Kelly Ballard, Chemical Review Manager
Pesticide Re-Evaluation Division (7508P)
Office of Pesticide Programs,
Environmental Protection Agency
1200 Pennsylvania Ave. NW.,
Washington, DC 20460-0001

Re: Imidacloprid Registration Review; Draft Pollinator Ecological Risk Assessment; Notice of Availability; docket EPA-HQ-OPP-2008-0844

I am submitting these comments concerning the **Imidacloprid Registration Review; Draft Pollinator Ecological Risk Assessment.**

Incomplete Research; Supplemental research; Field relevant research

When risk assessments of honey bees and native pollinators are conducted all aspects of exposures in the real-world must be included. The risk cup of managed honey bees includes:

- direct exposure to pesticides applied topically to a bee
- direct exposure through the consumption of pesticide-laced pollen, nectar, honeydew, and water
- exposure to imidacloprid via wood products used in hive construction

EPA's review of research presented mostly by the registrant, as well as open source literature review showed much conflicting information. Research protocols were inconsistent. Controls for water quality were not considered when creating sugar syrup, nor was the source of the sugar considered as to additional imidacloprid residue levels. Controlled feeding did not replicate the real-world of bees. The majority of research did not address the "other ingredients" in the trade formula. Research was highly focused upon acute kills or harm to honey bees observing the effects upon the bees for 24-96 hours at a maximum. None of the research examined sublethal effects of imidacloprid. Some research suggested examining the sublethal effects. When one research colony did not survive the winter, the researchers stated their study was not about "winter survival." Those same researchers had obvious hive management issues being unable to control for swarms, they did not split growing hives, and placed the bees in a harmful situation with not enough honey to survive the winter. The review of much of the literature in the EPA Imidacloprid docket was a testament to poor beekeeping management on the part of the researchers, and a lack of understanding by a number of researchers of best management practices in beekeeping. Researchers were unaware of typical bee behavior of "drifting bees." Placement of research hives in close proximity to each other, especially the "control hive" close to the "treatment hive" creates a situation of having "no control hive." Bees will "drift" between hives within close proximity to each other due to weather conditions, and opportunistic robbing.

The research studies provided in this docket also showed discrepancies within research studies wherein imidacloprid "technical grade" and "formulated grade" were tested inconsistently. Many of the studies used one aspect of Imidacloprid or the other. Testing the risk to non-target organisms with only a pesticide's active ingredient is unrealistic. The real-world of managed honey bees comprises exposure to the final product sold to the end user. The final product contains, inert ingredients, metabolites, surfactants, adjuvants, and "other ingredients." Real-world application of Imidacloprid, and all pesticides, involves mixing insecticides, herbicides, fertilizers, and fungicides into a single tank for a singular combined application to the crop, field, or even construction materials. The synergism of these farraginous chemicals is not evaluated, nor regulated. The US Governmental Accounting Office published a report Feb. 10, 2016 with the specific recommendation for EPA

> *"To help comply with the directive in the White House Pollinator Health Task Force's strategy, the Administrator of EPA should direct the Office of Pesticide Programs to identify the pesticide tank mixtures that farmers and pesticide applicators most commonly use on agricultural crops to help determine whether those mixtures pose greater risks than the sum of the risks posed by the individual pesticides."* (GAO, Bee Health, USDA and EPA Should Take Additional Actions to Address Threats to Bee Populations)

This should include the mix of chemicals combined in seed coatings, and the dust off drifting onto blooming plants as well.

Imidacloprid, and similar systemic pesticides are bee toxic from direct application as well as infecting the pollen and nectar of the plant with the toxin. Any bee attractive plant or bee dependent plant is no longer "bee friendly" at any time during its lifecycle if a pesticide, its residues, and/or degradates present exceed the EPA's accepted No Observable Effect Level (NOEL) for that pesticide for managed honey bees. The NOEL conflicts directly with EPA's "acute oral toxicity: one observes no effect, the other measures death. The No Observable Effect Level is worlds apart from a "plant that had been treated" with "a detectable level of pollinator lethal insecticide." An applied pesticide will always be detectable otherwise no one would waste their money applying a nonfunctioning pest control product. The NOEL could be construed as "apply any amount as long as it does not affect pollinators." As long as there is no observable effect, or it falls within the range or tolerance set by the pesticide manufacturer. This is evident in the research presented in the docket, when studies "observed" honey bees for 24-96 hours. Some effects were observed, some bees recovered, some did not. Ninety-six hours is not reflective of the hive organism. NOEL cannot be placed upon a single bee. Risk assessment cannot be compartmentalized to one honey bee, or a sample of thirty honey bee foragers, or just nurse bees. A honey bee hive is an entire organism. If one aspect of the organism is interrupted, indentures bee castes before their time, interrupts or stops the growth of the hive due to the Queen's poor reproductive abilities, or causes loss of one caste of bees at either end of the life cycle then damage has been done to the honey bee colony. Bees are dead whether it is in one swift all inclusive moment, or a torturous dwindling to a few nurse bees and a sterile Queen. While that organism encompasses tens of thousands of "individuals," and the organism makes for difficult research, the research is not meeting the needs of the bee industry. Research of the impact of pesticides upon managed and native pollinators must review the effect upon the entire hive, at minimum a twelve month cycle, and include the financial impact upon the beekeeper.

Imidacloprid concerns presented in Open Source Literature

Open source literature review of the impact of neonicotinoid pesticides, including imidacloprid hold greater value than the registrant's research of just the "technical grade" or even the "formulated grade" of imidacloprid, as this research comprises a myriad of geographic settings, and a greater number of "real-world/field-relevant" data.

> *"Plots treated with cow manure and allowed to age before sowing showed longer persistence of Imidacloprid in soils than in plots where the manure was more recently applied, and not allowed to age." . . . "Imidacloprid penetrates the plant, and moves from the stem to the tips of the plant."*
> *. . . "Typical application rates range from 0.05-0.125 pounds per acre. These application rates are considerably lower than older traditionally used insecticides. It can be phytotoxic if it is not used according to manufacturer's specifications, and has been shown to be compatible with fungicides when used as a seed treatment to control insect pests."* (Cornell, Extoxnet)

> *"The residues become more tightly bound to the soil with time. Imidacloprid is broken down into a number of other chemicals depending on which bonds in the molecule are broken." . . . " Imidacloprid is a systemic insecticide, which means that plants take it up from the soil or through the leaves and it spreads throughout the plant's stems, leaves, fruit, and flowers. Insects that chew or suck on the treated plants end up eating the Imidacloprid as well. Once the insects eat the Imidacloprid, it damages their nervous system, and they eventually die."*
> (Imidacloprid General Fact Sheet, National Pesticide Information Center)

> *" . . . the neonicotinoid class of pesticides can be a serious problem for honey bees because they can persist in soil, rivers and streams for months or years after a single application and spread within the entire body of plants including nectar and pollen that are collected by foraging bees. . . . . The present study aims to investigate effects of Imidacloprid and V. destructor, two factors that are suggested to play key roles in honey bee population decline, individually on the survival and health of adult workers of A. mellifera. Effects of the neonicotinoid pesticide on survivorship, growth, and physiology of adult workers were measured through changes in mortality rate, body mass, and expression of vitellogenin (Vg), a female-specific yolk precursor protein that regulates the honey bees development and behavior. Our study provides clear evidence that exposure to Imidacloprid and Varroa mites exerts a significantly negative effect on overall health and survival of honey bees and has important implications for our ongoing investigation on the negative synergistic effects of the neonicotinoid pesticides and Varroa mites as well as other parasites and pathogens on honey bee behavior and physiology as well on bee colony growth and survivorship. The host responses provoked by chemical and biological stressors provide unique insights into the*

molecular mechanisms that are involved in the host-vector-pathogen interactions . . . Our study provides clear evidence that the exposure to sublethal doses of Imidacloprid could exert significantly negative effect on health and survival of honey bees. We observed a significant reduction in the titer of vitellogenin, an egg yolk precursor that regulates the honey bee's development and behavior and often are linked to energy homeostasis in bees exposed to Imidacloprid. This result indicates that sublethal exposure to neonicotinoid could lead to increased energy usage in honey bees as detoxification is an energy-consuming metabolic process and suggests that Vg could be a useful biomarker for measuring levels of energy stress and sublethal effects of pesticides on honey bees." (Abbott 2008)

"The US Environmental Protection Agency (EPA), on Thursday, released results of a review of three neonicotinoid pesticides that are used for insect control on US soybean crops. The pesticides-generically, Imidacloprid, Thiamethoxam, and Clothianidin are also believed to be responsible for Colony Collapse Disorder (CCD), in which bees abandon their hives over the winter and eventually die. The EPA concludes: these seed treatments provide negligible overall benefits to soybean production in most situations. Published data indicate that in most cases there is no difference in soybean yield when soybean seed was treated with neonicotinoids versus not receiving any insect control treatment, . . .Multiple foliar insecticides are available in instances where pest pressure necessitates a pest management tactic and such foliar insecticides have been found to be as efficacious as neonicotinoid seed treatments for target pests, . . .In comparison to the next best alternative pest control measures, neonicotinoid seed treatments likely provide $0 in benefits to growers and at most $6 per acre in benefits (i.e. a zero percent to 1.7% difference in net operating revenue). Some neonicotinoid seed treatment usage could provide an insurance benefit against sporadic and unpredictable pests, particularly in the southern United States. However, BEAD did not find information to support the real-world significance of this benefit, and overall evidence indicates that any such potential benefit is not likely to be large or widespread in the United States. . . . If neonicotinoids are associated with killing bee colonies, and if the pesticides are ineffective when applied to seeds, maybe there's an obvious conclusion to be drawn." (Wall Street Journal, 2014)

"Several behavior studies showed the link between neonicotinoid exposure and adverse effects on foraging activity and reproduction. Vitellogenin showed a strong increase upon neonicotinoid exposures in the laboratory and field, while creb and pka transcripts were down-regulated. The induction in vitellogenin suggests adverse effects on foraging activity, whereas creb and pka down-regulation may be implicated in decreased long-term memory formation. Transcriptional alterations occurred at environmental concentrations and provide an explanation for the molecular basis of observed adverse effects of neonicotinoids to bees." (Christen, et.al. 2016)

"Although no single factor has been identified as causing CCD, the United States Department of Agriculture (USDA) in their progress report on CCD stated that CCD may be "a syndrome caused by many different factors, working in combination or synergistically." Several studies have found that sublethal levels of Imidacloprid increase honey bee susceptibility to the pathogen Nosema." (USDA-ARS 2010;Alaux, et.al. 2010;Didier, et.al. 2011; Pettis, et.al. 2012)

"Dave Goulson, 2012, of the University of Stirling, showed that trivial effects of Imidacloprid in lab and greenhouse experiments can translate into large effects in the field. The research found that bees consuming the pesticide suffered an 85% loss in the number of queens their hives produced, and a doubling of the number of bees who failed to return from food foraging trips. "(Carrington 2012; Whitehorn, et.al. 2012)

"Lu, et. al. (2012) reported they were able to replicate CCD with sublethal doses of Imidacloprid. The Imidacloprid-treated hives were nearly empty, consistent with CCD, and the authors exclude Varroa or Nosema as contributing causes." (Lu, et.al. 2012)

"In May 2012, researchers at the University of San Diego released a study showing that honey bees treated with a small dose of Imidacloprid, comparable to what they would receive in nectar and formerly considered a safe amount became "picky eaters," refusing nectars of lower sweetness and preferring to feed only on sweeter nectar. It was also found that bees exposed to Imidacloprid performed the "waggle dance," the movements that bees use to inform hive mates of the location of foraging plants at a lower rate." (Harvard Gazette 2012; Chensheng 2012)

"Researchers from the Canadian Forest Service showed that Imidacloprid used on trees at realistic field concentration decreases leaf litter breakdown owning to adverse sublethal effects on non-target terrestrial invertebrates. The study did not find significant indication that the invertebrates, which normally decompose leaf litter, preferred uncontaminated leaves and concluded that the invertebrates could not detect the Imidacloprid." (Kreutzweiser, et.al 2009)

"A 2012 in situ study provided strong evidence that exposure to sublethal levels of Imidacloprid in high fructose corn syrup (HFCS) used to feed honey bees when forage is not available causes bees to exhibit symptoms consistent to CCD 23 weeks post Imidacloprid dosing. The researchers suggested that "the observed delayed mortality in honey bees caused by Imidacloprid in HFCS is a novel and plausible mechanism for CCD, and should be validated in future studies." (Harvard Gazette 2012; Chensheng 2012)

"Sublethal doses (<10ppb) to aphids have been found to lead to altered behavior, such as wandering and eventual starvation. Very low concentrations also reduced nymph viability." (Wollweber, et.al. 1999)

"In January 2013, the European Food Safety Authority stated that neonicotinoids pose an unacceptably high risk to bees, and that the industry-sponsored science upon which regulatory agencies' clams of safety have relied might be flawed, concluding that, "a high acute risk to honey bees was identified from exposure via pollen." (European Food Safety Authority, 2013; Carrington, 2013)

Research Concerns

Issues have arisen in the past few years of USDA funded researchers being stifled in their work due to the economic value of pesticide sales versus the economic value of managed and native pollinators. The losses of bees due to pesticide exposure has exceeded beekeeping management thresholds, forcing beekeepers to adapt or go out of business. Splits are made from smaller colonies due to being damaged in one crop, but bees are still needed to meet a contract in the next crop. Less honey bees for pollination; crop yields will be reduced. When a pesticide is registered or in this case re-reviewed, the main factor ignored is the financial benefit or loss to beekeepers from a pesticide developed for a crop pest. If a crop does not get pollinated, what does it matter if there is a pest? No pollination, no crop. When a pesticide is reviewed for its "crop protection benefits," honey bees must also be examined for their "benefits to the crop."

Research of pesticides is not meeting the needs of farmers either. Farmers are provided with incomplete label language that does not protect pollinators, nor promote the safety of pollinators who are directly correlated to crop yields. Integral to agriculture are pollinators, managed and native. Integral to a balanced ecosystem are healthy, diverse pollinators. Research from around the world has shown varying detrimental effects of imidacloprid, and its fellow neonicotinoids, to cause lethal and sublethal effects upon pollinators. Whether a bee forgets where the forage is, where the hive is, or is strong enough to carry the bee toxic pesticide back to the hive to be stored in the comb, for the toxin to leach across the wax into other pollen to mix with other sublethal levels of insecticides, herbicides, fungicides, surfactants, adjuvants, and "other ingredients" of pesticides, to feed this "in the hive" tank mix to other "family members" in the hive, and then attempt to fight off pests and pathogens with a weakened immune system that colony is in its death throes, and will not survive another month. Regulators, and even researchers, can continue to postulate the LD50, the NOEL, the parts per billion in this plant, the parts per million in that pollen, acute kill versus sublethal: the bees are still dead. Dead is dead, and it made no difference to the bee whether it ingested imidacloprid based on its individual body weight, or simply carried it back to the hive and passed it off to a house bee: those bees are still dead.

Recommendations

The report of the Worldwide Integrated Assessment of the Impacts of Systemic Pesticides On Biodiversity and Ecosystems *summarizes the* scientific assessment of pesticides like Imidacloprid, stating "*the current large-scale prophylactic use of systemic insecticides is having significant unintended negative ecological consequences. The evidence indicates that levels of systemic pesticides that have been documented in the environment are sufficient to cause adverse impacts on a wide range of non-target organisms in terrestrial, aquatic, wetland, marine and benthic habitats. There is also a growing body of evidence that these effects pose risks to ecosystem functioning, resilience and services such as for example pollination and nutrient cycling."*

I respectfully request the following in support of the bee industry, honey bees, and native pollinators in relation to the Imidacloprid re-registration review:

1. Imidacloprid should be registered as a "Restricted Use pesticide," with use granted only during times of documented need, similar to the Ontario plan, until a complete risk assessment is conducted. This risk assessment must comprise acute, chronic, and sublethal effects and longitudinal reproduction studies to the second and third generation of bees at field relevant doses and field relevant exposure times.

2. The Tier II Colony Level Assessment is Insufficient
   Field realistic, colony level assessments must be completed when assessing pesticides, including water quality, fungicides, herbicides, insect growth regulators, adjuvants, surfactants, degradates, metabolites, and "other ingredients" in the "formulated grade."

3. Field studies should be conducted on all plants foraged by bees including a pollen analysis, including soybeans, cotton, and canola.

4. Conduct research on bee attractive crops for the value of pollination, the value of crop pollination services, and the loss of crop yield when bees are killed.

5. Institute incident reporting of bee losses to include the sublethal effects upon bees; ensure the investigation is not retaliatory, but data collection driven; remove primacy of states that decline investigating bee kills that are under an arbitrary financial threshold. Trends of product use, as well as problem end users can be observed from the loss of one hive as well as the loss of 100 hives.

6. EPA needs to complete a cumulative assessment of the multiple stress factors that managed and native pollinators currently experience including tank mixes, fungicides, insect growth regulators, "other ingredients" in pesticide formulas, and their interactions with bee pests and pathogens.

7. Evaluate the efficacy of acaricides used for Varroa control, and the synergisms with crop protection pesticides.

8. Evaluate Imidacloprid use across the landscape prior to creating pollinator habitat, especially for Monarchs. Research has shown the half-life of imidacloprid remains toxic for up to three years depending upon the soil. Agricultural buffer/pollinator strips, and similar pollinator habitat needs to be protected from imidacloprid soil and water residues, as well as dust off onto plants in bloom or water sources from coated seed planting.

9. Native pollinators must be included in colony level assessments. While there are unique concerns in assessing native pollinators they are a valuable contributor to the agricultural economy.

10. Institute comprehensive authentic Integrated Pest Management best practices to protect farmers, crop yields, and beekeepers from the impact of the prophylactic use of pesticides and coated seeds.

Resources

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