UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response from the Pesticide Re-evaluation Division to Comments on the Draft Risk Assessments and Benefits Assessments Supporting the Registration Review of the Nitroguanidine-substituted Neonicotinoid Insecticides

DATE: January 16, 2020

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Dockets: Clothianidin: EPA-HQ-OPP-2011-0865
Dinotefuran: EPA-HQ-OPP-2011-0920
Imidacloprid: EPA-HQ-OPP-2008-0844
Thiamethoxam: EPA-HQ-OPP-2011-0581

Summary

EPA issued notices in the Federal Register concerning the opening of public comment periods for the preliminary pollinator assessments, draft human health and non-pollinator ecological risk assessments, and several supporting benefits-related assessments. Imidacloprid's initial registration preceded the other nitroguanidine-substituted neonicotinoids (*i.e.* clothianidin, dinotefuran and thiamethoxam). Therefore, the *Preliminary Pollinator Assessment to Support the Registration Review of Imidacloprid* was published January 15, 2016 with a 60-day public comment period that closed on March 15, 2016, however, the agency approved a 30-day extension request that concluded on April 14, 2016. The preliminary pollinator assessments for the remaining three nitroguanidine-substituted neonicotinoids were announced on May 25, 2017

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with a 60-day public comment period that closed on July 24, 2017.[1] After the publication of these two preliminary pollinator assessments, the agency made a programmatic decision to align the registration review schedule for all four nitroguanidine-substituted neonicotinoids (clothianidin, dinotefuran, imidacloprid and thiamethoxam, referred to as neonicotinoids herein). As a result of that decision, the draft human health risk assessments and non-pollinator ecological risk assessments, as well as various supporting benefits-related registration review documents were announced on December 21, 2017 for an initial 60-day public comment period. The agency then granted an additional 120-day public comment period that closed on April 21, 2018.

During the public comment period for the neonicotinoid assessments, the agency received over 500,000 public comments on a wide variety of topics regarding the agency's assessments. Comments were submitted by various individuals, organizations and companies. Comments of a broader regulatory nature are summarized in this memorandum along with the agency's responses. Comments received concerning the chemical-specific potential human health risks, potential ecological risks (*e.g.*, pollinator, non-pollinator), uses, benefits, and/or the importance of neonicotinoids are addressed in separate memoranda, which are listed in the Proposed Interim Decisions (PIDs) and available in the public dockets.

This memorandum contains the agency's responses to generalized comments pertaining to the assessments for the neonicotinoid insecticides as a group. Chemical-specific comments, and the agency's response to those comments, are addressed in the chemical-specific PID (available in the chemical-specific dockets). This memorandum is divided into three sections. The first section contains a list of all public commenters on the neonicotinoid assessments. Section two contains summarized comments and the agency's response to those comments. Lastly, the third section lists all of the supporting documents that the agency is posting to the public dockets concurrently with the PIDs to support the neonicotinoid registration reviews.

The agency thanks all commenters for their comments and has considered them as part of the neonicotinoid registration reviews.

Note on Public Comment Identifier Numbers

The public commenters varied in how they submitted their neonicotinoid assessment comments to EPA, with some stakeholders cross-posting comments to each of the four neonicotinoid chemical dockets on [HYPERLINK "https://www.regulations.gov/"], and other stakeholders submitting comments to a single neonicotinoid docket, or a subset of the four neonicotinoid dockets. In accordance with regulations.gov protocol, cross-posted comments (duplicate comments submitted to multiple dockets) are assigned identifier numbers unique to each docket that they are submitted to. In this memorandum only a single representative comment was referenced when identifying a cross-posted comment. The docket numbers for the neonicotinoids covered by this document are listed in Table 1.

[1] Since clothianidin is a degradate of thiamethoxam, a decision was made to combine the preliminary pollinator assessments for these two chemicals.

Table 1: Neonicotinoid Insecticides Included in this Response to Comments

Chemical Name	Docket Number
Clothianidin	EPA-HQ-OPP-2011-0865
Dinotefuran	EPA-HQ-OPP-2011-0920
Imidacloprid	EPA-HQ-OPP-2008-0844
Thiamethoxam	EPA-HQ-OPP-2011-0581

Public Comments and Agency Responses

I. List of Neonicotinoid Public Commenters that Provided Substantive Comments

a. Academic / Extension: Cristi L. Palmer, IR-4 Ornamental Horticulture Manager, Rutgers, The State University of New Jersey.

b. Commodity Groups: John Heisdorffer, American Soybean Association (ASA); Don Bloss, National Sorghum Producers (NSP); Marcy L. Martin, Director, Trade, California Fresh Fruit Association (CFFA); Renee T. Rianda, PCA, QAL, CCA, Business Development, Agrochemicals & Sustainability Programs, Morning Star Company; Tyler Grove, General Agronomist, American Crystal Sugar Company; Dwight Little, President, National Barley Growers Association (NBGA); Gerald Long, President, Georgia Farm Bureau (GFB); Jimmie Musick, President, National Association of Wheat Growers (NAWG).

c. Federal Government: Dr. Sheryl H. Kunickis, Director, Office of Pest Management Policy, United States Department of Agriculture (USDA); Osama El-Lissy, Deputy Administrator, Plant Protection and Quarantine, Animal and Plant Health Inspection Service (APHIS), USDA.

d. State Governments: Dr. Charlotte Roy, Research Scientist, Minnesota Department of Natural Resources; Melissa Hoffer *et al.*, Chief, Energy & Environment Bureau, Massachussetts Office of the Attorney General; Pamela Wofford, Environmental Program Manager II, Environmental Monitoring Branch, California Department of Pesticide Regulation (CDPR).

e. e. Beekeepers and Honey Bee Businesses: Gene Brandi Apiaries, Robert Nolan (beekeeper), Beesponsible.Non-Governmental Organizations (NGO): Jennifer Sass *et al.*, Natural Resources Defense Council (NRDC); Dr. Dr. Nathan Donley *et al.*, Senior Scientist, Environmental Health Program, Center for Biological Diversity (CBD); Nichelle Harriott, Science and Regulatory Director, Beyond Pesticides; Sarah Hoyle, Pesticide Program Specialist, Xerces Society for Invertebrate Conservation; Scott J. Dahlman, Policy Director, Oregonians for Food & Shelter (OFS).

f. Pesticide Marketers and Distributors: Richard D. Gupton, Senior Vice President, Public Policy & Counsel, Agricultural Retailers Association (ARA).

g. Pesticide Registrants: Dr. Paul D. Mitchell, AgInformatics, LLC.; Keri Carstens, Integrated Product Research and Stewardship, Seed Treatment Enterprise, DuPont; Dr. Iain D. Kelly, Director, Regulatory Policy and Issues Management, Bayer CropScience.

h. Trade Organizations: Andrew W. LaVigne, American Seed Trade Association (ASTA); Janet E. Collins, CropLife America (CLA).

i. Other public commenters: private citizens and anonymous commenters.

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II. Responses to General (Applicable to Multiple Neonicotinoids) Comments:

a. Importance of Neonicotinoids and Integrated Pest Management (IPM)

i. Multiple comments

1. Description of Comments: The agency received numerous comments stating the importance of neonicotinoids to growers. The comments designate neonicotinoids as a broad-spectrum insecticide vital to controlling a number of pests (e.g. thrips, white flies, weevils, aphids, glassy-winged sharpshooters, etc.) across a number of agricultural crops (*e.g.* corn, cotton, soybeans, citrus, grapes, fruiting vegetables) and non-agricultural use sites (*e.g.* turf, poultry houses, ornamentals). Additionally, commenters asked EPA to recognize the importance of neonicotinoids in Integrated Pest Management (IPM).

2. Agency Response: The agency agrees that neonicotinoids are an important class of insecticides for many growers, and that there are many benefits related to their use, including their importance in IPM programs. The agency produced several benefits assessments that address the importance of these chemistries (for a full list, see section 3). However, recent EPA analyses indicate that there are a number of ecological risks, including risks to important pollinator insects and aquatic invertebrates, that are beyond the EPA's level of concern. As such, the agency is proposing new mitigation measures (*e.g.*, PPE, application rate reductions, crop-stage restrictions) to reduce potential risks while still maintaining the availability of these important tools for growers. For further details, please reference the chemical-specific PIDs and the supporting documents listed in section 3, which are available in the chemical-specific dockets.

b. Risk Management Strategies

i. Multiple comments.

1. Description of Comments: Commenters request that the agency consider the comparative risks of likely insecticide alternatives and focus on practical and feasible measures that minimize off-site movement of neonicotinoids, while maintaining the efficacy and utility of this insecticide class for growers.

2. Agency Response: The agency appreciates the concerns regarding the use of alternative insecticides. EPA considered the comparative risks of alternative insecticides for each crop group (*e.g.* carbaryl, chlorpyrifos, organophosphates, pyrethroids), which is discussed in Section III.C of the PIDs.

   Moreover, the agency is proposing spray drift and runoff label language to minimize off-site movement of neonicotinoids. The proposed label language includes statements for spray, foliar and treated seeds. For a detailed description of the proposed label language, refer to Section IV.A and Appendix B of the PIDs.

c. Request to Ban or Severely Restrict the Use of Neonicotinoids

i. Multiple comments.

1. Description of Comments: Multiple commenters, including the Massachusetts Office of the Attorney General, stated that the EPA should ban or severely restrict the use of neonicotinoids due to unreasonable adverse effects on the environment with reference to FIFRA.

2. Agency Response: Under section 3(c)(5), FIFRA requires that a pesticide not cause "unreasonable adverse effects on the environment" in order to be registered. FIFRA 7 U.S.C. § 136a(c)(5). Section 2(bb) defines "unreasonable adverse effects on the environment" as, among other things, "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide…". This language creates a "risk-benefit" standard that requires the agency to compare the potential risks from the use of a pesticide with the benefits to users of the pesticide. To determine whether neonicotinoids meet this standard, the agency carefully considered the risks and benefits of each neonicotinoid. The agency determined that there are potential chemical-specific risks of concern that can be managed via mitigation (*e.g.*, PPE, application rate reductions, spray drift language) that also considers the benefits of each neonicotinoid., These potential risks, benefits and proposed mitigation measures can be found in the chemical-specific PIDs, which are available in the dockets for each case.

d. Concerns about Dust-off from Treated Seeds

i. Multiple comments.

1. Description of Comments: Multiple commenters stated that the risk assessments did not fully consider the potential contributions to pollinator exposure from dust-off of abraded seed coatings.
2. Agency Response: The agency acknowledges that drift of abraded seed coat dust (i.e., dust-off) during seed planting operations is a potential route of pesticide exposure for pollinators. Reported incidents from dust-off are documented, and the agency considered these incidents in the risk characterization of the final pollinator risk assessments (available in each chemical-specific docket). Furthermore, for several years, the agency has been working with various stakeholders to better understand this issue and to identify practices that can reduce exposure to bees from dust-off. As a result, stakeholders have taken actions that include the following three developments: development of a treated seed stewardship manual by the American Seed Trade Association, development of alternative fluency agents to reduce the quantity of dust generated during planting, and improved design guidelines issued by the International Organization of Standards for agricultural planting equipment to reduce seed dust. The agency is a member of the Corn Dust Research Consortium, which is a public-private partnership that has researched this potential route of exposure to bees. The agency continues to work with stakeholders to explore additional opportunities to reduce drift from dust generated during the planting of pesticide-treated seed.

e. Best Management Practices (BMPs)

i. Multiple comments.

1. Description of Comments: Multiple commenters asked EPA to consider the role of Best Management Practices (BMPs) in reducing pollinator exposure.
2. Agency Response: The agency encourages the development of BMPs that result in pesticide use that reduces potential exposure to bees, and other non-target species, while meeting grower needs. Information on crop-specific BMPs can inform the agency's understanding of practices to reduce pesticide exposure, and

consequently play a part in both the agency's understanding of potential risk and determining of potential mitigation. Consistent with the President's National Strategy to Promote the Health of Honey Bees and Other Pollinators (May 2015), the agency has been working with states and tribes to develop pollinator protection plans. The agency is continuing to engage a range of stakeholders, including the State FIFRA Issues, Research and Evaluation Group (SFIREG), in the development of state and tribal managed pollinator protection plans (MP3s). The agency has also formed a workgroup within its Federal Advisory Committee (*i.e.*, the Pesticide Program Dialogue Committee) tasked with developing metrics to evaluate and measure the effectiveness of state and tribal-recognized pollinator protection plans at the national level, and developing a strategy to effectively communicate these plans to the public.

f. Request to Prohibit Tank Mixtures due to Potential for Synergy
   i. Center for Biological Diversity (EPA-HQ-OPP-2012-0948).
      1. Description of Comments: Center for Biological Diversity states that EPA must prohibit tank mixtures unless it is certain that they will not cause synergistic effects.
      2. Agency Response: The EPA is currently developing an agency policy on how to consider claims of synergy being made by registrants in their patents. On September 9, 2019, the EPA released an interim process for public comment, available at regulations.gov in docket EPA-HQ-OPP-2017-0433. After the agency has received and considered public comment on the proposed policy, and once that policy has been finalized, the EPA will consider its implications on the EPA's final decision for the neonicotinoids.

g. Request to Consider States, Other Jurisdictions and International Actions
   i. Multiple Comments
      1. Description of Comments: Multiple commenters urge EPA to consider the actions of individual states and other jurisdictions, here and abroad, to protect pollinators, ecosystems, and public health from potential adverse effects of neonicotinoid insecticides.
      2. Agency Response: The agency considered the risk mitigation strategies of other jurisdictions, domestic and foreign, when preparing the PID for insecticides in the neonicotinoid class. Moreover, the agency collaborated with other entities to prepare risk assessments that were used to develop risk mitigation approaches in the U.S. and abroad. However, distinct from other agencies such as Canada's Pest Management Regulatory Agency (PMRA), EPA is required to consider both the risks and benefits associated with the use of any pesticide registration as per FIFRA 7 U.S.C. §§ 136(bb), 136a(c)(5). Acting under this mandate, the agency also accounted for the increased pest pressures faced by US growers that is unique from foreign jurisdictions. Based on an extensive volume of risk assessments and benefits analyses, the agency is proposing a comprehensive mitigation strategy, detailed in the chemical-specific PIDs, that minimizes the risks and preserves societal benefits.

h. Endangered Species Act
   i. Multiple Comments

1. Description of Comments: Commenters, including the Center for Biological Diversity, noted that EPA did not perform an endangered species assessment for the neonicotinoid insecticides and that registration review cannot be complete until consultation with the Services occurs.
2. Agency Response: In November 2013, the EPA, along with the Services and the United States Department of Agriculture (USDA), released a summary of their joint Interim Approaches for assessing risks to endangered and threatened (listed) species from pesticides. The Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. The NAS report[2] outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the ESA and FIFRA.

   The joint Interim Approaches were released prior to a stakeholder workshop held on November 15, 2013. In addition, the EPA presented the joint Interim Approaches at the December 2013 Pesticide Program Dialogue Committee (PPDC) and State-FIFRA Issues Research and Evaluation Group (SFIREG) meetings. The agencies also held stakeholder workshops —in April and October 2014, in April 2015, and in June 2016 — allowing additional opportunities for stakeholders to comment on the Interim Approaches. Additional workshops are planned to enhance stakeholder involvement. As part of a phased, iterative process for developing the Interim Approaches, the agencies will also consider public comments on the Interim Approaches in connection with the development of upcoming Registration Review decisions. The details of the joint Interim Approaches are contained in the white paper *Interim Approaches for National-Level Pesticide Endangered Species Act (ESA) Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report*[3], dated November 1, 2013.

   Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the ecological risk assessment supporting the Proposed Interim Decision for the neonicotinoids does not contain a complete ESA analysis that includes effects determinations for specific listed species or designated critical habitat. Although EPA has not yet completed effects determinations for specific species or habitats, for this Proposed Interim Decision EPA's evaluation assumed, for all taxa of non-target wildlife and plants, that listed species and designated critical habitats may be present in the vicinity of the application of the neonicotinoids. This assessment will allow EPA to focus its future evaluations on the types of species where the

[2] *Assessing Risks to Endangered and Threatened Species from Pesticides.* Available at http://www.nap.edu/catalog.php?record_id=18344

[3] Available at http://www2.epa.gov/endangered-species/assessing-pesticides-under-endangered-species-act#report

potential for effects exist once the scientific methods being developed by the agencies have been fully vetted. Once the agencies have fully developed and implemented the scientific methodology for evaluating risks for listed species and their designated critical habitats, these methods will be applied to subsequent analyses for neonicotinoids as part of completing this registration review.

III. List of Documents Supporting the Neonicotinoid Registration Review

Health Risk Documents

- *Clothianidin. Response to Comments on HED's Draft Human Health Risk Assessment in Support of Registration Review, and an Updated Poultry House Assessment.* Signed October 30, 2019.
- *Flumethrin: Tier 1 Update Review of Human Incidents and Epidemiology for Proposed Interim Decision*. September 17, 2019.
- *Imidacloprid. Updated Residential Exposure Assessment in Response to Draft Risk Assessment (DRA) Comments.* Signed February 11, 2019.
- *Thiamethoxam. Response to Comments on the Thiamethoxam Draft Risk Assessments for Registration Review.* Signed November 12, 2019.

Ecological Risk Documents

- *Final Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam.* January 14, 2020.
- *Final Bee Risk Assessment to Support the Registration Review of Dinotefuran.* January 14, 2020.
- *Final Bee Risk Assessment to Support the Registration Review of Imidacloprid.* January 14, 2020.
- *Attachment 1. Tier II Method for Assessing Combined Nectar and Pollen Exposure to Honey Bee Colonies.* January 14, 2020.
- *Attachment 2. Residue Bridging Analysis for Foliar and Soil Agricultural Uses of Neonicotinoids.* January 14, 2020.
- *Attachment 3. Residue Bridging Analysis for Foliar and Soil Non-Agricultural Uses of Neonicotinoids.* January 14, 2020.
- *Attachment 4. Residue Bridging Analysis for Seed Treatment Uses of Neonicotinoids.* January 14, 2020.
- *EFED Response to Public Comments Common to the Preliminary Pollinator and Preliminary Non-Pollinator Registration Review Risk Assessments Across the Four Neonicotinoid Pesticides (Imidacloprid, Thiamethoxam, Clothianidin, and Dinotefuran).* January 6, 2020.
- *Clothianidin Non-pollinator Addendum and Chemical-specific Response to Comments Document for Public Comments Received on the Registration Review*

Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments. January 8, 2020.

- *Dinotefuran: Response to Comments Regarding the Draft Bee and Non-Bee Ecological Risk Assessments for the Registration Review of Dinotefuran.* January 7, 2020.
- *Imidacloprid: Response to Public Comments Related to the Preliminary Risk Assessments and Addendum to the Non-Pollinator Risk Assessments in Support of Registration Review (Docket No. EPA-HQ-OPP-2008-0844).* January 8, 2020.
- *Thiamethoxam: Non-pollinator Addendum and Chemical-specific Response to Comments Document for Public Comments Received on the Registration Review Preliminary Pollinator and Preliminary Non-pollinator Risk Assessments.* January 6, 2020.
- *Comparative analysis of Aquatic Invertebrate Risk Quotients generated for neonicotinoid using Raby et. al. (2018) toxicity data.* January 7, 2020.

Benefits Assessments

- *Assessment of Usage, Benefits and Impacts of Potential Mitigation in Stone Fruit Production for Four Nitroguanidine Neonicotinoid Insecticides (Clothianidin, Dinotefuran, Imidacloprid, and Thiamethoxam).* Signed December 6, 2019.
- *BEAD Response to Comments on Risk Assessments & 2017 Benefit Assessments.*
- *Benefits and Impacts of Potential Mitigation for Neonicotinoid Seed Treatments on Small Grains, Vegetables, and Sugarbeet Crops.* Signed August 30, 2018.
- *Benefits of Neonicotinoid Insecticide Use and Impacts of Potential Risk Mitigation in Vegetables, Legumes, Tree Nuts, Herbs, and Tropical and Subtropical Fruit.*
- *Benefits of Neonicotinoid Insecticide Use in Berries (Strawberry, Caneberry, Cranberry, and Blueberry) and Impacts of Potential Mitigation.* Signed December 6, 2019.
- *Benefits of Neonicotinoid Insecticide Use in Cucurbit Production and Impacts of Potential Risk Mitigation.* Signed December 11, 2019.
- *Benefits of Neonicotinoid Insecticides Usage in Grapes and Impacts of Potential Mitigation.* Signed October 23, 2019.
- *Estimate of Area Treated per Day for Insecticides in Poultry Houses and Amount of Clothianidin Handled per Day When Using a Mechanically Pressurized Handgun.* Signed July 9, 2019.
- *Review of "The Value of Neonicotinoids in North American Agriculture" prepared by AgInfomatics, LLC, for Bayer CropScience L.P., Mitsui Chemicals Agro, Inc., Syngenta Crop Protection, LLC, and Valent U.S.A. LLC.* Signed November 4, 2019.
- *Review of "The Value of Neonicotinoids in Turf and Ornamentals" prepared by AgInfomatics, LLC for Bayer CropScience, Mitsui, Syngenta, and Valent.* Signed December 11, 2019.
- *Usage and Benefits of Neonicotinoid Insecticides in Rice and Response to Comments.* Signed April 22, 2019.

- *Usage, Pest Management Benefits, and Possible Impacts of the Potential Mitigations of the Use of Four Nitroguanidine Neonicotinoids in Pome Fruits (Apple, Pear).* Signed December 11, 2019.