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October 24, 2024

Office of Pesticide Programs
Environmental Protection Agency, (28221T)
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Pesticide Registration Review: Draft Human Health and/or Ecological Risk Assessments for Several Pesticides [EPA-HQ-OPP-2011-0865-1411, EPA-HQ-OPP-2008-0844-1881, EPA-HQ-OPP-2011-0581-0721]

Dear Madam/Sir,

These comments are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers, and farmworkers. Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

Neonicotinoids and Human Health

With a focus on neonicotinoid insecticides clothianidin, imidacloprid, thiamethoxam, and others, EPA must consider a multitude of peer-reviewed scientific studies that highlight the chemicals' link to neurological impairments. Beyond Pesticides shared in previous comments in 2017 a study by Kimura-Kuroda et al. (2016), which finds that "chronic neonicotinoid exposure alters the transcriptome of the developing mammalian brain in a similar way to nicotine exposure."[1,2] In this context and EPA's assessments, the agency must recognize the common mechanism of toxicity among the neonicotinoids. Neonicotinoids, intended for targeting insects with this mechanism, have been found to affect mammalian nicotinic acetylcholine receptors (nAChRs). These receptors are of critical importance to human brain function, especially during development and for memory, cognition, and behavior.[3]

A review of the scientific evidence by Cimino et al. (2017) finds that there are reported associations between chronic neonicotinoid exposures and adverse developmental outcomes, including neurological effects.[4] Additional studies report that neonicotinoid pesticides impair mammalian reproduction and have developmental effects in mammals including reduced

sperm production and function; reduced pregnancy rates; higher rates of embryo death, stillbirth, and premature birth; and reduced weight of offspring.[5,6,7,8]

In addition, "the first comprehensive assessment of unpublished rodent developmental neurotoxicity (DNT) studies on five neonicotinoids that were submitted to the U.S. Environmental Protection Agency (EPA) by neonicotinoid manufacturers" highlights evidence of developmental neurotoxicity.[9] The study finds that exposure to five neonicotinoids, including clothianidin, imidacloprid, and thiamethoxam, causes statistically significant shrinkage of brain tissue. The authors report that even with this data, "EPA dismissed statistically significant adverse effects, accepted substandard DNT studies despite lack of valid positive control data, and allowed neonicotinoid registrants to unduly influence agency decision-making."

Under FIFRA, a pesticide is presumed to pose an unreasonable risk until reliable data demonstrate otherwise. Moreover, if the agency lacks the data and/or resources to fully evaluate endocrine risks to human health and wildlife, then the agency is obliged to suspend or deny any pesticide registration until it has sufficient data to demonstrate that the pesticide's registration is in compliance with the statutory standard—no "unreasonable adverse risk" of endocrine disruption. EPA does not consider neonicotinoids as endocrine disruptors, despite the wide body of science that finds neonicotinoid pesticides suppress natural hormone function, interfere with thyroid functions, disrupt hormone synthesis and metabolism, and adversely affect reproduction and the nervous system.[10,11,12,13]

Further health implications for the three aforementioned neonicotinoids include:

- Clothianidin is classified as being neurotoxic, as well as being labeled as toxic to birds, fish/aquatic organisms, and bees. [14,15]
- Imidacloprid has suspected links to cancer, endocrine disruption, reproductive effects, neurotoxicity, kidney/liver damage, and birth/developmental effects, as well as documented toxicity to birds, fish/aquatic organisms, and bees.[16,17]
- Thiamethoxam is shown to cause reproductive effects and kidney/liver damage in addition to being toxic to bees.[18,19]

Neonicotinoid residues are detected in food and water, as well as in breast milk and baby food—jeopardizing the health of growing infants and children.[20,21,22] The *Food Quality Protection Act* (FQPA), with its provisions that amend FIFRA, is meant to regulate pesticide residues in food, but EPA has not applied the FQPA's child-protective provisions to neonicotinoids, even with the scientific data showing developmental harm. It is paramount that the public's health is safeguarded from unnecessary exposure to these harmful chemicals. The

risks to the public are too high, and we urge EPA to move forward with the cancellation of neonicotinoid uses starting with these three pesticides.

Ecological and Environmental Effects

Beyond Pesticides' comments in 2018 shared a section of the report by the Task Force on Systemic Pesticides (Worldwide Integrated Assessment) that states that the use of neonicotinoids "does not guarantee an increase of yield of the crops they are protecting, particularly in pollinated crops," and the use of neonicotinoids is "limited by the rapid development of resistance in target pests."[23] Other research shows that neonics can lead to a decrease in crop yields by killing insects such as pollinators and natural predators of pests.[24] The questionable effectiveness of neonicotinoids, while they also present a threat to nontarget organisms, highlights the need for safer practices that protect all organisms and the environment.

EPA's own non-pollinator assessments confirm that harm to nontarget organisms and systems from neonicotinoid exposures is ubiquitous. The agency identifies risks to aquatic insects, birds, and small mammals, coupled with significant harm to honeybees and other native bees. The risks from continued use of neonicotinoids far outweigh their perceived benefits. Reports of declines in bird populations,[25] studies of the pervasiveness of these chemicals in the Great Lakes,[26,27] and the loss of natural pollination services for all pollinator reliant crops underscore the imminent danger faced by the natural world.[28]

"Poisoned Waterways," a report from Beyond Pesticides, documents the persistence of neonicotinoids in United States (U.S.) waterbodies and the danger they cause to aquatic organisms, resulting in complex cascading impacts on the aquatic food web.[29] The report also highlights current regulatory failures of EPA aquatic standards, which continue to underestimate risks to sensitive species, due to a reliance on test protocols that do not reflect real-world exposures or susceptibilities. Additional studies show the effects of neonicotinoids in amphibians, algae, and farmland birds that threaten biodiversity.[30,31,32] Continued use of neonicotinoids presents more risk than benefit. There is no place for neonicotinoids in the environment and, based on the risks identified by the agency's own assessment, we urge the revocation of registrations of this class of chemicals.

Occupational Hazards

In EPA's announcement of the updated occupational exposure assessments for seed treatments regarding clothianidin, imidacloprid, and thiamethoxam, it notes that, "If humans are exposed to very high amounts of neonicotinoids, they could also experience harmful effects such as neurotoxicity (e.g., tremors and decreased motor activity), reproductive, or

developmental effects. These pesticides are used on a wide variety of crops, turf, ornamentals, pets (i.e., flea treatments), and other residential and commercial indoor and outdoor uses. There are also over 100 different seed treatment products that contain clothianidin, imidacloprid, or thiamethoxam."[33] This information highlights how widespread neonicotinoids are in the environment and how they negatively impact humans who are exposed.

Most at risk for exposure are the workers who treat and process seeds with neonicotinoids. In the updated assessments, EPA uses new data that shows "higher worker exposure and risk estimates for various seed treatment tasks than were previously estimated and presented in the 2020 PIDs [proposed interim decisions]."[33] Within the updated occupational risk assessments, "EPA has identified several activities associated with seed treatment that can pose risks from dermal or inhalation exposures to workers for these three neonicotinoids. The majority of these risks result from commercial seed treatment, particularly the cleaning of seed treatment equipment, even when the use of maximum personal protective equipment [PPE] is considered."[33] EPA finds that PPE, which can include double-layered clothing and respirators, is not adequately protective and thus cannot be considered a prevention strategy. With the failure of PPE to protect workers, the lack of effective mitigation, and the availability of alternative practices and products, seed treatments should be eliminated to ensure no additional unreasonable harm occurs.

Within the "Clothianidin's, Imidacloprid's, and Thiamethoxam's Updated Occupational Exposure Assessments for Seed Treatment Uses - Guide to Commenters" document, EPA calls attention to risks of concern for exposure to these three pesticides, especially for those who clean the seed treatment equipment.[34] Hazards are also identified for individuals who treat, load, plant, package treated seeds. Adding to scientific findings on neonicotinoid hazards and the frequency of residues in waterways, higher occupational risks than previously estimated jeopardize the health of workers and their families contributing to unreasonable/unacceptable harm. EPA has a duty to prevent any further harm by prohibiting the use of neonicotinoids, including, but not limited to, clothianidin, imidacloprid, and thiamethoxam.

While the latest exposure assessments incorporate more data than previously used, there remain many gaps in data that EPA must consider. The Office of Pesticide Programs does not adequately incorporate into its protocol the independent scientific literature that informs a more robust analytical review of potential adverse health and environmental effects. The integrity of its work products, including the registration of pesticides and registration review, requires the agency to closely track and incorporate into its evaluation emerging science in the independent peer-reviewed literature.

Summary

Although pesticides are by definition harmful, what makes these adverse effects "unreasonable" is the existence of an alternative—an organic production system—that does not harm human health, other species, or ecosystems and, in addition, helps to mitigate climate change. In all its decisions, EPA must use organic production as a yardstick, denying any toxic chemical for which organic production is successful. EPA is required to consider these alternative management practices and materials that are available, such as those used in organic agriculture, to conduct an accurate assessment, compliant with the unreasonable adverse effects standard of FIFRA,[35] of the hazards associated with continued and expanded pesticide use. A failure to evaluate alternative practices and products to the proposed or existing pesticide registration results in a decision that lacks scientific integrity.

We urge the agency to revoke the registration of these compounds due to findings of high risk, including to workers, and the demonstrated adverse impacts on health and the environment. We implore the agency to adhere to FIFRA's statutory mandate and immediately remove all uses of clothianidin, imidacloprid, and thiamethoxam that pose unreasonable and adverse effects such as neurotoxicity and endocrine disruption.

Thank you for your consideration of our comments.

Respectfully,

Sara Grantham
Science, Regulatory, and Advocacy Manager

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