statements for users, and non-target species be included on a the product label prior to registration with the USDA.<sup>44</sup> After being amended in 1959 and again in 1964 to include additional chemical classes and changes to labeling, FIFRA was significantly changed in 1972 when it was placed under the administration of the newly formed EPA and adopted a standard which allowed for registration of a pesticide only where it could be shown “the pesticide would not cause unreasonable adverse effects on the environment.”<sup>45</sup> By 1975, concerns regarding environmental health led to regulation changes that brought registration to a near standstill.<sup>46</sup> In response, FIFRA was amended in 1978 to allow the EPA to grant conditional registrations of pesticides prior to the registrant’s submission of all required supporting data.<sup>47</sup>

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<sup>43</sup> See Stephen J. Toth, *Federal Pesticide Laws and Regulations* (1996), available at <http://ipm.ncsu.edu/safety/factsheets/laws.pdf> (providing an overview of the legislative history of FIFRA).

<sup>44</sup> *Id.*

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

<sup>46</sup> Pamela A. Finegan, *FIFRA Lite: A Regulatory Solution or Part of the Pesticide Problem?* 6 PACE ENVTL. L. REV. 615, 616-617 (“When Congress drastically overhauled FIFRA in 1972, the new law required the EPA to use new testing guidelines to assess the safety of, and then reregister, the thirty-five thousand pesticide products in existence at that time. In 1986, the United States General Accounting Office (GAO) estimated that the EPA would not accomplish this reregistration task until well into the twenty-first century. This is due to the Agency’s inadequate resources, the number of active ingredients the EPA must review, the amount of data involved, and the complexity of the regulatory decision-making process. These difficulties were further highlighted, two years later, when the House of Representatives reported that the EPA had completed review of only five active ingredients.”).

<sup>47</sup> Toth, *supra* note 43.

It is clear from the legislative history that such conditional registrations were to be the rare exception, not the rule.<sup>48</sup> However, since taking over pesticide regulation in 1972, the EPA has registered 90,000 different pesticides, approximately 25,000 of which were first approved using the conditional registration procedure.<sup>49</sup> Currently, as many as sixty-five percent of total pesticide registrations are conditional,<sup>50</sup> and the EPA's Office of Pesticide Programs has indicated that 11,000 of the more than 16,000 pesticides allowed on the market as of 2010 were conditionally registered.<sup>51</sup> Many of these registered chemical insecticides have become an important element in crop productivity in farming systems developing worldwide and are credited with preserving about one-fifth of total crop yield.<sup>52</sup> Despite heavy use, many conditionally registered chemicals have come under intense scrutiny for their potential harm to the environment.<sup>53</sup> One class of pesticides currently receiving much attention due to its purported role in Colony Collapse Disorder, is the neonicotinoid.<sup>54</sup>

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<sup>48</sup> See H.R. REP. NO. 343(I), at 3, 10 (1977), reprinted in 1978 U.S.C.C.A.N. 1966, 1977 WL 9636.

<sup>49</sup> Laura Fraser, *EPA Lets Pesticides on the Market Untested*, ON EARTH (Mar. 27, 2013), <http://www.onearth.org/articles/2013/03/epa-allows-pesticides-on-the-market-without-first-testing-for-safety>.

<sup>50</sup> Sass & Wu, *supra* note 37, at 2.

<sup>51</sup> See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-13-145, PESTICIDES—EPA SHOULD TAKE STEPS TO IMPROVE ITS OVERSIGHT OF CONDITIONAL REGISTRATIONS 13 (2013), available at <http://www.gao.gov/assets/660/656825.pdf> [hereinafter GAO REPORT].

<sup>52</sup> See Tjeerd Blacquiere et al., *Neonicotinoids in Bees: A Review on Concentrations, Side-Effects and Risk Assessment*, 21 ECOTOXICOLOGY 973, 974 (2012), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3338325/>.

<sup>53</sup> See generally Pilatic, *supra* note 12, at 6-7 (describing the rise in use of neonicotinoids such as imidaclopride, clothianidin, thiamethoxam, and dinotefuran, as well as the general risk they pose to honeybees); See generally Tom Philpott, *Is Your Workout Gear Ruining Farm Fields?*, MOTHER JONES (April 1, 2013, 3:00 AM), available at <http://www.motherjones.com/tom-philpott/2013/04/report-epa-really-sucks-vetting-toxic-chemicals> (describing the questionable conditional registrations of nanosilver and clothianidin and the health and environmental questions they are raising).

<sup>54</sup> See generally Press Release, EUR. FOOD SAFETY AUTH. (Jan. 16, 2013), available at <http://www.efsa.europa.eu/en/press/news/130116.htm> (describing a number of risks posed to bees by three neonicotinoid insecticides).

*B. Neonicotinoids*

Neonicotinoids were first introduced into agriculture abroad in the early 1990s and shortly after rapidly gained popularity for use in controlling agricultural pests through application by spray, seed coating, and soil treatments.<sup>55</sup> At that time, neonicotinoids were a welcomed replacement for older pesticides because it was believed that they were proficient at controlling targeted species while remaining relatively harmless to non-targeted species, including the honeybee.<sup>56</sup> Within fifteen years, neonicotinoids had gained sixteen percent of the global market share of synthetic pesticides and as much as seventy-five percent of the global seed treatment market.<sup>57</sup> Currently, approximately 143 million acres of the 442 million acres of available cropland in the United States are planted with crops that have been treated with a neonicotinoid pesticide—clothianidin, thiamethoxam, or imidacloprid.<sup>58</sup> While these pesticides can be sprayed aerially, they are more commonly used systemically through their application as seed coatings or soil treatments, which allow them to be taken up directly through a plant's vascular system and delivered to every part of the plant, including any nectar or pollen it produces.<sup>59</sup> Honeybees and other pollinating insects then feed on the affected pollen or nectar.<sup>60</sup> Recent and significant studies indicate that honeybees are also exposed to harmful levels of these toxins during automated planting when treated seed dust is inadvertently deposited into the ground along with the seed.<sup>61</sup> These toxic particles are also

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<sup>55</sup> See Blacquiere et al., *supra* note 52, at 974.

<sup>56</sup> See *Honey Bees and Colony Collapse Disorder*, *supra* note 13.

<sup>57</sup> Pilatic, *supra* note 12, at 6.

<sup>58</sup> *Id.* at 4.

<sup>59</sup> See *Pesticide Fact Sheet- Clothianidin*, ENV'T'L OFFICE OF PREVENTION, PESTICIDES, AND TOXIC SUBSTANCES 2 (May 30, 2003), [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); See also *Clothianidin & CCD Fact Sheet*, BEYOND PESTICIDES, <http://www.beyondpesticides.org/pollinators/Backgrounder.pdf> (last visited Oct. 27, 2013).

<sup>60</sup> *Clothianidin & CCD Fact Sheet*, *supra* note 59.

<sup>61</sup> See Christian H. Krupke et al., *Multiple Routes of Pesticide Exposure for Honey Bees Living Near Agricultural Fields*, PLoS ONE, Jan. 2012, at 1, 4-5, available at <http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pone.0029268&representation=PDF>.

released as planter exhaust during the planting of the seeds.<sup>62</sup> Additionally, honeybees are shown to be affected by neonicotinoids through consumption of the water that the treated plants expel.<sup>63</sup>

Neonicotinoids are highly toxic to honeybees in acute doses.<sup>64</sup> However, the acute toxicity of a particular substance merely accounts for the impact the toxin has on adult worker bees and only over a very short period of time.<sup>65</sup> New data is revealing that this acute toxicity-based form of risk assessment, relied on by the EPA for determining a pesticide's safety, is ineffective in evaluating the actual harm being posed to honeybees by neonicotinoid exposure in smaller doses, over longer periods of time, and through a multitude of routes.<sup>66</sup> Such a limited testing paradigm does not accurately reflect the true nature of the exposure hives experience when worker bees repeatedly forage on neonicotinoid treated crops, bring the toxin back to the hive, and expose other members of the colony at various sensitive stages of development.<sup>67</sup> Recent laboratory and field studies on the effects of, non-acute, or "sub-lethal" levels of these compounds on honeybees have revealed that real world honeybee exposure to neonicotinoids

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<sup>62</sup> *Id.* (describing how talcum powder applied to pesticide-treated corn seeds to prevent clumping during automated planting becomes contaminated and toxic to honeybees).

<sup>63</sup> Eric J. Hoffmann & Steven J. Castle, *Imidacloprid in Melon Guttation Fluid: A Potential Mode of Exposure for Pest and Beneficial Organisms*, 105 JOURNAL OF ECON. ENTOMOLOGY 67, 70 (2012), available at <http://afrsweb.usda.gov/SP2UserFiles/Place/53470000/HoffmanCastle%20JEE2012.pdf>.

<sup>64</sup> See Jennifer Hopwood et al., *THE XERCES S. FOR INVERTEBRATE CONSERVATION, Are Neonicotinoids Killing Bees?* vii, 3 (2012), available at [http://www.xerces.org/wp-content/uploads/2012/03/NeonicsSummary\\_XercesSociety.pdf](http://www.xerces.org/wp-content/uploads/2012/03/NeonicsSummary_XercesSociety.pdf) (describing how foliar spray of neonicotinoids is particularly hazardous to insect pollinators).

<sup>65</sup> The lethality of a particular pesticide on pollinators like the honeybee is based on acute toxicity which is determined by exposing a target group and noting the dose at which half of the exposed population dies within a specified time frame, usually forty-eight hours. Pilatic, *supra* note 12, at 7.

<sup>66</sup> See Pilatic, *supra* note 12, at 7-8 (stating that "[t]he acceptable risk for each pesticide is set by regulatory agencies based on acute toxicity and the expected rate and mode of pesticide application, both of which are determined by the manufacturer" but that "the most common field exposure scenarios are likely at the sub-lethal rather than the acute level."); See generally Krupke et al., *supra* note 61 (describing newly discovered ways in which bees encounter neonicotinoid pesticides).

<sup>67</sup> See Krupke et al., *supra* note 61, at 3.

may be contributing to Colony Collapse Disorder by reducing foraging activity, disrupting navigation, and impairing memory and learning capabilities.<sup>68</sup> The failure of the EPA to factor recently discovered sub-lethal effects into its procedure for issuing conditional registrations to pesticide manufacturers is one reason neonicotinoids are drawing fire from the beekeeping and environmental communities.<sup>69</sup>

### *C. Conditional Registration and Cancellation*

As it stands, FIFRA provides that when registration involves a new chemical yet to be approved by the agency, the EPA may conditionally register the pesticide “for a period reasonably sufficient for the generation and submission of data” only if the Administrator determines that: (1) “insufficient time has elapsed since the imposition of the data requirement for those data to be generated and submitted”; (2) “use of the pesticide during such period will not cause any unreasonable adverse effects on the environment”; and (3) that “use of the pesticide is in the public interest.”<sup>70</sup>

Cancellation of an existing registration may be required “if it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment . . . .”<sup>71</sup>

#### *1. Administrative Discretion to Set Conditions and Enforce Deadlines*

The “time reasonably sufficient for generation and submission of the data” requirement for conditional registration is not concrete but rather determined by the EPA on a case-by-case basis depending on amount and nature of data that the agency is requiring prior to issuing full

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<sup>68</sup> See Pilatic, *supra* note 12, at 8; Mary J. Palmer et al., *Cholinergic Pesticides Cause Mushroom Body Neuronal Inactivation in Honeybees*, NATURE COMM., Mar. 27, 2013, at 2, available at

<http://www.nature.com/ncomms/journal/v4/n3/full/ncomms2648.html>.

<sup>69</sup> Complaint, *supra* note 5, at 2-3.

<sup>70</sup> *Conditional Registration*, ENV'T. PROT. AGENCY (last updated Apr. 1, 2013),

<http://www.epa.gov/pesticides/regulating/conditional-registration.html#issues>.

<sup>71</sup> 7 U.S.C. § 136d(b) (West, Westlaw through P.L. 113-65 (excluding P.L. 113-54 and 113-59)).

registration.<sup>72</sup> Once a pesticide is granted conditional registration, “EPA typically grants a period of time, generally one to four years, for the registrant to provide the required data.”<sup>73</sup> Upon request from the registrant, the EPA can waive the requirement for additional information or extend the deadline.<sup>74</sup> This degree of discretion afforded the EPA in establishing and enforcing condition deadlines reveals a weakness in the conditional registration scheme.<sup>75</sup> For example, a product containing foramsulfuron was conditionally registered in November 2002, contingent upon submission by December of 2004 of two studies on its effects on plants.<sup>76</sup> Ten years after the conditions were imposed, the studies had yet to be provided but the conditional registration remained active.<sup>77</sup>

Similarly in 2003, the chemical manufacturer Bayer applied for registration of a product containing the neonicotinoid clothianidin but was denied due to fears expressed by the EPA’s Environmental Fate and Effects Division that the “possibility of toxic exposure to non-target pollinators” required field testing capable of evaluating “chronic exposure to honeybee larvae and the queen.”<sup>78</sup> Approximately two months later, the EPA changed course and issued clothianidin a conditional registration that was contingent upon Bayer’s ability to provide a chronic life cycle study by December 2004.<sup>79</sup> In 2005, after missing the deadline, Bayer was granted an extension until 2007 and given permission to conduct its study outside of the country on crops

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<sup>72</sup> *Conditional Registration*, *supra* note 70.

<sup>73</sup> See GAO REPORT *supra* note 51, at 10.

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

<sup>75</sup> See Complaint, *supra* note 5, at 2 (referring to the EPA’s actions concerning the neonicotinoids clothianidin and thiamethoxam as “a vast and risky experiment” and indicating indicate the agency’s actions did not comport with FIFRA).

<sup>76</sup> See GAO REPORT *supra* note 51, at 25.

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

<sup>78</sup> See Memorandum from Michael Rexrode, Senior Aquatic Biologist, Evt’l. Prot. Agency, Evt’l. Effects Div., to Meredith F. Law, Chief, Insecticide Branch, Evt’l. Prot. Agency, Registration Div. (Feb. 20, 2003), *available at* [http://www.epa.gov/pesticides/chem\\_search/cleared\\_reviews/csr\\_PC-044309\\_20-Feb-03\\_a.pdf](http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-044309_20-Feb-03_a.pdf).

<sup>79</sup> See Memorandum from Michael Rexrode, Senior Aquatic Biologist, Evt’l. Prot. Agency, Evt’l. Effects Div., to Meredith F. Law, Chief, Insecticide Branch, Evt’l. Prot. Agency, Registration Div. (Apr. 10, 2003), *available at* [http://grist.files.wordpress.com/2010/12/memo\\_2.pdf](http://grist.files.wordpress.com/2010/12/memo_2.pdf).

not representative of those being heavily treated in the United States.<sup>80</sup> Although Bayer failed to deliver the study until August of 2007, nearly three years after it was initially required, the conditional registration of clothianidin was never revoked.<sup>81</sup> Once the Bayer field study was submitted, some scientists had reservations about the way it was conducted.<sup>82</sup> In fact, criticisms were made by the EPA's own scientists who stated in a leaked memo the pesticide still presented "long-term risks to honeybees" and that the field test upon which it was approved was deficient and invalid.<sup>83</sup> To date, the comprehensive and scientifically valid field study upon which the conditional registration of clothianidin was granted has not been submitted.<sup>84</sup> Approximately nine years have elapsed since the EPA's initial deadline and it is arguable the excessive conditional registration period provided to Bayer was unjustified.<sup>85</sup>

## 2. *The EPA Lacks a Useful Registration Tracking System*

There is also evidence the EPA lacks a reliable system by which to track registration conditions once they are fulfilled by a registrant.<sup>86</sup> A recent study by the Government Accounting Office found, by the EPA's own admission, that the agency does "not have a reliable

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<sup>80</sup> Tom Philpott, *Leaked Document Shows EPA Allowed Bee-Toxic Pesticide Despite Own Scientists' Red Flags* (Dec. 11, 2010, 12:36 AM), available at <http://grist.org/politics/food-2010-12-10-leaked-documents-show-epa-allowed-bee-toxic-pesticide/>.

<sup>81</sup> See Memorandum from Allen Vaughn, Biologist, Emt'l. Prot. Agency, Emt'l. Effects Div., to Kable Davis, Risk Manager Reviewer, Emt'l. Prot. Agency, Registration Div. (Nov. 16, 2007), available at [http://beyondpesticides.org/pollinators/Clothianidin%20EPAmemo2007\\_2.pdf](http://beyondpesticides.org/pollinators/Clothianidin%20EPAmemo2007_2.pdf).

<sup>82</sup> See Memorandum from Joseph DeCant, Ecologist, Emt'l. Prot. Agency, Emt'l. Effects Div., to Kable Davis, Risk Manager Reviewer, Emt'l. Prot. Agency, Registration Div. (Nov. 2, 2010), available at

[http://grist.files.wordpress.com/2010/12/memo\\_nov2010\\_clothianidin.pdf](http://grist.files.wordpress.com/2010/12/memo_nov2010_clothianidin.pdf) (memorandum in which EPA scientists cast doubt on the reliability of the Bayer study).

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

<sup>84</sup> *Clothianidin Pesticide Harms Honeybees And Must Be Banned, Beekeepers Claim*, THE HUFF POST GREEN (Mar. 21, 2012, 6:37 PM), [http://www.huffingtonpost.com/2012/03/22/clothianidin-pesticide-honeybees-banned\\_n\\_1371274.html?view=print&comm\\_ref=false](http://www.huffingtonpost.com/2012/03/22/clothianidin-pesticide-honeybees-banned_n_1371274.html?view=print&comm_ref=false).

<sup>85</sup> See Complaint, *supra* note 5, at 30-31.

<sup>86</sup> See GAO REPORT *supra* note 51, at 19.

system, such as an automated data system, to track key information related to conditional registrations, including whether companies have submitted additional data within required time frames.”<sup>87</sup> For example, in the case of a product containing the active ingredient acetamiprid, which was conditionally registered in March 2002, the EPA discovered that it had received, but failed to review, a study related to its impact on honeybees submitted by the registrant in 2001 before the product was ever approved.<sup>88</sup>

Considered collectively, the EPA’s actions in the case of foramsulfuron, clothianidin, and acetamiprid suggest that the EPA either initially sets arbitrary deadlines on registrants, or that it is unable or unwilling to enforce them.<sup>89</sup> As a result, pesticides with conditional registrations are often marketed for years without EPA’s receipt and review of important data.<sup>90</sup> Regardless of whether the EPA’s relaxed enforcement of deadlines is intentional or negligent, this conduct seems to allow potentially harmful chemicals to enter the market before important information regarding their impacts on environment is received.<sup>91</sup>

### 3. “Unreasonably Adverse Effects” Standard

The standards for issuing a conditional registration and determining whether cancellation of an existing registration is warranted are the same.<sup>92</sup> The applicant for a conditional registration must show that the pesticide for which it seeks approval poses no risk of causing

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<sup>87</sup> *Id.*

<sup>88</sup> See GAO REPORT *supra* note 51, at 19, 25.

<sup>89</sup> See *supra* notes 76-88 and accompanying text.

<sup>90</sup> See GAO REPORT *supra* note 51, at 25.

<sup>91</sup> EPA acknowledged that thirteen years after thiamethoxam was granted conditional registration its environmental fate database was “only partially fulfilled” and wherein the agency identified “several ecological effects data gaps.” *Thiamethoxam Final Work Plan for Registration Review*, ENVT’L PROT. AGENCY (Jun. 2012), available at <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0581-0024>; See Complaint, *supra* note 5, at 30 (indicating that since clothianidin was originally approved for use on corn and canola in 2003, the field pollinator test, as well as the following additional required tests have yet to be submitted: “a) Whole Sediment Acute Toxicity, Invertebrates, Freshwater; b) Whole Sediment Acute Toxicity Invertebrates, Estuarine and Marine; c) Aerobic Aquatic Metabolism; d) Seed Leaching Study; and e) Small-Scale Prospective Groundwater Monitoring Study.”)

<sup>92</sup> *Defenders of Wildlife v. Jackson*, 791 F. Supp. 2d 96, 117 (D.D.C. 2011).

“unreasonably adverse effects” upon the environment.<sup>93</sup> Similarly, when there is evidence that an already-registered product may be causing “unreasonably adverse effects” on the environment, the EPA is required to initiate cancellation proceedings.<sup>94</sup> The courts have found such a risk to exist whenever there becomes “a substantial question about the safety of a registered pesticide.”<sup>95</sup> Stated differently, a product will not be granted registration, nor will an existing registration continue, if it poses “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.”<sup>96</sup> Such a determination requires the EPA to engage in a balancing of the pesticides risks against its purported benefits.<sup>97</sup>

In the case of neonicotinoid registrations, some stated benefits include the effective control of pests known to reduce crop yields and increased safety for many non-target species as compared to the older, seemingly more toxic substances they replaced.<sup>98</sup> However, it is arguable that such benefits are outweighed by the detrimental impact they may be having on honeybee populations vital to agriculture, particularly considering the amount of data surfacing that implicates them in Colony Collapse Disorder.<sup>99</sup> Despite the significant questions being raised regarding the widespread use of neonicotinoids, they remain registered and widely available on the market.<sup>100</sup> The reasons

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<sup>93</sup> 7 U.S.C. § 136a(c)(7)(C) (West, Westlaw through P.L. 113-65 (excluding P.L. 113-54 and 113-59)).

<sup>94</sup> § 136d(b) (Westlaw).

<sup>95</sup> Nat'l Coal. Against the Misuse of Pesticides v. E.P.A., 867 F.2d 636, 643 (D.C. Cir. 1989).

<sup>96</sup> *Id.* at 638.

<sup>97</sup> See § 136d(b) (West, Westlaw through P.L. 113-65 (excluding P.L. 113-54 and 113-59)).

<sup>98</sup> *Honey Bees and Colony Collapse Disorder*, *supra* note 13 (“The neonicotinoids were developed in the mid-1990s in large part because they showed reduced toxicity to honey bees, compared with previously used organophosphate and carbamate insecticides.”); See also Hopwood et al., *supra* note 64, at 1 (describing how neonicotinoids get inside a treated plant and protect it from harmful insects while purportedly remaining less toxic to birds and mammals than older classes of insecticides).

<sup>99</sup> See generally Pilatic, *supra* note 12 (a report based on a compilation of scientific studies implicating neonicotinoids in Colony Collapse Disorder).

<sup>100</sup> See Tom Philpott, *Europe Bans Bee-Harming Pesticides; US Keeps Spraying*, MOTHER JONES (May 3, 2013, 3:00 AM), <http://www.motherjones.com/tom-philpott/2013/05/eu-ban-bee-harming-pesticides-puts-pressure-us-epa> (describing the

for this dichotomy reveal additional weakness in the federal regulation of pesticides under FIFRA. The EPA considers them safe because its risk-assessment framework relies “on the establishment of acute toxicity exposure without requiring tests for sub-lethal effects.”<sup>101</sup> In other words, anything less than the quick death of an adult worker bee is not considered in determining the harmful potential of a pesticide.<sup>102</sup> It is quite possible that the risk-benefit balancing required of the EPA in determining the possibility of any unreasonably adverse effects would weigh in favor of denying some neonicotinoids conditional registration if the agency’s risk calculations actually accounted for the sub-lethal impact pesticides may have on vital pollinators such as the honeybee.<sup>103</sup> Failing to consider the myriad ways non-target organisms come into contact with a chemical, as well as less obvious ways in which those organisms are impacted by such contact, prevents the EPA from engaging in a proper balancing and undermines FIFRA’s ability to protect the public.<sup>104</sup>

#### 4. *Mislabeled*

The same “unreasonably adverse effects” standard is also utilized by the EPA when it initiates cancellation proceedings upon determining that a pesticide product is mislabeled.<sup>105</sup> In fact, one of the claims made by the plaintiffs in *Ellis* is that clothianidin and its parent compound thiamethoxam should be cancelled because they are

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EPA’s reluctance to institute a temporary ban on neonicotinoids similar to that found in some European nations).

<sup>101</sup> Pilatic, *supra* note 12, at 7.

<sup>102</sup> See *supra* note 65 and accompanying text; See Pilatic, *supra* note 12, at 7.

<sup>103</sup> The EPA determines the risk a particular pesticide poses to human health and the environment by considering 1) the amount of the chemical present in the environment, 2) how much contact a human being or other organisms (such as the honeybee) is likely to have with that contaminated environment, and 3) the inherent toxicity of the chemical itself. *Risk Assessment*, ENVT’L. PROT. AGENCY (last updated Jul. 31, 2012), <http://www.epa.gov/risk/basicinformation.htm>; See *supra* notes 65-69 and accompanying text.

<sup>104</sup> See *supra* notes 61-70 and accompanying text; The EPA notes that “[d]eveloping a risk assessment is often an iterative process, which involves researchers identifying and filling data gaps in order to develop a more refined assessment of the risk. This in turn may influence the need for risk assessors and risk managers to refine the scope of the risk assessment further triggering the need for more data or new assumptions.” *Risk Assessment*, *supra* note 103.

<sup>105</sup> See *infra* note 108.

misbranded.<sup>106</sup> Under FIFRA, a pesticide is “misbranded,” and therefore subject to cancellation, if the “labeling accompanying it does not contain directions for use which . . . if complied with . . . are adequate to protect health and the environment.”<sup>107</sup> The statute also provides that cancellation of a pesticide may be initiated by the EPA whenever “a pesticide or its labeling . . . does not comply with the provisions of the FIFRA, or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment.”<sup>108</sup> This very issue was addressed by the EPA in 2011 when the agency issued a Stop Sale, Use, or Removal Order to DuPont concerning the herbicide “Imprelis.”<sup>109</sup> It did so after receiving complaints about damage to trees associated with application of Imprelis and determining that warnings of such harm were not contained on the products label.<sup>110</sup>

This is analogous to clothianidin’s unforeseen impact on bees. Scientists have only recently uncovered the numerous routes by which the honeybee is exposed to harmful levels of clothianidin and other neonicotinoids.<sup>111</sup> The existence of this gap in knowledge indicates that neonicotinoid products went to market without warnings or application instructions that accounted for the newly discovered dangers. On its face, failure to cancel or reclassify products containing clothianidin for being improperly labeled appears to be a violation of the FIFRA, as these routes make it highly unlikely that such products, when used “in accordance with widespread and commonly recognized practice,” will not cause significant harm.<sup>112</sup> However, because cancellation requires application of the previously discussed “unreasonably adverse effects” standard, a risk-benefit analysis which does not currently account for sub-lethal harm to pollinators, labels on

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<sup>106</sup> See Complaint, *supra* note 5 at 21.

<sup>107</sup> 7 U.S.C. § 136(q)(1)(F) (West, Westlaw through P.L. 113-65 (excluding P.L. 113-54 and 113-59)).

<sup>108</sup> § 136d(b) (Westlaw).

<sup>109</sup> See *E.I. du Pont de Nemourse & Co.*, Docket No. FIFRA-03-2011-0277SS (Aug. 11, 2011), available at <http://www.epa.gov/compliance/resources/orders/civil/fifra/dupontimprelissuro.pdf>.

<sup>110</sup> *Id.*

<sup>111</sup> See Krupke et al., *supra* note 61, at 1.

<sup>112</sup> See § 136d(b) (Westlaw).

these products cannot be deemed to provide instructions for use which are “adequate to protect health and the environment.”<sup>113</sup>

The *Ellis* complaint and the general criticisms lodged above regarding conditional registration and cancellation by the EPA point to weaknesses in FIFRA’s “unreasonably adverse effects” standard which allow unproven products into the marketplace for extended unmonitored periods of time.<sup>114</sup> FIFRA does contain a provision that requires the EPA to immediately suspend any existing registration found to be harmful, but the mechanism requires a much higher standard of harm than that needed to institute cancellation proceedings.<sup>115</sup> Despite the different standards required by these two safety provisions, the results are disappointingly similar.<sup>116</sup>

#### *D. Immediate Suspension*

In addition to questioning the EPA’s decision to conditionally register clothianidin and other neonicotinoids, the plaintiffs in *Ellis* believe that the agency violated the law by denying their request for issuance of a suspension on the registration of products containing these chemicals in the face of mounting data indicating the role neonicotinoids play in Colony Collapse Disorder.<sup>117</sup>

Under the FIFRA, the EPA may immediately suspend a pesticide registration to prevent an “imminent hazard.”<sup>118</sup> “Imminent hazard” has been found to exist where it is determined that “continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonably adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered” under the Endangered Species Act of 1973.<sup>119</sup> Cancellation proceedings ordinarily run “from eighteen months to

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<sup>113</sup> See § 136(q)(1)(F) (Westlaw).

<sup>114</sup> See Complaint, *supra* note 5, at 2-3; See Sass & Wu, *supra* note 37, at 2, 4.

<sup>115</sup> See *infra* Part III.D.

<sup>116</sup> Marina M. Lolley, *Carcinogen Roulette: the Game Played Under FIFRA*, 49 Md. L. Rev. 975, 992 (1990) (“Under FIFRA, the process of suspending or cancelling the registrations of existing pesticides unnecessarily prolongs public exposure to dangerous pesticides.”).

<sup>117</sup> Complaint at 33, *Ellis v. Bradbury*, C-13-1266 MMC (N.D. Cal. Filed March 31, 2013).

<sup>118</sup> 7 U.S.C. § 136d(c)(1) (West, Westlaw through P.L. 113-65 (excluding P.L. 113-54 and 113-59)).

<sup>119</sup> 7 U.S.C. § 136(l) (West, Westlaw through P.L. 113-65 (excluding P.L. 113-54 and 113-59)).

several years, depending upon whether the registrant contests the EPA's actions,"<sup>120</sup> and a mechanism providing for immediate suspension may be necessary to keep harmful products off the market in the interim.<sup>121</sup> While FIFRA's cancellation and suspension provisions both incorporate the words "unreasonably adverse effects,"<sup>122</sup> the standards are markedly different.<sup>123</sup> In the case of suspension, a registrant is being denied the right to market his pesticide before a hearing has been conducted, which brings into question due process concerns.<sup>124</sup> Because of this deprivation of property, suspension decisions require "'more than a substantial question of safety:' there must be a 'substantial likelihood that serious harm will be experienced during the cancellation proceedings.'"<sup>125</sup> This could be difficult burden for the EPA to meet in the case of clothianidin because such an action is likely to deprive registrants of significant income from discontinued sales of their products.<sup>126</sup> Furthermore, alternative pesticides may pose similar, if not greater harm to the environment.<sup>127</sup> Finally, science is not in total agreement about neonicotinoids impact on honeybees.<sup>128</sup> The courts have determined that "in cases . . . where the scientific data are uncertain and scientific opinion divided, we do not think Congress intended FIFRA to compel the Administrator to initiate expedited procedures."<sup>129</sup> From this it can be inferred that, so long as there is no consensus among scientists regarding the harm posed to honeybees by neonicotinoids like clothianidin, the EPA can use its discretion to determine whether the weight of the evidence supports suspension during the long periods of time it takes to come to a final determination on cancellation.<sup>130</sup>

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<sup>120</sup> Lolley, *supra* note 116, at 986.

<sup>121</sup> See § 136d(c)(1) (Westlaw).

<sup>122</sup> § 136d(b) (Westlaw); § 136(l) (Westlaw); § 136d(c)(1) (Westlaw).

<sup>123</sup> See Lolley, *supra* note 116, at 989-990 (describing how the "imminent hazard" showing required for suspension is much more stringent).

<sup>124</sup> See *id.* at 992.

<sup>125</sup> *Id.* at 989-990.

<sup>126</sup> See Philpott, *supra* note 80 (indicating that Bayer made "about \$262 million" from sales of clothianidin in 2009).

<sup>127</sup> See *Honey Bees and Colony Collapse Disorder*, *supra* note 13.

<sup>128</sup> See generally Watanabe, *supra* note 3 (discussing different theories regarding the cause of CCD and various scientific approaches to the problem).

<sup>129</sup> *Nat'l Coal. Against the Misuse of Pesticides v. E.P.A.*, 867 F.2d 636, 644 (D.C. Cir. 1989).

<sup>130</sup> See Lolley, *supra* note 116, at 989

In some instances, the EPA has used its discretion to reduce the risk of harm to public health, such as its decision to suspend heptachlor and chlordane pesticides once it became known that they cause cancer in lab animals.<sup>131</sup> In upholding the agency's decision, the court held that the FIFRA "places a 'heavy burden' of explanation on an Administrator who decides to permit the continued use of a chemical known to produce cancer in experimental animals."<sup>132</sup> The EPA has not placed a similar burden upon itself when considering potential harm to honeybees, as evidenced by the agency's practice of measuring harm to pollinators in a manner that does not account for the multiple routes by which they are exposed to these chemicals and the cumulative impact of sub-lethal exposure.<sup>133</sup> Such a risk assessment tool appears to be ineffective in helping to protect honeybees from Colony Collapse Disorder.<sup>134</sup> If the imminent hazard standard is to be useful in determining when a product shows sufficient risk to be pulled from the market pending possible cancellation, FIFRA must be changed to encompass consideration of the unique dangers posed to honeybees, a species vital to human health, agriculture, and the economy.

#### IV. RECOMMENDATIONS FOR IMPROVING FIFRA AND PROTECTING HONEYBEES

The *Ellis* lawsuit has been useful in illustrating some of the major weaknesses in the federal regulation of pesticides under the FIFRA.<sup>135</sup> It is clear that under the current system, conditional registrations are sometimes granted and maintained with little oversight<sup>136</sup> and upon standards that are not always responsive to new scientific data.<sup>137</sup> This has led to the widespread use of some products before their efficacy

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<sup>131</sup> See *Envtl. Def. Fund, Inc. v. Env'tl. Prot. Agency*, 548 F.2d 998, 1002 (D.C. Cir. 1976) abrogated on other grounds by *Natural Res. Def. Council v. U.S. E.P.A.*, 735 F.3d 873 (9th Cir. 2013)

(describing the EPA's decision to suspend the use of the carcinogenic substances).

<sup>132</sup> *Id.* at 1005.

<sup>133</sup> Pilatic, *supra* note 12, at 7.

<sup>134</sup> See *supra* text accompanying notes 65-68.

<sup>135</sup> See generally Complaint, *supra* note 5.

<sup>136</sup> See GAO REPORT *supra* note 51, at 25.

<sup>137</sup> See Pilatic, *supra* note 12, at 7-8 (describing how, in the United States, risk assessment to pollinators does not incorporate sub-lethal effects and how new scientific data is revealing that sub-lethal effects impact honeybee survival).

and safety have been verified.<sup>138</sup> Science is beginning to show signs of the harmful impact of FIFRA's weaknesses as they relate to the registration of neonicotinoids and their role in the collapse of honeybee colonies.<sup>139</sup> However, significant changes must be made to FIFRA to prevent weaknesses in the federal regulation of pesticides as a whole from becoming manifest in forms of ecological and economical danger beyond the impact of the loss of this vital pollinator. The following suggestions for shoring up pesticide regulation are an important start in the right direction.

First, the EPA should completely change its approach to the grant of conditional registration and approve them only in rare instances and only in accordance with the purpose stated by Congress when amending FIFRA.<sup>140</sup> The 1978 amendment was designed to correct a backlog of registration applications that were preventing potentially beneficial chemicals from reaching the market.<sup>141</sup> However, if not used sparingly, the conditional registration could have the opposite effect.<sup>142</sup> There is a legitimate argument that, in special situations such as a national health emergency, some beneficial pesticides should be granted limited use even when some data regarding its use is missing.<sup>143</sup> However, the majority of pesticides have been approved through the grant of a conditional registration.<sup>144</sup> Allowing conditional registration only for chemicals deemed necessary to stave off disease or prevent a large calamity would help to ensure the legislative purpose for which they were created is not fulfilled at the expense of human and environmental health.<sup>145</sup>

Second, Congress should allocate funds to the EPA and require the EPA to develop and implement an effective system to monitor

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<sup>138</sup> See GAO REPORT *supra* note 51, at 25; See Complaint, *supra* note 5, at 2-3 (“In a vast and risky experiment, EPA has allowed over two million pounds of clothianidin and thiamethoxam to be used annually on more than 100 million acres and on dozens of different plant crops . . . with no adequate risk assessments in place.”).

<sup>139</sup> See generally Pilatic, *supra* note 12 (report indicating, *inter alia*, that the risk assessment standard created by the EPA under FIFRA is inadequate because it does not take into account sub-lethal impacts of pesticides on pollinators).

<sup>140</sup> See H.R. REP. NO. 343(I), *supra* note 48, at 3, 10; Sass & Wu, *supra* note 37, at 5.

<sup>141</sup> See *supra* notes 43-48 and accompanying text.

<sup>142</sup> (“[i]mproper use of conditional registration means that scores of untested or undertested pesticides may litter the market, potentially threatening human health.”). Sass & Wu, *supra* note 37, at 2.

<sup>143</sup> See *Id.*

<sup>144</sup> *Id.*

<sup>145</sup> See H.R. REP. NO. 343(I), *supra* note 48, at 3, 10.

conditional registrations.<sup>146</sup> As indicted in the GAO report, under the current system, the EPA lacks the ability to effectively track conditional registrations to determine whether a registrant is fulfilling its obligation to provide important data on a particular product.<sup>147</sup> Additionally, the current system utilized by the EPA does not signal the agency when required data has been provided,<sup>148</sup> which may account for the unreasonably long delays in its review of data on toxins such as acetamiprid.<sup>149</sup> The EPA is unsure about the exact number of conditions that remain unsatisfied for products actively registered and currently being used by the public.<sup>150</sup> An overhaul of the system it uses for monitoring the conditional registrations will allow the EPA to prevent harmful toxins from slipping through administrative cracks and jeopardizing the health and safety of the American people.

Third, Congress should order the EPA to immediately review all conditionally registered pesticides.<sup>151</sup> Although conditional registrations are subject to a Registration Review every fifteen years,<sup>152</sup> registrants are sometimes granted indeterminate extensions for fulfilling conditions during which time unknown risks to the environment remain unabated.<sup>153</sup> The EPA's lax enforcement of the conditions imposed on registrants in the approval of foramsulfuron<sup>154</sup> and clothianidin demonstrate a need for the agency to set and enforce concrete deadlines upon registrants.<sup>155</sup> Where the EPA determines that

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<sup>146</sup> See Sass & Wu, *supra* note 37, at 2 (describing the EPA lack of efficient system for tracking and managing conditional registrations).

<sup>147</sup> See GAO REPORT *supra* note 51, at 19.

<sup>148</sup> See Sass & Wu, *supra* note 37, at 2 (describing the EPA's lack of efficient system for tracking and managing conditional registrations).

<sup>149</sup> See *supra* note 88.

<sup>150</sup> See GAO REPORT *supra* note 51, at 19.

<sup>151</sup> Sass & Wu, *supra* note 37, at 4.

<sup>152</sup> 7 U.S.C. § 136a(g)(1)(A)(iii)(II) (West, Westlaw through P.L. 113-65 (excluding P.L. 113-54 and 113-59)).

<sup>153</sup> See *Notice of Pesticide Registration*, ENVT'L PROT. AGENCY 2 (Jun. 20, 2012), available at [http://www.epa.gov/pesticides/chem\\_search/ppls/000100-01383-20120620.pdf](http://www.epa.gov/pesticides/chem_search/ppls/000100-01383-20120620.pdf) (vague EPA requirement that Field Test for Pollinators be "submitted or cited no later than the time this study is required to be submitted or cited for current thiamethoxam registrations.").

<sup>154</sup> See GAO REPORT *supra* note 51, at 25 (ten years after test was required, it was not submitted by registrant).

<sup>155</sup> *Clothianidin Pesticide Harms Honeybees and Must Be Banned, Beekeepers Claim*, *supra* note 84 (indicating that a scientifically sound pollinator field test for clothianidin is long overdue).

a registrant has failed to satisfy one or more of the conditions imposed within the specified time given, it should adhere to FIFRA and immediately initiate cancellation proceedings.<sup>156</sup> Ongoing sales and use of pesticides in the absence of important data assuring their efficacy and safety place the public in danger.

Finally, the timely submission of data by registrants and its review by the EPA cannot reduce the harm posed to the environment unless the agency implements changes in its approach to risk assessment where it concerns toxicity to pollinators. The current method used by the EPA considers only acute toxicity when assessing potential harm to honeybees and other pollinators.<sup>157</sup> It does not account for the growing data showing that these insects are highly vulnerable to systemic pesticides like neonicotinoids through a number of exposure routes.<sup>158</sup> Nor does the risk assessment factor in the cumulative impact of sub-lethal doses of a pesticide that may not become immediately apparent in laboratory or field studies.<sup>159</sup> Honeybees and other pollinators are vital to human health and any risk assessment that does not account fully for the unique manner in which they may be affected by particular chemicals is ineffective for protecting the public.

While implementing these important regulatory policy changes, Congress should seriously consider the approach taken in Europe and impose a temporary moratorium on the use of products containing neonicotinoids on crops highly attractive to bees.<sup>160</sup> Even before the most recent studies connecting Colony Collapse Disorder to systemic neonicotinoid use, a number of European countries suspended the use of these chemicals until further research could be conducted regarding their impact on the health of bees.<sup>161</sup> However, following a January 2013 report published by the European Food Safety Authority indicating that neonicotinoids posed significant risk to honeybees and other pollinators from exposure to treated corn and sunflower,<sup>162</sup> all twenty-seven member countries which comprise the European Union severely restricted their use for a two-year period while further tests

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<sup>156</sup> 7 U.S.C. § 136d(e)(1) (West, Westlaw through P.L. 113-65 (excluding P.L. 113-54 and 113-59)).

<sup>157</sup> Pilatic, *supra* note 12, at 7.

<sup>158</sup> *See Id.*; *See also* Krupke et al., *supra* note 61, at 1.

<sup>159</sup> Pilatic, *supra* note 12, at 7-8.

<sup>160</sup> *See infra* notes 161-165 and accompanying text.

<sup>161</sup> *Europe Bans Bee-Harming Pesticides*, *supra* note 100.

<sup>162</sup> *Id.*

are conducted.<sup>163</sup> Based on the report, the European Union found that clothianidin, thiamethoxam, and imidacloprid no longer met the criteria under which they were initially approved and that without further restrictions placed on their use, the “high risk to bees could not be excluded.”<sup>164</sup>

In light of new scientific evidence, Europe chose to take a sweeping precautionary measure to reduce further harm to the vital honeybee rather than to wait for scientific studies to arrive which might vindicate neonicotinoids.<sup>165</sup> The United States has thus far chosen a different path, and the use of these substances continues here unabated despite mounting evidence of their destructive potential.<sup>166</sup> A temporary moratorium on these substances until more conclusive scientific data can be produced may be in order, especially considering the questionable circumstances under which both clothianidin and thiamethoxam were initially granted conditional registration by the EPA.<sup>167</sup> Although such heavy-handed action may be appropriate under these unique circumstances due to the gravity of the threat posed by Colony Collapse Disorder, working to shore up the weaknesses in the federal regulation of pesticides would likely prevent the need to resort to this type of reactionary ban in the future. The United States government could justify such a regulation by determining that continued unabated neonicotinoid use within the nation's borders constitutes too great of a risk to honeybees which are both an agricultural commodity and a species which substantially affect interstate commerce.<sup>168</sup> With one of every three bites of food an American consumes owed to the effort of honeybees,<sup>169</sup> immediate and

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<sup>163</sup> *Id.*

<sup>164</sup> David Jolly, *Hoping to Save Bees, Europe to Vote on Pesticide Ban*, N.Y. TIMES (Mar. 14, 2013), available at [http://www.nytimes.com/2013/03/15/business/global/hoping-to-save-bees-europe-to-vote-on-pesticide-ban.html?pagewanted=1&\\_r=0](http://www.nytimes.com/2013/03/15/business/global/hoping-to-save-bees-europe-to-vote-on-pesticide-ban.html?pagewanted=1&_r=0).

<sup>165</sup> See *supra* notes 160-164 and accompanying text.

<sup>166</sup> *Europe Bans Bee-Harming Pesticides*, *supra* note 100 (when asked about the European ban on neonicotinoids, the EPA responded stating “[a]t this time, the data available to the EPA do not support a moratorium.”).

<sup>167</sup> See *supra* Part III.C.1.

<sup>168</sup> U.S. CONST. art. I, § 8, cl. 3 (“The Congress shall have power to regulate commerce with foreign nations, and among the several States, and with the Indian Tribes;”); See *generally* *United States v. Lopez*, 514 U.S. 549 (1995) (explaining how Congress can regulate the instrumentalities and channels of interstate commerce as well as those activities which “substantially affect” interstate commerce).

<sup>169</sup> Walsh, *supra* note 14, at 26.

effective action is required to prevent empty hives from becoming empty plates, empty wallets, and failing ecosystems.<sup>170</sup>

## V. CONCLUSION

The honeybee is vanishing from the planet and many consider neonicotinoids the prime suspect.<sup>171</sup> Originally approved to protect plant life and to increase crop yields while reducing harm to non-target species,<sup>172</sup> these systemic pesticides are now the focus of many scientific investigations into large-scale bee vanishings.<sup>173</sup> Indeed, Colony Collapse Disorder requires immediate attention from the federal government if economic and environmental crises are to be averted.<sup>174</sup>

While massive bee die-offs are a real and immediate concern, the EPA's practice of granting of conditional registrations based on questionable science, its continuation of those registrations with little to no oversight, and its refusal to cancel or suspend them in the face of new science showing their harmfulness, reveals a much deeper issue within the regulation of pesticides under FIFRA. A federal ban on the use of neonicotinoids may improve the plight of the honeybee, but weaknesses in the EPA's regulatory framework left unaddressed are likely to continue putting the American public in danger. In order to protect the public health, the EPA must drastically reduce its dependency on conditional registrations and develop an efficient system for tracking registrations and monitoring compliance. Additionally, Congress must work to eliminate vagaries within the provisions of FIFRA which give the EPA unchecked discretion to allow harmful substances to remain in widespread use with little to no accountability. Finally, the EPA must revise the way it measures risk to pollinators. Outdated, narrowly developed criteria for gauging the harmful potential of pesticides must be replaced with guidelines which accommodate advancing science. Risk-assessment protocols based on short-term, acute toxicity must be replaced with more modern

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<sup>170</sup> See *supra* note 28 and accompanying text.

<sup>171</sup> *Chemicals Implicated*, BEYOND PESTICIDES,

<http://www.beyondpesticides.org/pollinators/chemicals.php> (last visited Oct. 28, 2013).

<sup>172</sup> See *supra* note 98 and accompanying text.

<sup>173</sup> See *generally* Pilatic, *supra* note 12 (report based on a compilation of scientific studies implicating neonicotinoids in Colony Collapse Disorder).

<sup>174</sup> See *supra* note 28 and accompanying text.

analytical processes that take into account the subtle, yet significant sub-lethal threats toxins pose to species in real world settings.

A quote, often attributed to Albert Einstein, illustrates the significance of the current threat posed by Colony Collapse Disorder: “[i]f the bee disappears from the surface of the Earth, man would have no more than four years to live.”<sup>175</sup> Some uncertainty exists regarding whether or not the renowned physicist actually made this statement,<sup>176</sup> but there is a general consensus that the loss of honeybees would leave mankind both hungrier and poorer.<sup>177</sup> The proposition that Colony Collapse Disorder might be a harbinger for the collapse of human civilization is certainly one deserving of reflection. However, the suggestions offered in this comment for shoring up weaknesses in the federal regulation of pesticides are pragmatic steps necessary to protect the honeybee and reduce the risk pesticides pose to human and animal welfare in the future.

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<sup>175</sup> Walsh, *supra* note 14, at 26-27.

<sup>176</sup> Walsh, *supra* note 14, at 27.

<sup>177</sup> *Id.*; See also SCHACKER, *supra* note 2, at 26-27.

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