PPC

PESTICIDE POLICY COALITION

A Coalition Working for Sound Pest Management Policies

July 24, 2017

U.S. Environmental Protection Agency
Office of Pesticide Programs
1200 Pennsylvania Ave. NW.
Washington, D.C. 20460-0001

Submitted via Federal eRulemaking Portal

Re: EPA's Registration Review Update for Four Neonicotinoid Insecticides; Docket ID Nos. EPA HQ-OPP-2017-0011; EPA-HQ-OPP-2008-0844; EPA-HQ-OPP-2011-0865; EPA-HQ-OPP-2011-0581 and EPA-HQ-OPP-2011-0920

The Pesticide Policy Coalition (PPC or "the Coalition") is pleased to submit comments to the U.S. Environmental Protection Agency (EPA) on its Registration Review Update for Four Neonicotinoid Insecticides. The Coalition's comments includes feedback on EPA's approach to risk assessment of this class of insecticides in general, as well as recommended refinements specific to the aquatic ecological assessment for imidacloprid (Doc. ID No. EPA-HQ-OPP-2008-0844-1086), and the combined preliminary pollinator risk assessment for clothianidin and thiamethoxam (Doc. ID No. EPA-HQ-OPP-2011-0865-0173).

PPC is an organization of food, agriculture, forestry, pest management and related industries that support transparent, fair and science-based regulation of pest management products. PPC members include: nationwide and regional farm, commodity, specialty crop, and silviculture organizations; cooperatives; food processors and marketers; pesticide manufacturers, formulators and distributors; pest-and vector-control operators; research organizations; and other interested stakeholders. PPC serves as a forum for the review, discussion, development and advocacy around pest management regulation and policy.

PPC's members are committed to protecting pollinator health while maintaining the safe and sustainable use of pesticides, including neonicotinoids. Neonicotinoid

pesticides are vital agricultural tools that protect a wide variety of crops, including corn, sorghum, cotton, rice, and the majority of fruits and vegetables grown in the U.S. and worldwide. Neonicotinoids can be used in both foliar and soil applications, and as seed treatments, with treated seeds representing greater than 90 percent of neonicotinoid use. The continued availability of neonicotinoids is critically important to producing food and fiber used by all Americans.

COMMENTS

The Coalition supports the long-established, rigorous, and science-based pesticide registration review process established under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Unlike other federal environmental statutes, FIFRA requires EPA to engage in a risk-benefit analysis in its regulation of pesticides. A thorough and holistic approach that relies on sound science and robust data ensures that risk conclusions are as closely tied to real-world conditions as practicably possible. The comments set forth below highlight the Coalition's recommended refinements and next steps for the neonicotinoid risk assessment process to ensure final risk characterizations are based on the best available science.

I. EPA Should Complete its Tiered Risk Assessment Process

The Coalition is pleased to see that EPA continued implementation of its two-tiered risk assessment framework in its review of neonicotinoid pesticides. This quantitative approach provides greater confidence that EPA's regulatory decisions are informed by actual exposures and real world scenarios provide by higher tier studies rather than lower tier laboratory toxicity data which produce overly conservative estimates. The PPC cautions that higher tier assessments are not necessary in all cases, and the need for further studies should be addressed on a case-by-case basis to avoid unnecessary and overly expansive data requirements.

At present, EPA's preliminary aquatic risk assessment for imidacloprid relies only on lower tier laboratory studies and does not account for relevant, field-based studies. EPA has acknowledged the availability of higher tier data, but has not committed to complete its review of the data and make any corresponding refinements to the current assessment. The PPC is aware that registrants have provided EPA with an abundance of higher tier studies, including wildlife field studies and water residue monitoring analyses. The PPC encourages EPA to follow through with its improved risk assessment framework and dedicate the resources necessary to review these higher tier studies to ensure that its final assessment is based on the best available science.

II. Recommended Process Refinements

The Coalition recommends EPA consider additional refinements to its risk assessment methodology and underlying assumptions, including the following areas:

A. Exposure Estimates

In evaluating neonicotinoid concentrations in pollen and nectar following seed treatments, soil applied, and foliar applications, EPA often relies on worst-case scenario inputs, which can result in overly conservative exposure estimates that are not reflective of real-world exposure. For example, the incorporation of maximum pesticide use rates, applied the maximum number of times, using maximum residue levels that are outliers in the data not representative of typical findings in the field. While the PPC understands the need to exercise caution, conservatism should still be subject to reasonable boundaries. The Coalition encourages the Agency to reexamine exposure estimates which are guided by extreme, worst-case exposure scenarios.

B. Bee bread methodology

EPA has incorporated a newly developed methodology to assess exposure from pollen in bee bread, a mixture of pollen and nectar or honey. EPA is considering bee bread data as an additional line of evidence in developing risk conclusions for clothianidin and thiamethoxam. EPA also anticipates implementing the same bee bread methodology in its final imidacloprid pollinator risk assessment. The Coalition is concerned with the incorporation of bee bread data as it assumes that the response of colonies in colony feeding studies is due to bee bread exposure alone. This assumption is flawed given that the majority of the dose ingested by bees in the colony study resulted from the ingestion of nectar/honey and not bee bread. The PPC recommends that EPA revise its assessment to determine expected concentrations in nectar and pollen, which are more appropriate indicator of total diet concentrations.

C. Off-field Risk Assessment Methodology

The Coalition has a few key issues with EPA's off-field risk assessment methodology. As a general matter, EPA's method was not part of its FIFRA Scientific Advisory Panel (SAP) 2012 white paper, and was not included in the 2014 "Guidance for Assessing Pesticide Risks to Bees." EPA should ensure that this method is verified through an independent, scientific vetting process before

implementing it in its final risk assessment. The PPC's specific concerns with the current approach include: 1) use of the AgDRIFT model; and 2) use of oral exposure risk components.

As EPA even acknowledges, AgDRIFT model assumptions, including no tree canopy interception, and unilateral and constant wind towards the off-field site, could result in overestimation of exposure attributed to drift from foliar and land applications. Going forward, EPA should consider refinements to the model, to adjust for droplet size, boom-height, wind speed, and other mitigating factors supported by product label language. EPA could also use other data from submitted studies, including semi-field tunnel studies, to further refine estimates derived from the AgDrift model.

The Coalition also finds that acute and chronic oral risk components are not relevant to the risk assessment. Only a very small fraction of drift particles will land on flowers, pollen, and nectar. The potential area of forage that would receive drift deposition represents a small proportion of the overall feeding range and overall colony habitat. These factors minimize significantly the potential risk from oral exposure. The PPC recommends that EPA refine its off-field assessment to focus on contact exposure and effects as the more reliable data to include in the assessments.

III. Agency Communication on Neonicotinoids Role in Pollinator Health

FIFRA requires that EPA ensure that pesticides registered for use in the U.S. do not pose unreasonable adverse effect on man and the environment. FIFRA requires that EPA engage in risk-benefit balancing that weighs potential risk against the economic and society benefits of pesticide use. The unreasonable adverse effects standard does not require an elimination of any and all risk, and will mean that some small fraction of non-target insects, including pollinators, may be harmed. Overall EPA's risk assessments for neonicotinoids indicate that widespread adoption of these products do not pose a significant risk to pollinator health. In particular, EPA has not found seed treatment with neonicotinoid products of significant risk. Not that long ago, the major regulatory concern for many stakeholders was that the seed treatment uses were the major cause of any detrimental impacts on honeybee health. Now that EPA's own analysis agrees with the registrants' conclusions that the risk from these uses is minimal, EPA seems reluctant to more publicly announce these reassuring findings. There often appears to be a disconnect between what the law and science says and the message EPA communicates to the public. These mixed messages contribute to the negative public perception of pesticides and the impact they have on pollinator health. The PPC

encourages the Agency to better communicate the protective regulatory standards any pesticide has to meet and any real risks pesticides pose to pollinators as supported by the appropriate data-driven regulatory analysis.

CONCLUSION

The PPC is encouraged by the preliminary findings of EPA's ongoing risk assessment for neonicotinoids. We recognize these are preliminary risk assessments, and encourage EPA to consider the aforementioned refinements, as well as additional studies and data where necessary to ensure the final assessment is based on the best available, sound science.

Sincerely,

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