

**EMERGENCY CITIZEN PETITION TO THE  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

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Docket Number \_\_\_\_\_

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**EMERGENCY CITIZEN PETITION TO THE  
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
SEEKING SUSPENSION OF REGISTRATION FOR CLOTHIANIDIN**

**SUMMARY OF PETITION**

Under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §136 *et seq.*, the Environmental Protection Agency (EPA) regulates pesticide use in the United States. In violation of FIFRA, EPA continues to permit the sale and use of clothianidin, a neonicotinoid pesticide, for which EPA is lacking a pollinator field study the agency required *eight years* ago as a condition of clothianidin's registration and as necessary to support the required "no unreasonable environmental effects" determination.<sup>1</sup> In short, EPA has violated its own conditional registration procedures for obtaining outstanding data. That legal defect is at the heart of this Petition.

Allowing the continued sale and use of *any* pesticide while EPA lacks the scientific studies it needs to ensure the compound does not pose a hazard is irresponsible. Doing so with clothianidin is particularly damaging because neonicotinoid pesticides, and clothianidin in particular, function as systemic insecticides with physical and chemical properties allowing them to move easily within a given plant and reach its flowers, fruit, pollen and nectar – essentially making the whole plant poisonous to insects. The plant becomes potentially highly toxic to bees. This phenomenon could be a significant contributing factor in the recent, devastating decline in honey bee numbers and health and is likely a contributing factor in the decline of indigenous bee species as well as other insects, including Federally-listed threatened and endangered species.

Due to EPA's actions and inactions, clothianidin and its "sister" pesticides now are spread widely throughout tens of millions of acres of both agricultural and neighboring lands. The neighboring lands are where these toxic compounds were not intended to be and often are lands not owned by the farmers applying the compounds. These lands adjacent to agricultural fields in many cases are prime remaining bee and native insect habitat. Due to the very long

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<sup>1</sup> EPA's PC Code is 044309. Common trade names for products containing clothianidin include, but are not limited to, Poncho, Titan, Prosper, Sepresto, Proceed, Belay, Clutch, NipsIt, Celero, Arena, Inovate, Aloft and Darlex (see Appendix A for details of registered products and approved uses; note that Petitioners cannot be certain Appendix A includes every such product and approved use; EPA must determine that).

persistence of these compounds, and the uncontrollable drifting and blowing of contaminated dust and soil, bees and other insects are victims of multiple exposure pathways that EPA failed to assess when the agency allowed the pesticide onto the market – and still has failed to assess. Key among these exposure pathways are residues in pollen and nectar, dust from treated seeds and soils, planter exhaust, untreated but contaminated non-crop plants adjacent to treated fields, guttation droplets on both treated and untreated but contaminated plants and residues from foliar uses.<sup>2</sup> With half-lives of several years in some situations and continuing uptake by rotational crops and volunteer weeds such as dandelions, neonicotinoids are drastically altering our nation’s rural insect populations and no label warnings or use directions are capable of mitigating this.

EPA has frankly dropped the ball and consistently underestimated the extent of translocation and the levels of exposure to clothianidin and other neonicotinoids that honey bees and other beneficial insects are suffering, as well as the extent to which non-crop lands that are not owned by the applicators are being contaminated. It is long past time for the agency to stop giving these pesticides a free pass. It is improper for the agency to continue to deflect responsibility by responding that abnormal bee mortality and poor health result from many factors and the precise contribution of neonicotinoids to these declines remains uncertain. The agency made a major procedural and analytical error that turned a blind eye to resolving that very uncertainty long ago. That error can be readily remedied by granting the relief sought in this document.

Accordingly, pursuant to the Right to Petition Government Clause contained in the First Amendment of the United States Constitution,<sup>3</sup> the Administrative Procedure Act (APA)<sup>4</sup> and

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<sup>2</sup> Christian H. Krupke, Greg J. Hunt, Brian D. Eitzer, Gladys Andino, Krispn Given, *Multiple Routes of Pesticide Exposure for Honey Bees Living Near Agricultural Fields*, 7 PLoS ONE 1, (2012), available at e29268.doi:10.1371/journal.one.0029268; Andrea Tapparo et al., *Assessment of the Environmental Exposure of Honeybees to Particulate Matter Containing Neonicotinoid Insecticides Coming From Corn Coated Seeds*, 46 ENVTL. SCI. & TECH. 2592 (2012), DOI: 10.1021/es2035152; V. Girolami et al., *Translocation of Neonicotinoid Insecticides From Coated Seeds to Seedling Guttation Drops: A Novel Way of Intoxication for Bees*, 102 J. ECON. ENTOMOLOGY, 1808 (2009).

<sup>3</sup> “Congress shall make no law . . . abridging . . . the right of the people . . . to petition Government for a redress of grievances.” U.S. CONST. amend. I. The right to “petition for a redress of grievances [is] among the most precious of the liberties safeguarded by the Bill of Rights.” *United Mine Workers of Am. v. Illinois State Bar Ass’n*, 389 U.S. 217, 222 (1967). It shares the “preferred place” accorded in our system of government to the First Amendment freedoms, and has “sanctity and a sanction not permitting dubious intrusions.” *Thomas v. Collins*, 323 U.S. 516, 530 (1945). “[A]ny attempt to restrict those First Amendment liberties must be justified by clear public interest, threatened not doubtfully or remotely, but by clear and present danger.” *Id.* The Supreme Court has recognized that the right to petition is logically implicit in, and

EPA's implementing regulations and Special Review procedures,<sup>5</sup> the Petitioners request the agency, on an emergency basis, to take four steps:

**1) Cure clothianidin's unlawful conditional registration.** EPA should promptly suspend the registration of clothianidin and issue a stop sale, use or removal order pending compliance with the agency's own procedural requirement to provide outstanding data, including but not limited to, the preparation, publication and agency review of a field study sufficient to support a finding that clothianidin does not pose any unreasonable adverse effects to honey bees and other insect pollinators.<sup>6</sup> The agency imposed that condition but has failed under FIFRA to enforce its own requirement since 2004.

**2) Prevent imminent harm.** Should EPA refuse to initially suspend clothianidin's conditional registration, Petitioners request EPA to promptly initiate Special Review and cancellation procedures for clothianidin pursuant to 7 U.S.C. § 136d; and then suspend its registration pending completion of the cancellation proceedings based on the ongoing and imminent harm posed.

Numerous peer-reviewed studies and other evidence of both acute and sub-lethal harm to bees from a variety of exposure pathways all across America's agricultural landscapes support the need to stop the use of clothianidin.<sup>7</sup> They demonstrate not only that it causes unreasonable adverse environmental effects, but also that it is an "imminent hazard" to the environment. Contributing to mass declines of honey bees and other beneficial insects and thus leading to severe economic and ecological impacts clearly meets that test.

**3) Recognize clothianidin's inadequate labels.** Prompt suspension and a stop sale, use or removal order are also necessary because clothianidin is misbranded. FIFRA authorizes EPA to take such action when there is reason to believe a pesticide is being distributed or sold with inadequate labeling.<sup>8</sup> Indeed, only seven months ago EPA issued just such an order when it discovered the herbicide "Imprelis," newly registered by DuPont, was killing non-target

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fundamental to, the very idea of a republican form of government. *United States v. Cruikshank*, 92 U.S. 542, 552 (1876).

<sup>4</sup> 5 U.S.C. § 553(e).

<sup>5</sup> 40 C.F.R. § 154 Subpart A and §154.10.

<sup>6</sup> 7 U.S.C. § 136k(a).

<sup>7</sup> *See State of the Science*, Appendix B.

<sup>8</sup> 7 U.S.C. § 136k(a).

coniferous trees.<sup>9</sup> Like Imprelis, the labels for clothianidin products do not contain directions “adequate to protect health and the environment.”<sup>10</sup> In the face of clear evidence that planting seeds treated with clothianidin is spreading this extremely persistent and accumulating pesticide across America’s crop fields and the product labels are inadequate to advise planters on how to prevent this, EPA’s labeling is defective.

**4) Comply with the Endangered Species Act.** EPA has violated Section 7(a)(2) of the Endangered Species Act (ESA) by failing to make required “effects” determinations and failing to undergo consultation concerning clothianidin’s impacts on native endangered and threatened species.<sup>11</sup> Numerous native Federally-listed insects may be directly impacted and non-insect species, such as insectivorous birds, may be indirectly affected. Petitioners request the agency to make the required effects determinations and complete the Section 7 consultation process. EPA has sought to comply with the ESA retroactively, after its approval decision, which is illegal. It must suspend use of clothianidin in the interim to make this request meaningful. Otherwise users of this deadly insecticide may continue to take threatened and endangered species without appropriate mitigation or ESA compliance.

Failure by EPA to take the actions Petitioners request herein would severely harm Petitioners’ interests. It also would be arbitrary, capricious and contrary to the mandates of FIFRA, the ESA and the APA. In view of the emergency nature of this matter, the severity of the impacts the Petitioners are suffering and EPA’s excessive delays in resolving the questions of clothianidin’s environmental effects, the agency is urged to grant the requests in this Petition within **90 days** of its filing date.

After identifying the Petitioners and their affected interests, and then citing the applicable law, this Petition provides an introduction to the argument (§ I), highlights a key new “State of the Science” report that supports the Petition (§ II), provides the background on EPA’s legal authority under FIFRA (§ III) and recounts EPA’s legal and procedural failures (§ IV). It then provides additional information on honey bee declines and the role of clothianidin (§ V), gives the flawed regulatory history of these pesticides (§ VI) and then gives five Statements of Legal Grounds to remedy the situation (§§ VII, VIII, IX, X and XI).

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<sup>9</sup> EPA Region III, *In re E.I. du Pont de Nemours & Co.*, Stop Sale, Use, or Removal Order, Docket No. FIFRA-03-2011-0277SS (Aug. 11, 2011).

<sup>10</sup> 7 U.S.C. § 136(q)(1)(F).

<sup>11</sup> The ESA is codified at 16 U.S.C. § 1531 *et seq.*

This Petition does not challenge the FIFRA conditional registration process as a whole, but Petitioners strongly urge EPA to review that process to determine whether it is being misused. The case of clothianidin, in which EPA has allowed a highly toxic compound to become extremely prevalent despite an eight year period of failure by the registrant to comply with a critical condition imposed specifically to assess the long-term threat the compound poses to honey bee survival, strikes Petitioners as a clear illustration that the conditional registration system is broken. In any event, the burden of proving clothianidin meets EPA's criteria to be "entitled" to continued registration rests not with Petitioners, or with EPA, but with Bayer A.G. and other companies with clothianidin-containing products, per 40 CFR§ 154.5 on Special Review petitions:

*Burden of persuasion in determinations under this part.*

*In making determinations under this part the Administrator shall be guided by the principle that the burden of persuasion that a pesticide product is entitled to registration or continued registration for any particular use or under any particular set of terms and conditions of registration is always on the proponent(s) of registration.*

## **PETITIONERS**

### **Petitioners' Interests**

This Petition is motivated by a vast array of interests of the many Petitioners, who come from across the United States. The beekeeper and honey producers seek emergency relief due to severe economic impacts centered on the unsustainable mortality rates and poor health of their privately-owned honey bees, which will be aided if the Administrator provides the relief requested herein. The listed Petitioners are representative of this industry sector, in which there are thousands of similarly-affected businesses. The environmental and consumer organizations seek to represent the strong public interest in preserving healthy pollinators in both agricultural and natural ecosystems, as well as conserving native insects jeopardized by the persistent, systemic insecticide at issue.

**Beekeeper and Honey Producer Petitioners.** The following 27 beekeepers and honey producers are Petitioners (due to their large number, full descriptions of their particular interests follows at the end of this Petition in Table 1):

**Jeff Anderson**, Minnesota; **Manley and Linda Bigalk**, Iowa; **Tim Brod**, Colorado; **Coalition4Bees**, Colorado; **Craig Byer**, New York; **Cynthia Cole**, Massachusetts; **Ross Conrad**, Vermont; **James Doyle**, Indiana; **Steve Ellis**, Minnesota; **Adam French**, Idaho; **Tim Fulton**, Wisconsin; **David Hackenberg**, Pennsylvania; **Paula Hendricks**, Ohio; **Dr. Carl Korschgen**, Missouri; **Dr. Daniel Mayer**, Montana; **Gary McCallister**, Colorado; **Miles McGaughey**, Colorado; **Cass Moore**, Ohio; **Charles Mraz**, Vermont; **Eloise Naylor**, New Jersey; **Michael Risk**, Michigan; **Gus Rouse**, Hawaii; **Tom Theobald**, Colorado; **Tim Tucker**, Kansas; **Charles Vorisek**, Pennsylvania; **Western Colorado Beekeepers Association**, Colorado; **Stephen Whittlesey**, Massachusetts.

**Environmental and Consumer Organization Petitioners.** The following four environmental and consumer organizations are Petitioners (full descriptions of their particular interests are at the end of this Petition in Table 2):

**Beyond Pesticides**, Washington, DC; **Center for Food Safety**, Washington, DC, and San Francisco; **International Center for Technology Assessment**, Washington, DC; **Pesticide Action Network of North America**, San Francisco.

### **Broader Public Interest in this Petition**

Petitioners are not alone in seeking emergency relief. Hundreds of thousands of Americans have endorsed an informal citizen petition already urging EPA's Administrator, Lisa P. Jackson, to stop the use of clothianidin.<sup>12</sup> Intense public concern over EPA's actions is visible through comments, position papers, articles and books representing a vast spectrum of stakeholders across the country. Administrator Jackson and the agency cannot ignore the public concern over the loss of honey bees, other beneficial insects, resulting economic and ecosystem damages and the unnecessary persistent toxic pollution of America's vast agricultural landscapes that EPA's actions and inactions enabled.

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<sup>12</sup> Pesticide Action Network N. Am., *Pull Bayer's Bee-Killing Pesticide. Now*, Action Alert (Dec. 8, 2010) available at [http://action.panna.org/p/dia/action/public/?action\\_KEY=5370](http://action.panna.org/p/dia/action/public/?action_KEY=5370).



## APPLICABLE LAW

- The Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136 *et seq.*
- The Endangered Species Act, 16 U.S.C. § 1531 *et seq.*
- The Administrative Procedure Act, 5 U.S.C. Subchapter II
- Code of Federal Regulations, EPA, 40 C.F.R. Parts 150, 152, 154
- EPA Guideline 850.3040: Field Testing for Pollinators (April 1996)

## ARGUMENT

### **I. Introduction**

Over the past decade, the proliferating use of the neonicotinoid class of pesticides has coincided with mass die-offs of honey bee (*Apis mellifera*) populations in the phenomenon known as Colony Collapse Disorder (“CCD”).<sup>13</sup> If left unchecked, these losses could precipitate an economic and ecological disaster impacting the Petitioners and the United States as a whole at a time when the nation can ill-afford it. Honey bees not only produce nutritious honey, but are also of enormous economic importance for American agriculture as pollinators. About 90% of all flowering plants require pollinators to reproduce and, in American agriculture, nearly a third of pollination is performed by honey bees.<sup>14</sup> By the U.S. Department of Agriculture’s most recent estimates in 2000, bee pollination is responsible for \$15 billion annually in added crop value. (That figure has surely increased in the last 12 years). Most of this value comes from specialty crops such as nuts, berries and fruits.<sup>15</sup> Healthy populations of pollinators are essential for the future of American agriculture.

Research has linked recent declines in honey bee colonies and other native bee pollinators to a constellation of stress factors, including pesticides, pathogens and nutrition.<sup>16</sup> Experts have singled out the recent, widespread, major increase in the use of systemic pesticides

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<sup>13</sup> See, e.g., *Honey Bee Die-Off Alarms Beekeepers, Crop Growers and Researchers*, SCIENCE DAILY (Apr. 22, 2007), available at [www.sciencedaily.com/releases/2007/04/070422190612.htm](http://www.sciencedaily.com/releases/2007/04/070422190612.htm).

<sup>14</sup> See Janet N. Abramovitz, *Putting a Value on Nature’s “Free” Services*, Worldwatch Institute (1998), available at [www.worldwatch.org/system/files/EP111B.pdf](http://www.worldwatch.org/system/files/EP111B.pdf); Renée Johnson, *Honey Bee Colony Collapse Disorder*, Cong. Research Serv. Report for Congress, 7-5700, RL33938.

<sup>15</sup> Roger A. Morse & Nichoals W. Calderone, *The Value of Honey Bees as Pollinators of U.S. Crops in 2000*, Cornell Univ. (Mar. 2000), [www.masterbeekeeper.org/pdf/pollination.pdf](http://www.masterbeekeeper.org/pdf/pollination.pdf); USDA Agricultural Research Service, “Questions and Answers: Colony Collapse Disorder” (Sept. 13, 2011), available at [www.ars.usda.gov/News/docs.htm?docid=15572](http://www.ars.usda.gov/News/docs.htm?docid=15572).

<sup>16</sup> See USDA Agric. Research Serv., *Colony Collapse Disorder Progress Report 6* (June 2010) available at [www.ars.usda.gov/is/br/ccd/ccdprogressreport2010.pdf](http://www.ars.usda.gov/is/br/ccd/ccdprogressreport2010.pdf).

like clothianidin, thiamethoxam and others as particularly responsible for mortality and poor health in bee populations and to bees' increasing vulnerability to other threats.<sup>17</sup>

While used on dozens of crops, the predominant use of neonicotinoids is as a seed treatment for corn. Production of corn for food, feed and ethanol production is the largest single use of arable land in North America, occurring in nearly every State and reportedly reaching a near-record 92 million acres in 2011 (a cumulative area virtually equivalent to the entire country of Germany); it is expected to continue to climb.<sup>18</sup> Almost all of the corn seed planted in North America, except for 0.2% used in organic production, reportedly is coated with neonicotinoids, primarily clothianidin and its closely related compound, thiamethoxam.<sup>19</sup>

Neonicotinoids are persistent and are fast-becoming nearly ubiquitous. Their half-lives can vary widely according to soil type and weather conditions, but are extremely long, ranging from 148 days to 1,155 days.<sup>20</sup>

## **II. State of the Science Report**

A substantial and increasing body of scientific literature addresses the levels of neonicotinoids in the environment. Numerous scientists have assessed the effects of these compounds on honey bees. A new report by Petitioner PANNA entitled *Pesticides and Honey Bees – The State of the Science* (hereinafter, “State of the Science report”; attached hereto as Appendix B), compiles a cross-section of these studies, providing significantly more detail than is reiterated in this Petition.

The State of the Science report provides the current baseline on key threats that neonicotinoids pose and that none of EPA’s risk assessments or other regulatory documents for clothianidin products adequately characterize. It covers key research on pesticide prevalence in agricultural areas, sub-lethal and chronic effects, synergistic effects of neonicotinoids and

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<sup>17</sup> *State of the Science*, Appendix B. See also Brian D. Eitzer, *The Role of Pesticides in Honeybee Decline*, Conn. Agric. Experiment Station (2011), available at [www.ct.gov/caes/lib/caes/documents/plant\\_science\\_day/plant\\_science\\_day\\_spring/2011/spring\\_open\\_house\\_2011\\_eitzer.pdf](http://www.ct.gov/caes/lib/caes/documents/plant_science_day/plant_science_day_spring/2011/spring_open_house_2011_eitzer.pdf).

<sup>18</sup> USDA Agric. Research Serv. Agric. Statistics Board, *Acreage* report (2011), available at [www.usda.gov/nass/PUBS/TODAYRPT/acrg0611.pdf](http://www.usda.gov/nass/PUBS/TODAYRPT/acrg0611.pdf); list of countries and outlying territories by total area, available at [http://en.wikipedia.org/wiki/List\\_of\\_countries\\_and\\_outlying\\_territories\\_by\\_total\\_area](http://en.wikipedia.org/wiki/List_of_countries_and_outlying_territories_by_total_area).

<sup>19</sup> Krupke et al., *supra* note 2.

<sup>20</sup> EPA Pesticide Fact Sheet: Clothianidin, Conditional Registration (May 30, 2003), available at [www.epa.gov/opprd001/factsheets/clothianidin.pdf](http://www.epa.gov/opprd001/factsheets/clothianidin.pdf).

pathogens and the significance of compromised bee health. In sum, it further demonstrates the need for the relief sought herein.

### **III. EPA’s Authority Over Pesticides**

Under FIFRA, EPA licenses the sale, distribution and use of pesticides through the process of registration.<sup>21</sup> FIFRA authorizes the agency to grant a “conditional registration” when the pesticide is so new that insufficient data exists to support unrestricted registration.<sup>22</sup> However, the Administrator must make an affirmative finding that the pesticide will not pose “unreasonable adverse effects” during the period of conditional registration.<sup>23</sup> An application for registration is incomplete if it contains insufficient information for the Administrator to make such a determination.<sup>24</sup> Registration of a pesticide—conditional or otherwise—cannot continue on the basis of an incomplete application.<sup>25</sup>

Once a pesticide is registered, FIFRA provides EPA with ongoing oversight authority. Section 6 states the Administrator may, at any time, propose cancellation of a registration if it appears to the Administrator that a pesticide “generally cause[s] unreasonable adverse effects on the environment.”<sup>26</sup> In the case of a conditional registration, if the registrant has failed to initiate or pursue appropriate action toward fulfilling any condition imposed on registration, the Administrator “shall” initiate cancellation proceedings.<sup>27</sup> While cancellation is pending, EPA may “suspend the registration of the pesticide immediately” if an “imminent hazard” exists,<sup>28</sup> that is, if continued use of the pesticide during the time required for the cancellation proceedings “would be likely to result in unreasonable adverse effects on the environment.”<sup>29</sup>

Further, section 12(a)(1)(E) of FIFRA makes it unlawful for any person to sell or distribute a “misbranded” pesticide.<sup>30</sup> Section 2(q)(1)(F) provides that a pesticide is misbranded

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<sup>21</sup> 7 U.S.C. § 136a(5)(D).

<sup>22</sup> *Id.* § 136a(c)(7)(C).

<sup>23</sup> *Id.*; 40 C.F.R. § 152.114(d).

<sup>24</sup> 40 C.F.R. § 152.104.

<sup>25</sup> *See id.* § 152.105.

<sup>26</sup> 7 U.S.C. § 136a(d)(1)(B).

<sup>27</sup> *Id.* § 136d(e)(1).

<sup>28</sup> *Id.* § 136d(c).

<sup>29</sup> *Id.* § 136(l).

<sup>30</sup> 7 U.S.C. § 136j(a)(1)(E).

if such pesticide's "labeling accompanying it does not contain directions for use which . . . if complied with . . . [is] adequate to protect health and the environment."<sup>31</sup>

#### **IV. Summary of EPA's Institutional and Legal Failures**

In the face of the evidence that neonicotinoid pesticides are a contributing factor in the ongoing, huge economic and environmental losses stemming from mass bee die-offs and compromised pollinator health, EPA should have adopted a *more* protective, *more* rigorous stance toward the data necessary for registration. Instead, EPA loosened its oversight, allowing farmers to inundate fields with toxic chemicals *before* EPA has confirmed their safety. In particular, the agency continues to maintain the registration status for clothianidin despite the fact that the registrant, Bayer AG, has failed to conduct a required study satisfying EPA's standards after having more than *nine years* to gather the needed data. EPA has definitively stated that Bayer's belated attempt to conduct a field study of clothianidin's effects on pollinators did not satisfy the condition on registration.<sup>32</sup> Yet, the agency has never identified any alternative study that supports a finding that clothianidin does not have any unreasonable adverse effects on the environment—including pollinators. Such a finding was, and remains, a prerequisite to conditional registration. Continuing to allow clothianidin to be marketed, sold and used when *not one study* meets EPA's condition for its registration is, as a matter of law, arbitrary, capricious and contrary to the mandates of FIFRA and the APA.

This is not merely a situation in which *new* evidence casts doubt on EPA's prior findings about the environmental hazards of clothianidin—although Petitioners include such evidence herein to underscore the urgency of this matter. Rather, the essential step EPA imposed for conditional registration *has never been completed*. Thus, FIFRA's typical procedures for cancelling and then suspending a previously properly-registered insecticide on the basis of new evidence do not apply.<sup>33</sup> The applicable remedy is for the agency to correct its mistake through immediate suspension of clothianidin's registration, pending preparation, publication and EPA review of the required field study with an evaluation of the long-term toxic effect that

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<sup>31</sup> 7 U.S.C. § 136(q)(1)(F).

<sup>32</sup> Memorandum: Clothianidin Registration of Prosper T400 Seed Treatment on Mustard Seed (Oilseed and Condiment) and Poncho/Votivo Seed Treatment on Cotton 2, 4, PC Code 044309, EPA Environmental Fate and Effects Division (Nov. 2, 2010) (hereinafter "November 2010 Memorandum").

<sup>33</sup> 7 U.S.C. §§ 136d(b)–(c).

clothianidin has on the worker bee life cycle, as well as an evaluation of exposure and effects to the queen and larvae.

EPA also has failed to aggressively seek potential adverse effects data from the registrants of clothianidin that would shed more light on its dangers. Petitioners are aware EPA has moved up its registration review of clothianidin and other neonicotinoids in response to concerns about their impacts on pollinators. However, this process is projected by EPA to take six to eight years and is thus grossly insufficient to address the urgency of this toxic threat and would not remedy the legal defects in clothianidin's current registration. Further, American agriculture relies on healthy pollinators. **The Petitioner beekeepers and honey producers, as they clearly articulate in the descriptions of their interests in Table 1 at the end of this Petition, cannot reasonably wait the many more years that EPA's registration review process will consume while their bees die off in dramatic numbers each year.**

EPA's process utterly failed to assess the environmental impacts of its actions before approving clothianidin. It would be specious to suggest that EPA's implementation of FIFRA in this case is the "functional equivalent" of the National Environmental Policy Act (NEPA),<sup>34</sup> whereas this equivalence has, to date, been the basis for excusing EPA from NEPA compliance in FIFRA regulatory matters.

## **V. Factual Background**

### **A. Colony Collapse Disorder**

Honey bees are the most economically valuable pollinators of agricultural crops worldwide. Other important pollinating bee species include: common eastern bumble bee (*Bombus impatiens*), alkali bee (*Nomia melanderi*), blue orchard mason bee (*Osmia lignaria*), hornfaced bee (*O. cornifrons*) and alfalfa (or Lucerne) leafcutter bee (*Megachile rotundata*). Many other unmanaged native insects are also effective pollinators of crops and other plants.

About 90% of flowering plants require pollinators.<sup>35</sup> Bee pollination of agricultural crops accounts for about one-third of the U.S. diet, including a wide range of high-value fruits, vegetables, tree nuts, forage crops, field crops and other specialty crops.<sup>36</sup> Meat, milk and cheese

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<sup>34</sup> 42 U.S.C. §§ 4321 *et seq.*

<sup>35</sup> See Abramovitz, *supra* note 14.

<sup>36</sup> See May R. Berenbaum, Statement Before the Subcomm. on Horticulture and Organic Agriculture, U.S. House of Reps. (Mar. 29, 2007), available at <http://agriculture.house.gov/testimony/110/h70329/Berenbaum.pdf>.

production are also reliant on the pollinated crops that livestock eat, such as alfalfa.<sup>37</sup> Overall, pollinator-dependent crops make up almost one-third of total U.S. agricultural production.<sup>38</sup> Pollinators are crucial pillars of non-crop plant health and survival generally, whether in horticulture or in nature.<sup>39</sup> Thus, it is clear healthy pollinators are essential to healthy food systems, healthy gardens and healthy ecosystems.

CCD is the name given to the abrupt decline of honey bee populations observed around the world beginning in the middle of the last decade. (For more complete analysis of CCD, see State of Science report, Appendix B.) Although first reported in 2006, cases probably indicative of CCD were documented as early as 2004 in the United States.<sup>40</sup> Each winter since then, roughly one-third of the U.S. honey bee population has died off or disappeared.<sup>41</sup> Such losses are approximately *double* the normally expected winter decrease. CCD is distinguishable from other ailments affecting honey bees in the past in that vast numbers of worker bees simply disappear rapidly, never returning to the hive where the queen still lives with a small cluster of bees amidst pollen and honey stores in the presence of immature bees (the brood).<sup>42</sup>

The first reported CCD losses in the United States coincided with the widespread ramp-up of clothianidin use following conditional registration in 2003. As commonly applied in field mixes clothianidin has been observed to cause the type of bee kills attributed to CCD. Other countries, such as Italy, experiencing similar die-offs of honey bees, have suspended neonicotinoid-coated corn seed use and have recorded no cases of colony collapse in subsequent

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For example, a number of agricultural crops are almost totally (90%-100%) dependent on honey bee pollination, including almonds, apples, avocados, blueberries, cranberries, cherries, kiwi fruit, macadamia nuts, asparagus, broccoli, carrots, cauliflower, celery, cucumbers, onions, legume seeds, pumpkins, squash, and sunflowers. Other specialty crops also rely on honey bee pollination, but to a lesser degree. These crops include apricot, citrus (oranges, lemons, limes, grapefruit, tangerines, etc.), peaches, pears, nectarines, plums, grapes, brambleberries, strawberries, olives, melon (cantaloupe, watermelon, and honeydew), peanuts, cotton, soybeans, and sugar beets.

<sup>37</sup> See James R. Hagler et al., *Foraging Range of Honey Bees, Apis mellifera, in Alfalfa Seed Production Fields*, 11 J. INSECT SCIENCE 1 (2011); Honey Industry Facts, Nat'l Honey Bd. (2011), available at [www.honey.com/nhb/media/press-kit](http://www.honey.com/nhb/media/press-kit).

<sup>38</sup> Johnson, *supra* note 14, at 1.

<sup>39</sup> See, e.g., J.C. Biesmeijer et al., *Parallel Declines in Pollinators and Insect-Pollinated Plants in Britain and the Netherlands*, 313 SCIENCE 351 (2006).

<sup>40</sup> Natalie Lounsbury, *Pollinators and Pesticides: Escalating Crisis Demands Action*, 28 Pesticides and You 13 (2008), available at [www.beyondpesticides.org/infoservices/pesticidesandyou/Fall08/pollinators.pdf](http://www.beyondpesticides.org/infoservices/pesticidesandyou/Fall08/pollinators.pdf).

<sup>41</sup> See Dennis vanEngelsdorp et al., *Preliminary Results: A Survey of Honey Bee Colonies Losses in the U.S. Between September 2008 and April 2009* (May 19, 2009), available at [www.apiaryinspectors.org/files/documents/Survey\\_2009.pdf](http://www.apiaryinspectors.org/files/documents/Survey_2009.pdf).

<sup>42</sup> See Johnson, *supra* note 14, at 8.

years.<sup>43</sup> Many bees are exposed to neonicotinoid residue levels several orders of magnitude above acute toxicity values; others may be exposed to lower levels that still are higher than levels known to cause chronic effects. The sub-lethal, chronic effects are consistent with CCD, most particularly the absence of dead bees inside the hive. Neonicotinoid pesticides are known to interfere with honey bees' cognition and orientation in ways that would prevent foraging bees from finding their way back to the hive.<sup>44</sup> The injury to bees from sub-lethal exposures is reported to be cumulative, that is, with every exposure more damage occurs.<sup>45</sup>

Critically, the injury to bees from neonicotinoids makes them more vulnerable to highly-damaging introduced parasites, such as the genus of gut parasites, *Nosema* spp. A major new study, published in January 2012 and led by the USDA Agricultural Research Station in Beltsville, Maryland, shows a clear link between these two bee hazards.<sup>46</sup> The abstract of this study, again, which was led by one of EPA's sister Federal agencies, is directly on point with the relief sought in this Petition (emphasis added):

*[W]e exposed honey bee colonies during three brood generations to sub-lethal doses of a widely used pesticide, imidacloprid, and then subsequently challenged newly emerged bees with the gut parasite, Nosema spp. The pesticide dosages used were below levels demonstrated to cause effects on longevity or foraging in adult honey bees. **Nosema infections increased significantly in the bees from pesticide-treated hives when compared to bees from control hives demonstrating an indirect effect of pesticides on pathogen growth in honey bees.** We clearly demonstrate an increase in pathogen growth within individual bees reared in colonies exposed to one of the most widely used pesticides worldwide, imidacloprid, at below levels considered harmful to bees. The finding that individual bees with undetectable levels of the target pesticide, after being reared in a sub-lethal pesticide environment within the colony, had higher Nosema is significant. **Interactions between pesticides and pathogens could be a major contributor to increased mortality of honey bee colonies, including colony collapse disorder, and other pollinator declines worldwide.***

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<sup>43</sup> *Relazione sull'attività svolta e sui risultati ottenuti nell'ambito del progetto APENET per la tematica "Effetti del mais conciato sulle api"*, CRA-API (2010) available at [www.reterurale.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/409](http://www.reterurale.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/409); *Relazione sull'attività svolta e sui primi risultati ottenuti nell'ambito del progetto Apenet per la tematica "Effetti del mais conciato sulle api"*, CRA-API (2009), available at [www.reterurale.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/81](http://www.reterurale.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/81).

<sup>44</sup> Axel Decourtye et al., *Imidacloprid Impairs Memory and Brain Metabolism in the Honeybee (Apis Mellifera L.)*, 78 *Pesticides Biochemistry & Physiology* 83 (2004).

<sup>45</sup> Henk Tennekes, *THE SYSTEMIC INSECTICIDES: A DISASTER IN THE MAKING* (Weevers Walburg Communicatie, Zutphen, The Netherlands) (2010), available at [www.disasterinthemaking.com](http://www.disasterinthemaking.com).

<sup>46</sup> Jeffery S. Pettis et al., *Pesticide Exposure in Honey Bees Results in Increased Levels of the Gut Pathogen Nosema*, *NATURWISSENSCHAFTEN* (2012) DOI: 10.1007/s00114-011-0881-1.

This study confirms previous findings of a synergistic effect between *Nosema* and other neonicotinoid pesticides wherein bee mortality is dramatically increased.<sup>47</sup>

Besides honey bees, there are many other U.S. native bees and other insects that EPA has a duty to conserve from these threats including, but not limited to, the rusty patched bumble bee (*Bombus affinis*), Franklin's bumble bee (*B. franklini*), yellow-banded bumble bee (*B. terricola*) and Western bumble bee (*B. occidentalis*). Several of these species are facing severe declines comparable to, or worse than, those faced by honey bees.<sup>48</sup> Additionally clothianidin has been documented to be highly toxic to other wild bee species like the common eastern bumble bee, alfalfa leafcutting bee and blue orchard bee, mentioned previously as valuable pollinators.<sup>49</sup>

## **B. Clothianidin and Other Neonicotinoid Pesticides**

Neonicotinoids are systemic, that is, they are taken up by the plant's vascular system as the seed grows and get expressed through its tissues, including flowers, pollen and nectar.<sup>50</sup> Neonicotinoids share a common mode of action that damages the central nervous system of insects. When bees and other insects forage on pollen or nectar from treated crops, they ingest the pesticide, resulting in paralysis and death.<sup>51</sup> Guttated water of seed-treated plants, which provides a source of water for bees, also can be a source of contamination and exposure.<sup>52</sup> Reetz et al. found that corn seeds treated with clothianidin could result in toxic concentrations up to 8,000 ng/mL in the guttated fluid; these concentrations, while decreasing rapidly, remained detectable over several weeks.<sup>53</sup> Additionally, and critically, neonicotinoid pesticides persist in

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<sup>47</sup> Cédric Alaux et al., *Interactions Between Nosema Microspores and a Neonicotinoid Weaken Honeybees (Apis Mellifera)*, 12 *Envtl. Microbiology* 774 (2010); Cyril Vidau et al., *Exposure to Sublethal Doses of Fipronil and Thiacloprid Highly Increases Mortality of Honeybees Previously Infected by Nosema ceranae*, 6 *PLoS ONE* e21550.

<sup>48</sup> Elaine Evans et al., *Status Review of Three Formerly Common Species of Bumble Bee in the Subgenus Bombus*, Xerces Society (2009), available at [www.xerces.org/wp-content/uploads/2009/03/xerces\\_2008\\_bombus\\_status\\_review.pdf](http://www.xerces.org/wp-content/uploads/2009/03/xerces_2008_bombus_status_review.pdf).

<sup>49</sup> Cynthia D. Scott-Dupree et al., *Impact of Currently Used or Potentially Useful Insecticides for Canola Agroecosystems on Bombus impatiens (Hymenoptera: Apidae), Megachile rotundata (Hymenoptera: Megachilidae), and Osmia lignaria (Hymenoptera: Megachilidae)*, 102 *J. ECON. ENTOMOLOGY* 177 (2009).

<sup>50</sup> Clothianidin Fact Sheet, *supra* note 20, at 15.

<sup>51</sup> See Joe Cummins, *Requiem for the Honeybee*, 34 *Inst. for Science in Society* 37 (2007).

<sup>52</sup> Eric Hoffmann & Steven Castle, *Imidacloprid in Melon Guttation Fluid: A Potential Mode of Exposure for Pest and Beneficial Organisms*, 105 *J. ECON. ENTOMOLOGY* 67 (2012).

<sup>53</sup> Jana E. Reetz et al., *Neonicotinoid Insecticides Translocated in Guttated Droplets of Seed-Treated Maize and Wheat: A Threat to Honeybees?* 42 *APIDOLOGIE* 596 (2011).



the environment, increasing the risk of cumulative toxic loading effects, especially with repeated applications, in both the short and long term.<sup>54</sup>

Clothianidin is Bayer AG's successor to imidacloprid, for which Bayer's U.S., German, French, Italian and U.K. patents expired in 2006.<sup>55</sup> Clothianidin has been linked to immune effects in lab animals.<sup>56</sup> It is categorized by EPA as "highly toxic" to all varieties of bees, insects and certain aquatic organisms, as well as to birds and other non-target organisms.<sup>57</sup>

**C. EPA's Awareness that Clothianidin Causes Mass Bee Kills.** EPA's awareness of clothianidin being "highly toxic" is not limited to experiments. The agency has full notice of the compound's ability to destroy large numbers of bee colonies in the field. The below bullets are from EPA's own non-comprehensive documentation of bee kill data, collections that are roundly criticized as spotty in coverage, inadequately advertised to beekeepers, containing numerous years of data gaps, being inconsistently maintained and not up to the task of giving a full picture of CCD-related mortalities. Nevertheless, over the last four years there are consistent alarm bells (emphasis added):

- EPA's Ecological Incident Information System (EIIS) data base on honey bee kills lists a 2008 incident for clothianidin-treated "Poncho" corn that states "**hundreds of thousands**" of hives were destroyed in a "highly probable" case involving a registered use.
- EPA's 2011 document *Registration Review: Problem Formulation for the Environmental Fate and Ecological Risk [etc.] of Clothianidin* re-characterizes the same 2008 incident as affecting "**11,000 colonies**".<sup>58</sup>
- The same EPA document states: "A similar incident affecting **2,500 colonies** was recently reported by Slovenia in April, 2011 where bees were affected by drift of abraded clothianidin-treated maize seed coats" and "Three incidents were also

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<sup>54</sup> See Clothianidin Fact Sheet, *supra* note 20; Imidacloprid Summary Document for Registration Review, PC Code 129099, EPA Office of Pesticide Programs (2008).

<sup>55</sup> Bayer AG Securities and Exchange Commission Filing: Form 20-F, at 57 (Mar. 15, 2007), available at [www.investor.bayer.com/user\\_upload/2622](http://www.investor.bayer.com/user_upload/2622).

<sup>56</sup> See Clothianidin Fact Sheet, *supra* note 20.

<sup>57</sup> *Id.*

<sup>58</sup> Registration Review: Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments of Clothianidin, EPA Office of Chemical Safety and Pollution Prevention (2011).

reported in Canada. In May of 2009, in Ste-Martine, Quebec, over **200 bee colonies** were reported lost. Residues of clothianidin and three other pesticides were detected. In Cocteau-du-Lac, Quebec in May, 2010, residues of clothianidin and thiamethoxam were detected after a number of dead or paralyzed bees were found. Also, in May 2010 in Quebec, residues of clothianidin were detected after reportedly high bee mortality in St-Dominique involving an unspecified number of colonies.” (p. 25)

- The same document mentions five other U.S. incidents involving destruction of multiple colonies due to clothianidin reported to the Agency, all of them since 2009, in Nevada, Indiana, Minnesota and two in Pennsylvania. (p. 26)

The capacity of clothianidin to kill bees *en masse*, together with consistent patterns of smaller kills in various reports, and together with the strong data on clothianidin causing sub-lethal effects consistent with CCD, and also together with new data on the synergistic effects of neonicotinoids and pathogens, strongly suggest the mass bee kills are just the “tip of the iceberg”. The reported kills likely represent the most visible, egregious incidents, while a much greater number of incidents exist “under the surface” in which clothianidin-caused bee deaths occur and hives are weakened and destroyed, but the losses are not readily observed, or they are not reported, or they are reported but not tabulated by EPA.

#### **D. Poor Reception in Europe for Clothianidin and Other Neonicotinoids**

Clothianidin was approved in Germany in 2004. Four years later, German authorities observed a massive bee kill across the Baden-Württemberg region which they linked to clothianidin use (the 2008 incident in the EIIS). Within two weeks, Germany banned clothianidin seed treatment on corn and several other crops.<sup>59</sup> While some suspensions were later lifted, the ban on clothianidin-treated corn seed remains.<sup>60</sup> Also in 2008, Italy’s agricultural ministry

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<sup>59</sup> See *Authorizations for Neonicotinoids are Still Suspended Due to the Hazards of Bees*, Fed. Office of Consumer Prot. and Food Safety (BVL), available at [www.bvl.bund.de/cln\\_027/nn\\_496790/sid\\_FFE204596E8096E5D0F6C6B9E657F9EA/EN/08\\_PresseInfothe k\\_engl/01\\_Presse\\_und\\_Hintergrundinformationen/PI\\_Maissaatgut\\_Mesuro1\\_engl.html\\_nnn=true](http://www.bvl.bund.de/cln_027/nn_496790/sid_FFE204596E8096E5D0F6C6B9E657F9EA/EN/08_PresseInfothe k_engl/01_Presse_und_Hintergrundinformationen/PI_Maissaatgut_Mesuro1_engl.html_nnn=true); Alison Benjamin, *Pesticides: Germany Bans Chemicals Linked to Honeybee Devastation*, GUARDIAN (May 23 2008), available at [www.guardian.co.uk/environment/2008/may/23/wildlife.endangeredspecies](http://www.guardian.co.uk/environment/2008/may/23/wildlife.endangeredspecies).

<sup>60</sup> *Colony Collapse Disorder: European Bans on Neonicotinoid Pesticides*, EPA, available at [www.epa.gov/pesticides/about/intheworks/ccd-european-ban.html](http://www.epa.gov/pesticides/about/intheworks/ccd-european-ban.html).

suspended neonicotinoid authorizations as a precautionary measure. In the following growing season, and for the first time since 1999, Italy's neonicotinoid-free corn sowing reportedly resulted in *no cases* of widespread bee mortality in apiaries near the crops.<sup>61</sup> Slovenia likewise has banned uses of both clothianidin and imidacloprid.<sup>62</sup>

French authorities instituted bans on progressively more neonicotinoid treatments. In 1999, approximately one-third of French honey bees died following widespread use of Bayer's imidacloprid. French authorities promptly banned its use as seed dressing for sunflowers and later on corn.<sup>63</sup> In 2008, having observed enough adverse impacts from neonicotinoids, France flatly rejected Bayer's application to register clothianidin.<sup>64</sup>

EPA has not aggressively investigated these European suspensions to determine their impact on the restoration of the bee populations or to unearth useful epidemiology data. Ignoring Europe's experiences makes little sense. Beyond the direct impacts on insects, data indicate persistent neonicotinoids have indirectly decimated populations of native farm, meadow and grassland insectivorous birds, such as starlings, spotted flycatcher and snipe, across wide swaths of Europe by killing off the large insects that make up their food supply and contaminating waters as well.<sup>65</sup> The United States can ill-afford to ignore this indirect impacts data, thereby putting a vast suite of North American farm, meadow and grassland birds, as well as aquatic organisms, at further risk, many of which already are in decline, such as the upland sandpiper, eastern meadowlark, greater and lesser prairie-chicken, sage-grouse and others, some of which are Federally-listed threatened or endangered species.

#### **E. U.S. Government Failure to Survey for CCD Causes**

In passing the 2008 Farm Bill, Congress called on Federal agencies to investigate and take coordinated action against CCD. However, USDA and Congress's multi-year failure to

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<sup>61</sup> See, e.g., Press Release, Italian Ministry of Health, Tutela patrimonio apistico: sospensione cautelativa dei prodotti fitosanitari utilizzati nel trattamento di concia delle sementi, (Sept. 19, 2008), available at [www.salute.gov.it/dettaglio/dettaglioNews.jsp?id=1054&tipo=old](http://www.salute.gov.it/dettaglio/dettaglioNews.jsp?id=1054&tipo=old); *Bees "Restored to Health" in Italy After This Spring's Neonicotinoid-Free Maize Sowing*, Youris.com (June 26, 2009), available at [www.youris.com/Environment/Bees/Bees\\_restored\\_to\\_health\\_in\\_Italy\\_after\\_this\\_springs\\_neonicotinoidfree\\_maize\\_sowing.kl](http://www.youris.com/Environment/Bees/Bees_restored_to_health_in_Italy_after_this_springs_neonicotinoidfree_maize_sowing.kl).

<sup>62</sup> See Vicky Kindemba, *The Impact of Neonicotinoid Insecticides on Bumblebees, Honey Bees and Other Non-Target Invertebrates*, BUG LIFE 24 (2009).

<sup>63</sup> *Id.*

<sup>64</sup> Benjamin, *supra* note 59.

<sup>65</sup> Tennekes, *supra* note 45.

follow through on that commitment and survey the national scope of CCD in a manner capable of isolating its causes has exacerbated EPA's parallel multi-year failure to require a comprehensive field study that would have assessed the contribution of clothianidin to excess bee mortality. Key points from the recent USDA Inspector General Audit report on this are here:<sup>66</sup>

*Approximately 4 years have passed since the CCD Action Plan was developed, and although the Plan called for a comprehensive survey of honey bee colony production and colony loss due to CCD, we found that USDA has not completed the survey. We also found that although the 2008 Farm Bill authorized \$2.75 million in annual funding between 2008 and 2012 that could potentially have been used for this purpose, Congress never actually appropriated the funds, and Departmental officials did not take other measures to identify funds that might have been available to use for this purpose. (p. 6)*

The Audit reinforces that this USDA and Congressional failure relates directly to the subject of this Petition:

*However, the Steering Committee agreed that a comprehensive survey would help identify where CCD was prevalent and on what potential causal factors to focus, i.e., pests, pathogens, poor nutrition, and or pesticides. They felt that comprehensive NASS surveys would have been a good reference point for CCD colony losses, and that they would be useful for assessing the extent of the CCD problem. **The Steering Committee also felt that data from a NASS colony decline survey might provide clues to the causes of honey bee decline, if correlated with other data, such as pesticide use patterns.** (p. 7, emphasis added)*

USDA's chastened response to the audit was to agree and commit to undertaking the neglected survey if and when it is funded (p. 15). Doing so and obtaining useful results will take many years and funding remains uncertain. Bee survival and health cannot wait. This is underscored by the alarming, albeit non-comprehensive, data EPA already possesses on extensive clothianidin-caused bee kills, discussed in the previous section, which again are the tip of the iceberg. Immediate steps are needed to mitigate this threat.

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<sup>66</sup> *USDA's Response to Colony Collapse Disorder*, Audit Report 50099-0084-HY, USDA Office of Inspector General (2012).

## VI. Regulatory History of Clothianidin

### A. Clothianidin's Conditional Registration

The U.S. regulatory history surrounding clothianidin is different from that in Europe and shows a disturbing pattern. In February 2003, EPA issued a risk assessment for clothianidin seed treatment for corn and canola.<sup>67</sup> EPA scientists raised serious concerns about the compound in that document, citing France's experience with the similar neonicotinoid pesticide, imidacloprid, as cause for proceeding with caution.<sup>68</sup> The EPA scientists also called for a field test evaluating clothianidin's environmental hazards *prior* to registration, specifically citing harm to pollinators as the reason for concern:

*The possibility of toxic exposure to nontarget pollinators through the translocation of clothianidin residues that result from seed treatment (corn and canola) has prompted EFED [Environmental Fate and Effects Division] to require field testing that can evaluate the possible chronic exposure to honey bee larvae and queen. In order to fully evaluate the possibility of this toxic effect, a complete worker bee life cycle study must be conducted, as well as an evaluation of exposure and effects to the queen.*<sup>69</sup>

Less than two months later, in an Addendum to the Risk Assessment, EFED reversed from this position, recommending conditional registration while Bayer arranged for the required chronic exposure study.<sup>70</sup> Thus, in contrast to its prior memorandum, EPA decided it would allow the nationwide sale and use of clothianidin while Bayer arranged for the very study necessary to determine whether EPA's decision would be a grave mistake. EPA provided no reason for its reversal; it merely prefaced the change with "after further consideration...".<sup>71</sup> Nonetheless, even the second memorandum confirmed **EPA determined a study evaluating the long term toxicity to pollinators was necessary as a condition for registration.**<sup>72</sup> This determination made the study of the impacts on the honey bee life cycle a "core" requirement for registration.

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<sup>67</sup>Memorandum: Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola, PC Code 044309, EPA Environmental Fate and Effects Division (Feb. 20, 2003), *available at* [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>68</sup>*See id.* at 4.

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

<sup>70</sup>Memorandum: Addendum Referring to EFED's Risk Assessment on Clothianidin Use as a Seed Treatment on Corn and Canola 2 (PC 044309), EPA Environmental Fate and Effects Division, (Apr. 10, 2003) (hereinafter "EPA Memo, April 2003"); *see also* See Clothianidin Fact Sheet, *supra* note 20.

<sup>71</sup>EPA Memo, April 2003, at 2.

<sup>72</sup>*Id.* at 1.

**B. Bayer's Fatally Flawed Field Study**

Bayer was initially given until December **2004** to complete the study as a condition for registration.<sup>73</sup> At the outset, EPA's decision to allow sale and use of clothianidin immediately on the condition that Bayer eventually complete the required study provided Bayer with a perverse incentive: rather than completing the study promptly according to established deadlines, Bayer could bolster its clothianidin sales by delaying the study for as long as possible. (As EPA was later to find out, reliance on registrant-supplied data can be a flawed process from the outset due to the registrant's conflict of interest.) The final protocols and methodology for this study were not established until March **2004**.<sup>74</sup> Bayer requested, and EPA granted, a retroactive extension of its conditional registration to complete the required field study by May **2005**, although EPA stated it would push the deadline further out if accurate data could not be produced that season.<sup>75</sup>

In addition to rewarding Bayer for dragging its feet, EPA approved protocols for the study that were so far removed from reality that, even once completed, the study was incapable of detecting the environmental impacts it purported to evaluate. For example, despite the facts that: (1) corn is visited by honey bees and bumble bees, (2) the vast majority of U.S. use for clothianidin is on corn seed (grown on approximately 90 million acres<sup>76</sup>), and (3) canola is a minor crop in the United States (grown on fewer than one million acres), EPA nevertheless permitted Bayer to conduct the field test in canola only.<sup>77</sup> Moreover, despite the fact that the purpose of a field study is to evaluate impacts based on representative crops grown in the United States that are treated with the pesticide,<sup>78</sup> EPA permitted Bayer to conduct the study in Canada, rather than in the United States where the more relevant agronomic field conditions and cultivation practices were present.<sup>79</sup> Finally, the study design virtually guaranteed very few of the honey bees studied would actually forage in the canola treated with clothianidin, resulting in observations of minimal harm to them. Four colonies of bees were set in the middle of just *one*

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<sup>73</sup> *Id.* at 2.

<sup>74</sup> Review of Bayer CropScience's Draft Protocol of a Honey Bee Field Study - Poncho 600 (264-789) [Clothianidin (044309), D2953 181], EPA EFED, (Mar. 11, 2004), *available at* [http://grist.files.wordpress.com/2010/12/memo\\_3.pdf](http://grist.files.wordpress.com/2010/12/memo_3.pdf).

<sup>75</sup> *Id.* at 2.

<sup>76</sup> USDA Statistics Board *Acreage* report, *supra* note 18.

<sup>77</sup> Review of Bayer CropScience's Draft Protocol, *supra* note 74, at 3-5.

<sup>78</sup> Ecological Effects Test Guidelines: Field Testing for OPPTS 850.3040 Pollinators, EPA Office of Prevention, Pesticides and Toxic Substances (Apr. 1996), *available at* [www.epa.gov/ocspp/pubs/frs/publications/OPPTS\\_Harmonized/850\\_Ecological\\_Effects\\_Test\\_Guidelines/Drafts/850-3040.pdf](http://www.epa.gov/ocspp/pubs/frs/publications/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Drafts/850-3040.pdf).

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

hectare (2½ acres) of treated canola, while the bees were free to forage over thousands of surrounding acres in bloom with untreated canola.<sup>80</sup>

This Canadian canola study (hereinafter, “Cutler and Scott-Dupree 2007”<sup>81</sup>) provided no relevant data for assessing the likely impact that the approximately 90 million U.S. acres of corn treated with clothianidin are having on honey bees. Despite these deficiencies, in November 2007, after the untested clothianidin had been applied in U.S. fields for four growing seasons, EPA categorized this study as “Acceptable” for the purposes of the condition on clothianidin’s registration.<sup>82</sup>

### C. EPA’s 2010 Re-Review of Bayer’s 2007 Study

In November 2010, EPA conducted a “re-review” of the Cutler and Scott-Dupree 2007 study as part of a new use assessment for clothianidin seed treatment on mustard seed and cotton.<sup>83</sup> (EFED scientists routinely reevaluate previously submitted studies to determine whether the information remains relevant or useful.) The EFED scientists doing this reevaluation determined the field study was “Invalid,” due to design and methodological errors.<sup>84</sup> In an apparent effort to salvage some use for the study, EPA subsequently revised its opinion and reclassified the Cutler and Scott-Dupree 2007 study as “Supplemental.”<sup>85</sup> This reclassification notwithstanding, EPA did not change its crucial determination for purposes of this Petition that this study no longer satisfied the field study requirement. Here is what EPA said:

*[D]eficiencies were identified that render the study supplemental. It does not satisfy 850.3040, and **another field study is needed** to evaluate the effects of clothianidin on bees through contaminated pollen and nectar. Exposure through contaminated pollen and nectar and potential toxic effects therefore remain an uncertainty for pollinators.*<sup>86</sup>

As of March 2012, more than 16 months after EPA’s 2010 downgrading of the Cutler and Scott-Dupree 2007 field study, Bayer still has not re-submitted the required field study

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<sup>80</sup> *Id.*

<sup>81</sup> G. Christopher Cutler & Cynthia D. Scott-Dupree, *Exposure to Clothianidin Seed-Treated Canola Has no Long-Term Impact on Honey Bees*, 100 J. ECON. ENTOMOLOGY 765 (2007).

<sup>82</sup> Memorandum: Review of Data Package DP336888 for Clothianidin 4, PC Code 044309, EPA (Nov. 16, 2007).

<sup>83</sup> EPA November 2010 Memorandum, *supra* note 32.

<sup>84</sup> See Memorandum: Reclassification of MRID 46907801/46907802 Data Package 336888 for Clothianidin 1, PC Code 044309, EPA (Dec. 22, 2010).

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

<sup>86</sup> EPA November 2010 Memorandum, *supra* note 32, at 2 (emphasis added).

complying with guideline 850.3040 and assessing the long-term toxicity of clothianidin on honey bees. In short, **Bayer still has neither provided the outstanding data nor complied with the condition for clothianidin’s registration, which was to have been completed by December 2004.** Nonetheless, clothianidin retains its registration status and EPA has approved its use on more than 30 crops as well as ornamental, turfgrass and structural applications.<sup>87</sup> Shockingly, EPA still has not assessed its effects on bees **eight years later.**

#### **D. EPA’s Endangered Species Act Violation**

Congress enacted the ESA, in part, to provide a “means whereby the ecosystems upon which endangered species and threatened species depend may be conserved.” 16 U.S.C. § 1531(b). When a species has been listed as threatened or endangered under the ESA, all Federal agencies – including EPA – must ensure that their programs and activities are in compliance with the ESA. When EPA first conditionally registered clothianidin for use on corn it recognized ESA compliance would be necessary:<sup>88</sup>

*Clothianidin is expected to present acute and/or chronic toxicity risk to endangered/threatened birds and mammals via possible ingestion of treated corn and canola seeds. Endangered/threatened non-target insects may be impacted via residue laden pollen and nectar. The potential use sites cover the entire U.S. because corn is grown in almost all U.S. states.*

Based on the admittedly clearly foreseeable and widespread effects, consultation with the Fish and Wildlife Service and/or National Marine Fisheries Service was necessary to ensure that EPA’s approval of clothianidin did not jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat of these species, under 16 U.S.C. §1536(a)(2) (known as “Section 7(a)(2)”). EPA has frankly admitted that it has not complied with Section 7(a)(2) to date. Despite having allowed clothianidin-based products to be used across now what amount to many tens of millions of acres

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<sup>87</sup> See Appendix A for the approved uses of clothianidin products; note that Petitioners cannot be certain Appendix A includes every such product and approved use; EPA must determine that.

<sup>88</sup> Clothianidin Fact Sheet, *supra* note 20, at 16.



annually, in almost 30 different formulations, EPA's recent Registration Review Problem Formulation document admits:<sup>89</sup>

*The Agency has not conducted a risk assessment that supports a complete endangered species determination for clothianidin. The ecological risk assessment planned during registration review will allow the Agency to determine whether clothianidin's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service and/or National Marine Fisheries Service (the Services), as appropriate.*

This is not an academic exercise; the ESA is a strong, proactive law that EPA has treated lightly. More than 15 ESA-listed insects, ranging from beetles to butterflies to grasshoppers and other taxa, are potentially directly affected now by clothianidin-based products.<sup>90</sup> The 2010 Risk Assessment for mustard seed and cotton uses admits as much:<sup>91</sup>

*[I]nformation from standard tests and field studies, as well as incident reports involving other neonicotinoid insecticides (e.g. imidacloprid) also suggest the potential for long term toxic risk to honey bees and other beneficial insects.*

Despite the "long term toxic risk," EPA has not even made the basic, required formal determination as to how clothianidin "may effect" any of the ESA-listed species more than nine years after its conditional registration, much less consulted on the key ESA action-forcing determination as to whether broad use of the compound "jeopardizes" the survival of these species. Harmful effects on many non-insect ESA-listed species are also foreseeable, based on

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<sup>89</sup> Registration Review: Problem Formulation for the Environmental Fate and Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments of Clothianidin, EPA Office of Chemical Safety and Pollution Prevention (2011).

<sup>90</sup> A non-exhaustive list shows 18 threatened or endangered insects that clothianidin may affect: American burying beetle (*Nicrophorus americanus*); Behren's fritillary (or Behren's silverspot) (*Speyeria zerene behrensii*); Callippe silverspot (*Speyeria callippe callippe*); Delhi Sands flower-loving fly (*Rhaphiomidas terminatus abdominalis*); Fender's blue (*Icaricia icarioides fender*); Hine's emerald dragonfly (*Somatochlora hineana*); Karner blue (*Plebejus melissa samuelis*); Kern primrose sphinx moth (*Euproserpinus euterpe*); Lange's metalmark (*Apodemia mormo langei*); Mitchell's satyr butterfly *Neonympha mitchellii mitchelli*; Myrtle's silverspot (*Speyeria zerene myrtleae*); Northeastern beach tiger beetle (*Cicindela dorsalis dorsalis*); Ohlone tiger beetle (*Cicindela ohlone*) Quino checkerspot butterfly (*Euphydryas editha quino*); Salt Creek tiger beetle (*Cicindela nevadica lincolniana*); San Bruno elfin (*Callophrys mossii bayensis*); Schaus swallowtail (*Papilio aristodemus ponceanus*); Zayante band-winged grasshopper (*Trimerotropis infantilis*). This list likely will need updating as more species are regularly added and numerous "Candidate" species await further action, including native bees.

<sup>91</sup> EPA November 2010 Memorandum, *supra* note 32, at 52.

the many declines of insectivorous birds documented in Europe due to neonicotinoid use.<sup>92</sup> EPA has not made the required “effects” determinations or consulted for them either.

The documents suggest EPA is seeking to paper over various inadequate forms of “compliance” that fall far short of actually making biologically-based “effects” determinations and doing the consultations that are mandated under Section 7(a)(2), not optional. Yet, elsewhere the agency admits its own violations. At Appendix H of the 2011 Registration Review Problem Formulation, EPA outlines the need for four studies, on “Pollinator Larval Toxicity”; “Pollinator Laboratory Chronic Feeding”; “Residues in Pollen and Nectar/ Field Residue Analysis”; and (once again) the long-missing “Field Test for Pollinators”. For each of those studies, the agency states (emphasis added)<sup>93</sup>:

*EPA is required by section 7(a)(2) of the ESA to ensure that any action it authorizes or takes “...is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction of or adverse modification of critical habitat” and to use the “best scientific data available” in carrying out this obligation. The data EPA intends to call in are necessary to inform the determination required by the ESA as to whether **continued registration** of a pesticide is not likely to jeopardize the species or its critical habitat. The lack of these data will limit the flexibility that the agency and registrants have in **coming into compliance with the ESA** and could result in use restrictions which are unnecessarily severe. In addition, the lack of these data may result in assumed risk and potential mitigation of clothianidin formulations under FIFRA.*

The statement’s focus on “continued registration” and “coming into compliance with the ESA” entirely begs the question of complying with the ESA before approving the pesticide, which the agency did not do, and not after it has approved clothianidin. EPA’s attempts to do *post hoc* Section 7(a)(2) “compliance” are inadequate and clearly violate the ESA.

#### **E. Clothianidin’s Rejection by New York State**

The rejection of clothianidin is not limited to prominent European nations. In 2005, the New York State Department of Conservation advised Bayer CropScience regarding the withdrawal of its application for “Poncho 600,” with the active ingredient clothianidin, stating:<sup>94</sup>

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<sup>92</sup> Tennekes, *supra* note 45.

<sup>93</sup> EPA Registration Review: Problem Formulation, *supra*, note 89, App. H.

<sup>94</sup> Letter from NY State Dep’t of Env’tl. Conservation to Bayer CropScience, *available at* [http://pmep.cce.cornell.edu/profiles/insect-mite/cadusafos-cyromazine/clothianidin/clothianidn\\_wth\\_1105.pdf](http://pmep.cce.cornell.edu/profiles/insect-mite/cadusafos-cyromazine/clothianidin/clothianidn_wth_1105.pdf).

*Based on the high toxicity of clothianidin and the potential long-term chronic effects to honey bees, environmental persistence, possible role as an endocrine disrupter, chronic toxic risk to non-endangered and endangered small birds, and acute/chronic toxicity to non-endangered and endangered mammals, Poncho 600 should not be accepted for registration in New York State.*

In 2007, the same Department rejected the application by Arysta LifeScience to register four insecticide products (variations of Arena, Clutch and Celero) containing clothianidin.<sup>95</sup> The Department justified that rejection based on a lengthy list of “unmitigated concerns” about required information that the company did not submit, including adequate pollinator field studies. These actions underscore the weakness of EPA’s conditional registration of this pesticide, as a prominent State agency cannot depend on EPA’s risk management decisions.

#### **F. Critical New Studies on Exposure Pathways**

Both EPA’s analytical failures and the emergency nature of this Petition are underscored by two recent studies. They illustrate that if a valid, comprehensive pollinator field study, as EPA imposed as a condition of registration nine years ago, had actually been undertaken, it would have demonstrated unacceptable adverse effects. The first study is from the United States, the second is from Italy.

The first was published in January of 2012 and conducted by Christian Krupke of the Department of Entomology at Purdue University, as well as several Purdue colleagues, and Brian Eitzer of the Department of Analytical Chemistry at the Connecticut Agricultural Experiment Station (hereinafter “Krupke et al.”).<sup>96</sup> They reported on their efforts to determine how bees are being exposed to pesticides commonly applied to either corn seed before planting or to corn plants later in the season. Two major systemic insecticides are used to treat corn seed, clothianidin and thiamethoxam (the latter is metabolized to the former in bees and plants). The researchers collected samples from a variety of potential exposure routes in and near fields and analyzed them to determine whether pesticides were present. They sampled soil, pollen both collected by honey bees and directly from plants, neighboring dandelion flowers and both dead and healthy bees. They also checked waste products produced during planting.

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<sup>95</sup> Letter from NY State Dep’t of Env’tl. Conservation to Arysta LifeScience (July 17, 2007), *available at* [http://pmep.cce.cornell.edu/profiles/insect-mite/cadusafos-cyromazine/clothianidin/clothianidin\\_den\\_0707.pdf](http://pmep.cce.cornell.edu/profiles/insect-mite/cadusafos-cyromazine/clothianidin/clothianidin_den_0707.pdf).

<sup>96</sup> Krupke et al., *supra* note 2.

Corn is sown with tractor-drawn planters using a forced air/vacuum system and a perforated disc to pick up individual seeds and drop them into the planting furrow at the selected spacing. Kernels treated with neonicotinoids do not flow readily and may stick to one another, causing uneven plant spacing. To overcome this, white talc powder is added to seed boxes to reduce friction and ensure smooth flow. Much of this talc then is exhausted across entire fields during planting, either down with the seed or behind the planter and into the air via an exhaust fan. The researchers sampled this waste talc after planting to determine whether this material was contaminated with pesticides abraded from treated seeds. The waste is a mixture of the talc that has been in contact with treated corn kernels and minute pieces of the seeds.

Among the concerns confirmed by the study is that clothianidin is accumulating in the environment; Krupke et al. found that soil from fields that had not been treated for two years still tested positive for clothianidin residues. The authors state:

*Soil collected from areas near our test site revealed that neonicotinoid insecticide residues were present in all samples tested, with clothianidin occurring in each field sampled ... These results demonstrate that honey bees living and foraging near agricultural fields are exposed to neonicotinoids and other pesticides through multiple mechanisms throughout the spring and summer ... We show that bees living in these environments will forage for maize pollen and transport pollen containing neonicotinoids to the hive.*

They found corn (or maize) pollen was frequently collected by foraging honey bees while it was available; corn pollen comprised over 50% of the pollen collected, by volume.

During the spring planting period, the contaminated dust that arises from this soil may settle on flowers frequented by bees, or possibly on the insects themselves. Of potentially greater concern are the very high levels of neonicotinoids found in the talc that has been exposed to treated seed. The report states:

*The large areas being planted with neonicotinoid treated seeds, combined with the high persistence of these materials and the mobility of disturbed soil and talc dust, carry potential for effects over an area that may exceed the boundaries of the production fields themselves.*

Later in the season, when planting is largely complete, the researchers found bees collect corn pollen that contains translocated neonicotinoids and other pesticides from seed. Translocation of neonicotinoids into pollen has previously been reported for corn grown from

imidacloprid-treated seed, but Krupke et al. say the degree to which honey bees in their study gathered corn pollen was surprising:

*The finding that bee-collected pollen contained neonicotinoids is of particular concern because of the risks to newly-emerged nurse bees, which must feed upon pollen reserves in the hive immediately following emergence.*

Importantly, the amount of the pesticides found in and around corn fields was near the range known to kill honey bees. Also, dead bees collected near treated fields contained pesticide residues, whereas none of the apparently healthy, live bees sampled from the same locations had any detectable clothianidin. Lethal levels in pollen are an obvious concern, but sub-lethal levels are also worthy of study as even slight behavioral effects may impact how affected bees carry out important tasks such as brood rearing, orientation and communication.

Krupke et al. specifically compared their findings of clothianidin's impact on bees in and near treated corn fields to those of the Cutler and Scott-Dupree 2007 commissioned by Bayer in treated canola fields and stated (emphasis added):

*The levels of clothianidin in bee-collected pollen that we found are approximately **10-fold higher** than reported from experiments conducted in canola grown from clothianidin-treated seed.*<sup>97</sup>

It is now shown that the study upon which EPA relied - and which the agency later admitted it should not have - was performed in a crop field that had a **10-fold lower exposure level of clothianidin to bees via collected pollen than the levels found in and near treated corn fields**. EPA must fully consider the Krupke et al. study, especially on the issue of there being an "imminent hazard" justifying suspension.<sup>98</sup>

In sum, Krupke et al. show that, contrary to EPA's initial assumption that the substance stays confined in the treated plants themselves when the agency approved clothianidin as a seed treatment product and approved its labeling, the material is broadcast over the soil of almost all

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<sup>97</sup> Krupke et al., *supra* note 2, citing to Cutler & Scott-Dupree, *supra* note 81.

<sup>98</sup> The Administrator is requested to take note of language in a very recent U.S. Circuit Court of Appeals decision, *Sierra Club v. EPA*, \_\_\_ 9th Cir. 567, No. 10-71457, (Jan. 20, 2012). This case involved a successful challenge to EPA's decisionmaking under the Clean Air Act about a State Implementation Plan; the scientific questions were about ozone levels. The Plaintiffs' claim was EPA failed to consider the most current ozone data. While based on a different context than presented in this Petition, the agency's obligations are the same with respect to reasoned decisionmaking. The Court stated, at 590-91:

*[W]e should not silently rubber stamp agency action that is arbitrary and capricious in its reliance on old data without meaningful comment on the significance of more current compiled data. We hold that EPA's failure to even consider the new data and to provide an explanation for its choice rooted in the data presented was arbitrary and capricious.*

of America's extremely vast corn acreage and is scattered over neighboring lands. EPA's recent assessments admit the "terrestrial ecosystems potentially at risk" from treated fields "include other cultivated fields, fencerows, hedgerows, meadows, fallow fields or grasslands, woodlands, riparian habitats, and other uncultivated areas."<sup>99</sup> Being persistent, and repeatedly spread each planting season, clothianidin dust and contamination from treated seeds create an essentially perennial exposure situation for bees and other beneficial insects across America, everywhere corn is grown commercially (in almost every State), and at toxicity levels roughly ten-fold higher than EPA had been led to believe by Bayer's discredited 2007 field study.

The second recent study was published in January 2012 and conducted by eight scientists at the University of Padova, Italy (hereinafter "Tapparo et al.").<sup>100</sup> They quantitatively measured the previously underestimated pathway of environmental exposure of honey bees to clothianidin (Poncho) as well as the other neonicotinoids, namely, the atmospheric emission of particulate matter by standard pneumatic corn seed planting machines (also used in Krupke et al.). Their results show that the environmental release of particles containing neonicotinoids can produce high exposure levels for bees, with lethal effects consistent with the colony loss phenomenon observed by beekeepers.

They also tested different configurations of the planter exhaust pipes, including modifications aimed at reducing emissions of the neonicotinoids. They concluded these various exhaust modifications "have a limited effect on both the factor emission and the effective bee contamination".

EPA's communications on reported, neonicotinoid-caused, mass bee kills regularly blame faulty planter exhaust systems. But, the findings of Tapparo et al. neutralize that blame-shifting, as exhaust modifications only have a "limited effect". Krupke et al., who made very clear that they followed the insecticide label directions for use, confirm Tapparo et al. on the point that the toxic dust from planting the coated seeds will escape in any event, regardless of the label warnings, directions for use or other farming techniques that EPA may urge (but is in no position to mandate or enforce).

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<sup>99</sup> Memorandum: Revised Assessment for Clothianidin Registration of Prosper T400 Seed Treatment on Mustard Seed (Oilseed and Condiment) and Poncho/Votivo Seed Treatment on Cotton, PC Code 044309, EPA Environmental Fate and Effects Division (Dec. 2, 2010), at 21.

<sup>100</sup> Tapparo et al., *supra* note 2.

Tapparo et al. concluded by suggesting reforms, not just to preserve honey bees but also to protect broader ecosystems from this pervasive and increasing contamination source:

*This emission source of particles with acute toxic effects on bees (and on other insects too) is of concern for both apiculture and crop productions based on bee pollination. But it is also a widespread ecological problem that, in view of the worldwide increase in corn production partly promoted by government subsidies to renewable energy sources, and the consequent predictable exacerbation of the problem, should require a deeper analysis of the related agricultural policies.*

As Krupke et al., Tapparo et al., and a vast number of other studies and real-world experiences show, the effect of EPA's policies and decisions has been to imprudently expose vast numbers of America's beneficial insects to damaging toxin levels and not just in and near corn fields as clothianidin is approved for dozens of other uses. For the owners of honey bees that are privately held, the economic and workload impacts are devastating (see Table 1). Many commercial beekeepers have gone out of business, filed for bankruptcy or both.

## **STATEMENT OF LEGAL GROUNDS**

### **VII. Allowing Sale and Use of Clothianidin Without a Field Study Required for its Conditional Registration is Arbitrary and Capricious; Immediate Suspension is Required**

Well over a year has passed since EPA finally acknowledged it had improperly relied on the Cutler and Scott-Dupree 2007 study as satisfying the outstanding data requirement that the agency made a condition of clothianidin's registration. Clothianidin thus exists in a regulatory limbo in which EPA continues to allow its sale and use even though Bayer failed to meet a crucial condition imposed back in 2003.

A conditional registration is authorized under three circumstances:

- EPA may conditionally register a pesticide if “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,”<sup>101</sup>

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<sup>101</sup> 7 U.S.C. § 136a(c)(7)(A)(i).

- EPA may conditionally amend a pesticide’s registration “to permit additional uses of such pesticide,”<sup>102</sup>
- EPA may conditionally 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” but “*only if* [EPA] determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.”<sup>103</sup>

Only the last of these circumstances—generating data for a newly-developed pesticide—even arguably applied in 2003, but none of these circumstances apply in 2012. Accordingly, maintaining the registration of clothianidin violates FIFRA for at least two reasons.

First, EPA no longer has statutory authorization to maintain the registration of clothianidin because of the outstanding data. By its own terms, FIFRA does not allow conditional registrations to go on indefinitely. A conditional registration may only last for a period “reasonably sufficient” to generate the outstanding data necessary for unconditional registration. **Nine years far exceeds the amount of time “reasonably sufficient” to generate those data.** Even the 16 months since EPA’s 2010 downgrade of Bayer’s 2007 study is more than “reasonably sufficient” time for Bayer to have conducted the missing pollinator field study that complies with guideline 850.3040. Because much more than a reasonably sufficient time has passed for Bayer to produce the missing data required for conditional registration, EPA now lacks authority to prolong clothianidin’s registration; immediate suspension is required. EPA must require completion of the missing field tests using actual commonly-applied mixes.

Second, EPA has not determined and, given the state of independent peer-reviewed scientific research, it could not reasonably determine, that clothianidin will not have unreasonable adverse effects on the environment if the compound’s registration is allowed to continue. Nor can EPA determine that maintaining its registration is in the public interest. Indeed, EPA itself admitted in an official memorandum in 2010 that clothianidin may have significant adverse impacts on pollinators:<sup>104</sup>

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<sup>102</sup> *Id.* § 136a(c)(7)(B).

<sup>103</sup> *Id.* § 136a(c)(7)(C); *Hardin v. Jackson*, 625 F.3d 739, 740 (D.C. Cir. 2010) (dismissal affirmed on other grounds) (emphasis added).

<sup>104</sup> *See, e.g.*, EPA November 2010 Memorandum, *supra* note 32, at 2.



*[I]nformation from standard tests and field studies, as well as incident reports involving other neonicotinoids insecticides (e.g., imidacloprid) suggest the potential for long term toxic risk to honey bees and other beneficial insects.*

In sum, EPA is maintaining conditional registration for clothianidin “without making the findings required by law for such a registration and contrary to the statutory terms which preclude a conditional registration.”<sup>105</sup> The agency’s actions and inactions, as a matter of law, are arbitrary, capricious and contrary to the mandates of FIFRA. The agency has severely harmed the Petitioners’ interests in maintaining healthy populations of honey bees and other beneficial insects, as well as in preventing further resulting economic and ecosystem damage. Immediate suspension of clothianidin’s registration is the required remedy.

### **VIII. Studies Linking Neonicotinoids to Declining Honey Bee Populations and Health Justify Immediate Suspension of Clothianidin’s Registration**

In addition to the law, the weight of the science justifies suspension as shown in this Petition and in the State of the Science report in Appendix B, because clothianidin use has been shown to be a likely factor in the abnormal declines in honey bee populations. This pesticide, in addition to its lethal effects, also affects bee behavior and cognition in ways that compromise the overall health of colonies.

To reiterate, honey bees are social insects that rely heavily on a certain level of memory, cognition and communication to coordinate activities essential for their survival.<sup>106</sup> Chronic ingestion of neonicotinoids damages foraging behavior, overall mobility and the communication that allows these social insects to coordinate their activities.<sup>107</sup> Neonicotinoid pesticides also have several other indirect effects on honey bees, such as premature shifts in hive roles.<sup>108</sup> They can impair honey bees’ medium-term olfactory memory and associative learning abilities, which

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<sup>105</sup> *Hardin, supra* note 103, 625 F.3d at 741.

<sup>106</sup> Judy Y. Wu et al., *Sub-Lethal Effects of Pesticide Residues in Brood Comb on Worker Honey Bee (Apis mellifera) Development and Longevity*, 6 PLoS ONE e14720 (2011).

<sup>107</sup> See, e.g., Piotr Medrzycki et al., *Effects of Imidacloprid Administered in Sub-Lethal Doses on Honey Bee Behaviour. Laboratory Tests*, 56 Bulletin of Insectology 59 (2003), available at [www.bulletinofinsectology.org/pdfarticles/vol56-2003-059-062medrzycki.pdf](http://www.bulletinofinsectology.org/pdfarticles/vol56-2003-059-062medrzycki.pdf); E.C. Yang et al., *Abnormal Foraging Behavior Induced by Sub-Lethal Dosage of Imidacloprid in the Honey Bee (Hymenoptera: Apidae)*, 101 J. OF ECON. ENTOMOLOGY 1743 (2008).

<sup>108</sup> Wu et al. *supra* note 6 at 1–2; see also Yang et al., *supra* note 107.

foraging honey bees rely on, *inter alia*, to find their way back to the hive.<sup>109</sup> Impairment of these functions is consistent with the absence of dead bees inside the hives in reported CCD cases.

As indicated above, recent studies also confirm neonicotinoids interact with common bee pathogens and parasites, making the bees more vulnerable to the deadly effects of both. Studies reveal that neonicotinoids weaken honey bees so they are more vulnerable to mortality from gut parasites like *Nosema* spp. and vice versa.<sup>110</sup> The combination of the increasing prevalence of *Nosema* spp. with high pesticide content in beehives can create synergistic effects, contributing further to colony depopulation.

In sum, peer-reviewed studies demonstrate neonicotinoids including clothianidin have the potential to wreak havoc on U.S. pollinators. Due to uncontrollable drift and blowing of contaminated dust and soils, this includes vast acreage of lands neighboring the fields where the pesticide is intentionally applied. EPA also has approved it in various formulations for use on ornamental and landscaping plants and as trunk injections to trees that are foreseeably visited by many species of bees and other beneficial insects, including threatened and endangered species (see Appendix A on Approved Uses). As shown in this Petition and bolstered by the State of the Science report, the levels of clothianidin applied through its spectrum of approved uses pose significant acute and chronic risks. Thus, the compound clearly meets EPA's own criteria for Special Review in Title 40 CFR 154 Subpart A:

*§ 154.7 Criteria for initiation of Special Review.*

*(a) The Administrator may conduct a Special Review of a pesticide use if he determines, based on a validated test or other significant evidence, that the use of the pesticide (taking into account the ingredients, impurities, metabolites, and degradation products of the pesticide):*

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*(3) May result in residues in the environment of nontarget organisms at levels which equal or exceed concentrations acutely or chronically toxic to such organisms, or at levels which produce adverse reproductive effects in such organisms, as determined from tests conducted on representative species or from other appropriate data.*

*(4) May pose a risk to the continued existence of any endangered or threatened species designated by the Secretary of the Interior or the Secretary of Commerce under the Endangered Species Act of 1973, as amended.*

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<sup>109</sup> Decourtye et al., *supra* note 4; see also Alex Decourtye et al., *Effects of Imidacloprid and Delamethrin on Associative Learning in Honeybees Under Semi-Field and Laboratory Conditions*, 57 *ECOTOXICOLOGY & ENVTL. SAFETY* 410 (2004).

<sup>110</sup> Pettis et al., *supra* note 46; Vidau et al., *supra* note 47.

*(6) May otherwise pose a risk to humans or to the environment which is of sufficient magnitude to merit a determination whether the use of the pesticide product offers offsetting social, economic, and environmental benefits that justify initial or continued registration.*

In addition to the fatal procedural and legal defects in clothianidin's conditional registration, the weight of the current science on its adverse effects mandates immediate suspension of its registration and its removal from the market and the environment.

### **IX. Immediate Suspension is Warranted Under 7 U.S.C. § 136d**

EPA also has more than enough evidence and cause to make the determinations necessary to suspend registration of clothianidin under 7 U.S.C. § 136d.

#### **A. Cancellation Proceedings are Required or at Least Warranted**

7 U.S.C. § 136d(e)(1) provides:

*The Administrator shall issue a notice of intent to cancel a registration issued under section 136(a)(c)(7) of this title if ... the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed.*

By using the word “shall,” in contrast to the use of “may” in section 136d(b), Congress imposed on EPA a *mandatory* duty to initiate cancellation proceedings when a registrant has, for example, effectively extended its conditional registration by delaying its own compliance with a condition.

Based on the unreasonable delays by Bayer, a determination by EPA that clothianidin did not now conform to the criteria for cancellation under section 136d(e)(1) would be contrary to FIFRA and arbitrary and capricious. Alternatively, even if EPA rejects this interpretation of FIFRA, initiation of cancellation proceedings is still warranted under 7 U.S.C. § 136d(b)(1). That section states the Administrator may initiate cancellation proceedings if she determines that a pesticide “generally causes unreasonable adverse effects on the environment.” As discussed above, the strong weight of the evidence shows that recent and widespread use of clothianidin is causing unreasonable adverse effects.

**B. Clothianidin Presents an “Imminent Hazard”; Immediate Suspension is Warranted**

Every year clothianidin remains in use, the viability of pollinator populations deteriorates more. After at least six consecutive winters resulting in significant, abnormal, die-offs of honey bees, their populations across the United States could collapse. Economic losses from the collapse of U.S. bee colonies would measure in the tens of billions of dollars.<sup>111</sup> The ecological impacts of lost pollinators also would be devastating and perhaps irreparable. With the stakes so high, and with America’s beekeepers and honey producers already suffering severe losses, EPA cannot reasonably interpret FIFRA to require putting off suspension until this hazard somehow becomes *more* imminent.

**X. Clothianidin’s Inadequate Labeling Renders It Misbranded; a Stop Sale, Use or Removal Order is Required**

Section 2(q)(1)(F) of FIFRA states a pesticide is “misbranded” if its labeling lacks “directions for use” which are “adequate to protect health and the environment.”<sup>112</sup> It is unlawful to sell or distribute a misbranded pesticide.<sup>113</sup> Section 13(a) authorizes EPA to issue an order prohibiting the sale, use or removal of any pesticide or device whenever there is reason to believe its use would violate any provision of FIFRA.<sup>114</sup>

Clothianidin seed treatment products are misbranded because their labeling lacks directions for use adequate to protect against devastating harm to beneficial insects, particularly honey bees and including Federally-listed threatened and endangered species.<sup>115</sup> The Krupke et al., Tapparo et al. and other studies show that farmers are broadcasting it far and wide via many pathways of exposure for which there is no foreseeable likelihood that label warnings could mitigate the exposure of unintended targets. (This is particularly the case because label warnings are very rarely enforced.) The researchers found that when corn seeds were treated with clothianidin according to the label guidelines it nevertheless became widespread across the agricultural landscape, including neighboring lands over which the user of the pesticide typically

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<sup>111</sup> *E.g.*, Johnson, *supra* note 14, at 1.

<sup>112</sup> 7 U.S.C. § 136(q)(1)(F); *see also id.* § 136(q)(1)(G) (pesticide is misbranded if its label lacks a warning adequate to protect health and the environment).

<sup>113</sup> 7 U.S.C. § 136j(a)(2)(I).

<sup>114</sup> *Id.* § 136k(a).

<sup>115</sup> Appendix C: Sample Labels of Pesticides Containing Clothianidin.

lacks any means of controlling the harmful effects and no modifications to the planting machinery have been shown to significantly reduce it.

Current labeling for clothianidin seed treatments, such as Poncho 600 and Poncho Beta (see Appendix C), lack any warnings or directions for use as to how pollinators and other beneficial insects, including threatened and endangered species, actually are to be protected. EPA should determine that no label warning or directions could provide adequate protection based on the available evidence.

Indeed, the agency's regulatory documents contain several assertions by EPA scientists to this effect. EFED's entomologist, Allen Vaughan, asserted in an official Memorandum that applied to cucurbits and fruiting vegetables, but also applies more generally, that:<sup>116</sup>

*Because of the extreme persistence of clothianidin in soil environments (half-life = 148 to 1,155 days) and the potential for translocation of this systemic pesticide to pollen and nectar, **EFED does not believe that precautionary bee labeling language will effectively mitigate hazards** from soil treatment or seed application of clothianidin to cucurbits and fruiting vegetables ...mitigation measures have not been developed to protect bees from exposure to soil-applied systemic pesticides.*

It would be specious to suggest that the inability of precautionary labeling language to mitigate the environmental hazards of clothianidin is limited to a "special case" of cucurbits and fruiting vegetables. The degree of hazard is many orders of magnitude greater for corn seed treatment, such as Poncho 600, planted now across tens of millions of acres, than for the relatively minor acreage of cucurbits and fruiting vegetables, and just as incapable of mitigation by label warnings or use directions. EPA lacks any basis to assert that unenforceable exhortations to farmers actually will protect bees from the risks; again, the evidence from the recent field studies is that even if farmers heed those exhortations, and even if their planter exhausts are modified, it would not significantly reduce the harmful effects.

Foliar applications of the products also are misbranded; many have label language warning against use when bees are "actively visiting" the plants even though the field half-life of clothianidin can be 25 days or more. This defect also applies to clothianidin-based products sold to landscapers and homeowners in retail stores across the nation. Huge volumes of these

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<sup>116</sup> Allen W. Vaughan, Clothianidin Registration of New Products and New Uses of Sepresto 75WS and PROCEED™ OPTIMUM: Addendum to Address Mitigation of Bee Hazard, Env'tl. Risk Branch, EFED, EPA (2009); emphasis added.

products reportedly are sold and the rates recommended on the container labels can be as high as 40 times the rate allowed for agricultural applications, resulting in lethal doses. Yet, these products can be sold without any bee hazard statement. Compared to crop uses, this entire use area is “flying under the radar” of EPA control.

These facts, in view of the Vaughan admission, show the labels on clothianidin products violate FIFRA. The statute is explicit and requires that EPA find a product is misbranded if:<sup>117</sup>

*(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 136a(d) of this title, are adequate to protect health and the environment; [or]*

*(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 136a(d) of this title, is adequate to protect health and the environment.*

As indicated, based on the above language, EPA recently issued a stop sale, use or removal order for a comparable herbicide based on the label because of similarly undisclosed impacts on non-target organisms. EPA registered DuPont’s broadleaf herbicide Imprelis in 2010. In the course of investigation, the agency discovered that the approved labels did not warn about potential damage to trees when the product was used in accordance with the label directions. EPA therefore determined Imprelis was misbranded because it lacked: “*directions for use and/or warning or caution statements that are adequate to protect the environment, namely certain species of trees.*”<sup>118</sup> Accordingly, the agency ordered DuPont to “*immediately cease the sale, use or removal of Imprelis products.*”<sup>119</sup>

The facts that led EPA to issue the order for Imprelis are indistinguishable from the facts here, namely, that clothianidin product labels lack warnings or directions for use adequate to protect non-target insects, including Federally-listed threatened and endangered species. It is irrelevant that in the Imprelis case the organisms being killed were large visible trees and in this case the organisms being killed are small insects that may go unnoticed until they are gone.

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<sup>117</sup> 7 U.S.C. § 136(q); emphasis added.

<sup>118</sup> EPA Region III, *In re E.I. du Pont de Nemours & Co.*, Stop Sale, Use, or Removal Order, Docket No. FIFRA-03-2011-0277SS (Aug. 11, 2011) ¶ 22.

<sup>119</sup> *Id.* ¶ 24 (emphasis in original).

Accordingly, Petitioners request EPA to formally determine that clothianidin is misbranded and issue a stop sale, use or removal order on an emergency basis.

**XI. EPA's Actions Violate the Endangered Species Act.**

As indicated, EPA has violated Section 7(a)(2) of the ESA by failing to make the required "effects" determinations and failing to undergo consultation with the Services concerning clothianidin's impacts on native endangered and threatened species. EPA has in effect admitted these violations and it explicitly acknowledged the foreseeability of adverse effects on ESA-listed species back in 2003 when it first registered the compound. Petitioners request EPA to make the needed effects determinations and initiate and complete the required consultation process. The agency must suspend the continued use of clothianidin in the interim to make this ESA compliance meaningful and in accordance with the statute's requirements, otherwise clothianidin may continue to take listed threatened and endangered species without the required take authorization under the ESA and may degrade designated critical habitat.

**CONCLUSION**

If EPA does nothing the collapse of honey bee populations nationwide and severe damage to the Nation's agriculture, as well as to populations of native pollinators and other beneficial insects, and to the Petitioners' interests, are foreseeable. But, it is not too late. Taking the actions requested in this Emergency Petition can preserve these remarkable insects for future generations and prevent massive economic and ecological damage, but not if the actions are delayed for years.

For the foregoing reasons, Petitioners respectfully request EPA to promptly suspend the registration of clothianidin. Petitioners also request EPA to make a formal determination that clothianidin is misbranded because its labeling is inadequate and to issue a stop sale, use or removal order. In the alternative, Petitioners request EPA to initiate Special Review and cancellation procedures and suspend clothianidin's registration pending the outcome of those procedures. Clothianidin does not meet the burden under EPA's criteria to be "entitled" to continued registration per 40 CFR§ 154.5 on Special Review petitions.

In view of the emergency nature of this matter, the severity of the impacts the Petitioners are suffering and EPA's excessive delays to date in complying with FIFRA and the ESA and in resolving the concerns over clothianidin's environmental effects, the agency is urged to grant the requests in this Petition within **90 days** of its filing date. Failure to promptly resolve these matters will create a high likelihood of significant harm to the Petitioners, the public and the environment.

DATED this 20th day of March, 2012.

/s/ \_\_\_\_\_  
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## **TABLES**

Table 1. Beekeeper and Honey Producer Petitioners

Table 2. Environmental and Consumer Organization Petitioners

## **APPENDICES**

Appendix A - Approved Uses of Clothianidin

Appendix B – PANNA report: *Pesticides and Honey Bees – The State of the Science*

Appendix C - Sample Labels of Pesticides Containing Clothianidin



**Table 1. Beekeeper and Honey Producer Petitioners (27)**

**Jeff Anderson**, owner of California Minnesota Honey Farms (CMHF), is a commercial beekeeper residing in Oakdale, California and Eagle Bend, Minnesota. CMHF is a 3,000 hive commercial migratory beekeeping operation. Mr. Anderson has worked in this operation for 36 years and owned it for that last 15; experiences include an extensive fight over improper use of insecticides in Minnesota which over the course of 5 years killed 11,000 of his bee hives. This first hand exposure has mad him adept at identifying abnormal bee mortality attributed to pesticides as compared to 'normal' pest and pathogen caused mortality. Abnormal bee mortality again reared its head for CMHF in the form of excessive overwinter mortality starting in the spring of 2005. Another issue related to bee health which has worsened in subsequent years is a 'light' bee kill which appears to correlate with corn planting in Minnesota. The hives fail to build in a normal fashion during planting season. The appearance of these and other similar symptoms correlate directly with the introduction of clothianidin seed treatment in 2004 on agricultural crops in his area. In 2011, the spring issues included abnormally high queen mortality. Of the 3,000 hives first brought to Minnesota, 25% plus had to be re-queened. Even with this extra manipulation which in essence should have raised the spring count to 3750 hives, the season's abnormal mortality resulted in a spring 2012 count of 1800 hives; representing over 50% actual mortality.

**Manley and Linda Bigalk** are beekeepers near Cresco, Iowa, which is in northeastern Iowa near the Minnesota border. They have been commercial beekeepers for over 50 years. They are producers-packers and supply a grocery chain of about 110 stores in the region. They also are farmers. They are very concerned about clothianidin as it pertains to the honey industry, environment and to consumers of honey. Their bees have been stressed these last years. They don't have the vigor they used to; evidently their immune systems have been stressed. The Bigalks used to run about 1,400 hives and are down to 600 at present. They are replacing 30% of their bees each year and some years more. Things have dramatically changed as it used to be about 15%. They believe the systemic insecticides, neonicotinoids including clothianidin, have had an effect.

**Tim A. Brod** of Highland Honey Bees, LLC., is a commercial beekeeper residing in Boulder, Colorado. He has been involved with bees for over 40 years, and for the last 6 with a registered licensed commercial operation. For the past 5 years, he has been experiencing an increase in bee mortality and poor brood-queen dysfunction. Some years the die off is as high as 40%. This pattern of die off and brood illness is alarming and not sustainable for the bees or for the business. He believes his excessive die off and "illness," is at the least partially due to new generations of pesticides, particularly neonicotinoids, and specifically seed treatments using these chemicals. He is very disappointed by EPA's poor management and science regarding these chemicals, and its inadequate enforcement and education of applicators.

**Coalition4Bees** is a grassroots group of beekeepers whose members share the goal of educating themselves and others in Boulder County, Colorado, about the effects of systemic pesticides on honeybees, other pollinators, soils, and groundwater. The members of this organization have all seen excessive mortality of their colonies over the past several years. A large percentage of the agricultural lands in Boulder County are planted in corn, the majority of which is treated with the neonicotinoid pesticide clothianidin. The members of Coalition4Bees believe this pesticide is very toxic to bees and other pollinators. They are reasonably certain that a significant percentage of their bee mortality is linked to this pesticide, and they are extremely concerned that if its use continues to be permitted, the damage to the food supply and the ecosystem could be devastating.

**Craig Byer** is a commercial beekeeper in Huntington/Smithtown, New York. He serves as a board member on the American Apitherapy Society which uses the products of the hive to aid in overall health. He also runs a large pest control operation on Long Island and is fully aware of the detrimental effects on the environment of residual pesticides used to control insects. Because of persistent chemicals in the environment he has difficulty in maintaining his bee hives in a normal fashion. He is sure the use of clothianidin and other neonicotinoid pesticides has impacted the health of his bees. This is compounded by the lack of labels on those pesticides adequate to inform the applicators how to avoid harm to bees and as well an inadequate enforcement of the label requirements.

**Cynthia Cole** is a beekeeper and market gardener residing in Barnstable, Massachusetts. She has kept bees for four years for the purposes of collecting honey and for pollination, which is extremely important for her flower business. She is a member of the Barnstable County Beekeepers Association and Market Manager of the Mid-Cape Farmers Market. Overwintering mortality has been a problem for her. Losing hives is costly in terms of out-of-pocket expenses, time to restock the hive and lost honey production. She believes that this mortality, at least in part, is a result of exposure of her bees to neonicotinoid pesticides, including clothianidin.

**Ross Conrad**, is a commercial beekeeper residing in Middlebury, Vermont. He manages 50-60 hives for pollination, as well as honey and wax production. He has relied on honey bees for part or all, of his income since 1993. His experience includes: -- author of one of the central books on the subject of Natural/Organic Beekeeping (Natural Beekeeping: Organic Approaches to Modern Apiculture, Chelsea Green publishing 2007); -- author of dozens of articles on beekeeping for bee related journals and periodicals in the United States and abroad; -- has taught dozens of courses and led dozens of bee related workshops and presentations throughout North America for groups from 4 to 300; -- offers Natural/Organic Beekeeping consultation services; -- is recognized nationally as a leader in the area of Natural/Organic Beekeeping. The ongoing effects of excessive overwintering mortality and other excess losses other beekeepers are experiencing are of serious concern to Mr. Conrad as he does not want his operation to be impacted by chemicals toxic to honey bees that have not been improperly approved for the marketplace. The evidence indicating that honey bees become more susceptible to disease after exposure to sublethal doses of chemicals may be impacting his operation and it may be impacted more directly at some point in the future.

**James Doyle** is a commercial beekeeper residing in Bainbridge, Indiana. He currently has 32 hives for honey production, and pollination services, including 10 years in it. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees has damaged his operation with an average of a 30% loss of hives over winter, and a general failure to thrive. Worker loss is preventing the hive from growing, thus making them vulnerable to predation by other insects. This has caused him to buy replacement bees each spring and feed sugar to replace the honey that was not gathered in an effort to keep the hives alive. The hive splits he is able to do go to replace losses to his own apiary so he cannot expand his operation or sell bees for profit. This damage is believed to have at least partly resulted from neonicotinoid pesticides, including clothianidin.

**Steve Ellis** owns and operates Old Mill Honey Company, a migratory beekeeping operation with 2,300 hives of bees during the summer honey-producing season. The managed hives of honey bees in this business produce honey for market over the summer months in Minnesota, and paid pollination services in the winter and spring in California. He has over 35 years of experience as a beekeeper; over that period he has observed many incidents related to pesticide poisoning. Each pesticide poisoning incident affects hives of honey bees differently, depending on the route of exposure of the bees and the mode of

action of the specific chemical. Monetary damages done to managed honey bees can become very great including the costs of replacing killed bees, contaminated beeswax comb, lost honey production, and lost income from failure to perform contracted pollination services. Over the course of the last five to six years, he has observed a new type of bee kill: bees dying of pesticide poisoning in the early spring, at corn seeding time, and early dandelion bloom. Neighboring beekeepers also have been reporting this unusual occurrence. Fall and winter mortality have remained between 30 and 40% over this period in his operation. Clearly this level of losses is unsustainable. He keeps bees in west central Minnesota where corn and soybeans are increasingly the dominant crops. It is not possible to locate his bees away from these crops during the summer growing season.

**Adam French** runs Cox Honey Farms, Inc., a commercial beekeeping operation in Shelley, Idaho. The business has operated for over 70 years. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have at times crippled its operation. Excessive manpower and hours have been spent to regroup and bring colony counts back to normal. This damage is believed to have at least partly resulted from neonicotinoid pesticides, including clothianidin, in the environment where it has impacted their bees. This is made worse by the lack of labels on those pesticides adequate to inform the applicators how to avoid harm to bees and inadequate enforcement.

**Tim Fulton** is a sideline beekeeper with a small operation based in Kenosha, Wisconsin. He has kept bees for over 15 years and produces about 2,000 lbs. of honey annually that he sells at a farmers market and from his home. He is President of Wisconsin Honey Producers, Program Chair of Kenosha Racine Beekeepers, and a member of the American Federation of Beekeepers. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged his operation significantly. When Mr. Fulton first started keeping bees, he had a high 90% overwintering success rate. Over the last 5 to 6 years however, he has suffered consistent losses of 30-40%, and this only seems to be getting worse. Mr. Fulton's hives are located between flying distance of two golf courses. The damage to his operation is believed to have at least partly resulted from neonicotinoid pesticides, including clothianidin, in the environment where it has impacted his bees. He recognizes this is a complex issue, but believes that the EPA needs to be more responsible to the pollinator and beekeeper population, especially in light of the growing local food movement, which depends heavily on honeybees.

**David Hackenberg** is a commercial beekeeper residing in Lewisburg, Pennsylvania. He has been keeping bees for 49 years, through his family business Hackenberg Apiaries. His experience includes serving 12 years on the National Honey Board, President of the American Beekeeping Federation, and has served as Chair and Co-chair of the National Honey Bee Advisory Board. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged his operation. In 2006, he saw huge losses in a little less than three weeks. These disappearances coincided with neonicotinoid pesticides coming on the market. This damage is believed to have at least partly resulted from these pesticides, including clothianidin, in the environment where it has impacted his bees. This is believed to be compounded by the lack of labels on those pesticides adequate to inform the applicators how to avoid harm to bees and inadequate enforcement of the label requirements. He currently has about 3300 hives this spring. His annual losses have run 75-80%, or with continual protein feeding, they can be held closer to 60% losses, but both these levels are excessive.

**Paula L. Hendricks**, is a commercial beekeeper residing in Ellsworth, Ohio. She has been a beekeeper for approximately ten years producing honey, soaps, candles, and other products. Her experience includes Columbiana-Mahoning County Beekeepers Association and Ohio State Beekeepers Association, she is a past secretary of the Columbiana-Mahoning County Beekeepers Association. The ongoing effects of

excessive overwintering mortality and other excess losses of honey bees has damaged this operation in the way of lost profits, lack of honey production, and bee loss in the upward numbers of 50% in the years 2007, 2008, 2009, 2010 and 2011. Bees are very costly to replace. She has crop fields adjacent to her land; on the other side of the property is a golf course. Both rely heavily on pesticide and herbicide usage. Her damage is believed to have at least partly resulted from neonicotinoid pesticides, including clothianidin, in the environment where it has impacted his bees. This is believed to be compounded by the lack of labels on those pesticides adequate to inform the applicators how to avoid harm to bees and inadequate enforcement of the label requirements.

**Dr. Carl E. Korschgen** is a commercial beekeeper residing in Columbia, Missouri. He has been a beekeeper for 4 years and is steadily increasing his operation by about 10 hives each year with an expectation of up to 50 hives in the next few years. His experience includes 32 years as a supervisory research biologist for the U. S. Department of Interior (USFWS and USGS), a member of the Boone Regional Beekeepers Association for 4 years. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged his operation. Over the past two years he has lost about 40% of his hives over the winter period. This damage is believed to have at least partly resulted from neonicotinoid pesticides, including clothianidin, in the environment where it has impacted his bees. This is believed to be compounded by the lack of labels on those pesticides adequate to inform the applicators how to avoid harm to bees and inadequate enforcement of the label requirements. Further, in the Columbia, Missouri region, he and many acquaintances have witnessed a noticeable lack of native insects, especially many species of grasshoppers, over the past several years. They do not know the cause of these declines but are very concerned that these declines are attributing to the reduction of wildlife species such as bobwhite quail and wild turkeys.

**Dr. Daniel F. Mayer** is a commercial beekeeper residing in Hamilton, Montana. He has been a beekeeper since 1973 and maintains somewhat less than 100 colonies selling honey from the farm and at local markets. His experience includes 3 years as a Research Technician, 3 years as a county Extension Agent and 22 years as an Extension/Research Entomologist with a State University working with bees and is past president of the Western Apicultural Society. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees has damaged this operation increased overwintering losses (up from 15% 20 years ago to 30% now) which has led to increased costs and less profits. This damage is believed to have at least partly resulted from neonicotinoid pesticides, including clothianidin, in the environment where it has impacted his bees. This is believed to be compounded by the lack of labels on those pesticides adequate to inform the applicators how to avoid harm to bees and inadequate enforcement of the label requirements. Having worked as an Extension/Research Entomologist for Washington State University and in the private sector for 40 years, much of his work experience focused on the effects of pesticides on bees. The symptoms he has seen of the dying off of honey bee colonies that began in the early 2000's and the continuing losses are classic for pesticide poisoning.

**Gary McCallister** is a commercial beekeeper residing in Grand Junction, Colorado. He has been building a small beekeeping operation since 2004. Beginning with one hive, he has expanded until, in 2012, he will have about 20 hives. He also sells and services native bee nests for small gardeners' pollination needs. There has been a measurable decline in native bee populations in areas of commercial agriculture due to pesticide usage. His is a small operation with plans to continue to increase in numbers of hives as he retires from full time employment. He is the founder of the Western Colorado Beekeepers Association and current Vice President of the WCBA. He also teaches beekeeping classes through the local University and Community College. The ongoing effects of excessive overwintering

mortality and other excess losses of honey bees have damaged his operation. In the last two years his winter losses have exceeded 30%. He had lost at least three hives during summer operations that were obviously due to pesticide contamination.

**Miles McGaughey** is the head of Mountain Warrior Honey in Longmont, Colorado. He has been a commercial beekeeper for 25 years. He is also the president of the Boulder County Beekeepers Association. Up until recently he had 120 hives. He lost over 90% of his hives; currently he only has about 60. This massive loss has put a hardship on my pocket book and on his family who have helped him through this. He believes his losses were due to the neonicotinoid pesticides sprayed in his area, which are poorly labeled about the effects they have on bees.

**Cass Moore** is a commercial beekeeper residing in Marysville, Ohio. He has a small bee-keeping operation (about 150 colonies) that provides supplemental income. He started bee-keeping when he was just 13 years old and has over 59 years of experience. He has formerly served on the Board of Directors for the American Honey Producers Association. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged this operation greatly in recent years. Annual loss for winter colonies has ranged from 50-99% in the last twenty years. During that time, Mr. Moore has lost 40 or more colonies per year, with each colony being valued around \$250. This damage is believed to have at least partly resulted from neonicotinoid pesticides, including clothianidin, in the environment where it has impacted his bees. This is believed to be compounded by the lack of labels on those pesticides adequate to inform the applicators how to avoid harm to bees and inadequate enforcement of the label requirements.

**Charles E. Mraz** is a third generation commercial beekeeper in Middlebury, Vermont, and current president of the 500 member Vermont Beekeepers Association. He has a producer/packer operation established by his grandfather in 1931. He operates 30 apiaries with a total of approximately 1,200 honeybee colonies. Excessive winter losses and queen failures has had a very negative impact on the viability of his operation. During the winter of 2004/2005 his operation lost 45% of its colonies. Since this time he has routinely suffered winter losses of 20-25% and is losing colonies in the regular season at a much higher rate than ever experienced in the past. Historically winter losses were less than 5% and rarely as high as 10%. Honey production averages have fallen from 58,000 lbs. to 39,000 lbs. since 2004. He feels that neonicotinoid pesticides are not the only problems honey bees have, but he sees good evidence that they are contributing to the problems.

**Eloise Naylor** is a commercial beekeeper residing in Moorestown, New Jersey. She has been keeping bees for four years and hopes to supplement her retirement income with honey sales. Her experience includes Member of American Beekeeping Federation, Member of Eastern Apicultural Society, Member of New Jersey Beekeepers Association, Vice President of the of South Jersey Beekeepers Association. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees has damaged this operation with yearly loss averages at 20 percent.

**Michael Risk** is a commercial beekeeper residing in Laingsburg, Michigan. He has a honey and queen rearing business and has been a beekeeper for 29 years. He is the President of the Center of Michigan Beekeepers Association and has been mentoring and instructing at the club level as well as at the Michigan State Beekeepers Association level for a number of years. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees has damaged this operation with losses last year of 70%, it resulted in buying packages of replacement bees and losing a full year of lost queen and nuc production and lost profits. These losses have cost an estimated \$6,000 in lost sales and

replacement bees. Last year was the worst but he has had a minimum of 30% overwintering losses the past 5 years. This damage is believed to have at least partly resulted from neonicotinoid pesticides, including clothianidin, in the environment where it has impacted his bees. This is believed to be compounded by the lack of labels on those pesticides adequate to inform the applicators how to avoid harm to bees and inadequate enforcement of the label requirements.

**Gus Rouse** is President of Kona Queen based in Hawaii. He owns and operates the largest honey bee queen breeding operation in the country, which furnishes replacement queens for many of the larger beekeeping operations in the country. He has been on the American Beekeeping Federation Board of Directors for the last twelve years. Over the past 30 years he has seen how the demand for queens has gone from a spring business to a year around as beekeepers must fight to keep up their hive numbers. Customers typically used to buy queens equaling half the number of hives they owned to re-queen every hive every two years. Now customers typically have to use one or two queens per year per hive.

**Thomas C. Theobald** is a commercial beekeeper and owner of the Niwot Honey Farm in Niwot, Colorado. He has conducted this beekeeping business for 37 years. He was one of the founders, and president for 30 years, of the Boulder County Beekeepers Association. He served two terms as vice-president of the Colorado Beekeepers' Association, and was the last County Bee Inspector in the State of Colorado. He is losing 40 to 60% of his colonies each year and in 2011 had the smallest honey crop in 36 years. He believes a primary cause of these continuing losses is the uncontrolled spread of neonicotinoid pesticides (clothianidin, imidacloprid, thiamethoxam and others) over 200 million acres of agricultural land and untold acres of urban and suburban land. If EPA does not regulate these chemicals properly, there may be no 38th year for his business.

**Tim Tucker** is a commercial beekeeper based in Niotaze, Kansas. He has been keeping bees since 1991 and currently runs between 3-400 colonies of bees. He has been a President of the Kansas Honey Producers Association and is currently on the National Honey Bee Advisory Board and is also Vice-President of the American Beekeeping Federation. During the past seven years he has had winter losses that have been dramatic when the bees were placed in intensively farmed areas. While these are areas which provide good nectar sources, such as soybean, cotton and alfalfa, they make an obvious difference in harming the health of the colonies. After heavy losses which were around 50% in 2006 and 2007 he had to move to locations which kept the bees from high exposure to the pesticides that are being used. Since moving away from intensively farmed areas the bees have been healthier and overwintered better but these areas tend to be less productive for production of honey. It is his opinion that the new neonicotinoid pesticides are responsible for winter dwindling of honey bee colonies and lack of vigor in the surviving colonies. He has had to resort to other means of earning income such as selling bee colonies and queens to other beekeepers to supplement income that has been dramatically impacted for the past seven or eight years.

**Charles Vorisek** is a full time beekeeper residing in Linesville, Pennsylvania. He has the largest bee keeping operation in his county in northwestern Pennsylvania. His operation provides critical pollination services for orchards along Lake Erie. His pollination and honey sales help fill a void left by a large number of bee keepers leaving the business in his areas. He was instrumental in reorganization of the Northwestern PA Beekeepers Association in 2001 and has held the offices of President and Vice President every year since and he is actively involved with Pennsylvania State Beekeepers Association, for which is currently Vice President. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged this operation. Losses over the past six years have been 50-75% each winter. It is increasingly difficult to meet regular expenses of utilities, fuel and health

insurance, because of the cost of just getting back to the previous year's level. He has pollination contracts in areas where neonicotinoid pesticides, including clothianidin, are used. He can routinely expect a 25% colony failure during pollination and as he track those same colonies through winter, he finds an approximately 75% failure rate. With the honeybee range of 2-3 miles, it is virtually impossible to avoid these pesticide exposures in his area. As a Farm Bureau member himself he knows, through talking with the average crop farmer, that they have no concept that these seed treatments can harm honeybees. Every farmer he knows has concern for honeybees, yet their education as far as their impacts on bees is inadequate.

**Western Colorado Beekeepers Association** is a beekeeper association located in Grand Junction, Colorado. They are a group of beginner, hobby, and commercial beekeepers that represent beekeeping in a large rural part of Colorado. There are those with over 1000 hives in the area, smaller commercial producers with 20+ hives, and the typical beginners and hobbyists as well. The ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged their operations. Winter losses have been above 30% for the last two years. Several members have reported obvious pesticide kills. The area is heavily agricultural and pesticide use is common. This damage is believed to have at least partly resulted from neonicotinoid pesticides, including clothianidin, in the environment where it has impacted bees.

**Stephen Whittlesey**, is a commercial organic blueberry farmer and beekeeper residing in West Barnstable, Massachusetts. He has owned about twenty bee colonies, beginning in 1971 until present, using them for propagating one 1,000 highbush blueberry bushes which are organically grown. He is a member of the Barnstable County Beekeepers Association and the Cape Cod Organic Growers Association. Ongoing effects of excessive overwintering mortality and other excess losses of honey bees have damaged his operation. Typical losses in the seventies and early eighties would amount to 10 to 15% annually, and were sustainable. Losses now are between 50 to 70% annually and are not sustainable. This has resulted in poor propagation and consequent decreased yields in the blueberry business and has resulted in his operating the blueberry business at a loss the last three years. He has had to buy many new colonies of bumble bees and honeybees every year, and each year the price of the bees and the shipping get higher and higher. The damage to his bees is I believe the result, at least partly, of neonicotinoid pesticides, including clothianidin, in the environment.

**Table 2. Environmental and Consumer Organization Petitioners (4)**

**Beyond Pesticides**, located in Washington, DC, is a nonprofit organization founded in 1981. Beyond Pesticides promotes safe air, water, land, and food and works to protect public health and the environment by encouraging a transition away from the use of toxic pesticides. With Beyond Pesticides' resources made available to the public on a national scale, Beyond Pesticides has contributed to a significant reduction in unnecessary pesticide use, thus improving protection of public health and the environment. The risks to public health and the environment from pesticides are large. Beyond Pesticides and its members have a vital interest in a thriving agricultural system, which includes healthy populations of honey bees and wild crop pollinators, as well as healthy natural ecosystems, managed landscapes and gardens. Honey bee Colony Collapse Disorder and general decline of pollinator health, along with inadequate regulation of pesticides known to kill and have sub-lethal impacts on bees and

other pollinators, are of grave concern to the organization and its members.

**Center for Food Safety (CFS)**, located in Washington, DC, and San Francisco California, is a nonprofit organization. Since its founding in 1997, CFS has sought to ameliorate the adverse impacts of industrial farming and food production systems on human health, animal welfare and the environment. CFS has over 200,000 members across the country. CFS seeks to protect human health and the environment by advocating for thorough, science-based, safety testing of new agricultural products prior to any marketing and cultivation of crops in a manner that minimizes negative impacts such as increased use of pesticides and evolution of resistant pests and weeds. CFS also seeks to provide consumers with a means of identifying genetically engineered (GE) foods on the market and to encourage full public participation in defining the issues presented by GE crops. Finally, a foundational part of CFS' mission is to further the public's fundamental right to know what is in their food. CFS and its members have a vital interest in the survival and health of honey bees and other crop pollinators to ensure a nutritious and safe food supply and healthy natural ecosystems and gardens. The ongoing collapse of populations of honey bees and other beneficial insects, and failure to provide adequate label warnings on these pesticides, has damaged this interest.

CFS has a sister organization, the Petitioner **International Center for Technology Assessment (ICTA)**, based at the same Washington, DC, location. It is a non-profit organization committed to providing the public with full assessments of technological impacts on society. ICTA explores the economic, ethical, social, environmental and political impacts that can result from the applications of technology or technological systems. ICTA's interest in the development of safe agricultural technologies has been harmed by the use of unsafe, improperly-labeled, pesticides that contribute to decline in honey bees and other insects.

**Pesticide Action Network of North America (PANNA)**, is a San Francisco-based, non-profit corporation that serves as an independent regional center of Pesticide Action Network International, a coalition of public interest organizations in more than 90 countries. For nearly 30 years, PANNA has worked to replace the use of hazardous pesticides with healthier, ecologically sound, pest management across the United States and around the world. PANNA provides scientific expertise, public education and access to pesticide data and analysis, policy development and coalition support to more than 100 affiliated organizations in North America. PANNA has more than 70,000 members across the United States. PANNA's members live and recreate in areas of the country where pesticides such as clothianidin are applied, and in which pesticide drift and transport occurs, and thus have a strong interest in ensuring that federal regulatory agencies protect public health and the environment from clothianidin contamination.