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OPP Docket  
Environmental Protection Agency Docket Center (EPA/DC)  
(28221T)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460-0001

**Re: Neonicotinoid Risk Assessments; Summary Response to Comments, and Updated Neonicotinoid Work Schedule, EPA-HQ-OPP-2008-0844-1090**

<u>Registration review case name and number</u>	<u>Docket ID number</u>	<u>Chemical review manager and contact information</u>
Clothianidin 7620	EPA-HQ-OPP-2011-0865	Ricardo Jones, jones.ricardo@epa.gov, 703-347-0493.
Dinotefuran 7441	EPA-HQ-OPP-2011-0920	Steven Snyderman, snyderman.steven@epa.gov, 703-347-0249.
Imidacloprid 7605	EPA-HQ-OPP-2008-0844	Ricardo Jones, jones.ricardo@epa.gov, 703-347-0493.
Thiamethoxam 7614	EPA-HQ-OPP-2011-0581	Thomas Harty, harty.thomas@epa.gov, 703-347-0338.

**Introduction**

The Pollinator Stewardship Council welcomes the ability to comment upon the Neonicotinoid Risk Assessments. Much knowledge has been gained since these compounds were initially registered, and much damage has occurred to our pollinators due to their widespread use. We applaud the EPA's decision to place a moratorium on new registrations of neonicotinoid chemistry products as a prudent move. We also appreciate the work done in the individual chemical reviews of imidacloprid, highlighting many significant data gaps, but pinpointing significant pollinator risk exposures.

Pesticide exposure is impacting bees: through direct contact with pesticides, lethal and sub-lethal levels of pesticides tainting the pollen, nectar, and water, and pesticides destroying their habitat. Bees need diverse food like all living creatures.

## Neonicotinoids (neonics) are unhealthy for pollinators

Research shows the impact upon honey bees by this class of pesticide results in:

- 24% decline in honey bee colonies able to survive winter
- Natural forage areas contaminated with bee toxic pesticides
- Reduced flight capacity in honey bees, decreasing food-collecting ability
- Impairs basic motor coordination of honey bees
- Invertebrate toxic levels found in surface water after rain events, in wetlands, and in snowmelt (a bee colony can drink up to three gallons of water daily)
- Contaminated pollen and nectar are returned to the hive leading to sub-lethal levels of toxins fed to honey bee larvae
- Reduces reproductive capability in queens and drones
- Contaminated soil, water, and plant products which translocate into the pollen and nectar
- Synergism with other pesticides increasing the toxicity levels of herbicides, fertilizers, fungicides, adjuvants, and surfactants in the pesticide tank mix
- 97% of neonicotinoids brought to the hive were collected from wildflowers, not crops, showing the drift through the soil, water, and air of these pesticides to natural forage areas
- Neonics affect the immunocompetence of honey bees leading to impaired disease resistance
- Neonics contribute to the spread and abundance of pathogens and parasites among honey bees

Environmental effects of these neonics have been studied more than any other insecticide, with the possible exception of DDT. *There is a preponderance of literature showing harmful effects to bees and other organisms.* EPA has this science-based literature available to them, conducted by independent researchers at land-grant universities across the U.S., as well as USDA researchers, USGS researchers, and international researchers. We could review each research paper over the past ten years, but EPA is fully aware of the damage being caused to honey bees, native pollinators, soil sustainability, water quality, and beekeeping.

Many pesticide products on the market are likely more harmful than the EPA has previously assumed because some of the most common combinations of ingredients cause synergistic effects, and most pesticide product labels do not meaningfully limit tank mixtures or co-application. Therefore, it is imperative that the EPA consider synergistic effects of pesticide products during its registration and registration review process, and include protective label restrictions to eliminate or mitigate adverse, synergistic environmental impacts. The EPA should prohibit tank mixes on the labels unless there is sufficient information demonstrating that no synergistic effects will occur.

Solutions must be found if we are to save the biodiversity not only of aquatic ecosystems, but all other ecosystems linked by the food web. Since the prophylactic use of seeds treated with neonicotinoids is responsible for most of the soil and aquatic contamination, while there is evidence of little productivity gain, one obvious solution is to stop the marketing of seeds coated with these insecticides (van der Sluijs et al., 2015) and use alternative and carefully targeted methods for pest control in agriculture (Douglas and Tooker, 2015; Furlan and Kreutzweiser, 2015), such as integrated pest management (IPM). At the same time, remediation systems based on photolytic processes (Malato et al., 2001) and wetlands phyto-

remediation(Beketov and Liess, 2008c) should be implemented to reduce as much as possible the current contamination by these and other pollutants (Sanchez-Bayo).

## **Legal and Cost vs. Risk**

We are gravely concerned that EPA has not acknowledged the [ELLIS V. HOUSENGER](#) case which is directly applicable to the registration of Clothianidin and Thiamethoxam, two of the four pesticides being considered in this re-registration process. Fifty-nine registered uses have not passed the requirements for registration, and these should have triggered vacatur of Clothianidin and Thiamethoxam registration until the requirements are met.

EPA is challenging the courts, and disobeying legal rulings by including Clothianidin and Thiamethoxam in this Re-registration process. EPA's non-response to the Courts decision calls into question the value of making public comments at all. It appears that EPA has no respect for the rule of law under which they allegedly are required to operate. That said, public comment is part of the process, and the Pollinator Stewardship Council is participating as it is our only available method to publicly state our position on the use of these highly acute bee toxic pesticides.

The bee industry is aware EPA determines pesticide registration based on a risk-benefit analysis, not a cost-benefit analysis. However, the cost or loss of the crop from the pest may be considered. Within FIFRA, under the definition of "unreasonable adverse effects," the statute does mention costs:

*“unreasonable adverse effects on the environment” means (1) 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 . . .*

EPA appears to interpret this as the costs of not using a pesticide, and never examining the cost of using it upon beneficial insects, groundwater, neighboring crops, or neighboring habitat. EPA then avoids estimating the total actual costs associated with pesticide use which may cause “unreasonable adverse effects upon the environment.” This is a failure of the registration process.

All four of these pesticides, imidacloprid, thiamethoxam, clothianidin, and dinotefuran kill bees. Currently the majority of their use is on treated articles, which are not considered to be a pesticide application. This is gravely problematic to both beekeepers and EPA at many levels. EPA is charged with prevention of unreasonable risk (to bees), yet beekeepers are stifled in communicating to EPA the severe damage being inflicted by the alleged non-use. States mandated to investigate bee kills do not investigate, do not have the funds to analyze evidence, and simply rely on beekeepers to move their bees. This is not a solution to “preventing unreasonable risk,” especially when the pesticides are systemic with long half-lives, and the ability to move through the ecosystem.

EPA Addendum to the [FIFRA Inspection Manual](#) specifically instructs pesticide investigators that seed coatings are not a pesticide application. If no pesticide is applied, obviously any resulting bee kill has to be from another source. Exacerbating this issue is that the State Primacy Partners lack EPA's definition of the term “incident” or “pesticide incident” and have [defined incident](#) narrowly: *“Incident” does not include a release from normal use of a pesticide.*” State investigators hide behind the combined confusion of a pesticide application not being a pesticide application when it is coated seeds being planted. Planting seeds is a “normal use,” but planting seeds coated with pesticides leaves damaged bee

operations and dead pollinators. EPA appears to be “officially and blissfully unaware” that a major pesticide problem even exists. EPA should conduct Rule Making concerning pesticide coated seeds and their miss-classification as “treated articles.”

EPA's definition of a pesticide is “Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest.” EPA Label Review Manual chapter 2 page 5, III. What makes a product a pesticide?

*“The term “pesticide” is defined at FIFRA 2(u). One of the most important words in the FIFRA definition of “pesticide” is “intended.” One of the analytical steps to determining whether a product is a pesticide is to consider whether the product is “intended” to be used as a pesticide. Products are generally considered to be pesticides if they are intended for preventing, destroying, repelling, or mitigating any pest or intended for use as a plant regulator, defoliant, or desiccant. OPP determines intent by examining claims on the label, advertising, composition/use, and/or mode of action of the product as distributed or sold. Section 40 CFR 152.15 sets forth the criteria.”*

Knowledge that the Substances Will Be Used as a Pesticide, page 6 clarifies:

1. *Even if pesticidal claims are not made for the product, if the person who distributes or sells the substance has actual or constructive knowledge that the substances will be used, or is intended to be used, for a pesticidal purpose, the product is a pesticide product required to be registered. 40 CFR 152.15(c).*

Recently retired EPA Director of OPP Jim Jones; told the National Honey Bee Advisory Board members during the 2013 February Almond Beehive Tour, that EPA estimates the direct annual cost to the bee industry of rebuilding pesticide killed hives to be \$300M. This does not include the significantly reduced robustness of the surviving pesticide damaged hives which potentially reduces the grower’s ability to obtain a crop set.

During 2015 ten states introduced legislation to ban the use of neonicotinoids. Eugene, Oregon, and Portland, Oregon have banned neonics. In 2016, Connecticut and Maryland restricted the use of neonics to protect bees and the fishing grounds of the Chesapeake Bay. (<http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/07/29/to-save-bees-some-states-take-aim-at-pesticides>, <http://kneb.com/agricultural/maryland-becomes-first-state-to-restrict-neonics/> and <https://www.clf.org/blog/beelieve-maryland-connecticut-pass-landmark-legislation-protect-pollinators/> . The State of Minnesota is also reviewing how neonics are used. <http://www.vmdtoday.com/news/state-news-minnesota-law-strives-to-save-bees-support-farmers>

A variety of states have revoked the use of neonics –see labels for <http://www.domyownpestcontrol.com/safari-20sg-systemic-insecticide-with-dinotefuran-p-2512.html> <http://www.domyownpestcontrol.com/temprid-sc-insecticide-p-1175.html>

The state of Vermont has placed a moratorium on soil drenches with imidacloprid. [http://agriculture.vermont.gov/sites/ag/files/pdf/apiary/PesticideRecommendations\\_DRAFT.pdf](http://agriculture.vermont.gov/sites/ag/files/pdf/apiary/PesticideRecommendations_DRAFT.pdf)

New York state has restricted uses of dinotefuran , Imidacloprid, clothianidin, thiamethoxam.  
[http://www.dec.ny.gov/docs/materials\\_minerals\\_pdf/nysactiveingredrev.pdf](http://www.dec.ny.gov/docs/materials_minerals_pdf/nysactiveingredrev.pdf)

BJ's Wholesale Club, Lowes, and Home Depot are requiring their vendors to stop using neonics or to clearly label products containing or treated with neonics. In partnership with Pollinator Stewardship Council, Ortho, associated with Scotts Miracle-Gro, announced its decision to stop using neonics completely. They are two years ahead of schedule to completely remove all neonics from their Ortho brand by 2019. <https://www.clf.org/blog/beelieve-maryland-connecticut-pass-landmark-legislation-protect-pollinators/> These entities are responding to the scientific research concerning neonics and to the public outcry to protect pollinators vital to an affordable and sustainable food supply from the adverse impact of this class of pesticide.

### **Research Reveals the unintended consequences of neonics: dust-off, acute, water**

The evidence of Neonicotinoids harming bees is plentiful and diverse. Neonics are toxic to honey bees and other invertebrates, per their labels on liquid formulations containing the active ingredient imidacloprid, thiamethoxam, clothianidin, dinotefuran. When just one of these pesticides are coated onto seeds, and the pesticide chips off during the planting process the pesticide drifts in the dust onto blooming plants where it will mix with the pollen and nectar and kill foraging bees. However, when neonics are coated onto seeds, the coated seed is now a “device” and not regulated by the U.S. Environmental Protection Agency.

Whether it is the synergisms created when tank mixing neonics with other pesticides, or the synergism of the neonics exacerbating varroa mite infestations within hives, this class of pesticide has revealed a variety of unintended consequences from acute kills to sub-lethal effects upon brood, queens, drones, reproduction of queen and drones, the hive matrices, and the very food the bees consume immediately and across the winter. Always forgotten in examining pesticide impact upon honey bees is the very vital fact a hive consumes 1.5-3 gallons of water daily. Water is also susceptible to pesticide drift and run-off, contaminating it, and creating a sub lethal and/or lethal resource for honey bees.

Planting of pollinator habitat near agricultural fields which use pesticides has shown to be problematic. Pollinator habitats are susceptible to drift, run-off, and translocation especially of systemic neonics thereby making that pollinator habitat now a killing field for honey bees and native pollinators. Research in buffer strips has shown that a buffer strip is needed to protect the pollinator habitat buffer strip. That may afford some filtering of the neonic translocation, but it will not protect the pollinator habitat from foliar drift of neonics. Research on pesticides clearly shows the products do not “stay put.” Whether a systemic pesticide or non-systemic, pesticides move through the soil, water, and air to other plants, crops, and waterways creating lethal and sublethal exposures to beneficial organisms.

Many pesticide products on the market are likely more harmful than the EPA has previously assumed because some of the most common combinations of ingredients cause synergistic effects, and most pesticide product labels do not meaningfully limit tank mixtures or co-application. Therefore, it is imperative that the EPA consider synergistic effects of pesticide products during its registration and registration review process, and include protective label restrictions to eliminate or mitigate adverse,

synergistic environmental impacts. The EPA should prohibit tank mixes on the labels unless there is sufficient information demonstrating that no synergistic effects will occur.

In addition to products that contain either multiple active or inert ingredients that result in synergism, pesticide products can often be mixed or co-applied in the field in a way that results in synergistic effects. For example, in the recent pollinator risk assessment for Imidacloprid, the EPA noted that this pesticide was often mixed with fungicides in tank mixtures. In the risk assessment, the EPA stated:

*“fungicides, particularly those of the sterol biosynthesis inhibitor class that include the triazole fungicides were detected with high frequency. There are reports in the literature that these chemicals may exhibit a greater than additive (e.g., synergistic) effect on toxicity when bees are exposed simultaneously with neonicotinoid chemicals like imidacloprid. While the extent of this relationship is beyond the scope of this assessment, it highlights the complex nature of interactions of different stressors that exist in the hive.”*

These mixtures have real impacts on pollinators and other wildlife that the EPA must take into account and act upon when it makes pesticide registration decisions.

Thus far, Federal action for protecting pollinators has included amending labels and requiring States to form Managed Pollinator Protection Plans (MP3). These amended labels have advisory language added which “facilitates” MP3s advising beekeepers to either cover or move managed bees. (<https://www.regulations.gov/docket?D=EPA-HQ-OPP-2014-0818>) This “amended” Advisory Language however directly conflicts with the label’s Mandatory statement; “Do not apply or allow residues on blooming crops or weeds if bees *and other pollinating insects* are visiting the treatment area.” EPA PR Notice 2000-5 is quite specific, Advisory Language on a label is only appropriate if it does not conflict with Mandatory Language. Further even the Mandatory Hazard Statements are inadequate; they only consider acute impacts, and not the long term systemic exposures or the ecological risks which are inherent with the use of systemic pesticides. We trust that EPA will take appropriate steps to rectify this situation. As pesticides, other than neonicotinoids, are identified as posing risks to pollinators, it is critical that pesticide product labels be clear and harmonized across pesticide classes and products. Furthermore, any risk assessment that drives the mitigation strategies listed on labels should be determined at the scale of use, not through isolated assessments by crop or use. Additionally, label statements must be relevant to on-the-ground conditions and enforceable. Partnerships with stakeholders can help inform label language and strategies to ensure that label restrictions are followed.

A 2016 report, “*Heavy costs weighing the value of neonicotinoid insecticides in agriculture*” compiled by the Center for Food Safety expressed the concern the Environmental Protection Agency (EPA) had “overvalued the “insurance” neonicotinoids offer against the mere risk of pest pressures, which are often not realized. This has led to heavy costs to the agricultural community and the nation as a whole. “Pre-sterilizing” fields has, in effect, rendered integrated pest management (IPM), in which pesticides are only used if economic pest damage thresholds are exceeded, obsolete for many major field crops.”

## Solutions

- Neonicotinoids should be a restricted use pesticide, only used when there is a documented need per an Integrated Pest Management analysis showing the crop is at a threshold of imminent risk.
- Neonics must not be allowed to drift into /onto water.
- If water on or near fields is determined to contain sublethal levels of neonics in the water remediation systems based on photolytic processes and wetlands phyto-remediation should be implemented to reduce as much as possible the current contamination by these and other pollutants.
- Since the prophylactic use of seeds treated with neonicotinoids is responsible for most of the soil and aquatic contamination, while many studies point to little productivity gain, one obvious solution is to stop the marketing of seeds coated with these insecticides (van der Sluijs et al., 2015) and use alternative and carefully targeted methods for pest control in agriculture.
- The current scientific-based research knowledge of these pesticides, shows it is not appropriate for these chemistries to be granted re-registration. Reversing pollinator decline demands this action be taken, and that the loophole of "treated article exemption" granted to seeds coated with these compounds must be revoked.
- Pesticide labels need clearly defined mandatory statements in the Environmental Hazard section of the label, as well as the Directions for Use that succinctly, and consistently state, "Do not apply or allow residues on blooming crops or weeds if bees and other pollinating insects are visiting the treatment area." As the label is the law, this must be enforced by EPA and its State Primacy partners.
- It is imperative that the EPA consider synergistic effects of pesticide products during its registration and registration review process, and include protective label restrictions to eliminate or mitigate adverse, synergistic environmental impacts. The EPA should prohibit tank mixes on the labels unless there is sufficient information demonstrating that no synergistic effects will occur.
- EPA must acknowledged the [ELLIS V. HOUSENGER](#) case which is directly applicable to the registration of Clothianidin and Thiamethoxam, two of the four pesticides being considered in this re-registration process. Fifty-nine registered uses have not passed the requirements for registration, and these should have triggered vacatur of Clothianidin and Thiamethoxam registration until the requirements are met.
- Mandatory Hazard Statements must also address long term systemic exposures and the ecological risks which are inherent with the use of systemic pesticides. It is critical that pesticide product labels be clear and harmonized across pesticide classes and products.
- Any risk assessment that drives the mitigation strategies listed on labels should be determined at the scale of use, not through isolated assessments by crop or use.
- Label statements must be relevant to on-the-ground conditions and enforceable.

The economic costs of the unreasonable adverse effects are vitally important to beekeepers working to maintain crop pollination livestock integral to increasing crop yields. The financial losses of honey bee livestock to service crop pollination contracts will adversely affect a variety of crops across the growing season. Damage to honey bee livestock in one crop affects the pollination service of the next crop as there are less bees to service the crop. As end of summer losses increase too many commercial beekeeping operations face a complete loss of livestock inventory. Honey bees are not feed lot livestock, nor are they raised to be slaughtered at the end of a season. Beekeepers are annually experiencing unreasonable adverse effects not realized by any other agricultural stakeholder.

## Conclusion

Environmental effects of these neonics have been studied more than any other insecticide, with the possible exception of DDT. There is a preponderance of literature showing harmful effects to bees and other organisms: *EPA has access to all of the research on neonics.*

Solutions must be found soon if we are to save the biodiversity not only of aquatic ecosystems, but all other ecosystems linked by the food web. Since the prophylactic use of seeds treated with neonicotinoids is responsible for most of the soil and aquatic contamination, while many studies point to little productivity gain, one obvious solution is to stop the marketing of seeds coated with these insecticides (van der Sluijs et al., 2015) and use alternative and carefully targeted methods for pest control in agriculture (Douglas and Tooker, 2015; Furlan and Kreuzweiser, 2015), such as integrated pest management (IPM). At the same time, remediation systems based on photolytic processes (Malato et al., 2001) and wetlands phyto-remediation (Beketov and Liess, 2008c) should be implemented to reduce as much as possible the current contamination by these and other pollutants.

Sincerely,



Michele Colopy  
Program Director

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