April 26, 2023

Nancy Rice
Minnesota Department of Health
Robert Street North
P.O. Box 64975
St. Paul, MN 55164-0975

RE: Proposed Amendments to Rules Governing Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Part 7500, Part 7850, and Part 7860; Revisor's ID Number RD4587, OAH Docket No. 5-9000-38941

Thank you for the opportunity to provide public input on the Minnesota Department of Health's (MDH's) proposed groundwater health risk limit for imidacloprid. Bayer Crop Science produces several products that rely on imidacloprid as an active ingredient to control insect pests. Bayer previously submitted written comments on the proposed groundwater health risk limit on March 8, 2023, and received the MDH's response letter, dated March 31, 2023[1].

In its response letter to Bayer, MDH stated, "The purpose of risk assessment is different between EPA and MDH. EPA's role is to register pesticides, MDH's role is to derive water guidance that is protective, including a margin of safety, for sensitive and highly exposed individuals in the general population." This statement mischaracterizes the purpose of EPA's risk assessments. When EPA considers aggregate human exposures resulting from drinking water, food, and residential exposures, it may only approve uses where it can conclude there is a "reasonable certainty of no harm."[2] EPA's "reasonable certainty of no harm" standard applies to infants, children, and other potentially-sensitive populations, with additional safety factors that EPA must apply by default unless sufficient data and information are available to demonstrate additional safety factors are not necessary. This is a high standard and is consistent with MDH's mission to protect public health.

In response to Bayer's comment that Badgujar et al. (2013)[3], the study MDH relied on to calculate the proposed health risk limit for imidacloprid, is missing key information that would allow it to inform a quantitative risk assessment, MDH stated, "It is unusual in the open

[1] https://www.health.state.mn.us/communities/environment/risk/docs/rules/comments/mdhbayerresp.pdf
[2] EPA. 2022. Summary of the Federal Food, Drug, and Cosmetic Act. https://www.epa.gov/laws-regulations/summary-federal-food-drug-and-cosmetic-act
[3] Badgujar, P.C., et al. 2013. Immunotoxic effects of imidacloprid following 28 days of oral exposure in BALB/c mice. Environmental Toxicology and Pharmacology. 35:408-418. doi: 10.1016/j.etap.2013.01.012

literature for academic peer-reviewed studies to include raw data, and minute study details, due to journal article space and word number constraints." In fact, scientific journals, including the journal that published Badgujar et al. (2013), allow authors to include additional data with the digital version of the publication to "validate research findings".[4] Nevertheless, the authors of the publication MDH relied on to calculate the proposed groundwater health risk limit for imidacloprid did not provide additional data or details in any form that readers could use to evaluate whether the publication's conclusions accurately reflect the raw data. MDH could contact the study authors to request the raw data and conduct its own review to establish whether the raw data support the study's conclusions.

In response to Bayer's comment that a valid, guideline compliant study conducted according to Good Laboratory Practices (GLPs) is available and is of higher quality than the study MDH relied on, MDH stated, "While it is true that industry uses GLP and follows EPA's Immunotoxicity Guidelines (EPA 1998), academia in the open literature uses peer-review and journal editors to assess the quality of their work." In fact, GLP regulations and peer review are not equivalent. GLP regulations enable thorough reviews not only of the data but also the qualifications of the people who conducted the study, the full chemical identity of the test material, calibration records for all laboratory equipment, and rigorous documentation of study conditions.[5] The quality of an individual peer review is specific to the people who conducted it and the amount of time and information they had available. Completing peer review does not establish that one study is of similar quality or reliability as another study conducted in compliance with GLP regulations according to internationally accepted guidelines.

To support its position that EPA's human exposure limit for imidacloprid is not sufficient to protect human health, MDH stated, "Furthermore, both the State of Wisconsin and The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) have stated that EPA's RfD for imidacloprid is not health protective." Authoritative bodies in Wisconsin and California responsible for regulating pesticides have affirmatively rejected groundwater standards that stem from analyses that conflict with EPA's human health risk assessment. Wisconsin's Department of Natural Resources reviewed the proposed imidacloprid groundwater standard that MDH cites and voted not to adopt it in February 2022[6]. In its review of OEHHA's assessment, the Human Health Assessment Branch of California's Department of Pesticide Regulation (DPR) "determined that several of the studies

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[4] Elsevier Publishing. 2023. Environmental Toxicology and Pharmacology instructions for authors: Research Data. https://www.elsevier.com/journals/environmental-toxicology-and-pharmacology/1382-6689/guide-for-authors

[5] EPA. 2022. Good Laboratory Practices Standards Compliance Monitoring Program. https://www.epa.gov/compliance/good-laboratory-practices-standards-compliance-monitoring-program

[6] https://widnr.widen.net/view/pdf/icborcvkrw/2022-02-APPROVED-February-Brief-of-Action.pdf?t.download=true&u=2ge66j ("At 4:47:05, the motion to approve item 4.C. Board Order DG-15-19 failed on a roll call vote of 3-3")

cited by OEHHA had experimental design, reporting, or statistical issues that precluded their use as the basis for a regulatory action."[7] OEHHA's analysis included Badgujar et al. (2013) that MDH seeks to use as the basis of Minnesota's proposed health risk limit for imidacloprid. In other words, California DPR reached a similar conclusion as EPA – that Badgujar et al. (2013) is not reliable for use in a quantitative risk assessment.

Choosing a single, low-quality study (Badgujar et al., 2013) as the basis for MDH's assessment does not satisfy the "reasonableness" requirements that the Minnesota Administrative Procedure Act (APA), Minnesota Statutes, Chapter 14 describes. Recent regulatory reviews of imidacloprid at the federal (EPA) and state (California DPR) levels have specifically considered Badgujar et al. (2013) and found that it is not suitable for quantitative risk assessment. MDH's response to Bayer's original comments do not provide any basis for relying on Badgujar et al. (2013) beyond that it examined the effects of imidacloprid on the immune system of female mice and that it appeared in a peer-reviewed journal.

A higher quality study (Kennel, 2010), conducted according to internationally accepted methods, in compliance with GLP standards, is available and serves as the basis of EPA's current human health risk assessment with respect to immunotoxicity. There is no basis to conclude that the results that Badgujar et al. (2013) present accurately reflect the underlying raw data – one of several reasons EPA chose not to rely on this publication in its most recent risk assessments. Absent an independent review of the raw data against the conclusions, there is no way to know how reliable Badgujar et al. (2013) is and there is no way to establish that it is sufficiently reliable to serve as the basis for quantitative risk assessment.

Best regards,

William R. Reeves, Ph.D.
Regulatory Scientific Affairs
Bayer U.S. LLC Crop Science Division
700 Chesterfield Parkway West
Chesterfield, MO 63017
Tel. +1 314 807 0974
william.reeves@bayer.com

[7] CDPR. Subcommittee of the Pesticide Registration and Evaluation Committee; Implementation of the Pesticide Contamination Prevention Act; Imidacloprid: Subcommittee Findings and Recommendations May 17, 2022. https://www.cdpr.ca.gov/docs/emon/grndwtr/imidacloprid/prec_findings_recommendations.pdf