July 24, 2017

Comments from Center for Food Safety on the
EPA's Preliminary Pollinator Assessment to
Support the Registration Reviews of Clothianidin and Thiamethoxam, dated Jan. 5, 2017

Clothianidin Docket ID: EPA-HQ-OPP-2011-0865
Clothianidin Document ID: ID: EPA-HQ-OPP-2011-0865
Thiamethoxam Docket ID: EPA-HQ-OPP-2011-0581
Thiamethoxam Document ID: EPA-HQ-OPP-2011-0581-0034

We are pleased to submit this comment on the above-referenced docket on behalf of Center for Food Safety. Center for Food Safety (CFS) is a non-profit membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and sustainable agriculture. Our membership has rapidly grown to include over 900,000 people across the country that support organic food and farming, grow organic food, and regularly purchase organic products. CFS and its members are concerned about the impacts of pesticides on biodiversity generally, and on honey bees and other pollinators specifically.

INITIAL COMMENTS:

Unacceptable Delays in the Registration Review Process

The Registration Review process for both of these compounds is behind the schedule to which the agency formally committed. In 2015, EPA announced it would expedite the Registration Reviews for clothianidin and thiamethoxam stating it would complete these initial Risk Assessments by 2016.[1] That did not occur until 2017 and now, with the long delays in opening this public comment period, the commitment to complete all of the Risk Assessments this year has been undone and pushed to 2018.[2] EPA must expedite completion of this process.

Noncompliance with the Endangered Species Act

EPA fails to include any Endangered Species Act (ESA) analysis or compliance despite the existence of endangered and threatened bee species. Illustrative examples of ESA-listed non-*Apis* bees, include: the rusty patched bumble bee (*Bombus affinis*) and seven yellow-faced bees (*Hylaeus anthracinus, H. assimulans, H. facilis, H. hilaris, H. kuakea, H. longiceps, and H. mana*).

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[1] White House Pollinator Health Task Force, National Strategy To Promote The Health Of Honey Bees And Other Pollinators May 19, 2015 https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/Pollinator%20Health%20Strategy%202015.pdf ; Appendix A. U.S. Environmental Protection Agency Pollinator Protection Plan https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/Pollinator-Strategy%20Appendices%202015.pdf.

[2] https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides

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It is essential that EPA act contemporaneously in this Registration Review risk analysis process to also include thorough analyses of foreseeable effects to ESA-listed bee species now. Under the ESA implementing regulation, 50 C.F.R. § 402.14(a), agencies must review their actions at the "earliest possible time". EPA must not delay this ESA-mandated review or else it will be in violation of the law.[3]

FURTHER COMMENTS:

I. The whole colony study underlying the Clothianidin Preliminary Pollinator Assessment was inadequate

a) The Bayer clothianidin Colony Feeding Study submitted in support of the Assessment is not robust, as it was based on just one North Carolina test area over a winter with very high mortality in almost all hives (treated and control) (p. 146). The very high mortality indicates the experiment followed substandard beekeeping practices that should not be accepted by EPA for this critical study. The goal of robust findings regarding possible overwintering chronic effects was defeated by the abnormally high mortality in the control hives that masked possible comparative effects in the treated hives that may appear under more typical overwintering mortality (see p. 12, where the PARA recognizes this).
b) The exposure model excluded any consideration of effects from exposure to pollen and contaminated dust, air, guttation fluid or marginal vegetation to which honey bees are normally exposed. Thus, the exposure model was unrealistic.
c) There is no accounting for any other synergistic effects to which honey bees are normally exposed. Single active ingredients were used, whereas in field exposures synergized mixes are the rule. The revelations of synergistic effects related to several specific clothianidin products should be addressed in the whole colony study for clothianidin.
d) The experiment length was inadequate. It was too short to detect chronic effects that weaken bee colonies. Honey bee experts generally agree that a study for less than one year is inadequate to detect chronic effects.
e) The feeding regime only lasted 6 weeks (from June to August), which is not long enough to assess bees' normal foraging activities in North Carolina, where bees likely could forage from March to October.
f) The researchers did not describe post-mortem observations for the dead hives in detail. When a dead hive was observed, were dead bees found at the bottom of the hive - or did they simply disappear? It is critical to differentiate hives that died from exposure from hives that may have died from other causes, such as Varroa mite. The report did not adequately mention Varroa mite baseline data to be able to assess whether the mites contributed to hive mortalities.
g) The study lacked analysis of chronic effects on queens. As the only fertile females in the hive, effects on queens are critical to understanding viability and productivity of the colony. Queens should have been marked and egg production should have been measured, as well as long-term brood viability. Supersedure of the queen by neonicotinoid stressors and other related effects are now well-documented in several studies published in 2016. However, those effects were not addressed in this study.
h) Finally, the whole colony feeding study suggests a NOAEL of 20 ppb. EPA should review other studies and incident reports that have indicated some clothianidin crop applications result in exposures that exceed that NOAEL. If the Bayer Clothianidin study were to be accepted as valid

[3] The scope of agency actions triggering Section 7 duties is broad, including all activities or programs of any kind authorized, licensed, funded, or carried out by federal agencies, including activities directly or indirectly causing modifications to land, water, or air. 50 C.F.R. § 402.02 (definition of "action"). The potential "effects" of an action that an agency must consider are similarly broad, and include both "direct" and "indirect" effects of the action and all activities "interrelated or interdependent" with that action. Id.

notwithstanding all of the defects outlined above, its findings would indicate that this active ingredient poses unacceptable risks to honey bees in those crop applications. Product registrations allowing those applications should be suspended.

II. The whole colony study underlying the Thiamethoxam Preliminary Pollinator Assessment was inadequate

a) The Syngenta thiamethoxam Colony Feeding Study is not robust, as the findings are based on just one North Carolina test area over a winter with extreme mortality in almost all hives (treated and control). The extreme mortality in almost all hives indicates the experiment followed substandard beekeeping practices that should not be accepted by EPA for this critical study (pp. 163-164).
b) The exposure model excluded any consideration of effects from exposure to pollen and contaminated dust, air, guttation fluid or marginal vegetation to which honey bees are normally exposed. Thus, the exposure model was unrealistic.
c) As with the Bayer clothianidin study, there is no accounting for any synergistic effects to which honey bees are normally exposed. The comment on synergy information that EPA should consider in our comment (c), above, also applies to the Syngenta thiamethoxam study.
d) The experiment length was inadequate. It was too short to detect chronic effects that weaken bee colonies. Honey bee experts generally agree that a study for less than one year is inadequate to detect chronic effects.
e) The feeding regime only lasted 6 weeks (from June through July), which is not long enough to cover bees' normal foraging activities in North Carolina, where bees likely could forage from March to October.
f) The researchers did not describe post-mortem observations for the dead hives in detail. When a dead hive was observed, were dead bees found at the bottom of the hive - or did they simply disappear? It is critical to differentiate hives that died from exposure from hives that may have died from other causes, such as Varroa mite. The report did not adequately mention Varroa mite baseline data to be able to assess whether the mites contributed to colony mortalities.
g) As noted above, for clothianidin, the thiamethoxam study also lacked analysis of chronic effects on queens. Those effects should be addressed.

III. The PPA fails to adequately assess risks to bees from field-realistic exposure

a) The PPA revision should consider critical new published research on the risks of clothianidin and thiamethoxam to honey bees and other pollinators, such as:
    - Woodcock et al., "Country-specific effects of neonicotinoid pesticides on honey bees and wild bees"[4]

        This study evaluated the impacts of neonicotinoid seed coatings on bees using field-realistic exposure levels. The findings confirm what previous studies have also indicated: field exposure to neonicotinoids adversely impacts honey bees, bumble bees, and solitary bees. This is the largest scale field study conducted thus far on the impacts of neonicotinoids and EPA must consider the findings of this research in its final risk assessment.
    - Tsvetkov et al., "Chronic exposure to neonicotinoids reduces honey bee health near corn crops"[5]

        This study indicated that uses of neonicotinoids on corn increased worker mortality and were associated with declines in social immunity and increased

[4] Woodcock, B. A., et al. (2017). Country-specific effects of neonicotinoid pesticides on honey bees and wild bees. *Science, 356*(6345), 1393-1395. http://dx.doi.org/10.1126/science.aaa1190
[5] Tsvetkov, N., et al. (2017). Country-specific effects of neonicotinoid pesticides on honey bees and wild bees. *Science, 356*(6345), 1393-1395. http://dx.doi.org/10.1126/science.aaa1190

queenlessness over time. The researchers also noted the harmful synergistic effects when neonicotinoids are used in combination with other pesticides, notably fungicides. Specifically, the authors found that the acute toxicity of neonicotinoids to honey bees doubled when bees were also exposed to field-realistic levels of the fungicide boscalid.

This research adds to the wealth of existing research indicating that field-realistic exposure to neonicotinoids in or around corn fields can reduce honey bee health. EPA must consider these synergistic impacts in its final risk assessment.

- Krupke et al., "Planting of neonicotinoid-treated maize poses risks for honey bees and other non-target organisms over a wide area without consistent crop yield benefit"[6]

  Researchers measured neonicotinoid dust drift (including for clothianidin and thiamethoxam) during the planting of neonicotinoid-coated corn seeds and found significant risks to honey bees and other non-target organisms over a wide area. Perhaps most alarming, the researchers found that over 94 percent of foraging honey bees throughout the state of Indiana are at risk of exposure to varying levels of neonicotinoid insecticides, including lethal levels, during the planting of neonicotinoid-coated corn seeds. Notably, the researchers also found no benefit of the neonicotinoid seed coatings for crop yield during the study.
- Alford et al., "Translocation of the neonicotinoid seed treatment clothianidin in maize"[7]

  Alford and Krupke conducted a two-year field trial to evaluate concentrations of clothianidin in corn root tissues several weeks after the clothianidin-coated seeds were planted. While their findings suggest the clothianidin seed coatings may provide protection from some early season secondary corn pests, the actual amount of clothianidin that was taken up into the majority of plant tissues throughout the growing season was low overall. These results confirm previous reports that benefits from neonic seed coatings with corn, soybeans, and other crops are inconsistent at best.

b) The PPA also fails to consider additional extensive published research on risks of clothianidin and thiamethoxam to honey bees and other pollinators, including, but not limited to:
   - Baron et al., "General and species-specific impacts of a neonicotinoid insecticide on the ovary development and feeding of wild bumblebee queens"[8]
   - Botías et al, "Quantifying exposure of wild bumblebees to mixtures of agrochemicals in agricultural and urban landscapes"[9]
   - Dance et al., "The combined effects of a monotonous diet and exposure to thiamethoxam on the performance of bumblebee micro-colonies"[10]
   - Fauser et al., "Neonicotinoids override a parasite exposure impact on hibernation success of a key bumblebee pollinator"[11]

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[6] Krupke, C.H., Holland, J.D., Long, E.Y., Eitzer, B.D. (2017). Planting of neonicotinoid-treated maize poses risks for honey bees and other non-target organisms over a wide area without consistent crop yield benefit. *Journal of Applied Ecology.* doi: 10.1111/1365-2664.12924

[7] Alford, A., & Krupke, C.H. (2017). Translocation of the neonicotinoid seed treatment clothianidin in maize. *PLoS ONE, 12*(3). https://doi.org/10.1371/journal.pone.0173836

[8] Baron, G.L., Raine, N.E., & Brown, M.J.F. (2017). General and species-specific impacts of a neonicotinoid insecticide on the ovary development and feeding of wild bumblebee queens. *Proceedings Biological Sciences, 284*(1854). http://doi.org/10.1098/rspb.2017.0123

[9] Botias, C., David, A., Hill, E. M., & Goulson, D. (2017). Quantifying exposure of wild bumblebees to mixtures of agrochemicals in agricultural and urban landscapes. *Environmental Pollution, 222*, 73-82. https://doi.org/10.1016/j.envpol.2017.01.001

[10] Dance, C., Botías, C., & Goulson, D. (2017). The combined effects of a monotonous diet and exposure to thiamethoxam on the performance of bumblebee micro-colonies. *Ecotoxicology and Environmental Safety, 139,* 194-201. http://doi.org/10.1016/j.ecoenv.2017.01.041

- Friol et al, "Can the exposure of Apis mellifera (Hymenoptera, Apiadae) larvae to a field concentration of thiamethoxam affect newly emerged bees?"[12]
- Hernández López et al., "Sublethal pesticide doses negatively affect survival and the cellular responses in American foulbrood-infected honeybee larvae"[13]
- Lentola et al., "Ornamental plants on sale to the public are a significant source of pesticide residues with implications for the health of pollinating insects"[14]
- Mogren et al., "Neonicotinoid-contaminated pollinator strips adjacent to cropland reduce honey bee nutritional status"[15]
- Rinkevich et al., "Influence of Varroa Mite (Varroa destructor) Management Practices on Insecticide Sensitivity in the Honey Bee (Apis mellifera)"[16]
- Samuelson et al., "Effect of acute pesticide exposure on bee spatial working memory using an analogue of the radial-arm maze"[17]
- Sgolastra et al., "Synergistic mortality between a neonicotinoid insecticide and an ergosterol-biosynthesis-inhibiting fungicide in three bee species"[18]
- Silvina et al., "Neonicotinoids transference from the field to the hive by honey bees: Towards a pesticide residues biomonitor"[19]
- Simmons et al., "Chronic exposure to a neonicotinoid increases expression of antimicrobial peptide genes in the bumblebee Bombus impatiens"[20]
- Spurgeon et al., "Chronic oral lethal and sub-lethal toxicities of different binary mixtures of pesticides and contaminants in bees (Apis mellifera, Osmia bicornis and Bombus terrestris)"[21]
- Stoner, "Current Pesticide Risk Assessment Protocols Do Not Adequately Address Differences between Honey Bees (Apis mellifera) and Bumble Bees (Bombus spp.)[22]
- Tosi et al., "Effects of a neonicotinoid pesticide on thermoregulation of African honey bees (Apis mellifera scutellata)"[23]

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[11] Fauser, A., Sandrock, C., Neumann, P., & Sadd, B. M. (2017). Neonicotinoids override a parasite exposure impact on hibernation success of a key bumblebee pollinator. *Ecological Entomology, 42*(3), 306-314. http://doi.org/10.1111/een.12385

[12] Friol, P., Catae, A., Tavares, D., Malaspina, O., & Roat, T. (2017). Can the exposure of Apis mellifera (Hymenoptera, Apiadae) larvae to a field concentration of thiamethoxam affect newly emerged bees? *Chemosphere, 185, 56-66*. http://dx.doi.org/10.1016/j.chemosphere.2017.06.113

[13] Hernández López, J., et al. (2017). Sublethal pesticide doses negatively affect survival and the cellular responses in American foulbrood-infected honeybee larvae. *Scientific Reports, 7*. http://doi.org/10.1038/srep40853

[14] Lentola, A., et al. (2017). Ornamental plants on sale to the public are a significant source of pesticide residues with implications for the health of pollinating insects. https://doi.org/10.1016/j.envpol.2017.03.084

[15] Mogren, C. L., & Lundgren, J. G. (2016). Neonicotinoid-contaminated pollinator strips adjacent to cropland reduce honey bee nutritional status. *Scientific Reports, 6,* 1-10. http://doi.org/10.1038/srep29608

[16] Rinkevich, F. D., Danka, R. G., & Healy, K. B. (2017). Influence of Varroa Mite (*Varroa destructor*) Management Practices on Insecticide Sensitivity in the Honey Bee (*Apis mellifera*). *Insects, 8*(1), 1-12. https://doi.org/10.3390/insects8010009

[17] Samuelson, E. E., Chen-Wishart, Z. P., Gill, R. J., Leadbeater, E. (2016). Effect of acute pesticide exposure on bee spatial working memory using an analogue of the radial-arm maze. *Scientific Reports, 6,* 1-11. http://doi.org/10.1038/srep38957

[18] Sgolastra, F., et al. (2016). Synergistic mortality between a neonicotinoid insecticide and an ergosterol-biosynthesis-inhibiting fungicide in three bee species. *Pest Management Science, 73*(6), 1236-1243. http://doi.org/10.1002/ps.4449

[19] Silvina, N., et al. (2017). Neonicotinoids transference from the field to the hive by honey bees: Towards a pesticide residues biomonitor. *Science of the Total Environment, 581-582*, 25-31. https://doi.org/10.1016/j.scitotenv.2017.01.011

[20] Simmons, W.R., & Angelini, D.R. (2017). Chronic exposure to a neonicotinoid increases expression of antimicrobial peptide genes in the bumblebee *Bombus impatiens*. *Scientific Reports, 7* (44773). http://doi.org/10.1038/srep44773

[21] Spurgeon, D., et al. (2016). Chronic oral lethal and sub-lethal toxicities of different binary mixtures of pesticides and contaminants in bees (*Apis mellifera, Osmia bicornis* and *Bombus terrestris*). *Centre for Ecology & Hydrology,* 1-66. http://doi.org/10.2903/sp.efsa.2016.EN-1076

[22] Stoner, A. (2016). Current Pesticide Risk Assessment Protocols Do Not Adequately Address Differences between Honey Bees (*Apis mellifera*) and Bumble Bees (*Bombus* spp.). *Fronteirs in Environmental Science, 4*(79). http://doi.org/10.3389/fenvs.2016.00079

- Wessler et al., "Non-neuronal acetylcholine involved in reproduction in mammals and honeybees"[24]
- Yasuda et al., "Insecticide Susceptibility in Asian Honey Bees (Apis cerana (Hymenoptera: Apidae)) and Implications for Wild Honey Bees in Asia"[25]

c) We note initially that the PPA's admitted focus on **agricultural uses only** (p. 6), to the exclusion of **approved residential, ornamental, landscaping, tree/forest, structural, and other uses** of clothianidin and thiamethoxam, is highly unfortunate. Those uses are extremely important in some risk scenarios and must be addressed in conjunction with the agricultural uses in order to gather the whole risk picture clothianidin and thiamethoxam present.

d) Other routes of exposure (e.g. soil, surface water, guttation) were not quantitatively considered in the risk assessment even though EPA acknowledges that these routes are potential sources of exposure (p. 7).

e) These points in the Executive Summary (p. 7) indicate that the conclusions are not representative of the real world of risks to honey bees and other pollinators:

> *Exposure Considerations*
>
> *Exposure of bees through direct contact by foliar spray of clothianidin and thiamethoxam (i.e., interception of spray droplets either on or off the treated field) and oral ingestion (e.g., consumption of residues in pollen and/or nectar) represent the primary routes of exposure considered in this assessment. Bees may also be exposed to clothianidin and thiamethoxam through other routes, such as contaminated surface water, plant guttation fluids, honey dew, soil (for ground-nesting bees), and leaves. However, the Agency 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. Exposure of bees to clothianidin and thiamethoxam via 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.*

That paragraph indicates that PPA's reliability is undercut by its major omissions. The last sentence in particular discounts and avoids an exposure pathway known to have killed or severely weakened tens of thousands of U.S., Canadian, and European bee colonies. Dust and soil contamination not only leads to acute bee kills but also creates chronic contamination through fields and marginal vegetation (weed, wildflowers, clover, willows, and so on) to which bees are attracted. For further explication, see these studies, none of which the PPA cites. All need to be cited and addressed in the revised final PPA:

- Alford et al., "Translocation of the neonicotinoid seed treatment clothianidin in maize"[26]

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[23] Tosi, S., et al. (2016). Effects of a neonicotinoid pesticide on thermoregulation of African honey bees (Apis mellifera scutellata). *Journal of Insect Physiology.* http://doi.org/10.1016/j.jinsphys.2016.08.010

[24] Wessler, I. K., & Kirkpatrick, C. J. (2017). Non-neuronal acetylcholine involved in reproduction in mammals and honeybees. *Journal of neurochemistry.* http://doi.org/10.1111/jnc.13953

[25] Yasuda, M., Sakamoto, Y., Goka, K., Nagamitsu, T., & Taki, H. (2017). Insecticide Susceptibility in Asian Honey Bees (Apis cerana (Hymenoptera: Apidae)) and Implications for Wild Honey Bees in Asia. *Journal of economic entomology, 110*(2). http://doi.org/10.1093/jee/tox032

[26] Alford, 2017.

- Botías et al, "Quantifying exposure of wild bumblebees to mixtures of agrochemicals in agricultural and urban landscapes"[27]
- Botias et al. 2015. "Neonicotinoid residues in wildflowers, a potential route of chronic exposure for bees"[28]
- David et al. 2016. "Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops"[29]
- Limay-Rios et al. 2015. "Neonicotinoid insecticide residues in soil dust and associated parent soil in fields with a history of seed treatment use on crops in southwestern Ontario"[30]
- Mogren et al., "Neonicotinoid-contaminated pollinator strips adjacent to cropland reduce honey bee nutritional status"[31]

f) The dust-off pathway must be addressed as quantitatively as feasible for the PPA to be an adequate risk assessment, as stated in the EPA's own "Guidance for Assessing Pesticide Risks to Bees*"* (2014). The PPA's failure to do that is mystifying, in light of the effects and the agency guidance. In particular, the PPA's proposal to address risks from neonicotinoid seed coatings through best management practices with industry stakeholders is woefully inadequate. This plan is not described nor is it mandated by EPA in any enforceable way. Hoping that farmers and the seed industry will follow voluntary "best management practices" is not realistic risk mitigation.

g) The assertion that the agency is working on non-mandatory best management practices (BMPs) to address dust-off is evasive. EPA has reiterated that evasion since at least 2013, claiming new technologies will address the risk. To date that has not been the case; there is no mandatory implementation of such technologies—and virtually no voluntary implementation is apparent. The fact that EPA has exempted the clothianidin and thiamethoxam-coated seeds from registration as pesticides under FIFRA (per EPA's past unexplained interpretations) and that clothianidin and thiamethoxam-coated seeds are not subject to mandatory labels or enforcement, are clear obstacles to EPA mandating any effective solution to that risk. EPA needs a clear regulatory path to making dust reduction technologies compulsory, or else it must stop approving the seed coating uses. At minimum, the final risk assessment must fully address the risks.

h) The list of uncertainties beginning on p. 343 is concerning and further indicates that the risk assessment lacks reliability. In particular, the points about "low exposure levels" (p. 346), copied below, undermine the analysis:
   - *Due to low exposures that are below effect levels for honey bees (either at the individual-level or the colony-level), seed treatments of clothianidin or thiamethoxam on canola, corn, cotton, pumpkin, soybean and sunflower are anticipated to pose a low risk for on-field exposures.*

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[27] Botías, C., David, A., Hill, E.M., & Goulson, D. (2017). Quantifying exposure of wild bumblebees to mixtures of agrochemicals in agricultural and urban landscapes. *Environmental Pollution*, *222,* 73-82. https://doi.org/10.1016/j.envpol.2017.01.001

[28] Botías, C, David, A., Horwood, J., Abdul-Sada, A., Nicholls, E., Hill, E., & Goulson, D. (2015). Neonicotinoid residues in wildflowers, a potential route of chronic exposure for bees. *Environmental Science and Technology*, *49*(21), 12731-12740. http://doi.org/10.1021/acs.est.5b03459

[29] David, A., Botías, C., Abdul-Sada, A., Nicholls, E., Rotheray, E.L., Hill, E.M., & Goulson, D. (2016). Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops*. Environment International*, *88*, 169-178. https://doi.org/10.1016/j.envint.2015.12.011

[30] Limay-Rios, V., Forrero, L.G., Xue, Yingen, Smith, J., Baute, T. Schaafsma, A., 2015. Neonicotinoid insecticide residues in soil dust and associated parent soil in fields with a history of seed treatment use on crops in southwestern Ontario. *Environ Toxicol Chem*. http://doi.org/10.1002/etc.3257

[31] Mogren, C.L. & Ludgren, J.G. (2016). Neonicotinoid-contaminated pollinator strips adjacent to cropland reduce honey bee nutritional status. *Scientific Reports, 6(*29608). http://doi.org/10.1038/srep29608

- *Given the large extent of seed treatment use of clothianidin on corn and thiamethoxam on corn, soybean and cotton, the risk conclusions indicate that the majority of pounds of clothianidin and thiamethoxam applied in the US pose a low on-field risk to honey bees.*
- *According to the USDA's crop attractiveness guidance, these crops are all considered attractive to honey bees, therefore, exposure is of concern on-field. As discussed in the problem formulation, contact-based exposures are not assessed for seed treatments, as it is assumed that bees are not present until after planting; therefore, contact exposures would not reasonably be expected to occur.*

EPA's failure to acknowledge the well-documented risks and numerous exposure pathways from uses of neonicotinoid seed coatings undermines the value of the PPA. Particularly disturbing is the admission that the Agency is aware of exposure routes for the abraded seed dust, but then shirks any responsibility for incorporating these exposure routes into the PPA by instead repeatedly noting its [undescribed] work with stakeholders to address this issue.

EPA itself notes that "when considering the usage data for clothianidin and thiamethoxam (Section 2.4), the majority of the mass applied per year in the US is via seed treatment." In fact, the vast majority of clothianidin is applied to corn alone (1,400,000 lbs/year; 94% of total use). For thiamethoxam, the vast majority is broken down between corn (300,000 lbs/year, 33% of total use), soybeans (300,000 lbs/year, 33% of total use), and cotton (100,000 lbs/year, 11% of total use) (p. 346-347). It is inexcusable that these widely used neonicotinoids lack an adequate risk assessment for their primary use: seed coatings for corn, soybean, and cotton.

i) Clothianidin and thiamethoxam are practically ubiquitous in agricultural areas due to their consistent use and long persistence, leading to chronic effects. As indicated, the seed coatings can abrade and otherwise blow or flow off-site. Limiting the off-field exposure analysis to spray drift may conveniently fit with EPA's existing analytical models, but it ignores extensive off-field pathways associated with the clothianidin and thiamethoxam seed coating application, which represent the main innovation associated with these systemic insecticides. These pathways simply cannot be acknowledged and then immediately discarded in the risk assessment process by stating, "The Agency is working with different stakeholders to identify best management practices and to promote technology-based solutions that reduce this potential route of exposure" (p. 362).

j) With respect to the "Incident Reports," beginning at p. 337, EPA and the beekeeping industry are well aware that many bee kill incidents are not reported. The analysis fails to account for the fact that beekeepers have no reason to report to the system for bee kills resulting from clothianidin and thiamethoxam-coated seeds. Because the seeds themselves are exempted from FIFRA enforcement due to EPA's application of the Treated Article Exemption, there are no mandatory label warnings or use directions, nor is there any required inspection or enforcement by EPA or the State Agencies. In fact, the Agency notes, "Much of the incident information made through phone and email correspondence to EFED does not usually include a thorough investigation of the incident or provide any confirmatory residue data to link a chemical with a particular incident". Furthermore, often times beekeepers feel that they are blamed for the kills, or that the onus is on the beekeeper to prove they are not responsible for the kill. There is also frustration throughout the beekeeping industry that bee kill samples collected at the scene are not analyzed, nor are the pesticide applicators (or those responsible for the pesticide exposure) questioned in the incident reporting process.

With no enforcement, or consequences for farmers who misuse or overuse clothianidin and thiamethoxam-coated seeds, beekeepers will not bother to report their losses via such exposures. With those caveats in mind it still is remarkable that everyday use according to label warnings has led to the numerous severe kill incidents described in Table 5.71 and 5.72.

III. The PPA fails to consider synergistic effects on honey bees and other pollinators

a) Risks to commercial honey bees in particular do not occur in isolation. The bees are transported to fill the nation's pollination needs, and are exposed to many factors. The PPA ignores these "field realistic" scenarios and fails to even mention fungicides as synergistically toxic to honey bees and other pollinators.

b) It is not reasonable for risks of synergistic effects to be ignored in EPA's risk assessment. As noted above, extensive scientific literature indicates that field-relevant toxicity levels for clothianidin and thiamethoxam may be heightened when used in combination with other pesticides, such as fungicides.

c) Five recent studies illustrate synergistic effects; the PPA failed to consider them and must take them into account:

- Brandt et al. 2016., "The neonicotinoids thiacloprid, imidacloprid, and clothianidin affect the immunocompetence of honey bees (*Apis mellifera* L.)"[32]
- Sgolastra et al., "Synergistic mortality between a neonicotinoid insecticide and an ergosterol-biosynthesis-inhibiting fungicide in three bee species"[33]
- Spurgeon et al., "Chronic oral lethal and sub-lethal toxicities of different binary mixtures of pesticides and contaminants in bees (Apis mellifera, Osmia bicornis and Bombus terrestris)"[34]
- Botías et al, "Quantifying exposure of wild bumblebees to mixtures of agrochemicals in agricultural and urban landscapes"[35]
- Tsvetkov et al., "Chronic exposure to neonicotinoids reduces honey bee health near corn crops"[36]

d) The U.S. Government Accountability Office raised concerns about EPA's failure to properly assess risks from pesticide mixtures and synergistic effects. According to the February 2016 GAO report, "EPA officials agreed that such mixtures may pose risks to bees but said that EPA does not have data on commonly used mixtures and does not know how it would identify them". [37] It is unacceptable for EPA officials to claim they are unable to evaluate risks from pesticide mixtures due to a lack of information about common pesticide mixtures. As the GAO report makes clear,

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[32] Brandt, A., Gorenflo, A., Siede, R., Meixner, M., & Büchler, R. (2016). The neonicotinoids thiacloprid, imidacloprid, and clothianidin affect the immunocompetence of honey bees (*Apis mellifera* L.). *Journal of Insect Physiology, 86*, 40–47. doi: https://doi.org/10.1016/j.jinsphys.2016.01.001

[33] Sgolastra, F. et al. (2016). Synergistic mortality between a neonicotinoid insecticide and an ergosterol-biosynthesis-inhibiting fungicide in three bee species. *Pest Management Science, 73,* 1236-1243. http://doi.org/10.1002/ps.4449

[34] Spurgeon, D. et al. (2016). Chronic oral lethal and sub-lethal toxicities of different binary mixtures of pesticides and contaminants in bees (*Apis mellifera*, *Osmia bicornis*and *Bombus terrestris*). *EFSA Journal, 13*(9). http://10.2903/sp.efsa.2016.EN-1076

[35] Botías, 2017.

[36] Tsvetkov, N., et al. (2017). Country-specific effects of neonicotinoid pesticides on honey bees and wild bees. *Science, 356*(6345), 1393-1395. http://dx.doi.org/10.1126/science.aaa1190

[37] United States Government Accountability Office. (2016). Bee Health: USDA and EPA Should Take Additional Actions to Address Threats to Bee Populations. *GAO-16-220*. Retrieved from http://gao.gov/assets/680/675109.pdf

this type of information can be acquired by surveying farmers, pesticide manufacturers, and other stakeholders.

III. Beyond honey bees, the PPA's scope is too narrow

a) The defects outlined above, for the PPA's assessment of honey bees, are magnified with respect to the more vulnerable bumblebees, solitary bees, and other pollinators that the PPA fails to address (as described on p. 12). By wrongly choosing to use the honey bee as a "reasonable" surrogate for other bee species, the PPA ignores many peer-reviewed studies that show impacts to native bees and butterflies from clothianidin and thiamethoxam.

b) The GAO has also called on EPA to improve the scope of its risk assessments and to develop a plan for evaluating pesticide risks to a range of bee species, beyond honey bees. As noted in the GAO's report, it would be prudent for EPA to develop testing models and guidelines for other types of bees, such as solitary bees and bumblebees. The GAO also recommends that EPA "direct the Office of Pesticide Programs to develop a plan for obtaining data from pesticide registrants on the effects of pesticides on non-honey bee species, including other managed or wild, native bees."

c) EPA must consider the significant life cycle and other differences between honey bees, bumble bees, and especially solitary bees. For instance, according to one 2016 study, "Unlike honeybees, bumble bees live in colonies for only a few months each year. Assessing the sublethal effects of systemic insecticides only on the colony level is appropriate for honey bees, but for bumble bees, this approach addresses just part of their annual lifecycle. Queens are solitary from the time they leave their home colonies in fall until they produce their first workers the following year. Queens forage for pollen and nectar, and are thus exposed to more risk of direct pesticide exposure than honey bee queens". EPA acknowledges the "differences in bee life history" (p. 344) but fails to incorporate these significant differences into the PPA.

d) Further, the PPA disregards the substantial risks to bumblebees and other native bees from the use of clothianidin and thiamethoxam seed coatings and soil treatments. When assessing potential risks through seed/soil treatments, the agency only analyzes risks from oral exposure through pollen from treated crops. In fact, because of this significant omission, the agency wrongly concludes, "Exposure of honey bees to clothianidin and thiamethoxam via soil applications are not expected to result in substantial spray drift to adjacent sites. Therefore, off-field risk from soil treatments are assumed to be low". By only considering spray drift and oral exposure routes, EPA completely disregards the significant contact exposure pathways for ground-nesting bees (70 percent of all bee species are ground nesting), yet ground-nesting species will come into contact with residues of clothianidin and thiamethoxam present in the soil.

e) The PPA fails to acknowledge the importance of non-*Apis* pollinators to tomato crop systems. The final risk assessment must assess risks to the full suite of pollinators—and take into account economic as well as environmental damage. A revised PPA should also consider all of the analytical defects outlined above for honey bees, such as the lack of consideration of synergistic effects, for the non-Apis pollinators. There are many other non-bee pollinators, including, but not limited to, monarch butterflies and bats, that the PPA failed to consider at all. This is

unacceptable, particularly as new research indicates that other comparable neonicotinoids threaten monarch larvae.[38]

REQUESTED ACTIONS:

The EPA should:

1. Expedite completion of the final risk assessments and the overall Registration Reviews for clothianidin and thiamethoxam, which are now at least two and likely three years behind the schedule to which EPA had committed.

2. Conduct full ESA Sec. 7 compliance now, contemporaneous with the risk assessments in the Registration Review process, rather than afterwards which would violate the ESA.

3. The high residue levels of clothianidin and thiamethoxam and high risks that EPA identified with respect to cucurbit vegetables, citrus, stone and berry fruits, and oilseed indicate the need to promptly suspend clothianidin and thiamethoxam products with respect to these uses.

4. In view of the: a) high overall risks as stated in this comment; b) the PPA's admitted gaps and substantial analytical uncertainties; c) additionally taking into account the other weaknesses, omissions, and gaps in the PPA described in this comment; d) in order to conserve ESA-listed endangered and threatened wild pollinators, as well as non-listed pollinators; and e) taking a precautionary approach to preserving honey bees and the livelihoods of the nation's essential commercial beekeepers, the risks are high enough to also promptly suspend all outdoor uses of clothianidin and thiamethoxam where pollinators may be exposed. The EPA must take protective actions consistent with the agency's fundamental mission.

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[38] Pecanka, J.R. & Lundren, J.G. (2015). Non-target effects of clothianidin on monarch butterflies. *The Science of Nature, 102* (19). http://doi.org/10.1007/s00114-015-1270-y