# 38941 Minnesota Department of Health Notice of Hearing (Initial Comment Period)

Closed Mar 08, 2023 · Discussion · 5 Participants · 1 Topics · 6 Answers · 0 Replies · 1 Votes

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**William Reeves** · Citizen · (Postal Code: unknown) · Mar 08, 2023 2:37 pm

0 Votes

Please find attached Bayer Crop Science's comments on the health risk level proposal.

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**Bill Gulledge** · Citizen · (Postal Code: unknown) · Mar 08, 2023 4:34 pm

0 Votes

Please see attached comments from the ACC Ethylene Glycols Panel.

March 8, 2023

Nancy Rice
Minnesota Department of Health
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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 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 met with the Department of Health on May 23, 2019 to discuss the proposed Health Based Guidance for Water published in March 2019 (651-201-4899). In this document, Minnesota proposed a health-based value of 3 µg/L for groundwater based on a reduced immunologic response in a 28-day mouse study.

Minnesota's regulations for establishing health standards (Minnesota statues 144.0751[1]) require that when establishing drinking water quality standards, the Commissioner of Health must base those standards on scientifically acceptable, peer-reviewed information. Furthermore, Minnesota's regulations for establishing health risk limits (Minnesota statutes 103H.201[2]) require that "the adopted health risk limits shall be derived using United States Environmental Protection Agency (EPA) risk assessment methods using a reference dose, a drinking water equivalent, and a relative source contribution factor."

Minnesota's proposed standard for imidacloprid does not meet any of these requirements because the underlying study Minnesota relied on (Badgujar et al., 2013[3]) is missing key information that would allow it to inform a quantitative risk assessment. Badgujar et al. (2013) does not provide sufficient information for reviewers to understand the details of the experiments they conducted, nor does it provide sufficient detail to determine whether the

[1] Minnesota Statutes 2022. Health Standards. 144.0751. https://www.revisor.mn.gov/statutes/cite/144.0751
[2] Minnesota Statutes 2022. Health Risk Limits. 103H.201. https://www.revisor.mn.gov/statutes/cite/103H.201
[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

authors' observations were the result of confounding factors that were unrelated to imidacloprid.

In two separate evaluations, the EPA has specifically considered Badgujar et al. (2013) and rejected it for use in quantitative risk assessments. EPA considered Badgujar et al. (2013) in its 2015 weight of evidence analysis of imidacloprid's ability to interact with the endocrine system[4] and in its 2017 imidacloprid risk assessment for terrestrial organisms[5]. In both cases, EPA concluded that Badgujar et al. (2013) was not of sufficient quality to inform a quantitative risk assessment. EPA's stated reasons included a lack of information about the imidacloprid sample used in the study, the absence of raw data to confirm the findings and statistical analysis, and limited information about test conditions.

Badgujar et al. (2013) purports to demonstrate that imidacloprid caused toxicity to the immune system of female mice that were administered imidacloprid for 28 days. EPA requires specific tests to understand the potential of pesticides to harm immune function. These tests follow internationally- accepted guidelines and must be conducted according to Good Laboratory Practice (GLP) Regulations[6]. These two requirements ensure that the studies are of sufficient quality to inform a quantitative risk assessment and that reviewers can understand whether the conclusions accurately reflect the data.

An immunotoxicity study that followed EPA's required methods and GLP regulations is available for imidacloprid (Kennel, 2010)[7]. The maximum dose in this study was 186 mg imidacloprid/kg body weight/day, 18.6 times higher than the maximum dose that Badgujar et al. (2013) tested. Additionally, Kennel (2010) conducted the study using male rats, in accordance with EPA's guidelines for an immunotoxicity study[8] based on evidence that males are more sensitive than females and rats are more sensitive than mice. Badgujar et al. (2013) tested female mice only. EPA relies on Kennel (2010) in its human health and ecological risk assessments and has concluded that imidacloprid did not cause immunotoxicity at any of the tested doses.

We support Minnesota's efforts to protect public health by adoption of health risk limits for chemicals that could be present in groundwater. We also believe those limits should rely on high quality studies that are of sufficient quality to inform quantitative risk assessments.

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[4] EPA. 2015. EDSP: Weight of Evidence Analysis of Interaction Potential with the Estrogen, Androgen or Thyroid Pathways. Chemical: Imidacloprid. https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-0137

[5] EPA. 2017. Imidacloprid -Transmittal of the Preliminary Terrestrial Risk Assessment to Support the Registration Review. https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1256

[6] 40 CFR Part 160. Good Laboratory Practice Standards. https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-160

[7] Kennel. 2010. Imidacloprid 28-day immunotoxicity study in the male Wistar rat by dietary administration. Bayer Crop Science, Study No. SA 09406; MRID 48298701

[8] EPA. 1996. Health Effects Test Guidelines. OPPTS 870.7800 Immunotoxicity. https://www.regulations.gov/document/EPA-HQ-OPPT-2009-0156-0049

Badgujar et al. (2013) does not meet that standard and this position is consistent with the views of expert risk assessors at EPA. EPA identified an appropriate, health protective value (Reference Dose, RfD) in its human health risk assessment of 0.08 mg/kg body weight/day that should be used to establish groundwater health risk limits for Minnesota.

Best regards,

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