



BEYOND PESTICIDES

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

Re: EPA Draft Biological Evaluations for Imidacloprid, Clothianidin, and Thiamethoxam [EPA-HQ-OPP-2021-0575]

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 reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

In the proposed Interim Registration Review Decisions for the neonicotinoid insecticides imidacloprid, clothianidin, and thiamethoxam issued in 2020, the agency made no final endangered species finding nor human health or environmental safety findings associated with the Endocrine Disruptor Screening Program. The agency's final registration review decision for these neonicotinoid insecticides will be dependent upon a complete nationwide Endangered Species Act (ESA) §7(a)(2) effects determination for these pesticides and, as appropriate, initiation of any ESA §7(a)(2) consultations with the Services (Fish and Wildlife Service and National Marine Fisheries Service) if EPA determines a listed species is likely to be adversely affected. In addition to the agency's ESA assessment and any needed consultation with the Services, a final EDSP FFDCA § 408(p) determination will also be needed. The agency has now issued draft Biological Evaluations for imidacloprid, clothianidin, and thiamethoxam for public comments.

The agency acknowledged in the draft Interim Registration Review Decisions the many serious health and ecological risks of concern associated with the uses of these neonicotinoids, but asserted the remaining serious risks after adoption of all proposed mitigation measures are outweighed by the benefits of their use. We ardently disagree with this assertion as the benefits are overstated and improperly considered. The agency's benefits assessments do not adequately consider loss of wildlife and ecosystem services from impaired habitats and did not include risks to endangered and threatened species in those decisions. The documented environmental impacts and health risks from surface and groundwater contamination are also not adequately diminished by the proposed mitigation measures. Therefore, the further risk of adverse effects manifestly outweighs the limited benefits and these interim decisions need to be revised accordingly.

The Draft Endangered Species Act (ESA) Biological Evaluations for imidacloprid, clothianidin, and thiamethoxam released for comments comprehensively assess potential risks that all registered uses for the respective chemical may pose to an individual of a listed species or designated critical habitat. The term "listed species" includes those that are federally listed as endangered and threatened, as well as those that are proposed and candidates for listing. The Biological Evaluations encompass the review of all registered uses and any agreed-upon changes from the technical registrants, and the approved product labels and mitigation measures for all pesticide products containing the specified chemical. However, the evaluations do not consider potential risks of combined or additive exposures for a given neonicotinoid insecticide with other neonicotinoid insecticides or pesticide products in formulations, nearby or overlapping treatments, or possible tank mixes. Such combined exposures with possible additive or synergistic toxicities could substantially elevate the likelihood of adverse effects to a given listed species and/or critical habitat.^{1,2,3,4} Although the draft Biological Evaluations do identify the majority of listed species and their critical habitat as likely to be adversely affected, the potential risks are even greater from combined exposures and the number of listed species and habitats identified as negatively affected would be even greater.

The methods employed in the Biological Evaluations follow the Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides (referred to as

¹ Thompson, H., Fryday, S., Harkin, S., Milner, S., 2014. Potential impacts of synergism in honeybees (*Apis mellifera*) of exposure to neonicotinoids and sprayed fungicides in crops. *Apidologie*, Springer Verlag, 45 (5), pp.545-553.

² Blacquiere, T., Smagghe, G., van Gestel, C.A.M., Mommaerts, V., 2012 Neonicotinoids in bees: a review on concentrations, side-effects and risk assessment. *Ecotoxicology* 21, 973–992.

³ Larson, J.L., Redmond, C.T. and Potter, D.A., 2014. Impacts of a neonicotinoid, neonicotinoid–pyrethroid premix, and anthranilic diamide insecticide on four species of turf-inhabiting beneficial insects. *Ecotoxicology*, 23(2), pp.252-259.

⁴ Bingham, G., Gunning, R.V., Delogu, G., Borzatta, V., Field, L.M. and Moores, G.D., 2008. Temporal synergism can enhance carbamate and neonicotinoid insecticidal activity against resistant crop pests. *Pest Management Science: formerly Pesticide Science*, 64(1), pp.81-85.

the “Revised Method”)⁵. As described in the Revised Method, a Biological Evaluation is a two-step process that includes an evaluation of whether an individual of a listed species is reasonably expected to be exposed to a pesticide at a level that results in a discernible effect, and, if so, distinguishes effects that are Likely to Adversely Affect (LAA) an individual of a species from those that are Not Likely to Adversely Affect (NLAA) an individual. This process is also applied to the designated critical habitat of listed species (when available). In Step 1, for every listed species and designated critical habitat, the EPA determines whether the subject pesticide will have No Effect (NE) or May Affect (MA). In Step 2, the agency will determine for those species and critical habitats deemed with MA determinations if the insecticide label use will NLAA or LAA each of these species and/or critical habitat.

Details on the method, models and tools used for making NE, MA, NLAA, and LAA determinations are provided in the Revised Method document. The tools and models are used to estimate exposures and risks to listed species and the taxa they depend upon for prey, pollination, habitat and dispersal. The tools and methods described are also used to characterize effects using available toxicity data.⁶

The principal integrative tool used in the Revised Method is the Magnitude of Effect Tool v.2.2 (MAGtool). This tool was created to assist in the determination of the magnitude of the effect of potential pesticide use on listed species. The output of the tool provides an estimate of the numbers of individuals of a given listed species that are potentially affected due to mortality losses or adverse sublethal effects. Additionally, the number of individuals of the listed species possibly harmed due to losses in their prey, pollination, habitat, or dispersal (PPHD) vectors is predicted. The MAGtool combines toxicological information, species traits, exposure analysis, and spatial results into one tool. Results may be generated for the species or critical habitat under different scenarios including variations in assumptions related to exposure, extent of pesticide usage on a crop, and extent of pesticide usage for the species.

The Biological Evaluation for each of the three neonicotinoids makes effects determinations (NE, MA, NLAA, or LAA) for 1821 listed species, and 791 designated critical habitats. However, the Biological Evaluations make no agency conclusion or recommendation for which effect determinations will trigger a request for initiation of formal ESA §7(a)(2) consultations with the Services to determine a possible jeopardy finding for the listed species and requisite mandatory use restrictions of the relevant pesticide. We recommend that the complete Biological Evaluations with all determinations and species considered be included with the formal consultation request and not just the LAA determinations. This will allow the Services to also corroborate the agency findings of NLAA and LAA as part of the consultation.

⁵ <https://www3.epa.gov/pesticides/nas/revised/revised-method-march2020.pdf>.

⁶ <https://www.epa.gov/endangered-species/models-and-tools-national-level-listed-species-biological-evaluations>.

For imidacloprid, the agency's draft Biological Evaluation made a May Affect determination for 89% of the 1821 species considered and 90% of the 791 critical habitats considered. Strikingly, a May Affect determination was made for 100% of amphibian and avian listed species and their critical habitat. It was also determined that imidacloprid is Likely to Adversely Affect 100% of the listed amphibian species exposed. A No Effect determination was made for only 11% of listed species considered because these species have a limited geographic distribution and would likely not be exposed to imidacloprid under the existing label use and mitigation instructions. Essentially, one could deduce that any species listed and exposed to imidacloprid is potentially adversely affected.

For clothianidin, a similar May Affect determination was made for 86% of listed species considered and 83% of the critical habitats considered. Likely to Adversely Affect findings overall were made for 67% of listed species and 56% of critical habitats considered. As imidacloprid, 100% of listed amphibian species are likely to be adversely affected by clothianidin uses.

Thiamethoxam degrades to clothianidin and therefore shares similar fate and behavior in the environment. May Affect determinations were made for 88% of species and 89% of critical habitats considered. Likely to Adversely Affect findings overall were made for 77% of listed species and 81% of critical habitats considered. As reported for the other neonicotinoids, 100% of amphibian species and critical habitat are likely to be adversely affected.

These serious risk findings for endangered and threatened species made for imidacloprid, clothianidin, and thiamethoxam are in light of the existing product labels and mitigation efforts. As per ESA §7(a)(2): "Each Federal agency shall, in consultation with and with the assistance of the Secretary, insure that any action authorized, funded, or carried out by such agency...is not likely to jeopardize the continued existence of **any** endangered species or threatened species or result in the destruction or adverse modification of habitat of such species...".

Although existing data used in the Biological Evaluations are adequate to demonstrate unacceptable environmental risks to most listed species from exposure to the neonicotinoid insecticides, additional data on fish reproduction and bird multigeneration toxicity are lacking and would be beneficial in understanding the full extent of associated deleterious effects attributable to these chemicals. Also as previously mentioned, mixtures of multiple active ingredients in formulated products, tank mixes, or combined treatments have not been fully assessed. An assessment of major co-exposures of environmental mixtures should be included in all Biological Evaluations and ESA §7(a)(2) consultations.

It is recommended that the agency also include the American bumble bee (*Bombus pensylvanicus*) in its revised Biological Evaluations for the neonicotinoid insecticides. Although

this insect is not a currently listed species, the Fish and Wildlife Service has recently (09/29/2021) determined a petition including substantial scientific and commercial information indicating that listing the American bumble bee as an endangered or threatened species may be warranted.⁷ Bumble bee species are highly susceptible to neonicotinoid exposures^{8,9,10} and are likely jeopardized by continued use of these insecticides.

The agency's final registration review decision for imidacloprid, clothianidin, and thiamethoxam is dependent upon the final ESA assessment and needed consultation with the Services based on the numerous Likely to Adversely Affect findings for all three chemicals. Additionally, an EDSP FFDCA § 408(p) determination is required. Imidacloprid was included in the EDSP List 1 and registrants submitted all Tier 1 EDSP data called-in. The agency completed a review of all Tier 1 data for imidacloprid (June 29, 2015) and concluded: "Overall, there was no convincing evidence to indicate a potential to interact with the thyroid hormone pathway. Based on weight of evidence considerations, mammalian or wildlife EDSP Tier 2 testing is not recommended for imidacloprid since there was no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways."¹¹ However, these conclusions should be revisited as emerging data and other scientifically relevant information have reported evidence of endocrine disrupting activity for imidacloprid.^{12,13,14} The other neonicotinoids have not completed EDSP Tier 1 testing and the agency states it will not complete its registration review of these chemicals until the agency completes its EDSP FFDCA § 408(p) determination. It is important for the agency to include all recent and other scientifically relevant information along with the full EDSP Tier 1 testing in its final determinations.

Must we wait until species are listed as threatened or endangered to protect them? Given the systemic character of neonicotinoids and their extreme toxicity to insects, EPA must assume that they will ultimately lead to the demise of insects that consume nectar, pollen, plant exudates, or plant tissues. The burden of proof is on the registrant(s) to demonstrate that

⁷ <https://www.federalregister.gov/documents/2021/09/29/2021-20963/endangered-and-threatened-wildlife-and-plants-90-day-findings-for-five-species>

⁸ Whitehorn, P.R., O'Connor, S., Wackers, F.L. and Goulson, D., 2012. Neonicotinoid pesticide reduces bumble bee colony growth and queen production. *Science*, 336(6079), pp.351-352.

⁹ Cutler, G.C. and Scott-Dupree, C.D., 2014. A field study examining the effects of exposure to neonicotinoid seed-treated corn on commercial bumble bee colonies. *Ecotoxicology*, 23(9), pp.1755-1763.

¹⁰ Feltham, H., Park, K. and Goulson, D., 2014. Field realistic doses of pesticide imidacloprid reduce bumblebee pollen foraging efficiency. *Ecotoxicology*, 23(3), pp.317-323.

¹¹ EPA-HQ-OPP-2008-0844-0137

¹² Yuan, X., Shen, J., Zhang, X., Tu, W., Fu, Z. and Jin, Y., 2020. Imidacloprid disrupts the endocrine system by interacting with androgen receptor in male mice. *Science of The Total Environment*, 708, p.135163.

¹³ Mikolić, A. and Karačonji, I.B., 2018. Imidacloprid as reproductive toxicant and endocrine disruptor: investigations in laboratory animals. *Archives of Industrial Hygiene and Toxicology*, 69(2), pp.103-108.

¹⁴ Pandey, S.P. and Mohanty, B., 2015. The neonicotinoid pesticide imidacloprid and the dithiocarbamate fungicide mancozeb disrupt the pituitary–thyroid axis of a wildlife bird. *Chemosphere*, 122, pp.227-234.

these products will not further exacerbate the ongoing insect apocalypse—and lead to further biodiversity loss through decimation of this essential link in food webs.

Furthermore, EPA must use organic production as the standard against which pesticide “benefits” are weighed. Any crop that can be produced with chemical-intensive methods can be produced organically.¹⁵ Organic producers use very few synthetic pesticides and no neonicotinoids. Therefore, the potential jeopardy of extinction to the 1445+ species identified by these biological evaluations must be considered unreasonable under the definition in FIFRA.

EPA has determined unequivocally that neonicotinoids pose risks to the environment that cannot be acceptably mitigated in any long-term, sustainable way. The agency in its proposed interim decisions for these chemicals identifies several uses for imidacloprid and clothianidin that are necessary to be cancelled. However, other uses for these neonicotinoids and for thiamethoxam (which degrades rapidly to clothianidin), the agency determined the benefits outweigh these serious risks and is only proposing limited or no mitigation measures. The agency’s benefits assessment did not adequately consider the many negative externalities such as loss of pollinators and ecosystem services from impaired habitats, increased insect resistance and crop loss, loss of beneficials and compromised biocontrol, and diminished benefits because of ample availability of alternatives. Given the frequency of detection in U.S. waterways, soil, and plants, the recognized acute and chronic risks posed to pollinators, aquatic invertebrates, vertebrate wildlife, and human health we find the risk/benefit determination as pitifully insufficient especially in light of the Biological Evaluations identifying the majority of listed species as potentially jeopardized by these neonicotinoid insecticides. Therefore, we urge EPA to quickly suspend all remaining neonicotinoid uses as it pursues the ESA §7(a)(2) consultations with the Services. Additional data to address existing uncertainties and gaps will not alter or lessen the environmental and health risks already unmistakably recognized.

Neonicotinoids are highly mobile and persistent in the environment and have been linked to numerous adverse health and environmental effects that have for decades motivated numerous public interest campaigns to ban their use in the U.S. as well as in Europe. The Draft ESA Biological Evaluations for each neonicotinoid insecticide (imidacloprid, clothianidin, and thiamethoxam) identify the majority of listed species and their critical habitat determined to be in jeopardy pending the necessary confirmation in ESA §7(a)(2) consultations with the Services to confirm. We urge the agency to move swiftly to complete its final registration review decision and revoke the registration of these compounds due to findings of high risk and demonstrated adverse impacts as reported in the draft Interim Registration Review Decisions. We reiterate our appeal that the agency adheres to FIFRA’s statutory mandate and immediately

¹⁵ See USDA’s Organic Integrity Database. <https://organic.ams.usda.gov/integrity/>.

suspend the registration of these pesticides that pose unreasonable and adverse health and environmental effects.

Respectfully,



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