April 14th, 2016

Comments from Center for Food Safety on the
EPA's Preliminary Pollinator Assessment to
Support the Registration Review of Imidacloprid (IMD PPA), dated Jan. 4, 2016

Docket ID: EPA-HQ-OPP-2008-0844

Document ID: ID: EPA-HQ-OPP-2008-0844-0140

We are pleased to submit this comment on the above-referenced docket on behalf of Center for Food Safety, together with: American Bird Conservancy, Maryland Pesticide Education Network, Pesticide Action Network North America, and People and Pollinators Action Network.

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 700,000 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.

COMMENTS:

I. The whole colony study underlying the IMD PPA was inadequate

a) The PPA notes that for the registrant-submitted whole colony feeding study,[1] the effects observed were in relation to very high overwintering mortality (36%) of the control hives (pp. 126-127). Unusually high mortality in the control hives may have skewed the comparison with the IMD-treated hives, leading to observations of a lesser effect from the treatment than would have been the case under more typical mortality levels for the control hives.

b) The feeding regime only lasted 6 weeks (from June to August), which is not long enough to cover bees' normal foraging activities in North Carolina, where bees likely could forage from March to October.

c) The mortality observations ended on Jan. 15, 2014. The researchers ended the mortality data collection too early in the winter. What would have happened to the findings from the surviving hives if the researchers extended the observation to March of 2014? This was a clear weakness of the study. The study 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.

[1] Interim Report: Honey bee brood and colony level effects following Imidacloprid intake via treated artificial diet in a field study in North Carolina. February 21, 2014. Prepared by Jessica Lawrence, Louque Eurofins Agroscience Services, Inc., Cedar Grove Research Facility, Mebane, NC 27302

NATIONAL HEADQUARTERS
660 Pennsylvania Avenue, SE, Suite 302
Washington, D.C. 20003
T: 202-547-9359 F: 202-547-9429

CALIFORNIA OFFICE
303 Sacramento Street, 2nd Floor
San Francisco, CA 94111
T: 415-826-2770 F: 415-826-0507

PACIFIC NORTHWEST OFFICE
917 SW Oak Street, Suite 300
Portland, OR 97205
T: 971-271-7372 F: 971-271-7374

HAWAI`I OFFICE
1132 Bishop Street, Suite 2107
Honolulu, Hawaii 96813
T: 808-681-7688

office@centerforfoodsafety.org centerforfoodsafety.org

d) 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? The report described the dead colony as "devoid of adult worker bees", but did not mention whether those dead worker bees were at the bottom of the hive, or simply disappeared. Also, the report made no mention of post-mortem observations for the 5 dead control hives. It is critical to differentiate hives that died from IMD exposure from hives that may have died from other causes, such as the Varroa mite. The report did not adequately mention Varroa mite baseline data and therefore was unable to assess whether the mites contributed to colony mortalities.

e) By design, the studied colonies were shielded from most "real world" influences such as synergistic effects from pathogens and parasites, which are known to significantly compound bee mortality rates when a neonicotinoid, like IMD, is added to the mix at field realistic exposure levels. The revised PPA needs to cite and fully address the seminal review paper on this, Sanchez-Bayo et al. 2016. "Are bee diseases linked to pesticides? – A brief review."[2]

f) The study did not take into account contaminated water or other contaminated vegetation and pollen resources, or synergies from multiple neonicotinoids and other pesticides, all of which could exist in field realistic exposures for typical honey bee colonies.

g) In sum, the whole colony IMD study that Bayer and EPA relied upon was not robust enough to support the PPA.

II. For risk to honey bees, the PPA's scope is too narrow

a) We note initially that the PPA's admitted focus on **agricultural uses only** (p. 25), to the exclusion of the dozens of **approved residential, ornamental, landscaping, tree/forest, structural and other uses** of IMD, 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 IMD presents. We note that the section on "Reported Pollinator Incident Information," (beginning p. 160) does refer to numerous incidents stemming from non-agricultural uses, but the whole of the PPA excludes consideration of those pathways of exposure. Thus, the mention of those non-agricultural incidents in that section adds nothing to the PPA. That inconsistency needs to be remedied.

b) These points in the Executive Summary, p. 14, indicate that the conclusions are not representative of the real world of risks to honey bees:

> *1.4. Exposure Assessment*
>
> *Exposure of bees through direct contact by foliar spray of imidacloprid (i.e., interception of spray droplets either on or off the treated field) and oral ingestion (e.g., consumption of contaminated pollen and nectar) represent the primary routes of exposure considered in this assessment. Bees may also be exposed to imidacloprid*

[2] Sanchez-Bayo, F., Goulson, D. Pennacchio, F., Na Koichi Goka, F., Desneux, N., 2016. Are bee diseases linked to pesticides?—A brief review. *Environment International* 89-90:7-11

through other routes, such as contaminated surface water, plant guttation fluids, honey dew, soil (for ground-nesting bees), and leaves; however, there is high uncertainty regarding the importance of some of these exposure routes, and the Agency lacks information to understand the relative importance of these other routes of exposure and/or to quantify risks from these other routes. With respect to potential exposure via drift of abraded seed coat dust, 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.

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 decimated tens of thousands of U.S., Canadian, and European bee colonies (see PPA, p. 161, for a discussion of extensive kills in Ontario due to this pathway). 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:

- Botias et al. 2015. "Neonicotinoid residues in wildflowers, a potential route of chronic exposure for bees"[3]

- David et al. 2016. "Widespread contamination of wildflower and bee-collected pollen with complex mixtures of neonicotinoids and fungicides commonly applied to crops"[4]

- 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"[5]

c) 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 view of the effects and the agency guidance. In particular, the PPA is defective and evasive in the lower left corner of Fig. 2-5, where this statement appears: ***"*Mitigation of risks from abraded seed coating are addressed outside of this process."*** That is meaningless in view of the extensive risks of the seed coating dust. The alleged mitigation "outside" of the PPA process 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. That misleading assertion in Fig. 2-5, also repeated on p. 37 and elsewhere, should be retracted and the dust-off risks should be fully addressed.

---

[3]Botias, C, David, A., Horwood, J., Abdul-Sada, A., Nicholls, E., Hill, E.M., Goulson, D., 2015. Neonicotinoid residues in wildflowers, a potential route of chronic exposure for bees. *Environmental Science and Technology*. doi: 10.1021/acs.est.5b03459

[4] David, A., Botias, 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*. 99:160-178.

[5] 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*. doi: 10.1002/etc.3257

d) 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 IMD-coated seeds from registration as pesticides under FIFRA (per EPA's past unexplained interpretations) and that IMD-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.

e) The PPA fails to consider <u>new</u> published research on the risks of IMD to honey bees, such as:

- Peng and Yang. 2016. "Sublethal dosage of imidacloprid reduces the microglomerular density of honey bee mushroom bodies"[6]

- Chaimanee, V., Evans, J., Chen Y., Jackson C., Pettis, J. 2016. "Sperm viability and gene expression in honey bee queens (Apis mellifera) following exposure to the neonicotinoid insecticide imidacloprid and the organophosphate acaricide coumaphos"[7]

- Abbo, P., et al. 2016. "Effects of Imidacloprid and Varroa destructor on survival and health of European honey bees, *Apis mellifera*"[8]

f) The PPA also fails to consider extensive <u>pre-existing</u> published research on risks of IMD to honey bees, including, but not limited to:

- Carillo et al. 2014. "Influence of agrochemicals fipronil and imidacloprid on the learning behavior of *Apis mellifera* L. honeybees"[9]

- Derecka et al. 2013. "Transient exposure to low levels of insecticide affects metabolic networks of honeybee larvae"[10]

- Hatjina et al. 2013. "Sublethal doses of imidacloprid decreased size of hypopharyngeal glands and respiratory rhythm of honeybees in vivo"[11]

- Palmer et al. 2013. "Cholinergic pesticides cause mushroom body neuronal inactivation in honeybees"[12]

---

[6] Peng, Y.C and Yang, E.C., 2016. Sublethal dosage of imidiacloprid reduced the microglomerurlar density of honey bee mushroom bodies. *Scientific Reports*. 6:19298.

[7] Chaimanee, V., Evans, J., Chen Y., Jackson C., Pettis, J. 2016. Sperm viability and gene expression in honey bee queens (Apis mellifera) following exposure to the neonicotinoid insecticide imidacloprid and the organophosphate acaricide coumaphos. *Journal of Insect Physiology.* 89:1-8.

[8] Abbo, P.M., Kawasaki, J.K., Hamilton, M., Cook, S.C., DeGrandi-Hoffman, G., Li, W.F.,...Chen, Y.P. 2016. Effects of Imidacloprid and Varroa destructor on survival and health of European honey bees, *Apis mellifera.Insect Science.* doi: 10.1111/1744-7917.12335

[9] Carillo, M.P., de Souza Bovi, T., Negrao, A.F., de Oliveira Orsi, R. 2013. Influence of agrochemicals fipronil and imidacloprid on the learning behavior of *Apis mellifera* L. honeybees. *Acta Scientiarum Animal Sciences*. 35(4): 431-434

[10] Derecka, K., Blythe, M.J., Malla, S., Genereux, D.P., Guffanti, A., Pavan, P.,...Stoger, R., 2013. Transient exposure to low levels of insecticide affects metabolic networks of honeybee larvae. *PLoS ONE* 8(7): e68191.

[11] Hatjina, F., Chrisovlantis, P., Leonidas, C., Dogaroglu, T., Bouga, M., Emmanouil, C., Arnold, G., 2013. Sublethal doses of imidacloprid decreased size of hypopharyngeal glands and respiratory rhythm of honeybees in vivo. *Apidologie*. doi: 10.1007/s13592-013-0199-4

g) The list of uncertainties on p. 23 is daunting, further indicating that the risk assessment lacks reliability. In particular, the sixth and the last bullets, copied below, undermine the analysis:

> *Available data from crop residue studies may not fully capture variation in temporal and spatial factors (e.g., weather patterns, soil type) that affect imidacloprid residues in pollen and nectar for the tested crop.*
>
> *Available full field data (Tier III) for sunflower, canola, and corn are considered inadequate to evaluate risk for use patterns where further refinement of risks to the colony are indicated. However, full field studies for pumpkin and cotton are expected in 2016.*

In the absence of this data and in view of the other defects and uncertainties, the PPA cannot be seen as adequate. Particularly disturbing is the admission that the studies to date are inadequate to assess the actual field-level risk of IMD use in cotton, given the high risk from cotton exposures the PPA identifies. Further, while IMD use on corn may be far less than the use of some other neonicotinoids, the fact remains that corn is by far the most extensively-planted crop in the United States, approaching 100 million acres annually. The PPA notes that IMD seed treatment is common for corn seeds (as well as soybeans, cotton, and potato) (p. 39). It is inexcusable that the oldest neonicotinoid lacks an adequate study of the honey bee colony risk for its use on the Nation's most important crop; corn. That fact compels immediate suspension of the corn uses, until such time as full field data indicates safety for bee colonies. There are key admissions in the PPA related to the inadequate analysis of corn use, where pollen is the exposure route:

> *At the colony level, tier II risk assessment is based on colonies feed imidacloprid spiked sucrose only… Had spiked pollen also been provided, the exposure of bees to imidacloprid would undoubtedly have been greater…* (p. 275)
>
> *The biggest impact for this assessment relating to the pollen route of exposure is the inability to assess risks at the colony level for crops where no nectar is produced.* (p. 276)

h) The explanation in the Executive Summary as to why and how the PPA focused only on nectar exposures, excluding pollen exposures, is obscure and unsupported (p. 16). The PPA needs proper scientific justifications and literature citations, not a set of assumptions, in order to discount the importance of pollen.

i) With respect to the 25 ppb in nectar threshold, below which its alleged effects are unlikely, the PPA is not convincing. At pp. 126-127, the PPA describes several serious limitations in the confidence to be ascribed to that threshold. Of particular concern is the fact that the analyses exclude the pollen exposure route, noting also that later, at p. 139, the PPA refers to limited study results for pollen exposure—indicating pollen may present risks at lower levels compared to studies of spiked sucrose or nectar.

j) An adequate assessment on how IMD can affect honey bees needs to be much broader, taking into account how IMD affects the entire vegetative environment the bees inhabit, and not just

---

[12]Palmer, M.J., Moffat, C., Saranzewa, N., Harvey, J., Wright, G.A., Connolly, C.N., 2013. Cholinergic pesticides cause mushroom body neuronal inactivation in honeybees. *Nature Communications*. 4:1634

focusing on the residues within the commercial crops they may visit. According to noted University of Guelph Professor of Pollinator Conservation, Nigel Raine:[13]

> *It's very important that we look very broadly at this…..Bees may actually be foraging in a landscape where these pesticides are very widely available to them so they may be exposed to these pesticides in many different plants they visit for nectar and pollen, so their exposure might be for a much longer period of time over the season…..Even if it is at a very low level, those kinds of chronic effects might be very important.*

k) IMD and other neonicotinoids 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. This fact renders the PPA's assertion that ***"off-field exposure is pertinent only for foliar uses… as a result of spray drift"*** factually incorrect (p. 63). 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 IMD seed coating application, which represent the main innovation associated with this systemic insecticide. These pathways simply cannot be ignored.

l) The most extensive use of IMD, accounting for close to one million pounds annually, is as a soybean seed coating.[14] Yet, the residue and risk data remain lacking, almost 20 years after this use was first approved. The EPA assessment notes that soybeans are "attractive to bees via pollen and nectar," meaning they could expose bees to dangerous levels of IMD, however, data on how much of the IMD appears in soybean pollen and nectar are **"unavailable"** (p. 39). This is an unacceptable information failure that rests on the pesticide manufacturers. It should not be tolerated. EPA is reminded of the Ninth Circuit Court of Appeals ruling that addressed similar problems with EPA's new registration of the insecticide Sulfoxaflor:[15]

> *The EPA's basis for unconditionally registering sulfoxaflor in the absence of sufficient data documenting the risk to bees does not hold up under its own rationale. Without sufficient data, the EPA has no real idea whether sulfoxaflor will cause unreasonable adverse effects on bees, as prohibited by FIFRA. Accordingly, the EPA's decision to register sulfoxaflor was not supported by substantial evidence.*

The Court of Appeals' vacation of Sulfoxaflor's registration provides direction to EPA here, where there is a comparable lack of "sufficient data" on whether IMD will cause unreasonable adverse effects on bees. The registrations of IMD products used as soybean seed coatings should similarly be suspended immediately.

m) The PPA contains this admission with respect to key published field studies, at p. 140 (emphasis added):

---

[13] Pesticide studies must look beyond bees and crops, expert says. 2016, Jan. 7. *CBC News.* Retrieved from: www.cbc.ca/news/canada/kitchener-waterloo/neonicotinoid-pesticide-studies-should-expand-beyond-bees-and-crops-1.3393517

[14] U.S. Geological Survey. 2016, March 2. Pesticide National Synthesis Project. Pesticide Use Maps- Imidacloprid. Retrieved from http://water.usgs.gov/nawqa/pnsp/usage/maps/show_map.php?year=2013&map=IMIDACLOPRID&hilo=L&disp=Imidacloprid

[15] *Pollinator Stewardship Council v. EPA*, __ F.3d __, 2015 WL 7003600 (9th Cir. Nov. 12, 2015).

*This summary is based on the results of a small number of studies and therefore there is uncertainty as to whether levels of imidacloprid in nectar or pollen above **or below** the concentrations described above could potentially impact the overall health of a colony following continuous exposure.*

In view of this admission and the many other limitations described above, there is very limited confidence in the colony effects thresholds of 25 ppb expressed in public statements by the agency.

n) With respect to the lessons drawn from the "Reported Pollinator Incident Information," beginning at p. 160, the analysis fails to account for the fact that beekeepers have no reason to report to the system for bee kills resulting from IMD-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. With no enforcement or consequences for farmers who misuse or overuse IMD-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 5-17.

o) The PPA also fails to consider a critical multi-year, nationwide UK study that covers IMD, Budge et al. "Evidence for pollinator cost and farming benefits of neonicotinoid seed coatings on oilseed rape."[16] The study shows a clear relationship across regions between IMD use (the most common neonicotinoid used during the period of the study) and overwintering honeybee colony losses. Further, the seed treatments on oilseed rape (canola) did not produce a consistent yield benefit. The revised risk assessment must consider the Budge et al. study.

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

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 exposed to many factors. The PPA ignores these "field realistic" scenarios. It mentions fungicides as synergistically toxic to honey bees, but fails to adequately account for the synergy, stating (p. 100):

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.

b) It is not reasonable for risks of synergistic effects to be placed "beyond the scope" of EPA's risk assessment. As admitted above, extensive scientific literature indicates that field relevant toxicity levels for IMD are far lower than those predicted in "isolated" studies that only observe IMD effects, such as the whole colony field study prepared for this PPA. When IMD exposure is combined with other typical risk factors—nosema, Varroa mites, other chemicals such as fungicides, and so on—the synergistic risks far exceed the risks predicted in isolation.

[16] Budge, G.E., Garthwaite, D., Crowe, A., Boatman, N.D., Delaplane, K.S., Brown, M.A., Thygesen, M.A., Pietravalle, S., 2015. Evidence for pollinator cost and farming benefits of neonicotinoid seed coatings on oilseed rape. *Scientific Reports* 5:12574

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.)"[17]

- Blanken et al. 2015. "Interaction between *Varroa destructor* and imidacloprid reduces flight capacity of honeybees"[18]

- Di Prisco et al. 2016. "A mutualistic symbiosis between a parasitic mite and a pathogenic virus undermines honey bee immunity and health." [19] (Paper notes that the neonicotinoids are a stressor that can synergistically harm bees in combination with the parasites/pathogens.)

- Sanchez-Bayo et al. 2015. "Are bee diseases linked to pesticides? – A brief review" [20] (The comprehensive review shows that the role of the neonicotinoids, including IMD, appears to be mediated through increases in harmful pathogens and parasites.)

- Chaimanee, V., Evans, J., Chen Y., Jackson C., Pettis, J. 2016. "Sperm viability and gene expression in honey bee queens (Apis mellifera) following exposure to the neonicotinoid insecticide imidacloprid and the organophosphate acaricide coumaphos"[21]

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

d) The report highlights a long-running blind spot within EPA's pesticide evaluation program: pesticide synergism, the risk of combining mixtures of different pesticide active ingredients, which independent science shows may be more or less toxic than a single active ingredient by itself.

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

[17] Brandt, A., Gorenflo, A., Siede, R., Meizner, M., Buchler, R., 2016. The neonicotinoids thiacloprid, imidacloprid, and clothianidin affect the immunocompetence of honey bees (*Apis mellifera* L.). *Journal of Insect Physiology* 86:40–47

[18] Blanken, L.J., van Langevelde, F., van Dooremalen, C., 2015. Interaction between Varroa destructor and imidacloprid reduces flight capacity of honeybees. *Proc. R. Soc. B* 282: 20151738

[19] Di Prisco, G., Cavaliere, V., Annoscia, D., Varricchio, P., Caprio, E., Nazzi, F.,..Pennacchio, F., 2016. A mutualistic symbiosis between a parasitic mite and a pathogenic virus undermines honey bee immunity and health. (Paper notes that the neonicotinoids are a stressor that can synergistically harm bees in combination with the parasites/pathogens). *Proc. Natl. Acad. Sci. USA.* 110:18466–18471.

[20] Sanchez-Bayo, F., Goulson, D. Pennacchio, F., Na Koichi Goka, F., Desneux, N., 2016. Are bee diseases linked to pesticides?—A brief review. *Environment International*. 89-90:7-11

[21] Chaimanee, V., Evans, J., Chen Y., Jackson C., Pettis, J. 2016. Sperm viability and gene expression in honey bee queens (Apis mellifera) following exposure to the neonicotinoid insecticide imidacloprid and the organophosphate acaricide coumaphos. *Journal of Insect Physiology*. 89:1-8.

[22] 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

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. The PPA ignores many peer-reviewed studies that show impacts to native bees and butterflies from IMD. Professor Raine also noted that honeybees are:[23]

> *….the bruisers of the bee world… To use honeybees as a surrogate for all of this is perhaps misleading and suggesting that these are safer than they might be.*

b) The 2016 GAO report also called on EPA to improve the scope of its risk assessments for evaluating pesticide risks to a range of bee species, beyond honey bees. The GAO stated, it would be prudent for EPA to develop testing models and guidelines for other types of bees, such as solitary and bumblebees. The GAO also recommended that the EPA Administrator "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." A revised PPA should obtain that data and take it into account.

c) The *Bombus* studies, summarized in the PPA, indicate concern for impacts on bumblebees at lower exposure levels than those that pose a risk to honey bees (pp. 140-153). Bee experts have noted that bumblebee effects are worrisome at IMD levels as low as 2.5 ppb, one-tenth the 25 ppb safe level the PPA claims for honey bees.[24] We note that the PPA does present extensive information characterizing the risks to non-*Apis* bees, yet does not adequately link that to field-relevant exposures by way of any conclusion. The PPA needs revision to more effectively assess and protect the non-*Apis* bees and other non-bee pollinators.

d) Further, the PPA disregards the substantial risks to bumblebees and other native bees from the use of IMD in tomato production. While harmful residue levels of imidacloprid are expected from tomato production, the PPA determined there was low risk because honey bees are not attracted to tomatoes. In contrast, bumblebees and other non-Apis pollinators are regular visitors to and essential pollinators of tomatoes, greatly yields. 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 agricultural, horticultural, ornamental, and wild plant pollinators—and take into account economic as well as environmental damage.

e) 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, such as, monarch butterflies, that the PPA failed to consider at

---

[23] Pesticide studies must look beyond bees and crops, expert says. 2016, Jan. 7. *CBC News*. Retrieved from: www.cbc.ca/news/canada/kitchener-waterloo/neonicotinoid-pesticide-studies-should-expand-beyond-bees-and-crops-1.3393517

[24] Mathiesen, K and Goldenberg, S. 2016. January 6. US government says widely used pesticide could harm honeybees. *The Guardian*. Retrieved from http://www.theguardian.com/environment/2016/jan/06/honeybee-populations-decline-pesticides-united-states-epa-study-imidacloprid; Moffat, C., Pacheco, J.G., Sharp, S., Samson, A.J., Bollan, K.A., Huang, J…Connolly, C.N., 2015. Chronic exposure to neonicotinoids increases neuronal
vulnerability to mitochondrial dysfunction in the bumblebee (Bombus terrestris). *The FASEB Journal*. 29 (5): 2112-2119

all. This is unacceptable, particularly as new research indicates that other comparable neonicotinoids threaten monarch larvae.[25]

f) Bats can be pollinators of some minor crops, but were not considered. New research indicates that bats may be harmed by IMD exposure, which presumably may occur either via direct exposure or via consumption of insects that contain IMD.[26] Researchers found that Formosan leaf bats (Hipposideras terasensis) dosed with imidacloprid through the oral route (dose delivered in mealworms) at a level of 20 ppm for five days experienced spatial memory disorders. Such exposures could occur in both agricultural and non-agricultural areas used by bats, through ingestion of contaminated insects flying over agricultural areas or foraging on foliage-dwelling insects.[27] The revised risk assessment must address this risk as well.

V. The Green Screen prepared for IMD indicates significant additional risk

a) In January 2016, IMD was reported on in a full GreenScreen prepared by ToxServices of Washington, DC, for the Natural Resources Defense Council. The report is attached to this comment and incorporated herein by this reference. EPA should fully consider it in the final PPA. The GreenScreen chemical hazard assessment method was chosen because of its widespread acceptance by governments, industry, and non-governmental organizations alike. GreenScreen integrates aspects of EPA's Design for Environment Alternatives Assessment and the Globally Harmonized System of Classification and Labelling of Chemicals. GreenScreen is routinely used by governments and industry and is increasingly being incorporated into environmental scorecards and standards.

b) While most of the report does not relate directly to pollinators, there are findings in the GreenScreen that do, especially this finding at p. 48:

> *Acute Foliar Invertebrates and Pollinators18 (AFI) Toxicity Score (H, M, or L): H*
>
> *Imidacloprid was assigned a score of High for acute foliar invertebrates and pollinators toxicity based measured oral and dermal LD50 values in bees as low as 1.1 ng/bee. GreenScreen® criteria classify chemicals as a High hazard for acute foliar invertebrates and pollinators toxicity when the oral and dermal LD50 values in bees are less than 2 µg/bee (2,000 ng/bee) as per the U.S. EPA DfE criteria. Confidence in the score is high because it is based on consistent results in several experimental studies.*

c) Unfortunately, a score on the Chronic Foliar Invertebrates and Pollinators Toxicity endpoint could not be provided due to weakness found in EPA's analytical framework (p. 49). However, this section of the GreenScreen includes numerous study summaries on the topic of chronic toxicity and should be used as a resource by EPA in its final risk assessment. It should be noted that the ToxServices conclusion was that IMD "may cause sublethal effects on bee health and behavior" (p. 53).

---

[25] Pecanka, J.R. and Lundren, J.G., 2015. Non-target effects of clothianidin on monarch butterflies. *Sci Nat* 102:19

[26] Hsiao, C., Lin, C., Lin, T., Wang, S., Wu, C., 2016. Imidacloprid toxicity impairs spatial memory of echolocation bats through neural apoptosis in hippocampal CA1 and medial entorhinal cortex areas. *NeuroReport* DOI: 10.1097/WNR.0000000000000562

[27] Stahlschmidt, P. and Brühl, C.A., 2012., Bats as bioindicators – the need of a standardized method for acoustic bat activity surveys. *Methods in Ecology and Evolution* 3(3): 503-508

VI. Immediate EPA action is warranted

a) The high residue levels of IMD and high risks that EPA identified with respect to cotton and citrus indicate the need to promptly suspend IMD products with respect to these uses.

b) In view of the: 1) high overall risks as stated in this comment; 2) the PPA's admitted gaps and substantial analytical uncertainties; 3) additionally taking into account the other weaknesses, omissions, and gaps in the PPA described in this comment; 4) in order to conserve threatened wild pollinators; and 5) 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 IMD where pollinators may be exposed. The EPA must take protective actions consistent with the agency's fundamental mission.

Attachment – Imidacloprid GreenScreen (82 pages)

For further information contact:
Larissa Walker
Pollinator Program Director | Policy Analyst
Center for Food Safety
660 Pennsylvania Ave. SE, Suite 302
Washington, DC 20003
(P): 202.547.9359 | (E): LWalker@CenterForFoodSafety.org