

May 20, 2025

VIA EFILING ONLY

Nancy Rice
Minnesota Department of Health
PO Box 64882
Saint Paul, MN 55164
nancy.rice@state.mn.us

**Re: In the Matter of Minn. R.4717.7500 and 4717.7860 Proposed
Amendment to Rules Governing Health Risk Limits, Revisor's ID
R-04803
OAH 22-9000-40331; Revisor 4803**

Dear Nancy Rice:

Enclosed herewith and served upon you is the **ORDER ON REVIEW OF RULES UNDER MINN. STAT. § 14.26** in the above-entitled matter. The Administrative Law Judge has determined there are no negative findings in these rules.

The Office of Administrative Hearings has closed this file and is returning the rule record so that the Minnesota Department of Health can maintain the official rulemaking record in this matter as required by Minn. Stat. § 14.365. Please ensure that the agency's signed order adopting the rules is filed with our office. The Office of Administrative Hearings will request the finalized rules from the Revisor's office following receipt of that order. Our office will then file the adopted rules with the Secretary of State, who will forward one copy to the Revisor of Statutes, one copy to the Governor, and one to the agency for its rulemaking record. The Department will then receive from the Revisor's office three copies of the Notice of Adoption of the rules.

The Department's next step is to arrange for publication of the Notice of Adoption in the State Register. Two copies of the Notice of Adoption provided by the Revisor's office should be submitted to the State Register for publication. A permanent rule without a hearing does not become effective until five working days after a Notice of Adoption is published in the State Register in accordance with Minn. Stat. § 14.27.

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If you have any questions regarding this matter, please contact William Moore at (651) 361-7893, william.t.moore@state.mn.us or via facsimile at (651) 539-0310.

Sincerely,

A handwritten signature in black ink that reads "Nichole Sletten". The script is fluid and cursive, with the first name "Nichole" and last name "Sletten" clearly distinguishable.

NICHOLE SLETTEN
Legal Assistant

Enclosure

cc: Legislative Coordinating Commission
Revisor of Statutes

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Minn. R.4717.7500 and
4717.7860 Proposed Amendment to Rules
Governing Health Risk Limits, Revisor's ID
R-04803

**ORDER ON REVIEW OF
RULES UNDER
MINN. STAT. § 14.26**

The Minnesota Department of Health (Department) is seeking review and approval of the above-entitled rules, which were adopted by the agency under Minn. Stat. § 14.26 (2024). On May 6, 2025, the Office of Administrative Hearings (OAH) received the documents that must be filed by the Department under Minn. Stat. § 14.26 and Minn. R. 1400.2310 (2023).¹

Based upon a review of the written submissions and filings, Minnesota Statutes, Minnesota Rules, and for the reasons provided in the Memorandum that follows,

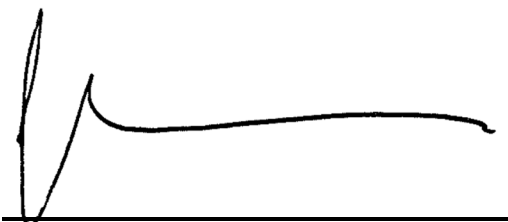
IT IS HEREBY DETERMINED:

1. The Department has the statutory authority to adopt the rules.
2. The rules were adopted in compliance with the procedural requirements of Minnesota Statutes, Chapter 14 (2024), and Minnesota Rules, Chapter 1400 (2023).
3. The record demonstrates the rules are needed and reasonable.

IT IS HEREBY ORDERED THAT:

The rules are **APPROVED**.

Dated: May 20, 2025



Christa L. Moseng
Administrative Law Judge

¹ On May 13, 2025, the Department supplemented its submission to include its response to the sole written comment received during the comment period, from the American Chemistry Council. The Department's response to the comment is not specifically required under Minn. R. 1400.2310, but it contributes to a fuller record for evaluating the proposed amendments' need and reasonableness.

MEMORANDUM

I. Introduction

Minn. Stat. § 103H.201, subds. 1–3 (2024), authorize the Department to adopt and to revise health risk limits (HRLs) for groundwater, which it must review at least every four years. The adopted HRLs must be “derived from a quantitative estimate of the chemical's carcinogenic potency published by the United States Environmental Protection Agency (EPA) or determined by the commissioner to have undergone thorough scientific review.”²

The Department now seeks approval of amendments to Minn. R. 4717.7500 and .7860, revising HRLs to update outdated HRL values and to add new HRLs for newly detected groundwater contaminants. With its request for review and approval of its proposed HRLs, the Department provided Exhibits A through P, corresponding to Items A–P required under Minn. R. 1400.2310.

Minn. R. 1400.2100 (2023) specifies the standard of review for proposed rules or rule amendments. Among other considerations, the Judge must disapprove a rule if it “is not rationally related to the agency's objective or the record does not demonstrate the need for or reasonableness of the rule.”³

The Department describes the need and reasonableness for its proposal to amend rules governing HRLs in its October 2024 Statement of Need and Reasonableness (SONAR).⁴ The Department received one comment during the comment period, from the American Chemistry Council (ACC).⁵

II. ACC Comments

The ACC offered comments “to further inform the Minnesota Department of Health's evaluation and to strengthen the underlying scientific information for the proposal.”⁶ In its comments, the ACC appears to challenge the reasonableness of the Department's proposed amendments pertaining to the health risk limits for Perfluorooctane sulfonate (PFOS)⁷ and Perfluorooctanoate (PFOA).⁸

Specifically, the ACC highlighted what are arguably shortcomings in the scientific support for, and data underlying, the Department's proposed limits. It criticized the Department's use of human epidemiology studies and the Department's breastmilk model to derive noncancer-based health risk limits. It similarly challenged the reliability of data underlying the Department's cancer-based health risk limits. The ACC also asserted that three of the four proposed health risk limits for PFOS and PFOA are lower

² Minn. Stat. § 103H.201, subd. 1(d).

³ Minn. R. 1400.2100 (B).

⁴ Exhibit (Ex.) D (Statement of Need and Reasonableness).

⁵ Ex. J., (Comments submitted by ACC) (December 4, 2024).

⁶ Ex. J., (Cover letter submitted by ACC Vice President Robert J. Simon to Department Commissioner Brooke Cunningham) (December 4, 2024).

⁷ Proposed amendment to Minn. R. 4717.7860, subp 15.

⁸ Proposed amendment to Minn. R. 4717.7860, subp 16.

than the US EPA maximum contaminant levels for those contaminants. The ACC's challenges on these points were supported with analytical detail and citations to scientific literature.

III. Department's Response

The Department's response to the ACC's comments is similarly detailed and supported. The Department explained its selection of human epidemiology studies for purposes of risk assessment for PFOS and PFOA, stating that "there has been a worldwide shift in PFAS risk assessment away from animal experimental data towards human epidemiological studies. Over the past several years, sufficient epidemiological data have become available to perform risk assessments and derive human health guidance values."⁹ The Department also noted that human studies are generally better than animal studies, and particularly better for PFOS and PFOA because humans are more sensitive to these contaminants than laboratory animals, particularly rats.

The Department asserted that the studies selected "were critically evaluated by Department toxicologists as well as by federal and state regulatory agencies and represent the best available science."¹⁰ It further stated that the studies and selected endpoints¹¹ "are in accordance with MDH's promulgated methodology directing us to protect the most sensitive and most highly exposed populations."

In support of its use of a breastmilk model, the Department states that the model has been validated and has undergone multiple rounds of internal and external review. For the proposed 2025 PFOS and PFOA noncancer HRLs, the Department developed an updated and refined breastmilk model. The updated model was similarly validated with empirical data and development was documented in a 2024 peer-reviewed publication.

In support of its proposed cancer-based PFOS and PFOA HRLs, the Department responded that they were derived using information from US EPA's PFOS Maximum Contaminant Level Goal (MCLGs) and the California EPA's Public Health Goal PFOA (PHG), which each went through multiple rounds of public drafts and public comment periods, over multiple years, before final adoption. The Department explained that MCLGs and PHGs are both comparable values to HRLs in that they are strictly human-health based.

The Department responded that the concerns raised in the ACC's comments were considered by Department scientists during the review process for the proposed HRLs, and were also included in the analyses by other regulatory agencies consulted during the derivation of the proposed PFOS and PFOA HRLs. The Department

⁹ Ex. J (Letter from Kristine S. Klos, PhD to Robert J. Simon) (February 21, 2025), 2.

¹⁰ Ex. J (Letter from Kristine S. Klos, PhD to Robert J. Simon) (February 21, 2025), 2.

¹¹ "Endpoint refers to the organ systems that are most susceptible to harm and that should be grouped together for evaluation when more than one chemical is present (additivity endpoint)." Ex. D, 18.

considers its evaluations supporting the proposed 2025 PFOA and PFOS HRLs as based on the best available science.

IV. Analysis

Through its SONAR and its response to the ACC's comments, the Department has met its burden to demonstrate the need for, and reasonableness of, its proposed HRLs. The Department has rationally explained the bases for the HRLs and has explained how the data supporting the derived HRLs have undergone the requisite scientific review by Department scientists, other regulatory agencies, and the general public. The Department is not required to show that its decision was the best available one. Rather, it is sufficient that the Department's decision was reasonable and rationally supported.

The Department has satisfied the requirements of Minn. Stat. § 14.26 and Minn. R. 1400.2310. There is no basis to disapprove the rule under Minn. R. 1400.2100.

V. Conclusion

The Department's proposed amendments to Minn. R. 4717.7500 and .7860 are **APPROVED**.

C. L. M.