March 31, 2023

Ms. Jean Wagenius
4804 11th Ave South
Minneapolis, MN 55417

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

Dear Jean Wagenius:

Thank you for your comments of March 4, 2023, and March 6, 2023, on the proposed Health Risk Limits Rules Amendments via the Office of Administrative Hearing's Rulemaking eComments website.

As you correctly note, Minnesotans are exposed to nitrate in their drinking water, both from public and private sources. Recognizing this, the Health Risk Assessment unit has a long-standing history of surveilling the published scientific literature for new nitrate data and follows the regulatory and risk assessment actions in other states and by the federal government. We are ready to reassess the nitrate Health Risk Limits (HRL) when the scientific literature points to the need and/or the literature reports new data in a way that can be used by MDH for HRL development.

At the time of this rulemaking, we believe that the federal nitrate Maximum Contaminant Level (MCL) used as the basis for the MDH nitrate HRL is sufficiently health protective for the most well-documented effect of nitrate, methemoglobinemia in infants. There are several reasons we continue to use the MCL standard. Unlike the vast majority of HRLs, the nitrate MCL is based on epidemiology data from human infants exposed to nitrate. Most HRLs are based on laboratory animal data, and MDH staff must extrapolate from effects seen in a rodent, dog, or rabbit to effects we think we will see in humans. There is uncertainty in this process that does not occur in epidemiology studies in humans. Additionally, the epidemiology studies are in infants, the most sensitive population for nitrate health effects. While the epidemiology data for nitrate is old (from the 1940s and 1950s), there have not been well-conducted peer reviewed studies since then that showed that nitrate can cause methemoglobinemia at concentrations below the MCL.

In addition, MDH staff conducted an investigation in 2018 to determine how many cases of methemoglobinemia had occurred in Minnesota in the previous two decades. After scouring medical records, staff identified 11 cases of methemoglobinemia in infants. Of these, only five were related to nitrate in drinking water. Methemoglobinemia is not a reportable disease in Minnesota, so it is likely that the five cases identified are an underestimation. Methemoglobinemia is also hard to diagnose because of its subtle symptoms in infants — fussiness, diarrhea, vomiting, lethargy. Most cases resolve when the water source is removed, and no medical intervention is needed. It is not clear from the identified cases whether Minnesota infants are getting sick from water with nitrate concentrations below the MCL in large numbers. Mandated reporting would help fix this issue, but that is outside the scope of this rulemaking.

There is growing concern within MDH and the risk assessment community at large about the health impacts related to long-term nitrate exposures from drinking water and other sources. There have been studies suggesting drinking water with nitrate concentrations below the MCL for a lifetime may cause cancer, including colon cancer. Currently, the epidemiology literature is not robust enough for MDH to calculate a new HRL. Most of the epidemiology studies that report illnesses, including cancer, from these types of low-concentration long-term exposures are considered 'ecological' studies. Ecological studies are designed as a preliminary investigation into a hypothesis and are also called 'hypothesis generating' studies because they inform and focus future, better quality studies. They truly are not designed to describe a dose response relationship between a chemical and a health outcome (e.g., as the concentration of a chemical increases, the number or severity of health effects increases). A quantitative reporting of data in a format that can be used for risk assessment is very rare in epidemiology, and a HRL cannot be based on a study that lacks this type of reporting.

One of the limitations also inherent in this type of study is a lack of evaluation of other exposures that can cause the health outcome being studied. Many of the recent nitrate studies did not complete a suitable exposure review that would have looked for the presence of trihalomethanes or other disinfection byproducts in the drinking water, smoking, eating red meat, lack of vitamin C, sedentary behavior, and/or alcohol consumption. All of these factors are associated with increased risk for cancer and chronic disease. Because the researchers did not look to see if people in the study had any of these confounding factors, we cannot be certain that it is the nitrate, and not the cigarettes, for example, that causes the cancer reported in the study participants.

In addition, these studies often lack any true measurement of exposure to nitrate, rather, using estimated population-level values. This would mean that instead of actually sampling the wells

in the study for nitrate levels, the researchers might apply an average nitrate concentration, or a concentration developed from a computer model, across the entire study population. This approach fails to catch natural variability in the environment. For example, in instances where there is the expected outcome, such as cancer, in a study participant, but little or no nitrate in their well water, this practice will link the cancer to a set value, rather than the actual value the person was exposed to. It will also not detect a situation where the well water is much higher in nitrate than the average concentration or the modeled concentration and the participant develops the health outcome, such as cancer. These types of inconsistencies are not acceptable in studies used for HRL development because again, we cannot accurately quantify the dose of the chemical that is causing the health effect.

Your comment quoted our Health Standards Statutes (MN Statutes 144.0751) and cites reports from the Environmental Working Group and Minnesota Center for Environmental Advocacy as reasons a new HRL is warranted. Neither of these reports qualify as information that can be used to develop a HRL under this statute. These reports are neither "scientifically acceptable, peer-reviewed information" nor "conducted by individuals with substantial knowledge and experience in toxicology, health risk assessment, or other related fields as determined by the commissioner," as required by the Health Standards Statute. Rather, these are policy reports that cite the epidemiology studies discussed above, which again, are not suitable for quantitative risk assessments that form the basis of HRLs.

The state of California published a review of epidemiology studies in 2018 (California Environmental Protection Agency, 2018) as part of their process to develop a new Public Health Goal for nitrate, which are similar to MDH's HRLs. Their review walked through the scientific literature, publication by publication, and cited why each study was or was not appropriate for risk assessment purposes. MDH paid careful attention to this document and reviewed it in 2018-9. California concluded that the epidemiology literature available was not sufficient to update their public health goal to a value different than the current MCL. Additionally, the United States Environmental Protection Agency (EPA) suspended its review of nitrate in 2018, citing other more important priorities.

MDH has a long history of leading the nation with safe, health-based values that protect the public health of our residents, notably including our work on PFAS. One only needs to look at our 20-year track record of providing values for PFAS, despite a lack of such action from US EPA. However, MDH also has a track record of standing on the science and not developing "policy" numbers. Our HRL authority and the methods derived under it for developing or updating values directs us to base them on careful quantitative scientific considerations (2009 SONAR, Appendix C; Minn. R. 4717.7830.) The available recent and historic toxicology information from

animal studies and epidemiology studies on nitrate and its health effects are not sufficient for the development of a new nitrate HRL. This may change as new information becomes available.

It is not reasonable to remove the HRLs for 37 contaminants from rulemaking just because a specific chemical is not included. This reasoning would allow anyone to provide an argument for any chemical as a reason to stop rulemaking. For example, there are three PFAS in this current rulemaking. Using this logic would allow a company that manufactures the three PFAS to simply say iron, for example, which is found in groundwater sometimes at very high levels, is not in this rulemaking and that makes the entire proposed rule null and void, stopping the three PFAS from being adopted into rule.

In your comment you also asserted that MDH must enforce the HRLs, apparently as industry regulations, based on its separate and general authority to enforce standards for "environmental health hazards" in a statute (144.05). This statute makes no mention of HRLs themselves. The legislature, however, specifically requires HRLs to be set in rule and defines them, not as directly enforced limits on any particular party's conduct, but as baselines for operationalizing the point where a concentration of a given substance becomes a potential health risk (103H.005, subd. 3). That MDH has general statutory authority to regulate environmental health hazards does not prohibit MDH from complying with a clear directive from the legislature to set HRLs in rule. In more than 20 years MDH has not interpreted the statute this way, nor has any administrative law judge during previous rulemakings.

Sincerely,

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References

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