PETITION FOR INTERIM ADMINISTRATIVE REVIEW OF NEONICOTINOID PESTICIDES

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The Natural Resources Defense Council (NRDC) petitions the U.S. Environmental Protection Agency (EPA) to undertake urgent interim administrative review of neonicotinoid pesticides in light of serious potential harm to honey bees and native bees. Given mounting scientific evidence that neonicotinoids are toxic to bees and threaten both individual and population survival, the agency should also initiate cancellation proceedings for all neonicotinoid pesticide products, beginning with those for which safer alternatives are available. In the meantime, however, EPA should take immediate steps to protect bees and to prevent ongoing adverse effects on the environment. As set forth in in this petition, EPA should—at a minimum—immediately initiate interim administrative review to evaluate the serious threat that neonicotinoids pose to bees.

EPA should complete this interim review within one year. The agency has proposed deferring an evaluation of how neonicotinoids impact bees until the completion of registration review in approximately 2019. This delay cannot be justified. A substantial and growing body of evidence has linked neonicotinoids to the drastic decline in bee populations in recent years, compelling urgent agency review of neonicotinoids' effects on bees. To the extent that EPA determines, after its review, not to prohibit use of neonicotinoids on all bee-pollinated crops and ornamentals—despite known risks and critical missing information—the agency must provide a reasoned explanation for that decision. This petition is filed pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 *et seq*., and the Administrative Procedure Act (APA), 5 U.S.C. § 551 *et seq*.

I. INTRODUCTION

Neonicotinoids are a class of pesticides—including dinotefuran, acetamiprid, clothianidin, thiacloprid, imidacloprid, and thiamethoxam—registered for many agricultural and non-agricultural uses.[1] EPA has approved the use of neonicotinoids on over 150 terrestrial crops, including fruit, vegetable, and field crops.[2] The agency has also registered neonicotinoids for use in non-agricultural settings for preventative pest control.[3] Non-crop areas to which neonicotinoids are applied include residential, industrial, greenhouse, ornamental, and other sites.[4] Neonicotinoids can be administered as a soil, seed, or foliar treatment.[5]

Compared with organophosphates, neonicotinoids appear to pose fewer risks to human health, based on available data. However, there are substantial concerns about neonicotinoids' environmental persistence and harmful effects on beneficial non-target pollinators.[6] Unlike

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[1] U.S. EPA, Pesticide Fact Sheet: Dinotefuran (Sept. 2004), http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-044312_01-Sep-04.pdf; U.S. EPA, Pesticide Fact Sheet: Acetamiprid (Mar. 15, 2012), http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-099050_15-Mar-02.pdf; U.S. EPA, Pesticide Fact Sheet: Clothianidin (May 30, 2003), http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-044309_30-May-03.pdf; U.S. EPA, Pesticide Fact Sheet: Thiacloprid (Sept. 26, 2003), http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-014019_26-Sep-03.pdf; U.S. EPA, Imidacloprid: Pesticide Tolerances, 68 Fed. Reg. 35303-15 (June 13, 2003), *available at* http://www.epa.gov/fedrgstr/EPA-PEST/2003/June/Day-13/p14880.htm; U.S. EPA, Thiamethoxam: Pesticide Tolerances, 76 Fed. Reg. 50905-13 (Aug. 17, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-08-17/html/2011-20839.htm.

[2] *Id.*

[3] U.S. EPA, Registration for Imidacloprid (NTN 33893) at 1-2 (Mar. 10, 1994), http://www.epa.gov/pesticides/chemical/foia/cleared-reviews/reviews/129099/129099-051.pdf [hereinafter 1994 Imidacloprid Registration].

[4] *Id.*; Pesticide Fact Sheet: Dinotefuran, *supra* note 1, at 1-2.

[5] David M. Whitacre & Kristin R. Eads, *§ 13.28 Nicotinoids*, Defending Pesticides in Litigation (2013).

traditional pesticides that are typically applied to a plant's surface, neonicotinoids are systemic pesticides that are absorbed into plant tissue, turning a plant into a "tiny poison factory" that emits toxins from its pollen down to its roots.[7] As non-selective pesticides, neonicotinoids do not discriminate between target and non-target insect species, including beneficial pollinators.

Based on the best information available, EPA appears to have granted neonicotinoids conditional registrations dependent upon further study.[8] The agency has, however, acknowledged that its system for tracking conditional registrations is functionally inadequate.[9] Although the agency recently made publicly available a document that appears to show that the original registration conditions for neonicotinoids have been satisfied,[10] this document has notable

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[6] *See* Int'l Union for Conservation of Nature, *Systemic pesticides pose global threat to biodiversity and ecosystem services* (June 24, 2014), http://www.iucn.org/?uNewsID=16025; Task Force on Systemic Pesticides, *Worldwide Integrated Assessment*, http://www.tfsp.info/worldwide-integrated-assessment/ (last visited July 3, 2014); Matt McGrath, *Widespread Impacts of Neonicotinoids 'Impossible to Deny,'* BBC News (June 23, 2014).

[7] Sonia Shah, *Behind Mass Die-Offs, Pesticides Lurk as Culprit*, Yale Environment 360, (Jan. 7, 2010), *available at* http://e360.yale.edu/content/feature.msp?id=2228.

[8] Government Accountability Office, Pesticides: EPA Should Take Steps to Improve Its Oversight of Conditional Registrations (Aug. 2013), http://www.gao.gov/assets/660/656825.pdf [hereinafter 2013 GAO Report]; U.S. EPA, Dinotefuran Conditional Registration (Sept. 2004), http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-044312_01-Sep-04.pdf; U.S. EPA, Thiacloprid Conditional Registration (Sept. 26, 2003), http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-014019_26-Sep-03.pdf; U.S. EPA, Acetamiprid Conditional Registration (March 15, 2002), http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-099050_15-Mar-02.pdf; U.S. EPA, *Fact Sheet*, Thiamethoxam Summary Document: Registration Review Case No. 7614 (Dec. 2011); U.S. EPA, Clothianidin Conditional Registration (May 30, 2003), http://www.epa.gov/opp00001/chem_search/reg_actions/registration/fs_PC-044309_30-May-03.pdf; 1994 Imidacloprid Registration, *supra* note 3.

[9] *See* 2013 GAO Report, *supra* note 8.

[10] EPA, Status of Conditional Registrations Under FIFRA sec. 3(c)(7)(C) from 2000 to 2014, http://www2.epa.gov/sites/production/files/2014-06/documents/conditional_registration_status_4-15-2014.pdf.

limitations. For example, EPA had required pollinator field testing for clothianidin that included a complete worker-bee life cycle study and an evaluation of the exposure to and effects of clothianidin on the queen bee.[11] However, the study that EPA received was so poorly undertaken that the agency initially considered it to be invalid (although the agency later deemed the study to be "supplemental" based on the study's inclusion of some information of limited utility), meaning that the study did not satisfy the data requirements.[12] Despite the inadequacy of this study, EPA's newly released conditional registration status document states that the pollinator field test requirement for clothianidin has been "satisfied."[13]

Even if the original conditions for registration of any individual neonicotinoid have been satisfied, many new studies have since arisen, demonstrating significant and hitherto unknown adverse effects to bees. In light of the emerging science, there is no evidence that any registrant has submitted to EPA well-designed and properly conducted studies of adequate statistical power addressing the threats that neonicotinoids pose to bee health, let alone evidence that such studies—if they exist—have been reviewed by the agency and deemed sufficient for EPA to support a regulatory decision that these pesticides pose no unreasonable adverse effects on the environment. On the contrary, and as reflected in the Final Work Plans for registration review of each of the neonicotinoids at issue, EPA recognizes that further investigation, ranging from pollinator larval toxicity studies to pollen residue analyses, must be conducted to understand more fully neonicotinoids' adverse effects to bees.[14]

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[11] NRDC, Superficial Safeguards: Most Pesticides Are Approved by Flawed EPA Process 4 (2013), http://www.nrdc.org/health/pesticides/files/flawed-epa-approval-process-IB.pdf.

[12] *Id.*

[13] *See* EPA, *supra* note 10, at 12.

[14] *See infra* Section I.A.

As of 2011 (the most recent year for which there is publicly available data), approximately 3.5 million pounds of neonicotinoids were applied annually to nearly 127 million acres of agricultural crops—compared to about 1.6 million pounds used in 2005.[15] Having experienced a two-fold increase in use in a five-year period, and comprising roughly 25% of the global agrochemical market, neonicotinoids comprise the most widely used class of insecticides in the world today.[16]

A growing body of scientific evidence, summarized below, shows that the dramatic recent increase in neonicotinoid use has adversely affected honey bees and native bumble bee species essential to the food supply. Over the last decade, there has been a sharp worldwide decline in bee populations, with beekeepers reporting an average hive loss of 45.1% for the winter of 2012-13, up 78.2% from 2011-12.[17] As with commercial honey bees, native bee populations have also experienced catastrophic declines over the past decade.[18] The approximately three thousand wild bee species that are found in North America are responsible for pollinating gardens, wild flowers and blossoming trees. Wild bees also help to pollinate agricultural crops including coffee, watermelons, tomatoes, blueberries, sunflowers, grapes, and canola.

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[15] Jennifer Hopwood, et al., *Beyond the Birds and the Bees: Effects of Neonicotinoid Insecticides on Agriculturally Important Beneficial Invertebrates*, The Xerces Soc'y for Invertebrate Conservation 4-5 (2013), http://www.xerces.org/wp-content/uploads/2013/09/XercesSociety_CBCneonics_sep2013.pdf.

[16] Peter Jeschke, et al., *Overview of the Status and Global Strategy for Neonicotinoids*, 59 J. Agric. & Food Chemistry 2897, 2987-88 (2011).

[17] Jennifer S. Holland, *The Plight of the Honeybee*, National Geographic News (May 10, 2013), http://news.nationalgeographic.com/news/2013/13/130510-honeybee-bee-science-european-union-pesticides-colony-collapse-epa-science/#close-modal.

[18] The Xerces Soc'y for Invertebrate Conservation, *Bumble Bee Conservation: Protecting North America's Disappearing Pollinators* (2012), http://www.xerces.org/wp-content/uploads/2010/08/bumble-bee-conservation-factsheet.pdf.

Studies have demonstrated that neonicotinoids may suppress bee immunity, disrupt brood cycles, impair foraging behavior by interfering with memory and learning, and cause disorientation, preventing bees from finding their way back to the hive.[19] Through such serious adverse effects on bee physiology, the pervasive use of neonicotinoids has contributed to the alarming decline of bee populations.

A. Individual Pesticides Comprising the Neonicotinoid Class

As defined by EPA, six individual pesticides comprise the neonicotinoid class at issue: imidacloprid, clothianidin, thiamethoxam, dinotefuran, acetamiprid, and thiacloprid.[20] All were registered after 1984 and were not subject to reregistration.[21] Urgent interim registration review of these pesticides is needed, in light of their potential harmful effects on bees and the extensive uncertainties regarding the scope of their impacts on beneficial pollinators. The consensus view is that EPA lacks adequate information regarding the adverse impacts of these pesticides on bees.[22]

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[19] M. Henry, et al., *A Common Pesticide Decreases Foraging Success and Survival in Honey Bees*, 336 Science 348-50 (Apr. 20, 2012); *see also* Ken Brownlee, *§ 12:58 Agricultural-related Disasters*, Catastrophe Claims: Insurance Coverage for Natural and Man-Made Disasters (Nov. 2013).

[20] This petition does not address sulfoxaflor, which EPA has identified as having a mechanism of action that is distinct from that of other neonicotinoids. *See* EPA, *Environmental Fate and Ecological Risk Assessment for Sulfoxaflor Registration* at 8 (posted January 2013) (characterizing sulfoxaflor as "the only member of the sulfoxamine subclass of neonicotinoid insecticides").

[21] U.S. EPA, *Neonicotinoids (NN)*, Overview of the Registration Review Program (Sept. 30, 2013), http://www.epa.gov/oppsrrd1/registration_review/highlights.htm.

[22] USDA, *Report on the National Stakeholders Conference on Honey Bee Health*, National Honey Bee Health Stakeholder Conference Steering Committee 16-20 (Oct. 15-17, 2012), *available at* http://www.usda.gov/documents/ReportHoneyBeeHealth.pdf.

1. Imidacloprid

Imidacloprid is used in agriculture as a foliar, seed, and soil treatment, as well as for indoor and outdoor insect control, home gardening, and turf and ornamental production.[23] First registered in 1994, it has since been approved for use on an extensive array of field crops, root and tuber vegetables, tree fruits, and legumes—such as corn,[24] cauliflower, artichokes, strawberries, stone fruit, cranberries, okra, papayas, lychees, avocados, persimmons, guavas, star fruit, passion fruit, apples, and grapes—despite EPA's previous determination that imidacloprid is "highly toxic to honey bees."[25] Inadequate data exist to understand the full scope of adverse effects that imidacloprid exposure may have on beneficial pollinators.[26]

In its Final Work Plan for the registration review of imidacloprid, EPA recognized that the following pollinator-related studies are needed:

- field test for pollinators (guideline 850.3040); and
- a special repeat dose field study.[27]

The agency has published a schedule for registration review of neonicotinoids, with imidacloprid's registration review scheduled for completion in 2017.[28]

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[23] 1994 Imidacloprid Registration, *supra* note 3.

[24] Although bees do not pollinate corn, they forage on corn pollen and nectar.

[25] *Id.*; U.S. EPA, *Imidacloprid in/on Related Commodities, Root and Tuber Vegetables, and Legume Vegetable – Risk Assessment*, Office of Pesticide Programs Health Effects Division (Mar. 4, 2003), http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-129099_04-Mar-03.pdf.

[26] *Report on the National Stakeholders Conference on Honey Bee Health* at 16-20.

[27] EPA, Imidacloprid Amended Final Work Plan 3 (2010), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2008-0844-0121.

2. Clothianidin

First registered in 2003, clothianidin is commercially used as a seed treatment on corn, canola, rice, turf, and row crops such as grapes, strawberries, and cucurbits, as well as tree crops such as pome fruit and stone fruit.[29] According to EPA, "[c]lothianidin is highly toxic to honey bees on an acute contact basis (LD_{50}>0.0439 µg/bee)" and "has the potential for toxic chronic exposure to honey bees, as well as other non-target pollinators, through the translocation of clothianidin residues in nectar and pollen."[30] Moreover, "this toxic chronic exposure may include lethal and/or sub-lethal effects in the larvae and reproductive effects in the queen."[31]

To fully evaluate the possible effects of chronic exposure to honey bees, EPA has acknowledged that "a complete worker bee life cycle study will be required, as well as an evaluation of exposure and effects on the queen."[32] However, it appears that these studies have never been conducted. In its Final Work Plan for the registration review of clothianidin, EPA also identified the following outstanding data requirements:

- data on honey bee toxicity of residues on foliage (guideline 850.3030)
- field testing for pollinators (guideline 850.3040);
- a special study on larval toxicity;

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[28] U.S. EPA, *EPA Actions to Protect Pollinators*, Pollinator Protection (Mar. 21, 2014), http://www2.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides [hereinafter Pollinator Protection Schedule].

[29] Clothianidin Conditional Registration, *supra* note 8, at 2, 15; *see, e.g.*, Pesticide Label for Clutch 50 WDG Insecticide, http://www.valent.ca/valentus/Data/Labels/20140211_CLUTCH%2050%20WDG%20INSECTICIDE.FRUITING%20VEGETABLES%20CUCURBIT.E_FINAL%20LABELS.pdf.

[30] *Id.*

[31] *Id.* at 15.

[32] Clothianidin Conditional Registration, *supra* note 8, at 16.

- a special study on chronic pollinator feeding; and
- a special study on pollen and nectar residues.[33]

Clothianidin's registration review is tentatively scheduled for completion in 2018.[34]

3. Thiamethoxam

Since its registration in 1999, thiamethoxam has been approved for use on agricultural and non-agricultural commodities, including field crops, vegetable crops, stone fruit, coffee, spices, turf, ornamentals, and building structures, as well as for use as a wood preservative.[35] Use of the pesticide has an "[e]stimated risk to beneficial insects" that is "presumed to be high, as thiamethoxam is highly toxic to bees on an acute contact and oral exposure basis."[36] EPA has acknowledged that the "environmental fate database for thiamethoxam is considered only partially fulfilled," and that "[f]or compounds, such as thiamethoxam, which (1) show acute toxicity to bees and, (2) have exposure routes for bees, EPA anticipates requiring toxicity and exposure studies to allow for evaluation of risks to pollinators."[37]

In its Final Work Plan for the registration review of thiamethoxam, EPA identified the following missing data:

- a study on the honey bee toxicity of residues on foliage (guideline 850.3030);

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[33] EPA, Clothianidin Final Work Plan 4, 8 (2012), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0865-0166.

[34] U.S. EPA, Clothianidin Emergency Citizen Petition Denial Memorandum 5-6 (July 17, 2012), http://www.epa.gov/pesticides/about/intheworks/epa-respns-to-clothianidin-petition-17july12.pdf; *see also* Pollinator Protection Schedule, *supra* note 28.

[35] U.S. EPA, Thiamethoxam Final Work Plan (FWP): Registration Review Case No. 7641, at 3 (2012), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2011-0581-0024; Thiamethoxam Summary Document, *supra* note 8, at 14.

[36] Thiamethoxam Summary Document, *supra* note 8, at 15.

[37] Thiamethoxam Final Work Plan, *supra* note 35, at 4-5.

- field tests for pollinators (guideline 850.3040);
- a special study on larval toxicity;
- a special study on pollen and nectar residues; and
- and a special study on chronic pollinator feeding.[38]

Thiamethoxam's registration review is scheduled for completion in 2018.[39]

4. Dinotefuran

Dinotefuran was conditionally registered in 2004 for use on leafy vegetables, residential and commercial buildings, pet flea and tick treatments, turf and ornamental plants including flowering plants that attract bees, golf courses, and residential gardens. Dinotefuran is approved for soil incorporation, foliar application, bait application, and spot treatment.[40] The registration memo acknowledged that dinotefuran "is highly toxic to bees on an acute oral basis (LD50 – 0.023 µg ai/bee) and on an acute contact basis (LD50 – 0.047 µg ai/bee[)]," making "protection of pollinators . . . a concern."[41] Application instructions also warn that users "not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the area," as it is "highly toxic to bees exposed to direct treatment or residues."[42] There is no available evidence that these instructions are effective at preventing exposure to bees.

In its Final Work Plan for the registration review of dinotefuran, EPA acknowledged that pollinator-related data gaps for dinotefuran currently include:

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[38] *Id*. at 5.

[39] Pollinator Protection Schedule, *supra* note 28.

[40] Dinotefuran Conditional Registration, *supra* note 8, at 28.

[41] *Id.* at 28, 34.

[42] *Id.* at 35.

- field testing for pollinators (guideline 850.3040);
- a special study on larval toxicity;
- a special laboratory study on chronic feeding; and
- an analysis of residues in pollen and nectar/field.[43]

Dinotefuran's registration review is scheduled for completion in 2018.[44]

5. Acetamiprid

First registered in 2002, acetamiprid is used by commercial sprayers for ground and aerial applications on leafy vegetables, fruiting vegetables, cole crops, citrus fruits, pome fruits, grapes, cotton, and ornamental plants and flowers—almost all of which are attractive to bees.[45] EPA identifies acetamiprid as being "moderately toxic to bees."[46] In its Final Work Plan for the registration review of acetamiprid, EPA anticipated the following data needs:

- a study on larval toxicity; and
- a nectar and pollen residue study.[47]

EPA anticipates completing the registration review for acetamiprid in 2019.[48]

[43] EPA, Dinotefuran Final Work Plan 10 (2012), https://outside.vermont.gov/agency/agriculture/vpac/Other%20VPAC%20Documents/Dinotefuran/EPA-HQ-OPP-2011-0920-0012finalworkplan.pdf.

[44] Pollinator Protection Schedule, *supra* note 28.

[45] Acetamiprid Conditional Registration, *supra* note 8, at 2.

[46] *Id.* at 5.

[47] EPA, Acetamiprid Final Work Plan 5-6 (2013), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0329-0017.

[48] Pollinator Protection Schedule, *supra* note 28.

6. Thiacloprid

Thiacloprid was first registered in 2003 as a foliar spray for outdoor non-residential, food/feed use on cotton and pome fruits—including apples, crabapples, oriental pears, and pears; use on stone fruit and peppers is currently under review.[49] Based on the results of bee toxicity tests, EPA distinguished thiacloprid from other neonicotinoids and predicted that it "will not adversely affect bees."[50] Nonetheless, EPA identified the need for more data on thiacloprid's impacts on beneficial insects, residues in pollen and fields, and toxicity to pollinator larvae.[51] In its Final Work Plan for the registration review of thiacloprid, EPA specified the following data needs relating to pollinators:

- a special study on residues in pollen and nectar/field; and
- a special study on pollinator larval toxicity.[52]

Thiacloprid's registration review is scheduled for completion in 2019.[53]

II. LEGAL STANDARD

FIFRA requires EPA to register any pesticide before it is sold or distributed in the United States. 7 U.S.C. § 136a(a). A FIFRA registration is a product-specific license setting forth the terms and conditions under which the product can be legally distributed, sold, and used. *See id.* § 136a(a), (c)-(e). EPA can register a pesticide only upon determining that "it will perform its

[49] Thiacloprid Conditional Registration, *supra* note 8, at 1-2; U.S. EPA, Thiacloprid Final Work Plan (FWP): Registration Review Case No. 7622, at 2 (2013).

[50] Thiacloprid Conditional Registration, *supra* note 8, at 10.

[51] Thiacloprid Final Work Plan, *supra* note 49, at 5.

[52] EPA, Thiacloprid Final Work Plan 5 (2013), http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPP-2012-0218-0014.

[53] Pollinator Protection Schedule, *supra* note 28.

intended function without unreasonable adverse effects on the environment," *id.* § 136a(c)(5)(C), and that "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment," *id.* § 136a(c)(5)(D). FIFRA has defined "[u]nreasonable adverse effects on the environment" to include "any unreasonable risk to . . . the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide," *id.* § 136(bb).

A. Data Requirements

"As a precondition for registration of a pesticide, manufacturers must submit research data . . . concerning the product's health, safety, and environmental effects." *Thomas v. Union Carbide Agric. Prods. Co.*, 473 U.S. 568, 571 (1985). The registrant "must demonstrate with sufficient scientific evidence that . . . [the pesticide] will not generally cause unreasonable adverse effects on the environment." *Love v. Thomas*, 858 F.2d 1347, 1350 (9th Cir. 1988). It is well established that "[t]he burden of persuasion that a pesticide product is entitled to registration . . . is always on the proponent(s) of registration." 40 C.F.R. § 154.5.

FIFRA directs EPA to "publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide." 7 U.S.C. § 136a(c)(2)(A). To this end, the regulations promulgated by EPA and codified in Title 40, Part 158 of the Code of Federal Regulations specify "the kinds of data and information EPA requires in order to make regulatory judgments under FIFRA . . . about the risks and benefits of pesticide products." 40 C.F.R. § 158.1(a). "EPA will not approve an application unless there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA . . . ." *Id.* § 152.85(e).

As set forth in the FIFRA regulations, registrants are required to conduct a "honeybee acute contact LD_{50}" study for all pesticide outdoor end-uses. 40 C.F.R. § 158.630(b)(3). Registrants must also submit data on "[h]oney bee toxicity of residues on foliage," *id.* § 158.630(d), "when the formulation contains one or more active ingredients having an acute LD_{50} of < 11 micrograms per bee as determined in the honey bee acute contact study and the use pattern(s) indicate(s) that honey bees may be exposed to the pesticide," *id.* § 158.630(e). In addition, registrants must conduct "[f]ield testing for pollinators," *id.* § 158.630(d), when any of the following conditions are met: (i) "[d]ata from other sources (Experimental Use Permit program, university research, registrant submittals, etc.) indicate potential adverse effects on colonies, especially effects other than acute mortality (reproductive, behavioral, etc.)"; (ii) "[d]ata from residual toxicity studies indicate extended residual toxicity"; and (iii) "[d]ata derived from studies with terrestrial arthropods other than bees indicate potential chronic, reproductive or behavioral effects," *id.* § 158.630(e).

If the requisite data specified in the FIFRA regulations "is not sufficient to evaluate the potential of the product to cause unreasonable adverse effects on man or the environment, additional data requirements will be imposed." *Id.* § 158.75.

B. Conditional Registration

FIFRA authorizes EPA to 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 (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement)." 7 U.S.C. § 136a(c)(7)(C). However, EPA may do so only "on the condition that by the end of such period the [agency] receives such data and the data do not

meet or exceed risk criteria enumerated in [the FIFRA] regulations . . . and on such other conditions as the Administrator may prescribe." *Id.* The agency shall grant a conditional registration only if it "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." *Id.*

C. Registration Review

For every registered pesticide, EPA must complete a registration review no later than 2022, and subsequent registration reviews "each 15 years thereafter." *Id.* § 136a(g)(1)(A)(iv). The standard for registration review is the same as the standard for initial registration. *See id.* § 136a-1(g)(2)(C). A pesticide product remains registered until cancelled pursuant to FIFRA section 6. *See id.* § 136d. Under section 6, if it appears to EPA that a registered pesticide causes "unreasonable adverse effects on the environment" when "used in accordance with widespread and commonly recognized practice," then EPA may undertake cancellation proceedings. *Id.* § 136d(b). Before taking any final action pursuant to section 6, EPA "shall consider restricting a pesticide's use or uses as an alternative to cancellation." *Id.* If EPA classifies a pesticide for restricted use "because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be . . . subject to such . . . restrictions as the Administrator may provide by regulation." *Id.* § 136a(d)(1)(C)(ii).

EPA may, moreover, undertake interim administrative review of a pesticide at any point, either as part of a formal cancellation proceeding or based on "a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk . . . to the environment." *Id.* § 136a(c)(8). EPA has defined "[o]ther significant evidence" to include "factually significant information that relates to the uses of the pesticide and its adverse risk . . .

to the environment." 40 C.F.R. § 154.3. The agency may issue "an interim registration review decision," which "may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review." *Id.* § 155.56.

III. NEONICOTINOIDS' EFFECTS ON BEES

Neonicotinoids are the fastest growing and most heavily used class of insecticides in the United States.[54] The unprecedented increase in neonicotinoid use has adversely affected honey bee and bumble bee populations, species whose pollinating activities are essential to agricultural production. Out of some 100 crop species responsible for providing 90% of the world's food supply, 71 are dependent on bee pollination.[55] The estimated annual value of crops dependent on bee pollination is $15 billion in the United States alone.[56]

Alarmingly, however, there has been a sharp decline in bee populations worldwide over the last decade; this phenomenon has generally been referred to as "Colony Collapse Disorder,"

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[54] *See* United States Geological Survey, Pesticide Use Maps – Imidacloprid, Acetamiprid, Clothianidin, Thiamethoxam, Thiacloprid, Dinotefuran, Pesticide National Synthesis Project (1995-2011), http://water.usgs.gov/nawqa/pnsp/usage/maps/compound_listing.php?year=2011&hilo=L; *see also* UNEP, Global Honey Bee Colony Disorders and Other Treats to Insect Pollinators, UNEP Emerging Issues, *available at* http://www.unep.org/dewa/Portals/67/pdf/Global_Bee_Colony_Disorder_and_Threats_insect_pollinators.pdf [hereinafter UNEP Global Honey Bee Report].

[55] UNEP Global Honey Bee Report, *supra* note 54, at 1.

[56] USDA, *Honey Bees and Colony Collapse Disorder (CCD)*, http://www.ars.usda.gov/News/docs.htm?docid=15572 (last visited Apr. 28, 2014); The White House, Fact Sheet: The Economic Challenge Posed by Declining Pollinator Populations (June 20, 2014), http://www.whitehouse.gov/the-press-office/2014/06/20/fact-sheet-economic-challenge-posed-declining-pollinator-populations.

a multi-factor syndrome that causes sudden and rapid loss of a colony's adult worker bee population.[57] While scientific consensus previously identified the Varroa mite (*Varroa destructor*) as a major contributor to bee decline, current theories increasingly point to a combination of environmental and anthropogenic factors, including neonicotinoid use in particular.[58] A recent Harvard study found that "sub-lethal exposure of neonicotinoids . . . affected the winterization of healthy colonies that subsequently [led] to CCD [i.e., Colony Collapse Disorder]."[59] CCD has caused massive honey bee hive losses, with replacements borne by beekeepers alone.[60] These costs have been estimated at up to $2 billion,[61] and EPA must take this enormous cost into account when considering whether documented harm to bees from neonicotinoid exposure is "unreasonable."

A. Neonicotinoids Can Cause Serious Harm to Bees

The harm to bees from neonicotinoid exposure can be acute (such as death within a short time after exposure) or chronic (such as weakening the colony so that over-wintering or breeding success is impaired) and can have population-level effects. Studies suggest that bees exposed to neonicotinoids in small but repeated or extended doses have significant behavioral and functional impairments, such as diminished learning, food collection abilities, navigational capabilities, and

[57] Alberto Alemanno, *The Science, Law and Policy of Neonicotinoids and Bees: A New Test Case for the Precautionary Principle*, 4 Eur. J. Risk Reg. 191, 193 (2013).

[58] *Id.* at 194.

[59] Chensheng Lu et al., *Sub-lethal Exposure to Neonicotinoids Impaired Honey Bees Winterization Before Proceeding to Colony Collapse Disorder*, 67 Bulletin of Insectology 125 (2014).

[60] USDA, *supra* note 22, at 1-2; The White House, *supra* note 56.

[61] USDA, *supra* note 22, at 2; The White House, *supra* note 56.

immune function, as well as reduced fecundity and queen production.[62] Any one of these harmful effects is likely to hinder a colony's ability to maintain its health and survive the winter.[63]

In all cases of neonicotinoid exposure, bees bring pesticide-contaminated pollen and nectar back to the hive or nest (native bees have nests), where ongoing exposure to the entire population takes place.[64] Neonicotinoids have been found in hive components such as pollen, bee bread, royal jelly (used for larvae and queen bee nutrition), and honey at levels exceeding field pollen levels due to concentration within the hive.[65] Experts have suggested that honey bees partially buffer their young from neonicotinoid toxicity by processing food for their young, whereas bumble bees and solitary native bees may be more vulnerable to neonicotinoid toxicity, insofar as adults complete little to no food processing for their young.[66] This raises particular ecological concerns, as it is native bees, not commercial honey bees, that are responsible for pollinating many of the seeds, nuts, and fruits that a wide variety of wildlife, from songbirds to grizzly bears, rely on for food.

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[62] M. Henry, et al., *supra* note 19, at 348-50.

[63] USDA, *supra* note 56 (noting that combinations of environmental stresses may unexpectedly weaken colonies, leading to collapse when additional stressors like pesticides are introduced); *see also* Penelope Whitehorn, et al., *Neonicotinoid Pesticide Reduces Bumble Bee Colony Growth and Queen Production*, 336 Science 351-52 (Apr. 20, 2012).

[64] Jennifer Hopwood, et al., *Are Neonicotinoids Killing Bees? A Review of Research Into the Effects of Neonicotinoid Insecticides on Bees, with Recommendations for Action*, The Xerces Society for Invertebrate Conservation (2012), http://www.xerces.org/wp-content/uploads/2012/03/Are-Neonicotinoids-Killing-Bees_Xerces-Society1.pdf.

[65] *Neonicotinoid Pesticides and Honey Bees*, Washington State University Extension Fact Sheet (Nov. 2013), http://cru.cahe.wsu.edu/CEPublications/FS122E/FS122E.pdf.

[66] Amanda Ellis, et al., *The Benefits of Pollen to Honey Bees*, University of Florida IFAS Extension (Sept. 2013), http://edis.ifas.ufl.edu/in868; Beatriz Moisset & Stephen Buchmann, *Bee Basics: An Introduction to Our Native Bees*, USDA, U.S. Forest Service & Pollinator Partnership (Mar. 2011), https://www.pollinator.org/PDFs/BeeBasicsBook.pdf.

Dozens of independent, peer-reviewed studies have assessed the impacts of neonicotinoids on bees and found significant lethal and sublethal effects.[67] Laboratory studies have shown that such chemicals can cause losses in sense of direction, impairment of memory and brain metabolism, and death.[68]

B. Synergistic Effects Amplify Harm to Bees

Neonicotinoid risk assessments focus primarily on three main routes of exposure: residues in nectar and pollen; dust produced during the sowing of treated seeds; and residues in the guttation fluid, or sap, produced by treated plants.[69] An additional area of risk, however, is exposure to the combined synergistic effects of neonicotinoids mixed with other chemical compounds. Studies have found that some neonicotinoids, when combined with certain fungicides, synergize to increase the systemic pesticides' toxicity over 1,000 times.[70] In laboratory experiments, acetamiprid, for example, becomes 244 times more acutely toxic to honey bees (as measured by the dose that kills 50% of test bees within 24 hours, called the acute LD_{50}) when combined with the fungicide triflumizole, while thiacloprid becomes 1,141 times

[67] *See, e.g.*, J.P. Van der Sluijs et al., *Conclusions of the Worldwide Integrated Assessment on the Risks of Neonicotinoids and Fipronil to Biodiversity and Ecosystem Functioning*, Envtl. Sci. & Pollution Res. (forthcoming summer 2014), *available at* http://www.lpo.fr/images/Presse/cp/2014/impact_pesticides/WIA_The_following_is_a_summary_of_the_conclusions_chapter_that_will_appear_in_Environmental_Sciences_and_Pollution_Research.pdf (discussing survey of peer-reviewed articles published over the past two decades and concluding that "[i]n bees, field-realistic exposures in controlled settings have been shown to adversely affect individual navigation, learning, food collection, longevity, resistance to disease and fecundity," and that "[f]or bumblebees, colony-level effects have been clearly demonstrated, with exposed colonies growing more slowly and producing significantly fewer queens); *see also* Int'l Union for Conservation of Nature, *supra* note 6.

[68] Colin M.E., et al., *A Method to Quantify and Analyze the Foraging Activity of Honey Bees: Relevance to the Sublethal Effects Induced by Systemic Insecticides*, 47 Archives of Envtl. Contamination & Toxicology 387, 389-94 (Sept. 2004).

[69] Alemanno, *supra* note 57, at 197.

[70] UNEP Global Honey Bee Report, *supra* note 54, at 7.

more toxic when combined with the same fungicide.[71] These "chemical cocktails" are acutely toxic and interfere with the relatively few bee genes that encode detoxification enzymes, thus rendering exposed bees more vulnerable to pathogens.[72] Interactions between pesticides and pathogens could be a major contributor to increased mortality of bee colonies, including Colony Collapse Disorder.

C. Neonicotinoids Are Persistent and Mobile, Increasing the Risk of Bee Exposure

Neonicotinoids are extremely persistent, and can accumulate in the soil with half-lives ranging from 148 to 6,932 days, depending on the soil type and weather conditions.[73] Because neonicotinoids can remain in the soil for extended periods after the suspension of active use, new plants are able to absorb the pesticides through their roots and subsequently poison beneficial pollinators.[74] Soil from fields where treated seeds had not been planted in over two growing seasons, for example, has tested positive for neonicotinoid contamination, and measurable amounts of residue have been found in woody plants up to six years after application.[75]

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[71] Iwasa T, et al., *Mechanism for the Differential Toxicity of Neonicotinoid Insecticides in the Honey Bee, Apis mellifera*, 23 Crop Protection 371, 375-76 (May 2004).

[72] *Id.*

[73] U.S. EPA, Memorandum EFED Risk Assessment for the Seed Treatment of Clothianidin 600FS on Corn and Canola 40 (Feb. 25, 2003), http://www.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-044309_20-Feb-03_a.pdf.

[74] Rowan Jacobsen, *Fruitless Fall: The Collapse of the Honey Bee and the Coming Agricultural Crisis* 91 (2009).

[75] Christian H. Krupke, et al., *Multiple Routes of Pesticide Exposure for Honey Bees Living Near Agricultural Fields*, 7 PLoS ONE 4 (Jan. 2012); Jennifer Hopwood, et al., *supra* note 64, at v.

Neonicotinoid concentrations also persist in the guttation water of treated plants during the first 10-15 days after the plants' emergence from the soil.[76] Thiamethoxam and clothianidin, for example, have been documented in guttation drops from corn plants germinated from treated seeds, and imidacloprid has been reported in guttation fluid from greenhouse and field plants grown from treated seeds.[77] These concentration levels may represent lethal doses for bees and other beneficial pollinators that use guttation drops as a source of water. Moreover, given that these residues are water-soluble and persistent, repeated applications, even at presumably safe levels, may cumulatively lead to sublethal effects. In order to evaluate the risks that guttation drop exposure poses to pollinator health, it is necessary to conduct targeted studies analyzing the frequency and amount of guttation water consumed by bees in the field.

In addition to their persistence, neonicotinoids are highly mobile. Studies show that plants in fields nearby those directly exposed to the pesticides have become indirectly contaminated with neonicotinoids.[78] This may result from the spread of airborne talc powder applied to pesticide-coated seeds to reduce stickiness during planting. The excess talc contains acutely lethal levels (exceeding the LD_{50}) of neonicotinoids that can be dispersed into the air, soil, and neighboring fields during planting, resulting in documented bee deaths.[79] Seed treatments are especially harmful, contributing to both high-level acute exposures to beneficial

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[76] Andrea Tapparo, et al., *Rapid Analysis of Neonicotinoid Insecticides in Guttation Drops of Corn Seedlings Obtained from Coated Seeds*, 13 J. Envtl. Monitoring 1564, 1564-68 (June 2011).

[77] *Id.*; Vincenzo Girolami, et al., *Translocation of Neonicotinoid Insecticides from Coated Seeds to Seedling Guttation Drops: A Novel Way of Intoxication for Bees*, 102 J. Econ. Entomology 1808, 1808-17 (Oct. 2009).

[78] Christian H. Krupke, et al., *supra* note 75, at 2-6.

[79] *Id.* at 4.

insects during seed planting and subsequent low-level chronic exposures from systemic plant contamination. And, of course, honeybees used for commercial pollination are highly mobile too; honeybee colonies are transported around the country to pollinate different crops, which increases their chances of being exposed both to neonicotinoids and to mixtures of different pesticides.

IV. THERE IS AN URGENT NEED FOR INTERIM ADMINISTRATIVE REVIEW AND APPROPRIATE RESTRICTIONS ON NEONICOTINOID USE

The current registration review for neonicotinoids is scheduled for completion by 2019.[80] In the meantime, EPA continues to allow the use of neonicotinoids despite significant evidence raising prudent concerns about unreasonable adverse effects on the environment.[81] Bees are indicator species, and the serious effects of neonicotinoids on pollinators are cause for alarm.[82] As reflected in the *White Paper in Support of the Proposed Risk Assessment Process for Bees* coauthored by EPA, the agency recognizes that more needs to be done to study the risks that neonicotinoids pose to bees.[83] The lack of sufficient information on the toxic effects of neonicotinoids is corroborated by the data gaps identified in each of the Final Work Plans for the registration review of the six neonicotinoids at issue. In particular, many of the basic data requirements listed in Section II.A. above have never been satisfied for neonicotinoid pesticides. It is unlawful for EPA to allow continued widespread use of neonicotinoids while

[80] *See* Pollinator Protection Schedule, *supra* note 28.

[81] *See* 2010 EPA Clothianidin Memo, *supra* note **Error! Bookmark not defined.**.

[82] Elaine Evans, et al., *Status Review of Three Formerly Common Species of Bumble Bee in the Subgenus Bombus*, The Xerces Society for Invertebrate Conservation (2008), http://www.xerces.org/wp-content/uploads/2009/03/xerces_2008_bombus_status_review.pdf.

[83] U.S. EPA, Health Canada, & Cal. Dep't of Pesticide Regulation, White Paper in Support of the Proposed Risk Assessment Process for Bees (2012), *available at* http://www.cdpr.ca.gov/docs/emon/surfwtr/presentations/epa_whitepaper.pdf.

acknowledging that the agency lacks sufficient information to evaluate the harm these pesticides cause.

Five more years of bee population decline at the current rate could be devastating to bee populations. This is so even assuming that the agency adheres to its current plan to complete registration review by 2019. The toxic effects of neonicotinoids on bee populations may have already started to disrupt food webs on a broad scale.[84] In 2008, it was reported that "at least four species of formerly common North American wild [bee] species have experienced catastrophic declines over the past decade—two of them may be on the brink of extinction."[85] The diverse pathways of exposure support the need for an immediate interim administrative review of neonicotinoids. This interim review should be completed within one year and focus on the effects of neonicotinoids on bees, in light of serious potential harm.

In April 2013, the European Union approved a minimum two-year moratorium on the use of certain neonicotinoid chemicals across the continent in response to a European Food Safety Authority report identifying the "high acute risk" to honey bees from certain neonicotinoid uses.[86] Specifically, the suspension applies to use on crops that are "attractive to bees" and on certain cereal grains that cause pesticide drift during planting.[87] Meanwhile, EPA continues to

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[84] *See* Int'l Union for Conservation of Nature, *supra* note 6 ("Far from protecting food production, the use of neonics is threatening the very infrastructure which enables it, imperiling the pollinators, habitat engineers and natural pest controllers at the heart of a functioning ecosystem."); McGrath, *supra* note 6.

[85] Xerces, *supra* note 18, at 1.

[86] European Commission, Commission Regulation 485/2013 on Conditions of Approval of the Active Substances Clothianidin, Thiamethoxam and Imidacloprid, 2013 O.J. (L 139/12); Press Release, *EFSA Identifies Risks to Bees from Neonicotinoids,* European Food Safety Authority (Jan. 16, 2013).

[87] *Id.*

allow widespread neonicotinoid use, while recognizing that the agency has never adequately evaluated impacts to bees.

In light of the substantial scientific uncertainties surrounding the use of neonicotinoids, and the serious potential harm to beneficial pollinators, EPA should undertake an interim administrative review of neonicotinoids to, at a minimum:

- Evaluate whether to prohibit the use of neonicotinoids on all bee-pollinated crops and, if not, provide a reasoned explanation for declining to do so;
- Evaluate whether to prohibit the use of neonicotinoids on all bee-pollinated ornamentals, and, if not, provide a reasoned explanation for declining to do so;
- Review all published, peer-reviewed science regarding potential impacts of neonicotinoids on native bees and honeybees;
- Compel submission of adequate field studies that evaluate neonicotinoid residue build-up after repeated applications, chronic exposures at environmentally relevant levels (including realistic worst-case scenarios), and cumulative effects of multiple pesticide exposures;
- Require the completion of studies on the immune-system impacts of neonicotinoids on bees;
- Require the completion of all studies needed to fill the data gaps identified in the Final Work Plans for registration review of each of the neonicotinoids;
- Evaluate adverse, population-level effects that neonicotinoids have on bees;
- Assess whether neonicotinoid-containing products have effective bee warning labels that require applicators to take into consideration bee foraging activity, and

evaluate whether any label warning can adequately protect against harm to beneficial insects from systemic insecticides; and

- Evaluate the harmful effects on bees of neonicotinoid treatments applied to plants sold at home and garden centers.

The interim review process authorizes EPA to undertake this evaluation immediately, without waiting for completion of the Agency's ongoing registration review. If EPA determines, after completing interim review, not to prohibit use of neonicotinoids on all bee-pollinated crops and ornamentals—despite known risks and critical missing information—the agency must provide a reasoned explanation for that decision.

Additionally, in response to a recent GAO report regarding conditional registrations, EPA acknowledged major flaws in the agency's oversight and management of the conditional registration process.[88] EPA conceded that the agency's records regarding what pesticides are conditionally registered—and on what basis—are inaccurate and incomplete.[89] In light of these admissions, it is impossible to have confidence in publicly available agency documents regarding the status of conditional registrations for neonicotinoids. Since the GAO released its report, EPA placed on its website a document identifying the pesticides conditionally registered since 2000. Although this document does provide some information about the studies that were required and the status of those study requirements, there are concerns, as noted earlier, about whether those conditions were actually satisfied.

For all pesticides containing the six neonicotinoids at issue, we therefore request that EPA identify in response to this petition:

[88] 2013 GAO Report, *supra* note 8, at 46-49.

[89] *Id.*

- which active neonicotinoid registrations are conditional;
- what studies EPA has requested for each pesticide to satisfy the terms of those conditional registrations;
- whether and when the studies on which those registrations were conditioned were submitted to EPA;
- whether and when EPA reviewed any such studies submitted to satisfy the terms of the conditional registrations; and
- what EPA's review, if any, of those studies found.

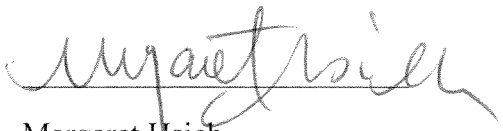
If EPA conditioned the registration of any neonicotinoid pesticide on studies that were never produced or evaluated, the passage of a period of time "reasonably sufficient for the generation and submission of required data," 7 U.S.C. § 136a(c)(7)(C), renders the continued registration of that pesticide unreasonable.

Finally, we ask EPA to identify all conditional registrations for neonicotinoid pesticides that the agency later converted to unconditional registrations, to disclose when those conversions occurred, and to explain the justification for those changes in registration status.

V. CONCLUSION

The dramatic increase in neonicotinoid use since EPA first registered imidacloprid over a decade ago has almost certainly contributed to severe declines in bee population levels in recent years. These devastating declines, and the significant threats they pose to agricultural food production and ecological food webs, justify cancellation of neonicotinoid pesticides. They moreover compel EPA, in the meantime, to conduct an urgent interim administrative review of neonicotinoids. Given the critical circumstances here, we ask EPA to initiate this review within thirty days and to complete the review within one year.

Respectfully submitted,



Margaret Hsieh
Natural Resources Defense Council
40 W. 20th Street
New York, NY 10011
212-727-2700

Jennifer Sass
Natural Resources Defense Council
1152 15th Street NW, Suite 300
Washington, DC 20005
202-289-2362

Date: July 7, 2014

Cc: Administrator Gina McCarthy
Assistant Administrator Jim Jones, Office of Chemical Safety and Pollution Prevention
Avi Garbow, General Counsel
Kevin McLean, Acting Associate General Counsel
Michael Stebbins, Assistant Director for Biotechnology, Science Division, Office of Science and Technology Policy
Rusty Wasem, Chemical Review Manager for Imidacloprid and Clothianidin
Carissa Cyran, Chemical Review Manager for Thiamethoxam
Steven Snyderman, Chemical Review Manager for Dinotefuran
Margaret Hathaway, Chemical Review Manager for Acetamiprid
Wilhelmena Livingston, Chemical Review Manager for Thiacloprid