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Comments on Office of Health Assessment and Translation (OHAT) Nomination of Neonicotinoid Pesticides for Review of Non-Cancer Health Outcomes. 80 FR 60692. October 7, 2015.

Valent U.S.A. Corporation (hereafter "Valent") appreciates the opportunity to review and comment on the Office of Health Assessment and Translation's (OHAT) nomination of neonicotinoid pesticides for review of non-cancer health outcomes ("Proposal"). Valent is the primary registrant and data owner for multiple EPA pesticide registrations, including two neonicotinoids technical active ingredients. As a registrant, Valent possesses a deep understanding of both neonicotinoid toxicology and the pesticide regulatory framework at EPA.

While the OHAT Proposal is specific to neonicotinoid insecticides, Valent finds that in making this nomination, the OHAT may have failed to consider certain facts with respect to data available on health outcomes for *all* pesticides.

The purpose of these comments is therefore:

1. to make sure the OHAT is aware of additional facts regarding health data available on pesticides in general and neonicotinoids specifically,
2. to direct the OHAT to expert resources and data residing within the federal government, and
3. to formally request the delisting of neonicotinoid pesticides from the proposed nomination, and pending determination on such a decision, to request an extension of 60 days to the deadline for comments on the Proposal, to allow for additional consultation and consideration of additional relevant information.

Legal and Regulatory Framework

40 CFR part 158 Subpart F outlines the extensive toxicological studies that are required for registration of any pesticidal active ingredient, including, but not limited to, acute and chronic toxicity, mutagenicity, neurotoxicity, immunotoxicity, developmental toxicity, and an evaluation of reproductive and fertility effects. There is a robust and extensive toxicological database available for pesticides registered under the Federal Insecticide, Fungicide, and Rodenticide Act

(FIFRA). These submitted studies, conducted under GLP and according to strict internationally-acceptable scientific guidelines, are reviewed by EPA scientific experts and are the backbone of the Agency's human health and risk assessment. These studies, while generally not available in the common literature, are available from the Agency under the Freedom of Information Act (FOIA). In addition to these submitted studies, EPA toxicologists are required by statute to evaluate all available data including peer reviewed and literature data.

Registration Review

In addition to the substantial data requirements for registration of a pesticide, FIFRA mandates that all pesticides undergo a thorough scientific data and risk reevaluation every 15 years called registration review[1]. Within the registration review program, EPA's Office Pesticide Programs (OPP) evaluates available data submitted by pesticide registrants, and "calls in" additional data from these companies where existing data are found to be insufficient to meet the latest guidelines. Thus, by law, the safety data base supporting these products is continuously upgraded as scientific methods and knowledge evolve.

All of the most commonly used neonicotinoid pesticides are nearing completion of their first registration review cycle. The review schedule and links to the federal dockets containing regulatory correspondence, previous health assessments and data requirements on these cases may be found on EPA's web site.[2] Review of these documents will make it clear that these chemicals are already receiving intense scrutiny by the federal government, and therefore *any additional review by OHAT risks being duplicative and an unnecessary use of taxpayer funds*.

Data Quality

While the scientific peer-review process is an indicator of data quality, especially in academic publishing, it is not the only measure. Guideline compliance under Good Laboratory Practice (GLP) regulations is the standard under which pesticide safety data are evaluated.[3] A recent literature review evaluating and comparing both mechanisms for ensuring data quality concluded that "Both peer review and GLP provide useful insights into data and results from scientific studies, but neither alone is sufficient for establishing relative merit and scientific soundness of the research."[4] It is important to note that the definition of peer review in the context of this review included not only journal peer review, but also other forms including evaluation of research contracts and grants, government scientific reports, policy documents, and regulatory directives. The FIFRA

[1] 7 U.S.C. §136a (g); 40 CFR Part 155, Subpart C.
[2] http://www2.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides
[3] 40 CFR Part 160
[4] L.S. McCarty et. al. 2012. Information Quality in Regulatory Decision Making: Peer Review versus Good Laboratory Practice. Environ Health Perspect; DOI:10.1289/ehp.1104277

Science Advisory Panel (FIFRA SAP) is a good example of non-journal peer review used by the OPP for pesticides.[5]

Duplication of Effort

Given the existing legal and regulatory mandate for pesticide registrants to generate health effects data, and for EPA review such data along with public literature in support of FIFRA pesticide registration and registration review, we question the value of OHAT's Proposal. While we have no cause to object to OHAT's review *per se* regarding health outcomes, any such review relying solely on peer-reviewed literature will be inherently incomplete and inadequate unless considered along with the hundreds of volumes of data submitted by neonicotinoid registrants and the government's reviews already in the files of EPA-OPP. All data supporting pesticide registration is available publicly (via Freedom of Information Act). It would be inappropriate to perform such a review with the knowledge that this critical body of information is systematically being excluded. Furthermore, any conclusions drawn would be heavily biased by dependence on such a limited data set.

Valent maintains that considerable expertise regarding the health effects of the neonicotinoids and other pesticides already resides within EPA's Office of Pesticide Programs, and OHAT staff have simply to consult with these experts to avoid duplication of effort.

Request for Withdrawal and Extension

In light of the extensive high quality scientific data supporting the registration of neonicotinoid pesticides, and the comprehensive reviews already conducted or being conducted by EPA toxicologists and health risk assessment experts, Valent requests that OHAT withdraws the nomination of these chemicals for non-cancer health outcomes assessment. Pending a final determination regarding such a decision to withdraw, we request a 60-day extension to the deadline for comments, to allow for submission and consideration of additional relevant information.

[5] http://www2.epa.gov/sap