

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

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) [stakeholders 1st]
) *et al.*,
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) Petitioners,
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) ***Filed With:***
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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 *nine years* ago as a condition of clothianidin’s registration and as necessary to support the required “no unreasonable environmental effects” determination.¹ 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

¹ 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.² 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,³ the Administrative Procedure Act (APA)⁴ and

² Krupke CH, Hunt GJ, Eitzer BD, Andino G, Given K. 2012. Multiple routes of pesticide exposure for honey bees living near agricultural fields. *PLoS ONE* 7(1) e29268. doi:10.1371/journal.pone.0029268; Tapparo R, Marton D, et al. 2012. Assessment of the environmental exposure of honeybees to particulate matter containing neonicotinoid insecticides coming from corn coated seeds. *Environ. Sci. Technol.*, DOI: 10.1021/es2035152.; Girolami V, Mazzon L, Squartini A, et al. 2009. Translocation of neonicotinoid insecticides from coated seeds to seedling guttation drops: a novel way of intoxication for bees. *Journal of Economic Entomology* 102(5): 1808-1815.

³ “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 redress of grievances is among the most precious of the liberties safeguarded by the Bill of Rights.” United Mine Workers of Am., Dist. 12 v. Ill. 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 doubtful or remotely, but by clear and present danger.” *Id.* The Supreme Court has recognized that the right to petition is logically implicit in, and fundamental to, the very idea of a republican form of government. United States v. Cruikshank, 92 U.S. 542, 552 (1875).

EPA’s implementing regulations and Special Review procedures,⁵ 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.⁶ The agency imposed that condition but has failed under FIFRA to enforce its own requirement since 2003.

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.⁷ 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.⁸ Indeed, only six months ago EPA issued just such an order when it discovered the herbicide “Imprelis,” newly registered by DuPont, was killing non-target coniferous trees.⁹ Like Imprelis, the labels for clothianidin products do not contain directions

⁴ 5 U.S.C. § 553(e).

⁵ 40 C.F.R. § 154.10.

⁶ 7 U.S.C. § 136k(a).

⁷ See State of the Science Appendix B.

⁸ 7 U.S.C. § 136k(a).

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

“adequate to protect health and the environment”.¹⁰ 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 that the 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.¹¹ 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).

¹⁰ 7 U.S.C. § 136(q)(1)(F).

¹¹ 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 a nine 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.

PETITIONERS

[[[LIST BEEKEEPER PETITIONERS FIRST AND BRIEF (5 SENTENCES MAX.) STATEMENT OF HOW THEY ARE IMPACTED BY CCD AND NEONIC.S HERE]]]

Petitioners’ Interests

Petitioner **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.

Petitioner **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.

Petitioner **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.

[[[Others - insert]]]

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.¹² 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.

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 family of pesticides has coincided with mass die-offs of honey bee (*Apis mellifera*) populations in the phenomenon known as Colony Collapse Disorder (“CCD”).¹³ If left unchecked, these losses could precipitate an economic and ecological disaster impacting the Petitioners and the United States as a whole at

¹² PANNA Action Alert, “Pull Bayer’s bee-killing pesticide. Now.” *available at* http://action.panna.org/p/dia/action/public/?action_KEY=5370 .

¹³ *See, e.g.*, “Honey Bee Die-Off Alarms Beekeepers, Crop Growers and Researchers,” *Science Daily* (April 22, 2007), *available at* www.sciencedaily.com/releases/2007/04/070422190612.htm .

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.¹⁴ 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.¹⁵ 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.¹⁶ Experts have singled out the recent, widespread, major increase in the use of systemic pesticides like clothianidin, thiamethoxam and others as particularly responsible for mortality and poor health in bee populations and to bees’ increasing vulnerability to other threats.¹⁷

While used on dozens of crops, the vastly 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 record 88 million acres in 2010 (a cumulative area virtually as large as the entire country of Germany); it is expected to continue to climb.¹⁸ 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 thiamethoxam.¹⁹

¹⁴ See Abramovitz, J. 1998. Putting a Value on Nature’s “Free” Services. Worldwatch Institute. Available at <http://www.worldwatch.org/system/files/EP111B.pdf>; Johnson, R. 2010. *Honey Bee Colony Collapse Disorder*. Congressional Research Service Report for Congress. 7-5700, RL33938.

¹⁵ R. A. Morse and N. W. Calderone, *The Value of Honey Bees as Pollinators of U.S. Crops in 2000*, March 2000, Cornell University, 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.

¹⁶ See USDA Agricultural Research Service, Colony Collapse Disorder Progress Report (June 2010), p. 6.

¹⁷ State of the Science report, Appendix B. See also: The role of pesticides in honeybee decline. Conn. Agric. Exper. Stn., available at www.ct.gov/caes/lib/caes/documents/plant_science_day/plant_science_day_spring/2011/spring_open_house_2011_eitzer.pdf.

¹⁸ 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.

¹⁹ Krupke *et al.*, *supra*, note 2.

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.²⁰

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, often experimentally, 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 and summarizes this information, providing vastly more detail than is reiterated in this Petition. The State of the Science report 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.²¹ FIFRA authorizes the agency to grant a “conditional registration” when the pesticide is so new that insufficient data exists to support unrestricted registration.²² However, the Administrator must make an affirmative finding that the pesticide will not pose “unreasonable adverse effects” during the period of conditional registration.²³ An application for registration is incomplete if it contains insufficient information for the Administrator to make such a determination.²⁴ Registration of a pesticide—conditional or otherwise—cannot continue on the basis of an incomplete application.²⁵

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 causes unreasonable adverse effects on the environment.”²⁶ In the case of a conditional registration, if the registrant has failed to initiate

²⁰ EPA Pesticide Fact Sheet: Clothianidin, Conditional Registration, May 30, 2003, *available at*: www.epa.gov/opprd001/factsheets/clothianidin.pdf.

²¹ 7 U.S.C. § 136a(5)(D).

²² *Id.* § 136a(c).

²³ *Id.* § 136a(c)(7)(C); 40 C.F.R. § 152.114(d).

²⁴ 40 C.F.R. § 152.104.

²⁵ *See id.* § 152.105; *id.* § 158.1.

²⁶ 7 U.S.C. § 136d(b).

or pursue appropriate action toward fulfilling any condition imposed on registration, the Administrator “shall” initiate cancellation proceedings.²⁷ While cancellation is pending, EPA may “suspend the registration of the pesticide immediately” if an “imminent hazard” exists,²⁸ 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.”²⁹

Further, section 12(a)(1)(E) of FIFRA makes it unlawful for any person to sell or distribute a “misbranded” pesticide.³⁰ Section 2(q)(1)(F) provides that a pesticide is misbranded if such pesticide’s “labeling accompanying it does not contain directions for use which ... if complied with ... are adequate to protect health and the environment.”³¹

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.³² 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.

²⁷ *Id.* § 136d(e)(1).

²⁸ *Id.* § 136d(c).

²⁹ *Id.* § 136(l).

³⁰ 7 U.S.C. § 136j(a)(1)(E).

³¹ 7 U.S.C. § 136(q)(1)(F).

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

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.³³ 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 clothianidin has on the worker bee life cycle, as well as an evaluation of exposure and effects to the queen.

EPA also has failed to aggressively seek potential adverse effects data from the registrants of clothianidin that would shed light on their 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 Petitioners cannot reasonably wait the many more years that EPA’s review process will consume while bee populations are dying 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), whereas this equivalence has, to date, been the basis for excusing EPA from NEPA compliance in FIFRA regulatory matters.³⁴

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

³³ 7 U.S.C. §§ 136d(b), (c).

³⁴ 42 U.S.C. §§ 4321 *et seq.*

(*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.³⁵ 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.³⁶ Meat, milk and cheese production are also reliant on the pollinated crops that livestock eat, such as alfalfa.³⁷ Overall, pollinator-dependent crops make up almost one-third of total U.S. agricultural production.³⁸ Pollinators are crucial pillars of non-crop plant health and survival generally, whether in horticulture or in nature.³⁹ 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.⁴⁰ Each winter since then, roughly one-third of the U.S. honey bee population has died off or disappeared.⁴¹ 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

³⁵ See Abramovitz J. 1998. Putting a Value on Nature’s “Free” Services. Worldwatch Institute, available at www.worldwatch.org/system/files/EP111B.pdf.

³⁶ See Berenbaum MR, University of Illinois, Statement before the Subcommittee on Horticulture and Organic Agriculture, U.S. House of Representatives, March 29, 2007, available at <http://agriculture.house.gov/testimony/110/h70329/Berenbaum.pdf>.

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.

³⁷ See Hagler JR, Mueller S, Teuber LR, Machtley SA, Van Deynze A. 2011. Foraging range of honey bees, *Apis mellifera*, in alfalfa seed production fields. *Journal of Insect Science* 11:144; National Honey Board. Honey Industry Facts, available at www.honey.com/nhb/media/press-kit/.

³⁸ Johnson, *supra*, note 14, at 1.

³⁹ See, e.g., Biesmeijer, J.C., Roberts, S.P., Reemer, M., Ohlemuller, R., Edwards, M., Peeters, T., *et al.* 2006. Parallel declines in pollinators and insect-pollinated plants in Britain and the Netherlands. *Science* 313: 351–54.

⁴⁰ Natalie Lounsbury, “Pollinators and Pesticides: Escalating Crisis Demands Action,” *Pesticides and You*, vol. 28 no. 3 (Fall 2008), p. 13.

⁴¹ See Van Engelsdorp D, Hayes J, Pettis J. *Preliminary Results: A Survey of Honey Bee Colonies Losses in the U.S. Between September 2008 and April 2009* [need full cite]

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).⁴²

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 years.⁴³ 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.⁴⁴ The injury to bees from sub-lethal exposures is reported to be cumulative, that is, with every exposure more damage occurs.⁴⁵

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.⁴⁶ 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

⁴² See Johnson, *supra*, note 14, at 8.

⁴³ Cra-Api, 2010. Relazione sull’attività svolta e sui risultati ottenuti nell’ambito del progetto APENET per la tematica “Effetti del mais conciato sulle api”, available at: www.reterurale.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/409 ; Cra-Api, 2009. Relazione sull’attività svolta e sui primi risultati ottenuti nell’ambito del progetto Apenet per la tematica “Effetti del mais conciato sulle api”, available at: www.reterurale.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/81 .

⁴⁴ Decourtye A, Armengaud C, Renou M, Devillers J, Cluzeau S, Gauthier M, Pham-Delegue MH. 2004. Imidacloprid impairs memory and brain metabolism in the honeybee (*Apis mellifera* L.). *Pesticides Biochemistry and Physiology* 78: 83-92.

⁴⁵ Tennekes H. 2010. *The Systemic Insecticides: A Disaster in the Making*, Zutphen, The Netherlands; Weevers Walburg Communicatie, available at www.disasterinthemaking.com .

⁴⁶ Pettis JS, Vanengelsdorp D, Johnson J, Dively G. 2012. Pesticide exposure in honey bees results in increased levels of the gut pathogen *Nosema*. *Naturwissenschaften* DOI: 10.1007/s00114-011-0881-1.

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.

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

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.⁴⁸ 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.⁴⁹

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.⁵⁰ 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

⁴⁷ Alaux C, Brunet J, Dussaubat C, et al. 2010. Interactions between *Nosema* microspores and a neonicotinoid weaken honeybees (*Apis mellifera*). *Environmental Microbiology* 12(3): 774–782; Vidau C, Diogon M, Aufauvre J, Fontbonne R, Viguès B, et al. 2011. Exposure to sublethal doses of fipronil and thiacloprid highly increases mortality of honeybees previously infected by *Nosema ceranae*. *PLoS ONE* 6(6): e21550 .

⁴⁸ Evans E, Thorp R, Jepsen S, Hoffman Black S. 2009. *Status Review of Three Formerly Common Species of Bumble Bee in the Subgenus Bombus*. Xerces Society, available at www.xerces.org/wp-content/uploads/2009/03/xerces_2008_bombus_status_review.pdf .

⁴⁹ Scott-Dupree CD, Conroy L, Harris CR. 2009. 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). *J Econ Entomol.* 102(1):177-82.

⁵⁰ Clothianidin Fact Sheet, *supra*, note 20, at 17; EPA Clothianidin – Registration Status and Related Information (Feb. 18, 2011), available at www.epa.gov/opp00001/about/intheworks/clothianidin-registration-status.html .

the pesticide, resulting in paralysis and death.⁵¹ Guttated water of seed-treated plants, which provides a source of water for bees, also can be a source of contamination and exposure.⁵² 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.⁵³ Additionally, and critically, neonicotinoid pesticides persist in the environment, increasing the risk of cumulative “toxic loading” effects, especially with repeated applications, in both the short and long term.⁵⁴

Clothianidin is Bayer AG’s successor to imidacloprid, for which Bayer’s U.S., German, French, Italian and U.K. patents expired in 2006.⁵⁵ Clothianidin is moderately toxic to humans and has been linked to immune effects in lab animals.⁵⁶ 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.⁵⁷

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

⁵¹ See Jones AK, Raymond-Delpech V, Thany SH, Gauthier M, Sattelle DB. 2006. The nicotine acetylcholine receptor gene family of the honey bee, *Apis mellifera*. *Genome Res.* 16: 1422-1430, available at <http://genome.cshlp.org/content/16/11/1422>. See also Cummins J. 2007 Requiem for the honeybee. *Science in Society* 34: 37-38.

⁵² Hoffmann E, Castle S. 2012. Imidacloprid in melon guttation fluid: A potential mode of exposure for pest and beneficial organisms. *J Economic Entomology* 105(1):67-71.

⁵³ Reetz J. et al. 2011. Neonicotinoid insecticides translocated in guttated droplets of seed-treated maize and wheat: a threat to honeybees? *Apidologie* 42(5): 596-606.

⁵⁴ See Clothianidin Fact Sheet, *supra*, note 20; EPA Office of Pesticide Programs, Imidacloprid Summary Document for Registration Review (2008).

⁵⁵ Bayer AG Securities and Exchange Commission Filing: Form 20-F, at 57 (March 15, 2007), available at www.investor.bayer.com/user_upload/2622/.

⁵⁶ See Clothianidin Fact Sheet, *supra* note 20.

⁵⁷ *Id.*

“**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**”.⁵⁸
- 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 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, 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

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

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.⁵⁹ While some suspensions were later lifted, the ban on clothianidin-treated corn seed remains.⁶⁰ Also in 2008, Italy’s agricultural ministry 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.⁶¹ Slovenia likewise has banned both clothianidin and imidacloprid.⁶²

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.⁶³ In 2008, having observed enough adverse impacts from neonicotinoids, France flatly rejected Bayer’s application to register clothianidin.⁶⁴

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

⁵⁹ See The Federal Office of Consumer Protection and Food Safety (BVL) website, “Authorizations for neonicotinoids are still suspended due to the hazards of bees,” *available at* www.bvl.bund.de/cln_027/nn_496790/sid_FFE204596E8096E5D0F6C6B9E657F9EA/EN/08_PresseInfothe_k_engl/01_Presse_und_Hintergrundinformationen/PI_Maissaatgut_Mesuro_l_engl.html_nnn=true; Benjamin, A. 2008. Pesticides: Germany bans chemicals linked to honeybee devastation. Guardian.co.uk, Friday May 23, *available at* www.guardian.co.uk/environment/2008/may/23/wildlife.endangeredspecies.

⁶⁰ EPA webpage: Colony Collapse Disorder: European Bans on Neonicotinoid Pesticides, *available at* www.epa.gov/pesticides/about/intheworks/ccd-european-ban.html.

⁶¹ See, e.g., Italian Ministry of Health, Press Release: “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; “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.

⁶² See Kindemba V. 2009. The impact of neonicotinoid insecticides on bumblebees, honey bees and other non-target invertebrates. *BUG LIFE*, p. 24.

⁶³ *Id.*

⁶⁴ Benjamin, *supra*, note 59.

waters as well.⁶⁵ 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 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:⁶⁶

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)*

⁶⁵ Tennekes, *supra*, note 45.

⁶⁶ USDA, Office of Inspector General. 2012. *USDA’s Response to Colony Collapse Disorder*. Audit Report 50099-0084-HY, USDA, Washington, DC.

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 ongoing threat.

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.⁶⁷ 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.⁶⁸ 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.*⁶⁹

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.⁷⁰ 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

⁶⁷ EPA Environmental Fate and Effects Division, Memorandum: Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola (PC Code 044309) (February 20, 2003), *available at* www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-044309_20-Feb-03_a.pdf.

⁶⁸ *See id.* p. 2.

⁶⁹ *Id.*

⁷⁰ EPA Environmental Fate and Effects Division, Memorandum: Addendum referring to EFED’s Risk Assessment on Clothianidin Use as a Seed Treatment on Corn and Canola (PC 044309) (April 10, 2003) (hereinafter “EPA Memo, April 2003”), p. 2; *see also* See Clothianidin Fact Sheet, *supra*, note 20.

reversal; it merely prefaced the change with “after further consideration...”.⁷¹ Nonetheless, even the second memorandum confirmed **EPA determined a study evaluating the long term toxicity to pollinators was necessary as a condition for registration.**⁷² This determination made the study of the impacts on the honey bee life cycle a “core” requirement for registration.

B. Bayer’s Fatally Flawed Field Study

Bayer was initially given eight months—until December **2003**—to complete the study as a condition for registration.⁷³ 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.) To illustrate this, the final protocols and methodology for this study were not even established until March **2004**, three months after Bayer’s deadline for *completing* it had passed.⁷⁴ 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.⁷⁵

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 80 million acres⁷⁶), 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.⁷⁷ Moreover, despite the fact that the purpose of a “field study” is to evaluate impacts based on where the pesticide is going to be

⁷¹ EPA Memo, April 2003, p. 2.

⁷² *Id.* p. 1.

⁷³ *See id.* p. 2.

⁷⁴ EPA EFED, Review of Bayer CropScience’s Draft Protocol of a Honey Bee Field Study – Poncho 600 (264-789) [Clothianidin (044309), D2953 181 (March 11, 2004).

⁷⁵ *Id.* p. 2.

⁷⁶ Economic Research Service. 2010. Corn. USDA, *available online at* www.ers.usda.gov/Briefing/Corn/ .

⁷⁷ *Id.* pp. 3-5.

applied,⁷⁸ 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.⁷⁹ 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 hectare* (2½ acres) of treated canola, while the bees were free to forage over thousands of surrounding acres in bloom with untreated canola.⁸⁰

This Canadian canola study (hereinafter, “Cutler and Scott-Dupree 2007”⁸¹) provided no relevant data for assessing the likely impact that the approximately *80 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.⁸²

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.⁸³ (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,” likely due to basic design and methodological errors.⁸⁴ 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.”⁸⁵ 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:

⁷⁸ EPA Office of Prevention, Pesticides and Toxic Substances, Ecological Effects Test Guidelines – Field Testing for Pollinators, OPPTS 850.3040(b)(2)(iii) (April 1996).

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ Cutler GC, Scott-Dupree C. 2007. Exposure to clothianidin seed-treated canola has no long-term impact on honey bees. *J Econ Entomol* 100:765–772.

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

⁸³ EPA November 2010 Memorandum, *supra*, note 32.

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

⁸⁵ *Id.*

*[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.⁸⁶*

As of March **2012**, more than 15 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 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 2003**. 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.⁸⁷ Shockingly, EPA still has not assessed its effects on bees **nine 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:⁸⁸

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

⁸⁶ *Id.* Emphasis added

⁸⁷ 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.

⁸⁸ Clothianidin Fact Sheet, *supra*, note 20, at 16.

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 annually, in almost 30 different formulations, EPA’s recent Registration Review Problem Formulation document admits.⁸⁹

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.⁹⁰ The 2010 Risk Assessment for mustard seed and cotton uses admits as much.⁹¹

[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 taxa more than nine years after its registration, much less consulted on the key ESA action-forcing determination as

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

⁹⁰ 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 fenderi*); 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 mitchellii*; 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 lincolniiana*); 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.

⁹¹ EPA November 2010 Memorandum, *supra*, note 32, at 52.

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 the many declines of insectivorous birds documented in Europe due to Neonicotinoid use.⁹² 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)⁹³:

*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

⁹² Tennekes, *supra*, note 45.

⁹³ EPA Registration Review: Problem Formulation, *supra*, at App. H.

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 its application for “Poncho 600,” with the active ingredient clothianidin, stating:⁹⁴

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.⁹⁵ The Department justified the 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 lack of reliability of EPA’s conditional registration, as a prominent State agency cannot depend on what EPA did.

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 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.”).⁹⁶ They reported on their efforts to determine how bees are being exposed to pesticides commonly applied to either corn seed or to corn plants later in the

⁹⁴ Nov. 16, 2005, letter from the NY State Department of Environmental Conservation to Bayer CropScience, available at http://pmep.cce.cornell.edu/profiles/insect-mite/cadusafos-cyromazine/clothianidin/clothianidn_wth_1105.pdf.

⁹⁵ July 17, 2007, letter from the NY State Department of Environmental Conservation to Arysta LifeScience, available at http://pmep.cce.cornell.edu/profiles/insect-mite/cadusafos-cyromazine/clothianidin/clothianidin_den_0707.pdf.

⁹⁶ Krupke et al., *supra*, note 2; see Harman, A. 2012. Catch the buzz - corn seed treatment as lethal as it gets for honey bees all season long, and long after the season is gone - it just keeps on killing, available online <http://home.ezezone.com/1636/1636-2012.01.04.21.46.archive.html> .

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 dead and healthy bees. They also checked waste products produced during planting.

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.⁹⁷*

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.⁹⁸

⁹⁷ Krupke et al., *supra*, note 2, citing to Cutler and Scott-Dupree 2007.

⁹⁸ The Administrator is requested to take note of language in a very recent U.S. Circuit Court of Appeals decision, Sierra Club v. United States EPA, 12 C.D.O.S. 817, 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 p. 590-91:

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 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.”⁹⁹ Being persistent, and repeatedly spread each planting season, clothianidin-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 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.”).¹⁰⁰ 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

[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.

⁹⁹ EPA November 2010 Memorandum, *supra*, note 32, at 21.

¹⁰⁰ Tapparo R, Marton D, et al. 2012. Assessment of the environmental exposure of honeybees to particulate matter containing neonicotinoid insecticides coming from corn coated seeds. *Environ. Sci. Technol.*, DOI: 10.1021/es2035152.

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).

Tapparo et al. conclude 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. 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,”¹⁰¹

- EPA may conditionally amend a pesticide’s registration “to permit additional uses of such pesticide,”¹⁰²
- 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.”¹⁰³

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 15 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 (indeed, EPA had allotted Bayer just eight months to complete the original study.) 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

¹⁰¹ 7 U.S.C. § 136a(c)(7)(A).

¹⁰² *Id.* § 136a(c)(7)(B).

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

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:¹⁰⁴

[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.”¹⁰⁵ 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. EPA must require actual applied mixes testing

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.¹⁰⁶ Chronic ingestion of neonicotinoids damages foraging behavior, overall mobility and the communication that allows these social insects to coordinate their activities.¹⁰⁷ Neonicotinoid pesticides also

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

¹⁰⁵ *Hardin v. Jackson*, 625 F.3d 739, 741 (D.C. Cir. 2010) (dismissal affirmed on other grounds).

¹⁰⁶ Wu JY, *et al.* 2011. Sub-lethal effects of pesticide residues in brood comb on worker honey bee (*Apis mellifera*) development and longevity. *PLoS ONE*. 6(2).

¹⁰⁷ See, e.g., Medrzycki P, Montanari R, Bortolotti L, Sabatini A G, Maini S, Porrini C. 2003. Effects of imidacloprid administered in sub-lethal doses on honey bee behavior. Laboratory tests. *B Insectol*. 56(1): 59-62, available at www.bulletinofinsectology.org/pdfarticles/vol56-2003-059-062medrzycki.pdf; Yang EC, Chuang YC,

have several other indirect effects on honey bees, such as premature shifts in hive roles.¹⁰⁸ They can impair honey bees’ medium-term olfactory memory and associative learning abilities, which foraging honey bees rely on, *inter alia*, to find their way back to the hive.¹⁰⁹ 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.¹¹⁰ 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). The levels of clothianidin applied in those contexts can pose an immediate risk to such bees and other insects. 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.

Chen YL, Chang LH. 2008. Abnormal foraging behavior induced by sub-lethal dosage of imidacloprid in the honey bee (*Hymenoptera: Apidae*). *J. of Econ. Entomol.* 101(6): 1743-1748.

¹⁰⁸ Wu et al. *supra*, note 107 at 1–2; *see also* Yang et al., *supra*, note 108.

¹⁰⁹ Decourtye et al, *supra*, note 45; Decourtye A, Devillers J, Cluzeau S, Mercedes C, Pham-Delegue MH. 2004. Effects of Imidacloprid and Delamethrin on associative learning in honeybees under semi-field and laboratory conditions. *Ecotoxicology and Environmental Safety* 57 (3), 410–419.

¹¹⁰ Pettis et al., *supra*, note 46; Vidau et al., *supra*, note 47.

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.¹¹¹ 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.

¹¹¹ *E.g.*, Johnson, *supra* note 14, at 1.

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.”¹¹² It is unlawful to sell or distribute a misbranded pesticide.¹¹³ 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.¹¹⁴

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.¹¹⁵ 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 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

¹¹² 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).

¹¹³ 7 U.S.C. § 136j(a)(2)(I).

¹¹⁴ *Id.* § 136k(a).

¹¹⁵ Appendix C - Sample Labels of Pesticides Containing Clothianidin.

applied to cucurbits and fruiting vegetables, but also applies more generally, that (emphasis added):¹¹⁶

*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 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 current labels on clothianidin violate FIFRA. The statute is very explicit and requires that EPA find a product is misbranded if (emphasis added):¹¹⁷

¹¹⁶ Allen W. Vaughan. Environmental Risk Branch, EFED, EPA. 2009. Clothianidin Registration of New Products and New Uses of Sepresto 75WS and PROCEED™ OPTIMUM: Addendum to Address Mitigation of Bee Hazard.

¹¹⁷ 7 U.S.C. § 136(q).

(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 and warnings “adequate to protect the environment, namely certain species of trees.”¹¹⁸ Accordingly, the agency ordered DuPont to “**immediately cease** the sale, use or removal of Imprelis products.”¹¹⁹

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. 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 to initiate and complete the required consultation

¹¹⁸ *Id.* ¶22.

¹¹⁹ *Id.* ¶ 24 (emphasis in original).

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.

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 ____ day of March, 2012.

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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