BEYOND PESTICIDES
701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

July 24, 2017

Environmental Protection Agency
Office of Pesticide Programs
Docket Center (EPA/DC), (28221T),
200 Pennsylvania Ave. NW.,
Washington, DC 20460-0001.

Re: Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam. Docket No: EPA-HQ-OPP-2011-0865 and EPA-HQ-OPP-2011-0581

Dear Sir/Madam,

We are writing in response to U.S. Environmental Protection Agency's (EPA) pollinator assessment of the neonicotinoids, clothianidin and thiamethoxam. Both insecticides are commonly used for corn and soybean as seed coatings, foliar, soil drench, and chemigation applications. The vast majority of clothianidin uses are as seed treatment on corn, while thiamethoxam is mostly used on corn, soybean and cotton. For instance, EPA cites 45% of the total corn crop (42 million acres) in the U.S. is treated with clothianidin, and 25% for thiamethoxam (24 million acres).[1] These pesticides, along with others in its class, have been found to be highly toxic to honey bees and native bees, and linked to pollinator declines. A recent published study, investigating the impacts of clothianidin and thiamethoxam on bees reports negative effects on honey bees that persist over winter, resulting in smaller colonies the following spring, including reduced worker bees. In wild, non-*Apis* species, reduced reproduction was observed, allowing the researchers to conclude that neonicotinoids do cause "a reduced capacity of bee species to establish new populations in the year following exposure."[2] This study was the largest field study on its kind, spanning 33 sites in three countries, which shows the effects of real-world exposures.

Similar to the 2016 pollinator assessment for imidacloprid, the agency has identified use patterns and exposure pathways that pose risks to bees. However, there are also several uncertainties that continue to plague these neonicotinoid assessments. The agency defined protection goals "for assessing pesticide risks to bees" which include: 1) maintenance of

[1] USEPA. 2017. Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam. Office of Pesticide Programs. Washington DC.
[2] Woodcock, BA, Bullock, JM, Shore, RF, Heard, MS, et al. 2017. Country-specific effects of neonicotinoid pesticides on honey bees and wild bees. Science. 356,6345: 1393-1395. DOI: 10.1126/science.aaa1190.

pollination services, 2) hive product production, and 3) bee diversity."[3] EPA believes these protection goals will be protective for honey bee and non-*Apis* species, and will help characterize endpoints. However, as we have shown in previous comments, some wild non-*Apis* species are more sensitive than honey bees, and must be uniformly incorporated into these assessments since potential harms cannot be extrapolated from honey bee data.

In light of the risks identified in this assessment, we again call on the agency to take action against this hazardous class of pesticides and restrict uses to protect vulnerable non-target organisms.

Risk Conclusions

Since clothianidin is the major degradate of thiamethoxam, and they both have similar toxicity and use patterns, EPA evaluated both compounds using a 'total residue approach,' and exposures and effects were expressed as clothianidin equivalents. Once again, EPA has focused its assessment on bee exposure to pollen and nectar, and by contact exposure.

According to the agency's tier I assessment, many clothianidin and thiamethoxam foliar, seed, and soil uses pose on-field acute and chronic risks to adult bees. Chronic risks were identified for larvae for certain uses, and off-site risks from foliar applications have also been noted. Certain crops –those not attractive to honey bees— can result in on-field risks to non-*Apis* species, e.g. bumble bees.

In tier II chronic feeding assessments, colony effects were observed, including reduced pollen stores, reduced brood, and number of adult females –which indirectly leads to reduced pollen stores and brood. The agency finds on-field risks from seed coating uses pose minimal risks, while foliar applications result in higher risk potentials. Off-field risks, as a result of spray drift, as well as off-site dust drift from corn plantings are identified as concerns.

1. *On-field Risks*:

In general, the agency identified all uses of clothianidin and thiamethoxam (foliar, soil, seed) to have on-field acute and chronic risks. EPA found that applications to certain crops result in unacceptable risks to bees for both thiamethoxam and clothianidin:

-Cucurbit vegetables (foliar and soil)
-Cotton (foliar)
-Citrus (soil)
-Stone Fruit (foliar)
-Berries and small fruit (foliar)

These uses result in elevated residues in nectar and bee bread that were above levels of concern (LOCs), and led to observed colony effects. Foliar application to tree nuts, soybean,

[3] USEPA. 2017. Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam. Office of Pesticide Programs. Washington DC.

root and tuber vegetables, pome fruits, and soil applications for potatoes, pome and stone fruits result in uncertainties in the refined risk assessment, but had preliminary risk concerns which cannot be overlooked.

For tier II assessments, the agency reviewed colony feeding studies to assess chronic impacts to bee colonies, and observed declines in brood and worker bees. However, the studies' colonies did not overwinter successfully, including the controls, making the studies' results unreliable. Further, other studies which also examined bee bread observed similar effects (decreased brood, workers, pollen stores) but at lower levels than the colony feeding studies. However, these bee bread results present uncertainties in the refined assessment since potential risks were indicated for bee bread exposures, but not for nectar in some cases.

There were some tier III assessments performed evaluating the effects from seed coatings. However, they also presented uncertainties due to high variability in the data collected, as well as transient, observed effects.

As with the previous imidacloprid pollinator assessment, no residue data was available for many crops, and analysis could not be completed. Some results presented tier I on-field risks, but no data was available for Tier II assessments.

2. Other routes of exposure:

Again, like the previous imidacloprid pollinator assessment, EPA identifies many pathways through which honey bees can be exposed to clothianidin and thiamethoxam with primary exposure via direct contact of foliar spray and oral ingestion of contaminated pollen and nectar. Foraging bees therefore are expected to have relatively high exposure as a result of their frequent interaction with crops in treated fields, while in-hive bees are exposed from processing and ingesting contaminated pollen and nectar. Exposure via contaminated surface water, guttation droplets, honey dew, and soil are also identified. EPA states again it "lacks information to understand the relative importance of these other routes of exposure and/or to quantify potential risks from these other routes, and as such, they are not quantitatively assessed." However, bees' risks to these other routes of exposure are critical to a comprehensive hazard assessment and understanding of the complex exposures to this complex organism. EPA must call for and use existing information to set minimum risk thresholds and incorporate margins of safety based on aggregate and cumulative exposures.

a. Soil

Both clothianidin and thiamethoxam have relatively long soil half-lives. EPA lists clothianidin's field dissipation half-life as 277-1386 days, and thiamethoxam's as 1-111 days.[4] Other sources have reported soil half-lives upwards of 6931 days under certain conditions for clothianidin,[5] making clothianidin one of the most persistent neonicotinoids. EPA's states that it

[4] Ibid.
[5]USEPA. 2010. Clothianidin registration of Prosper T400 seed treatment on mustard seed (oilseed and condiment) and Poncho/Votivo seed treatment on cotton. Office of Pesticide Programs. Washington DC.

expects contact exposure from soil not to be significant since applications are made when crops are not attractive to bees (honey bees). However, 70 percent of native bee species in the U.S. have ground/soil nests[6] where they can come into contact with residues, especially in agricultural regions. Clothianidin-contaminated soil therefore becomes a substantial source of exposure to much of the nation's bee population. Clothianidin's persistence in soil will put these bees at risk long after initial applications. Therefore, the agency cannot assume that contact exposure from soil will not be significant. It will be significant for at least 200 to 1300 days.

EPA acknowledges that the persistence of clothianidin and thiamethoxam in soil can lead to residues in soil that can be taken up by successive crops that may be attractive to bees. EPA finds that 70% of applied clothianidin remained in the soil surface, meaning that direct soil contact and exposure from subsequent plantings taking up residues continually put bees, especially native bees, at risk.

b. Guttation, surface water, seed dust

While EPA recognizes that guttation, surface water, and seed dust can potentially expose bees to clothianidin and thiamethoxam residues, the agency did not conduct assessment for these exposure pathways because the agency is unable to quantify these exposures. However, these exposures are important to understanding overall bee and colony health. For instance, Johnson and Pettis (2014) note that honey bees frequently use open water as a source that is transported into the hive for consumption, to cool the hive, dilute honey for brood use, and maintain humidity for brood rearing.[7] Consumption and hive use of water is therefore very critical to the long-term health of the colony and should not be underestimated.

Clothianidin and thiamethoxam residues have been detected in surface waters, with the highest concentrations detected in water puddles surrounding agricultural fields.[8] Similarly, another study investigating the risk of intoxication to honey bees from contaminated water sources, finds that water collected from corn fields contained multiple systemic pesticides, including neonicotinoids.[9] This study reports that the concentrations detected are enough to induce sublethal effects in honey bees (0.01 to 63 ppm). The authors here note that cumulative exposure to these insecticides from combined residues in pollen, nectar and water are being underestimated.

---

[6] Vaugh, M, Hopwood, J, Mader, EL, et al. 2015. Farming for Bees: Guidelines for Providing Native Bee Habitat on Farms. The Xerces Society. Available at http://www.xerces.org/wp-content/uploads/2008/11/farming_for_bees_guidelines_xerces_society.pdf

[7] Johnson, JD and Pettis, JS. 2014. A Survey of Imidacloprid Levels in Water Sources Potentially Frequented by Honeybees (*Apis mellifera*) in the Eastern USA. Water Air Soil Pollut. 225(11): 2127.

[8] Schaafsma, A, Limay-Rios, V, Baute, T et al. 2015. Neonicotinoid Insecticide Residues in Surface Water and Soil Associated with Commercial Maize (Corn) Fields in Southwestern Ontario. *PLoS One*. 2015; 10(2): e0118139.

[9] Samson-Robert, O, Labrie, G, Chagnon, M et al. 2014. Neonicotinoid-Contaminated Puddles of Water Represent a Risk of Intoxication for Honey Bees. *PLoS One.* 2014; 9(12): e108443.

When it comes to seed dust, EPA notes that "drift of abraded seed coat dust is considered a route of concern given that bee kill incidents have been associated with planting of clothianidin or thiamethoxam treated corn." However, separate assessments have not been conducted since EPA chooses to rely on stakeholder best management practices to reduce the contaminated dust-off. Contaminated dust can result in residues in soil, surface water and plants. EPA notes that exposures to the dust "may occur over a wide time scale," meaning bees are potentially at risk during the planting season, growing season, and harvest season --i.e., all times bees are active.

Studies exist that have examined honey bee exposure to abraded dust and have assessed the amount of active ingredient with which the flying insect gets in contact during the planting of coated seed.[10,11] Other studies confirm high bee mortality resulting from dust exposure and the possibility of subsequent colony decline.[12,13,14,15] In the recent field study by Woodcock et al. (2017) seeds coated with clothianidin and thiamethoxam were found to have deleterious impacts on bees including reduction in hive fitness and long-term colony viability.[16]

The continued exclusion of an evaluation of the impacts of seed dust on bees will not allow the agency to adequately understand how toxic the dust can be, or the full cumulative, ecological impacts of seed dust (e.g., how much in ejected into the air, size of particulates, distance dust can travel, impact of environmental conditions, etc.), nor would it help the agency determine whether efforts to minimize dust-off have been successful. The agency would not have information to support potential mitigation measures to reduce dust emission and contamination (e.g. wind speeds recommendations for planting, buffer zones, etc)[17] --assuming the agency is working toward zero field emission of abraded seed dust, which it should. It stands therefore that data on the toxicological characteristics of abraded seed dust and drift must be known, and EPA has a responsibility to gather and assess this information. The impact

[10] Pochi, D, Biocca, M, Fanigliulo, R, et al. 2015. Sowing of seed dressed with thiacloprid using a pneumatic drill modified for reducing abrasion dust emissions. *Bulletin of Insectology* 68 (2): 273-279.
[11] Pistorius, J, Wehnew, A, Kriszan, M, et al. 2015. Application of predefined doses of neonicotinoid containing dusts in field trials and acute effects on honey bees. *Bulletin of Insectology* 68 (2): 161-172.
[12] Tapparo, A, Marton, D, Giorio, C et al. 2012. Assessment of the Environmental Exposure of Honeybees to Particulate Matter Containing Neonicotinoid Insecticides Coming from Corn Coated Seeds. *Environ. Sci. Technol.*, *46* (5), pp 2592–2599.
[13] Sgolastra, F, Renzi, T, Draghetti, S, et al. 2012. Effects of neonicotinoid dust from maize seed-dressing on honey bees. *Bull Insectology* 65(2):273-280.
[14] Girolami, V, Marzaro, M, Vivan, L, Mazzon, L, et al. 2012. Fatal powdering of bees in flight with particulates of neonicotinoids seed coating and humidity implication. J Applied Entomology. 136, 1-2; 17-26.
[15] Krupke CH, Hunt GJ, Eitzer BD, Andino G, Given K. 2012. Multiple Routes of Pesticide Exposure for Honey Bees Living Near Agricultural Fields. PLoS ONE 7(1): e29268.
[16] Woodcock, BA, Bullock, JM, Shore, RF, Heard, MS, et al. 2017. Country-specific effects of neonicotinoid pesticides on honey bees and wild bees. Science. 356,6345: 1393-1395. DOI: 10.1126/science.aaa1190.
[17] Forster, R. 2011. Risk mitigation measures for seed treatments using neonicotinoids. 11th International Symposium of the ICP-BR Bee Protection Group, Wageningen (The Netherlands), November 2-4, 2011. DOI: 10.5073/jka.2012.437.013.

of coated seeds on pollinators cannot be separated from EPA's larger assessment and mitigation strategy.

3. Wild, Non-Apis Bee Assessment

The agency acknowledges non-*Apis* bees "play an important role in crop and native plant pollination," and are part of a healthy biodiverse ecosystem. EPA states that for this assessment it considered other non-*Apis* bees even though "standard methods are currently not available to quantitatively assess exposure and effects..." Additionally, a number of crops, while they may not be attractive to honey bees, are attractive to other wild bees and present risks for non-*Apis* bees. We welcome the agency's deliberate consideration of wild bees in this assessment, despite the general lack of data on these species. Non-*Apis* bees reviewed include bumblebees, mason bees, alfalfa leafcutter bees, and others. EPA finds, mostly through open literature review, that bumblebees are more sensitive than honey bees on an acute oral basis, although the agency finds there is uncertainty in this assumption.

Effects to non-*Apis* bees include elevated mortality, reduced colony size, number of adults, and queen longevity (for bumble bees), and reduced number of completed nests, brood cells and offspring development. In many cases, these effects were seen at concentrations lower than that of the registrant's colony feeding study with honey bees. Overall, the conditions and effects reported in the reviewed studies varied and EPA states that "the ability to reliably determine a no-effect concentration is limited." In light of the variation and uncertainty in the available data for non-*Apis* bees, the agency should take the precautionary approach and restrict non-*Apis* bee exposures to clothianidin and thiamethoxam.

The Government Accountability Office (GAO) recommends that the U.S. Department of Agriculture (USDA) "coordinate with other agencies to develop a plan to monitor wild, native bees, and evaluate gaps in staff expertise in conservation practices."[18] EPA in collaboration with USDA must gather ecological data on the fitness, development, and survival of wild bees. These species are as important as honey bees to agriculture and broader ecosystem services.

Other Toxicity Endpoints

For years, studies have been published that describe the negative impact of pesticide exposure on the overall immune system of bees and subsequent pathogen loads. For clothianidin specifically, a recent study reports its adverse impact on immune parameters in honey bee queens.[19] This study looked at the immune defense competence of queens (total and differential hemocyte counts, wound healing/melanisation, and antimicrobial activity of the hemolymph) and finds individual immunity is negatively affected by sublethal, environmentally relevant concentrations of neonicotinoids in newly emerged honey bee

[18] GAO. USDA and EPA Should Take Additional Actions to Address Threats to Bee Populations. Report to Congressional Requesters. Bee Health. February 2016 http://www.gao.gov/assets/680/675109.pdf.
[19] Brandt, A, Grikscheit, K, Siede, R, et al. 2017. Immunosuppression in Honeybee Queens by the Neonicotinoids Thiacloprid and Clothianidin. *Scientific Reports.* 7: 4673 DOI:10.1038/s41598-017-04734-1.

queens. This means that the spread of pathogens from compromised queens to offspring can be exacerbated in exposed colonies, leading to increased pathogen loads that impact overall colony health. Another study by Di Prisco et al. (2016) also demonstrates clothianidin's impact on immune signaling and antiviral defenses. Here, clothianidin reduced immune defenses by affecting the NF-kB protein activation and signaling, and promotes the replication of the deformed wing virus (DWV).[20] Another study also finds that clothianidin (as well as other neonicotinoids) compromises the immune-competence of honey bees at sublethal doses.[21] In certain cases, higher larval mortality was observed in colonies when clothianidin existed synergistically with bacterial infections.[22]

Since pathogens and disease are identified by EPA and industry groups as a significant contributor for pollinator decline, there must be consideration and acknowledgment of the role of pesticide exposure in this phenomena. Neonicotinoids (and other pesticide classes) have been linked to immune suppression on bees, and EPA must thoroughly examine their role in increasing pathogenic rates in colonies across the U.S.

Consideration of Chemical Mixtures Needed

Foraging bees are exposed to multiple pesticides, especially those in agricultural regions.[23] These different pesticides can have synergistic and/or additive effects. Some of these interactions have already been identified. For instance, Bayer CropScience demonstrated that the combination of clothianidin and the fungicide trifloxystrobin resulted in a 150-fold increase in kill rate to *Phaedon* leaf beetle larvae over clothianidin alone.[24] It is a common practice in the U.S. for pesticide applicators to combine multiple pesticides in tank mixes, but the environmental impacts of these mixtures are rarely considered in risk assessments. EPA's Inspector General recently directed the agency to collect and assess information on chemical mixtures and potential synergistic effects in order to improve oversight over pesticides.[25] Similarly, the Government Accountability Office's (GAO) report, in its critique of EPA's efforts to protect pollinators, notes that EPA can source data on commonly used mixtures which can be collected from farmers, pesticide manufacturers, and others.[26] In doing this, "EPA would have greater assurance that it could assess those mixtures to determine whether they pose greater

---

[20] Di Prisco, G, Cavaliere, V, Annoscia, D et al. 2013. Neonicotinoid clothianidin adversely affects insect immunity and promotes replication of a viral pathogen in honey bees. PNAS. 110, 46: 18466–18471.

[21] Brandt, A, Gorenflo, A, Siede, R et al. 2016. The neonicotinoids thiacloprid, imidacloprid, and clothianidin affect the immunocompetence of honey bees (*Apis mellifera* L.). *J Insect Phys.* 86:40-47.

[22] López, J. H., Krainer, S, Engert, A., *et al*. 2017. Sublethal pesticide doses negatively affect survival and the cellular responses in American foulbrood-infected honeybee larvae. *Sci. Rep.* 7, 40853; doi: 10.1038/srep40853.

[23] Hladik ML, Vandever M, Smalling KL (2016) Exposure of native bees foraging in an agricultural landscape to current-use pesticides. Sci Total Environ 542:469–477.

[24] Wachendorff-Neumann U, Mauler-Machnik A, Erdelen C, Ohtake H (2012) Synergistic mixture of trifloxystrobin and imidacloprid. Google patents. United States: Bayer Cropscience AG.

[25] EPA Office of Inspector General. 2017. EPA Can Strengthen Its Oversight of Herbicide Resistance With Better Management Controls. Report No. 17-P-0278.

[26] GAO. USDA and EPA Should Take Additional Actions to Address Threats to Bee Populations. Report to Congressional Requesters. Bee Health. February 2016 http://www.gao.gov/assets/680/675109.pdf.

risks than the sum of the risks posed by individual pesticides." This research is already being done, and EPA has the responsibility to evaluate real-world pesticide mixtures and their impact on bees so as to not underestimate risks.

Conclusion

Clothianidin and thiamethoxam are heavily used in agricultural fields across the U.S. and therefore present dangers to foraging bees and other pollinator species. Identified on-field risks to bees from citrus, cotton, and certain vegetable and fruit crops are unacceptable. Like imidacloprid, this clothianidin-thiamethoxam pollinator assessment continues to suffer from data gaps and uncertainties. Additionally, for relevant exposure pathways, EPA states that it lacks the information to understand and quantify the risks from certain exposure routes such as soil, surface water and guttation, and chemical mixtures. Having a lack of understanding of the complexities surrounding pollinator exposures to pesticides, given existing research efforts cannot be a reason to allow risks from these pathways to go unchecked. While this assessment focuses on agricultural uses, residential uses, ornamentals and other non-agricultural sites are also important contributors to pollinator exposures to pesticides. Although efforts are underway to provide and support pollinator habitats, caution must be taken that these sensitive areas are free from these toxic pesticides. Therefore, we urge EPA to issue cancellations for neonicotinoid pesticides due to their unreasonable adverse effects on pollinators.

Respectfully,

Nichelle Harriott
Science and Regulatory Director