

July 20, 2023

VIA EMAIL ONLY

Josh Skaar
Attorney at Law
Minnesota Department of Health
625 N Robert St
Saint Paul, MN 55164
Josh.skaar@state.mn.us

Re: *In the Matter of the Proposed Amendments to Rules Governing Health Risk Limits for Groundwater, Minn R. 4717, Revisor's ID No. 4587*
OAH 5-9000-38941; Revisor R-4587

Dear Mr. Skaar:

Enclosed please find the Report of the Chief Administrative Law Judge in the above-entitled matter and the Report of Administrative Law Judge Jim Mortenson. The Department may resubmit the rule to the Chief Administrative Law Judge for review after changing it, or may request that the Chief Administrative Law Judge reconsider the disapproval.

If the Agency chooses to resubmit the rule to the Chief Administrative Law Judge for review after changing it, or request reconsideration, the Department must file the documents required by Minn. R. 1400.2240, subps. 4 and 5.

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,



DARA XIONG
Legal Assistant

Enclosure

cc: Office of the Revisor of Statutes
Legislative Coordinating Commission

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of the Proposed Rules of the
Department of Health Governing Health
Risk Limits for Groundwater, Minn.
R. 4717.7860, .7500, and .7850

**ORDER OF THE CHIEF
ADMINISTRATIVE LAW JUDGE
ON REVIEW OF RULES**

This matter came before the Chief Administrative Law Judge pursuant to the provisions of Minn. Stat. § 14.15, subd. 3 (2022), and Minn. R. 1400.2240, subp. 4 (2021). These authorities require that the Chief Administrative Law Judge review an administrative law judge's findings that a proposed agency rule is defective and should not be approved.

The proposed rules concern the Minnesota Department of Health's (Department) amended Health Risk Limits (HRLs) for contaminants in groundwater. Following public rulemaking hearings held on April 5 and 6, 2023, Administrative Law Judge Jim Mortenson disapproved the proposed rules in a Report dated July 10, 2023.¹

Based upon a review of the record in this proceeding, the Chief Administrative Law Judge **CONCURS** with the disapproval of the proposed Rules based on the Department's failure to make the required determination under Minn. Stat. § 14.127 (2022) concerning potential compliance costs for small businesses and cities. The Chief Judge **disagrees** with the disapproval of the proposed Rules based on the Department's cost analyses under Minn. Stat. § 14.131(2), (5), (6) (2022).

For the reasons provided in the Memorandum that follows,

IT IS HEREBY DETERMINED THAT:

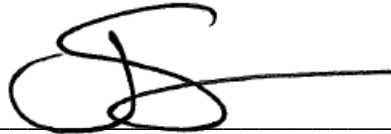
1. Except for the required determination under Minn. Stat. § 14.127, the rules were adopted in compliance with the procedural requirements of Minn. Stat. §§ 14.001-.69 (2022); Minn. R. 1400.0200-.2310 (2021).
2. The Department's failure to address a procedural requirement is a defect but it may be cured by supplementing the record.

¹ Report of the Administrative Law Judge (July 10, 2023).

THEREFORE, IT IS HEREBY ORDERED:

1. The proposed Rules are **DISAPPROVED** based on the Department's failure to adequately make the required determination under Minn. Stat. § 14.127 related to cost of compliance.
2. To cure the procedural defect, the Department must supplement its Statement of Need and Reasonableness (SONAR) and Order Adopting Rule to explicitly make the determination required under section 14.127.
3. In all other respects, the proposed rules are **APPROVED**.

Dated: July 20, 2023



JENNY STARR
Chief Administrative Law Judge

NOTICE

The changes or actions necessary for approval of the disapproved rules are identified in the Memorandum below. If the Department elects not to correct the defects associated with the proposed rules, the Department must submit the rule to the Legislative Coordinating Commission and the House of Representatives and Senate policy committees with primary jurisdiction over state governmental operations, for review under Minn. Stat. § 14.15, subd. 4.

If the Department chooses to make changes to correct the defects, it must submit to the Chief Administrative Law Judge a copy of the rules as originally published in the State Register, a supplemented SONAR reflecting the required determination under Minn. Stat. § 14.127, the order adopting the rules, and the rule showing the Department's revisions. The Chief Administrative Law Judge will then determine whether the defect has been corrected and whether the modifications to the rules make them substantially different than originally proposed.

MEMORANDUM

I. Legal Standards

If an assigned administrative law judge disapproves an agency's proposed rule, the written reasons for the disapproval must be submitted to the Chief Administrative Law

Judge for review.² When undertaking a legal review of proposed rules, the Chief Judge must assess whether the proposed rules comport with applicable legal standards, including whether the rule was adopted in compliance with procedural requirements and whether the record demonstrates the need for and reasonableness of the rule.³

A rule must be disapproved if it was not adopted in compliance with the procedural requirements of Minnesota Statutes, chapter 14, or Minnesota Rules, chapter 1400, or other law or rule, unless the error must be disregarded as harmless error.⁴ Under the harmless error standard in Minn. Stat. § 14.15, subd. 5, an administrative law judge must disregard a defect in the proceeding due to an agency's failure to satisfy a procedural requirement if the administrative law judge finds that: (1) the defect did not deprive a person or entity of an opportunity to meaningfully participate in the proceeding; or (2) the agency took corrective action to cure the defect so that no person or entity was deprived of such an opportunity.

II. Background

The proposed rules in this matter govern HRLs for contaminants found in groundwater. An HRL value is a concentration of a groundwater contaminant, or a mixture of contaminants, that people can consume with little or no risk to health.⁵ The value is expressed as micrograms of a chemical per liter of water (µg/L).⁶ The Groundwater Protection Act authorizes the Department to adopt rules that set HRL values for those contaminants in groundwater that might be used for drinking water.⁷ The Department reevaluates and revises HRLs every few years to ensure that these standards incorporate the latest scientific findings and continue to be relevant.⁸ In this rulemaking, the Department is proposing new or modified HRLs for 37 contaminants identified in groundwater.⁹ Seventeen contaminants do not have previous HRLs assigned.¹⁰ Twenty contaminants are proposed for updated HRLs.¹¹

The Department developed the proposed HRL values using the scientific risk-assessment methods it adopted into rule in 2009,¹² as well as the most recent water

² Minn. R. 1400.2240, subp. 4.

³ Minn. R. 1400.2100.

⁴ Minn. R. 1400.2100(A).

⁵ Exhibit (Ex.) D (SONAR) at 1.

⁶ *Id.*

⁷ See Minn. Stat. § 103H.201 (2022).

⁸ Minn. Stat. § 103H.201, subd. 3(a) (The commissioner must review each adopted HRL at least every four years); Ex. D at 12.

⁹ Ex. D at 1; Public Hearing Transcript (Tr.) at 25 (Apr. 5, 2023) (Presentation by Sarah Fossen, Department Health Risk Assessment Supervisor and Manager for the Department's Environment Surveillance and Assessment Section).

¹⁰ Ex. D at 1; Tr. at 25 (S. Fossen) (Apr. 5, 2023).

¹¹ Ex. D at 1; Tr. at 25 (S. Fossen) (Apr. 5, 2023).

¹² See Minn. R. 4717.7830, subp. 2, .7840 (2022).

intake rates values from the U.S. Environmental Protection Agency’s (EPA) Exposure Factors Handbook.¹³ The EPA updated its water intake rate values in 2019.¹⁴

Generally, HRL values serve as benchmarks in state water monitoring and contamination response programs intended to protect the health of Minnesotans.¹⁵ HRLs are used by agencies to determine whether groundwater is subject to regulatory or advisory action based on human health concerns.¹⁶ The Department’s Health Risk Assessment (HRA) Unit develops the HRL values but, as the Department reiterates throughout its SONAR, it does not enforce the HRLs.¹⁷ Rather, other programs within the Department¹⁸ or other agencies, such as the Minnesota Pollution Control Agency (MPCA) or the Department of Natural Resources (DNR) apply HRLs along with other criteria when assessing risks and setting their own standards for protecting Minnesota’s water resources.¹⁹ These other Department programs and other state agencies may incorporate the HRLs within enforceable requirements related to their permitting or remediation activities.²⁰

Following public rulemaking hearings, Administrative Law Judge Jim Mortenson disapproved the Department’s proposed rules based on procedural defects.²¹ Judge Mortenson found the Department failed to adequately conduct the required cost analyses under Minn. Stat. §§ 14.127, and 14.131(2), (5), (6).²² Judge Mortenson further concluded that the procedural defects were not harmless errors.²³

III. Analysis

After reviewing the submissions of the agency, the Chief Administrative Law Judge concurs with Judge Mortenson and finds the Department failed to make the cost of compliance determination required under Minn. Stat. § 14.127. The Chief Judge further concurs that this failure was a procedural defect warranting disapproval of the rules. Nevertheless, the Chief Judge concludes that the defect may be cured by supplementing the record.

The Chief Judge also disagrees with Judge Mortenson’s findings with respect to the Department’s regulatory analyses under section 14.131. The Chief Judge finds that the Department adequately addressed the eight regulatory factors under Minn. Stat.

¹³ Ex. D. at 12.

¹⁴ *Id.*

¹⁵ *Id.* at 76.

¹⁶ Minn. Stat. § 4717.7810, subp. 2B (2022).

¹⁷ Ex. D at 8.

¹⁸ The Department’s Site Assessment and Consultation Unit, Drinking Water Protection, and Well Management programs use HRL values in a context specific to their programs. See Ex. D at 7.

¹⁹ E.g., MPCA’s solid waste and surface water rules. See Ex. D at 76, 81-82.

²⁰ *Id.* at 81-82.

²¹ Report of Administrative Law Judge (July 10, 2023).

²² *Id.*

²³ *Id.* at 23 (Findings of Fact 88 - 89), 25-26 (Findings of Fact 101-104), 27 (Findings of Fact 107-109).

§ 14.131 in its SONAR, including section 14.131(2), (5) and (6).²⁴ The reasons for these conclusions are discussed below.

A. Cost to Small Businesses and Cities under Minn. Stat. § 14.127

Minn. Stat. § 14.127 requires an agency to “determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed \$25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees.”²⁵ The agency must make this determination before the close of the hearing record, and the administrative law judge must review the determination and approve or disapprove it.²⁶ If the agency determines that the costs of compliance exceeds the \$25,000 threshold, then the affected business or city “may file a written statement with the agency claiming a temporary exemption from the rules.”²⁷

The Department addressed the cost of compliance requirement under Minn. Stat. § 14.127 in its SONAR as follows:

MDH *cannot* determine small business or city costs incurred in complying with the proposed amendments because the rules do not have any implementation, regulation, or enforcement requirements. The amendments simply provide health-based guidance for water contaminants; the rules do not address application or use. The guidance is one set of criteria for risk managers to evaluate potential health risks from contaminated groundwater. Risk managers, including those at other agencies, have the flexibility in determining if and when to apply the HRL values and how costs should be considered.²⁸

The statutory requirement, however, does not give an agency the option to take the position that it “*cannot* determine” whether the cost of complying with a proposed rule in the first year after the rule takes effect will exceed \$25,000 for businesses with less than 50 full-time employees or statutory or home rule charter cities with less than ten full-time employees. Minn. Stat. § 14.127 states that an agency “must” make such a determination so that impacted small businesses and cities may file a written statement claiming a temporary exemption.

The Chief Judge notes that the rulemaking record includes Minnesota Management and Budget’s (MMB) cost analysis in which it indicated it does not anticipate a direct fiscal impact to local units of government. MMB based its conclusion on the lack of enforcement provisions associated with the proposed amendments.²⁹ MMB noted that any fiscal costs that may occur would be due to the enforcement of the HRLs by other

²⁴ Minn. Stat. § 14.131.

²⁵ Minn. Stat. § 14.127, subd. 1.

²⁶ *Id.*, subd. 2.

²⁷ *Id.*, subd. 3.

²⁸ Ex. D at 86 (emphasis in original).

²⁹ Ex. K2 (Memo to the Department from MMB dated Mar. 20, 2023).

agencies. MMB further noted that local governments do not develop or enforce groundwater quality standards through ordinances or regulations.³⁰

To meet the statutory requirement, the Department must similarly determine whether, because of the lack of enforcement provisions associated with the proposed rule amendments, there is no evidence that complying with the rules will exceed \$25,000 for any small business or city.

Once the Department makes such a determination, the corrected defect may then be disregarded as harmless error despite the statutory requirement that an agency make the determination before the close of the hearing record. The purpose of the determination is to provide notice to affected small businesses and cities so that they may seek an exemption using the procedure set forth by Minn. Stat. § 14.127, subd. 3, if necessary.

The Department's failure to adequately address the cost of compliance for small businesses and cities under section 14.127 is a procedural error. However, the record does not support finding that this error caused actual prejudice to the rulemaking process. A deficient SONAR causes prejudice "when it does not adequately preview the agency's intentions, evidence, and rationale so as to afford parties the opportunity to meaningfully participate in the rulemaking process."³¹

Here, the Department frequently revises the HRLs and it demonstrated that it makes more than reasonable efforts to notify affected parties. The Department has amassed and maintains a large subscriber list of interested and affected parties and it sends notice of its proposed rules to these individuals and entities.³² Under its approved Additional Notice Plan in this matter, the Department sent notice of the proposed HRL rules to over 4,000 subscribers enrolled in its GovDelivery Water Rules, Guidance and Chemical Review Account. Subscribers to this account represent interested stakeholders, including trade associations and industry advocates, state agencies, chemical manufacturers, and environmental advocacy groups.³³ Judge Mortenson approved the Department's notice practice and commended its extensive additional notice plan and decision to hold two public rulemaking hearings.³⁴

Though the Department must cure the defect, as explained herein, there is no evidence the Department's failure to discuss compliance costs for small businesses or cities deprived parties of adequate notice or of the opportunity to "meaningfully participate in the rulemaking process."³⁵ The Department received six written comments prior to the

³⁰ *Id.*

³¹ *Builders Ass'n of Twin Cities v. Board of Electricity*, 965 N.W.2d 350, 361 (Minn. Ct. App. 2021).

³² Report of the Administrative Law Judge at 17 (July 10, 2023).

³³ *Id.*; Ex. D at 82-83; Ex. H.

³⁴ Report of the Administrative Law Judge at 17-18.

³⁵ Minn. Stat. § 14.15, subd. 5. *See Builders Ass'n of Twin Cities v. Board of Electricity*, 965 N.W.2d 350, 361 (Minn. Ct. App. 2021).

rulemaking hearings and four written comments were submitted after the hearings. None of the comments addressed possible compliance costs for small businesses and cities.³⁶

The Department may cure its procedural error by supplementing its SONAR to make the required determination under Minn. Stat. § 14.127, and by including information regarding this determination in its order adopting rules.

While the Department's supplementation of the record does not give rise to prejudice, it is also recommended that the Department take note of this analysis and ensure that it includes the necessary determination in the SONAR when it next undertakes efforts to revise HRLs. This issue has been addressed in several prior reports issued by Administrative Law Judges on the Department's past rule proposals governing HRLs for groundwater. In those reports, the administrative law judges found the Department's determination under section 14.127 to be inadequate for the same or similar reasons to those expressed here.³⁷

B. Regulatory Analysis Under Minn. Stat. § 14.131

Under the Administrative Procedure Act, an agency adopting or amending its rules must address eight factors in its SONAR, to the extent the agency, through reasonable effort, can ascertain the information.³⁸ In his Report, Administrative Law Judge Mortenson found that the Department failed to adequately address and analyze costs under Minn. Stat. § 14.131(2), (5) and (6).³⁹

Minn. Stat. § 14.131(2) requires the Department to address: "probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues." In response to this factor, the Department stated:

The proposed amendments *do not* have any direct impact on state revenues. There are no fees associated with the rules. The amendments simply provide health-based levels for certain water contaminants. Other agencies might choose to implement and enforce these amendments. Other agencies that apply HRL values will need to determine costs on a case-by-case basis.⁴⁰

Judge Mortenson found the Department failed to adequately address or assess probable costs of implementation or enforcement of the proposed rules by it or other

³⁶ Ex. I; Comments of S. Paske; J. Wegenius, B. Losey, W. Reeves (on file with the Off. Admin. Hearings). See Report of the Administrative Law Judge at 2.

³⁷ See *In the Matter of (ITMO) the Proposed Rules Governing Health Risk Limits for Groundwater*, OAH No. 15-0900-19846-1, Report of the Administrative Law Judge ((Dec. 11, 2008); *ITMO the Proposed Rules of the Department of Health Relating to the Rules on Health Risk Limits for Groundwater*, OAH No. 68-0900-32663, Order on Review of Rules under Minn. Stat. § 14.26 (Nov. 19, 2015); and *ITMO the Proposed Rules of the Department of Health Relating to Health Risk Limits in Groundwater*, OAH No. 82-9000-34834, Report of the Administrative Law Judge (May 29, 2018).

³⁸ Minn. Stat. § 14.131.

³⁹ Report of the Administrative Law Judge at 21-27.

⁴⁰ Ex. D at 76.

agencies.⁴¹ Judge Mortenson noted that other units within the Department and other state agencies use HRLs in their regulatory practices related to groundwater management and protection.⁴² Judge Mortenson found that there are probable costs for these agencies associated with monitoring, detecting, and remediating groundwater contaminants as determined by the HRL values.⁴³ According to Judge Mortenson, the Department failed to make a reasonable effort to identify and address these probable enforcement costs.⁴⁴

The Chief Judge respectfully disagrees. The proposed rule amendments ensure that the HRL values identified by the rule incorporate the latest scientific findings, including the most recent water intake rates values from the EPA. The proposed rule amendment does not specify how to apply or enforce those values. Other agencies, including the MPCA and DNR, are authorized to adopt and enforce water protection requirements that use HRL values as part of their enforcement framework. Those other agencies are not enforcing the Department's proposed rule. Rather, they are enforcing water quality regulations under their jurisdiction.⁴⁵ As a result, there are no probable costs to address regarding other agencies and "the implementation and enforcement of *the* proposed rule."⁴⁶

Minn. Stat. § 14.131(5) requires the Department to address: "the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals." In responding to this regulatory factor, the Department again reiterated that its proposed HRL rules only establish limits for contaminants, and do not specify how to apply or enforce them.⁴⁷ The Department further emphasized that the HRL values are only one set of criteria used to evaluate groundwater.⁴⁸ As a result, the Department contends it cannot quantify probable costs.

Nevertheless, the Department described generally how applying HRLs could lead to costs for parties regulated by other agencies.⁴⁹ The Department acknowledged that costs of remediation or prevention of water contamination might increase for some parties regulated by other agencies or entities following the adoption of the revised HRLs.⁵⁰ The Department noted that because the lowest proposed HRL values for 11 contaminants are lower (and therefore more stringent) than their previously adopted HRL values, affected parties may incur additional costs associated with remediating or preventing water contamination.⁵¹ The Department added, however, that costs related to implementing any of the new HRL values for chemicals not previously subject to HRLs could not be

⁴¹ Report of the Administrative Law Judge at 21-22.

⁴² *Id.* at 23.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ See Minn. Stat. §§ 103H.275, 144.35 (2022).

⁴⁶ Minn. Stat. § 14.131(2) (emphasis added).

⁴⁷ Ex. D at 78.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.* at 78.

determined and would need to be evaluated on a case-by-case basis in enforcement actions by other agencies.⁵²

Judge Mortenson found the Department's response to this factor inadequate because it failed to quantify the probable cost of compliance for regulated parties.⁵³ Judge Mortenson stated that, while implementation costs are uncertain and an "analysis may require some significant effort in coordinating and discussing with other agencies and regulated entities about what the probable costs of the new HRL limits might be, that is one of the tasks Minn. Stat. § 14.131 requires of the rulemaking agency."⁵⁴

The Chief Judge respectfully disagrees with Judge Mortenson's interpretation of section 14.131(5), particularly in this instance where the information contained in the proposed rule is not enforced by the adopting agency but instead used by other agencies to undertake enforcement through their programs. The Minnesota Supreme Court has held that an agency is not required to present trial-type facts to establish need and reasonableness.⁵⁵ Rather, the law requires agencies to address the eight regulatory factors "to the extent the agency, through reasonable effort, can ascertain the information."⁵⁶

In this instance where the rule's information is not enforced by the adopting agency but instead used by other agencies to undertake enforcement through their programs, the Chief Judge finds that, by describing generally how the rule's information can be incorporated into other agency programs and lead to costs under those programs, the Department adequately addressed the factor required by Minn. Stat. § 14.131(5).

Minn. Stat. § 14.131(6) requires the Department to assess, "the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals." In response to this regulatory factor, the Department stated that not adopting the proposed amendments would impose "immeasurable costs or consequences affecting water safety and quality."⁵⁷ The Department noted that Minnesota's groundwater is a primary source of drinking water for many Minnesotans, and that a failure to revise and update the HRLs would leave outdated standards in place hindering the state's goal to prevent water degradation and ensure there is minimal risk to human health from using water sources for drinking.⁵⁸

Judge Mortenson found the Department failed to adequately address this requirement and deemed its general statement that not adopting the HRLs would impose "immeasurable" negative consequences affecting the state's ability to prevent water degradation to be a critical defect.⁵⁹ According to Judge Mortenson, the Department must

⁵² *Id.*

⁵³ Report of the Administrative Law Judge at 25.

⁵⁴ *Id.* at 26.

⁵⁵ *Manufactured Hous. Inst. v. Pettersen*, 347 N.W.2d 238, 244 (Minn. 1984).

⁵⁶ Minn. Stat. § 14.131.

⁵⁷ Ex. D at 79.

⁵⁸ *Id.*

⁵⁹ Report of the Administrative Law Judge at 27.

specifically delineate the consequences of not adopting the proposed HRLs. Judge Mortenson suggests, for example, that the Department provide specific information about the effects that each toxin may have on different groups of people if the proposed HRL is not adopted and enforced.⁶⁰ Judge Mortenson maintains that the impact those effects may have on individuals, families, government agencies, and the economy is key to an informed and transparent rulemaking.⁶¹

The Chief Judge respectfully disagrees that the agency was required to undertake the analysis Judge Mortenson proposes. The Department has a statutory obligation to adopt HRLs by rule.⁶² As described by the Department, a failure to revise the information contained in the rule “would ignore legislative directives.”⁶³ Further leaving “outdated” information in place, creates risk for other agencies who rely on the rule’s information to be updated, as legislatively required.⁶⁴

The Chief Judge does observe that the Department’s choice of “immeasurable” to describe both “costs” and “consequences,” muddles the analysis.⁶⁵ “Immeasurable” could mean “vast” or “endless,” or could mean “incalculable.” The Chief Judge reads the phrase as meaning “incalculable,” which is consistent with the Department’s position that the proposed rule changes provide up-to-date, scientific information and do not enforce or regulate groundwater.

The Chief Judge finds that the Department adequately addressed the probable consequences of not adopting the proposed rule as required by section 14.131(6).

IV. Conclusion

The Department did not comply with the procedural requirement under Minn. Stat. § 14.127 but may cure this defect. The Department should supplement its SONAR to make an explicit determination under section 14.127, and then revise its order adopting rules to note the change. In all other respects the rules are approved.

J. S.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² See Minn. Stat. § 103H.201, subd. 2(a).

⁶³ Ex. D at 79.

⁶⁴ *Id.*

⁶⁵ *Id.*

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE DEPARTMENT OF HEALTH

In the Matter of the Proposed Rules of the
Department of Health for Health Risk
Limits for Groundwater, Minnesota Rules
4717.7860, .7500, and .7850

**REPORT OF THE
ADMINISTRATIVE LAW JUDGE**

Administrative Law Judge Jim Mortenson presided over public hearings in this rulemaking on April 5 and 6, 2023. The hearings were conducted virtually via WebEx and began at 9:30 a.m. on each of the dates. The Judge ensured everyone who wished to make a statement or ask a question concerning the proposed rules had the opportunity to do so.

The hearings and this Report are part of a rulemaking process governed by the Minnesota Administrative Procedure Act (MAPA).¹ The Minnesota legislature designed the rulemaking process to ensure that state agencies have met all requirements of Minnesota law for adopting rules. Those requirements include evidence that the proposed rules are necessary and reasonable, and that any modifications made by the agency after the proposed rules were initially published do not result in the rules being substantially different from what the agency originally proposed.

The rulemaking process also includes a hearing when a sufficient number of persons request one or when ordered by the Department. The hearing is intended to allow the Department and the judge reviewing the proposed rules to hear public comments regarding the impact of the proposed rules and consider what changes might be appropriate.

The Department was represented at the hearing by Tom Hogan, Environmental Health Division director; Josh Skaar, legal counsel and rules coordinator; and Sarah Fossen Johnson, supervisor and manager of the Department's Environmental Surveillance and Assessment Section. Hogan made a presentation at the hearing on April 5, 2023, as did Johnson. Only Johnson presented at the hearing on April 6, 2023. There were no questions or comments from the public during either day of the hearing.

¹ Minn. Stat. §§ 14.131-.20 (2022).

Skaar offered the Department's exhibits for the rulemaking record on April 5, and the Judge included them in the record.²

The Department received two written comments on the proposed rules from Jean Wagenius, former state representative, during the initial prehearing comment period (February 6, 2023, to March 8, 2023).³ The Department responded to the comments on March 31, 2023.⁴ In addition, comments during this period were received from four organizations: the American Chemistry Council; the Alkylphenols & Ethoxylates Research Council (APERC); Bayer Crop Science; and the American Chemistry Council Ethylene Glycol Panel. The Department responded to the comments from each of these organizations.⁵

After the hearing, the Judge kept the administrative record open for an additional 20 calendar days, until April 26, 2023, to allow interested persons and organizations, as well as the Department, to submit written comments. The Metropolitan Council submitted comments on April 7, 2023.⁶ The Department responded on April 25, 2023.⁷ Wagenius submitted additional comments on April 24, 2023.⁸ The Department responded on April 26, 2023.⁹ APERC submitted additional comments on April 26, 2023.¹⁰ The Department responded on April 26, 2023.¹¹ Bayer Crop Science submitted additional comments on April 26, 2023.¹² The Department responded on April 26, 2023.¹³

The Judge received no additional rebuttal comments and the hearing record closed on May 3, 2023.

Due to the technical complexity of the rule and written comments, and the Judge's need to carefully examine the procedural issues found, the Chief Administrative Law Judge extended the due date for this Report to July 10, 2023.¹⁴

NOTICE

Because the Judge has determined that the proposed rules are defective in certain respects, state law requires that this Report be submitted to the Chief Administrative Law Judge for her approval. If the Chief Judge approves the adverse findings contained in this

² Exhibits (Exs.) A through K and subparts.

³ Exs. 1.2.a.i and 1.2.b.ii.

⁴ Exs. 1.2.a.ii. and 1.2.b.ii.

⁵ Ex. 1.2.c.ii, 1.2.d.ii., 1.2.e.ii., and 1.2.f.ii.

⁶ Letter to Nancy Rice from Sam Paske, dated Mar. 23, 2023 (on file with the Minn. Off. Admin. Hearings).

⁷ Letter to S. Paske from S. Johnson, dated April 24, 2023 (on file with the Minn. Off. Admin. Hearings).

⁸ Comment by J. Wagenius (Apr. 24, 2023) (on file with the Minn. Off. Admin. Hearings).

⁹ Letter to J. Wagenius from S. Johnson, dated Apr. 26, 2023) (on file with the Minn. Off. Admin. Hearings).

¹⁰ Comment by Barbara Losey (Apr. 26, 2023) (on file with the Minn. Off. Admin. Hearings).

¹¹ Letter to B. Losey from S. Johnson, dated Apr. 26, 2023 (on file with the Minn. Off. Admin. Hearings).

¹² Comment by William Reeves (Apr. 26, 2023) (on file with the Minn. Off. Admin. Hearings).

¹³ Letter to W. Reeves from S. Johnson, dated Apr. 26, 2023 (on file with the Minn. Off. Admin. Hearings).

¹⁴ Order Extending Deadline (May 22, 2023); Second Order Extending Deadline (June 29, 2023).

Report, she will advise the Department of actions that will correct the defects, and the Department may not adopt the rules until the Chief Judge determines that the defects have been corrected. However, if the Chief Judge identifies defects that relate to the issues of need or reasonableness, the Department may either adopt the actions suggested by the Chief Judge to cure the defects or, in the alternative, submit the proposed rules to the Legislative Coordinating Commission for the Commission's advice and comment. The Department may not adopt the rules until it has received and considered the advice of the Commission. However, the Department is not required to wait for the Commission's advice for more than 60 days after the Commission has received the Department's submission.

If the Department elects to adopt the actions suggested by the Chief Judge and make no other changes and the Chief Judge determines that the defects have been corrected, it may proceed to adopt the rules. If the Department makes changes in the rules other than those suggested by the Administrative Law Judge and the Chief Judge, it must submit copies of the rules showing its changes, the rules as initially proposed, and the proposed order adopting the rules to the Chief Judge for a review of those changes before it may adopt the rules in final form.

After adopting the final version of the rules, the Department must submit them to the Revisor of Statutes for a review of their form. If the Revisor of Statutes approves the form of the rules, the Revisor will submit certified copies to the Administrative Law Judge, who will then review them and file them with the Secretary of State. When they are filed with the Secretary of State, the Judge will notify the Department, and the Department will notify those persons who requested to be informed of their filing.

REPORT SUMMARY

The legislature's regulatory framework for protecting groundwater for the benefit of human health is complex and involves many government agencies and laws. The Department of Health is just one agency with responsibility for the protection of groundwater for the benefit of people. This rulemaking concerns a single aspect of the complex regulatory scheme. That aspect is the level of a pollutant in groundwater caused by human activity. It is the Department's job to determine the level at which a given substance or chemical is a "potential drinking water contaminant" and, therefore, a pollutant.¹⁵

In this rulemaking, the Department established its statutory authority to adopt the proposed rules and the scientific basis for its proposed amendments to the rule. It also established it followed and implemented notice and public engagement requirements. The Department did not, however, address the cost-benefit analysis required for rulemaking under Minn. Stat. §§ 14.127, .131 (2), (5), and (6).

¹⁵ Minn. Stat. §§ 103H.001, .005, subds. 3, 11 (2022).

This finding was difficult to make because in prior amendments to this rule the Department was rarely held to the cost analysis requirements.¹⁶ A key problem leading to the defects is that the Department views the health risk limits (HRLs) as suggested guidance. Rules, by definition, must have the force and effect of law.¹⁷ Chapter 103H does not state, as the Department claims, that HRLs do not have the force and effect of law. They are, in fact, limits which, when exceeded, trigger additional regulatory action by any number of agencies, including the Department.¹⁸

Based on a careful examination of the law, the Department's explanations, and prior decisions of administrative law judges, this Judge does not agree that HRLs are only guidance which lack the force and effect of law and therefore do not require a reasonable effort to ascertain information about the probable costs related to the rules. As explained in this Report, the Department must provide information on those costs to meet the requirements of Minn. Stat. §§ 14.127 and 14.131. Moreover, such cost analyses may trigger additional notice requirements for appropriate affected parties or classes of people who may then wish to weigh in on the proposed changes. To the extent that legally required cost analyses are absent or deficient, the proposed rules are defective and must be **DISAPPROVED**.

As a result of this finding, this Report is submitted to the Chief Administrative Law Judge for approval.

Based on the administrative record and applicable law, the Judge makes the following:

¹⁶ Judge Beverly Jones Heydinger found a defect in 2008 when the Department failed to make an explicit determination about costs of compliance for small businesses. *In the matter of the Proposed Rules Governing Health Risk Limits for Groundwater*, 2015 WL 5427556, OAH No. 15-0900-19846-1 Report of the Administrative Law Judge at 18, 51-52 (Dec. 11, 2008), Chief Judge's Order (Dec. 15, 2008); *See also*, *In the matter of the Proposed Rules of the Department of Health Relating to the Rules on the Health Risk Limits for Groundwater*, 2015 WL 4518139, OAH No. 68-0900-32663, Order on Review of Rules Under Minn. Stat. § 14.26 at 3 (Nov. 19, 2015) (Judge Jeanne Cochran cautioned the Department to demonstrate compliance with the required statutory cost analysis under section 14.127); *In the matter of the Proposed Rules of the Department of Health Relating to Health Risk Limits in Groundwater*, OAH No. 82-9000-34834 Report of the Administrative Law Judge at 18 (May 29, 2018).

¹⁷ Minn. Stat. § 14.02, subd. 4 (2022); Minn. R. 1400.2100 (G) (2021). *See also* Minn. Stat. § 103H.005, subd. 3 "Health risk limits' means a concentration of a substance or chemical adopted by rule of the commissioner of health that is a potential drinking water contaminant because of a systemic or carcinogenic toxicological result from consumption."

¹⁸ *See e.g.*, Minn. Stat. §§ 103G.105; 103H.101, .105, .111, .151, .201, .251, .275, .280; 144.35 (2022).

FINDINGS OF FACT

I. Nature of the Proposed Rules

1. It is the State's goal to maintain groundwater in its natural condition, free from human-caused pollution.¹⁹

2. The Commissioner of the Department has "general charge of all springs, wells, ponds, and streams" "used as a source of water supply for domestic use."²⁰ State law prohibits the pollution of such water sources.²¹ The Commissioner is required to "take all necessary and proper steps to preserve [domestic water sources] from such pollution as may endanger the public health."²² The legislature authorizes the Commissioner to "order any person to desist from causing such pollution and to comply with such direction as the commissioner may deem proper and expedient in the premises."²³

3. Because the legislature recognizes that the goal to prevent human-caused pollution cannot be practicably achieved, multiple government agencies and private landowners have duties to work toward prevention of ground water degradation.²⁴ Part of the Department's role in preventing and addressing water pollution is prescribed in Minn. Stat. § 103H.201. When groundwater quality monitoring results show a degradation of groundwater, the Commissioner of the Department has authority to promulgate HRLs for substances degrading the groundwater.²⁵ This rulemaking concerns the promulgation of HRLs.

4. Once HRLs are adopted in rule and filed with the Secretary of State, they "have the force and effect of law five working days after [their] notice of adoption is published in the State Register."²⁶

5. Minnesota law defines HRLs as:

a concentration of a substance or chemical adopted by rule of the commissioner of health that is a potential drinking water contaminant because of a systemic or carcinogenic toxicological result from consumption.²⁷

¹⁹ Minn. Stat. § 103H.001.

²⁰ Minn. Stat. § 144.35 (2022).

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ Minn. Stat. §§ 103H.001, .015, .111, .151, .175.

²⁵ Minn. Stat. § 103H.201, subd. 1(a).

²⁶ Minn. Stat. § 14.38, subd. 1; see *also* subd. 4 (2022).

²⁷ Minn. Stat. § 103H.005, subd. 3.

6. HRLs are expressed as micrograms of a chemical per liter of water ($\mu\text{g/L}$).²⁸

7. For a degrading substance which is a systemic toxicant that is not carcinogenic, the HRL must be determined using United States Environmental Protection Agency (EPA) risk assessment methods using a reference dose, a drinking water equivalent, and a relative source contribution factor.²⁹

8. For a degrading substance which is a toxicant that is a known or probable carcinogen, the HRL must be determined from a quantitative estimate of the chemical's carcinogenic potency published by the EPA or determined by the Commissioner to have undergone thorough scientific review.³⁰

9. The legislature requires that HRLs be adopted by rule.³¹ HRLs must be reviewed at least every four years and, if appropriate, revised.³²

10. This rulemaking concerns the Department's proposal to amend the rules on HRLs for groundwater (Minn. R. 4717.7860), and to repeal certain subparts (Minn. R. 4717.7500 subps. 11, 15, 34a, 45a, 54, 58a, 61, and .7850 subp. 2(E)). This rulemaking revises the HRLs for 19 groundwater contaminants, adds 17 new contaminants with HRLs, and repeals one contaminant.³³

11. Specifically, the proposed amendments concern the following 19 contaminants:³⁴

- (1) Acetone
- (2) Biphenyl
- (3) Bromodichloromethane
- (4) 1,4-Dichlorobenzene
- (5) Trans-1,2 Dichloroethene
- (6) 1,1- Dichloroethylene
- (7) 1,2-Dichloropropane
- (8) Ethylbenzene
- (9) Ethylene Glycol
- (10) Fluorene
- (11) Manganese
- (12) Metolachlor and s-metolachlor
- (13) Metolachlor ESA
- (14) Metolachlor OXA

²⁸ Minn. R. 4717.7820, subp. 17 (2021); Statement of Need and Reasonableness (SONAR) at 7.

²⁹ Minn. Stat. § 103H.005, subd. 1(c).

³⁰ *Id.* at subd. 1(d).

³¹ Minn. Stat. § 103H.201, subd. 1(a).

³² *Id.* at subd. 3.

³³ Ex. D, SONAR at 9.

³⁴ *Id.* at 10-11.

- (15) Perfluorobutane sulfonate (PFBS)
- (16) Tetrachloroethylene (PERC or PCE)
- (17) Toluene
- (18) 1,3,5-Trimethylbenzene
- (19) Xylenes

12. The proposed amendments repeal the HRL for n-hexane.³⁵

13. The proposed amendments add HRLs for the following 17 contaminants:³⁶

- (1) Aminomethylphosphonic acid (AMPA)
- (2) Benzo[a]pyrene
- (3) Benzophenone
- (4) 1H-Benzotriazole
- (5) 17 α -Ethinylestradiol
- (6) Fomesafen
- (7) Imidacloprid
- (8) Nonylphenol
- (9) 4-tert-Octylphenol
- (10) Perflurohexane sulfonate (PFBS)
- (11) Perflurohexanoate (PFHxA)
- (12) Quinoline
- (13) 1,2,3-Trimethylbenzene
- (14) 1,2,4- Trimethylbenzene
- (15) Tris(2-butoxyethyl) phosphate (TBEP)
- (16) Tris(1,3-dichloroisopropyl)phosphate (TDCPP)
- (17) Venlafaxine

14. Safe drinking water standards established or revised by the Commissioner must be: (1) based on scientifically acceptable, peer-reviewed information; and (2) address a comprehensive set of factors pertaining to human health and development.³⁷ The legislature specifically requires the Commissioner, when establishing or revising safe drinking water standards, to:

include a reasonable margin of safety to adequately protect the health of infants, children, and adults by taking into consideration risks to each of the following health outcomes: reproductive development and function, respiratory function, immunologic suppression or hypersensitization, development of the brain and nervous system, endocrine (hormonal)

³⁵ Ex. D at 9, 10.

³⁶ *Id.* at 10-11.

³⁷ Minn. Stat. § 144.0751 (2022); Ex. D at 3.

function, cancer, general infant and child development, and any other important health outcomes identified by the commissioner.³⁸

15. In formulating HRL values, the Department uses calculations based on toxicity, intake rate, and uncertainty factors (to account for what is not known about a chemical's toxicity to humans).³⁹ These formulae are set forth in rule at Minn. R. 4717.7830, and .7840 (2021).

16. The Department selected the contaminants for these amendments based on two separate nominating processes. In the first process, the Department held an annual meeting for representatives from relevant agencies, including the Department of Agriculture (MDA) and the Pollution Control Agency (PCA), to discuss their concerns about specific contaminants. Chemicals are ranked according to each agency's need for new or updated water guidance. A final list of priority chemicals is generated from the first process.⁴⁰

17. In the second process, anyone may nominate chemicals through the Department's Contaminants of Emerging Concern (CEC) program website or by contacting the Department. The Department then screens these chemicals for toxicity and exposure potential and ranks them for review priority.⁴¹

18. The Department also routinely reevaluates previously adopted HRLs. Twenty contaminant HRLs that were adopted from 2009 to 2013 were reevaluated from 2017 to 2022. Revised HRLs based on this reevaluation are included in the proposed rule.⁴²

19. The Department posted information regarding the chemical review on the Department's "Chemicals Under Review" webpage (<https://www.health.state.mn.us/communities/environment/risk/review.html>), including the chemical's name, its Chemical Abstracts Service (CAS) Registry Number, and the date it was posted.⁴³ Upon completion of each chemical review, the Department posted the guidance values and the chemical-specific summary sheets on the Human Health Based Water Based Guidance webpage (<https://www.health.state.mn.us/communities/environment/risk/guidance/gw/table.html>). The Department also notified subscribers to the Department's Groundwater Rules, Guidance and Chemical Review email notification account about the new or updated guidance.⁴⁴

³⁸ Minn. Stat. § 144.0751 (a)(2).

³⁹ Ex. D at Appendix C.

⁴⁰ Ex. D at 11-12.

⁴¹ *Id.* at 12.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

20. The Department utilized the 2009 methodology to derive the proposed HRL values.⁴⁵ According to the Department, these methods align with current scientific risk-assessment principles, and it does not intend to modify these methods for the current proposed amendments.⁴⁶ However, the Department uses the most recent water intake rates from the EPA, last updated in 2019.⁴⁷

21. The Department notes that applying revised EPA intake rates to prior HRL values, results in changes to HRL values.⁴⁸ These fluctuations in the intake values are associated with various factors, including:

- Extent and quality of toxicity data for a chemical;
- Application of dosimetric adjustment factors (DAFs) to derive human equivalency doses (HEDs) which are used to estimate the amount of a chemical a human would need to ingest to have the same exposure as the tested animal; and
- Changes in water intake rates within the guidance algorithms to consider the effect on sensitive subpopulations (e.g., infants and children).⁴⁹

22. The following table shows the current lowest HRL values and the proposed new HRL values for the 19 contaminants with current HRLs which are being amended in some way.⁵⁰

Table 1. Comparison of Lowest Current HRL and Lowest Proposed HRL, by Chemical⁵¹

| Chemical Abstract Service Number | Chemical Name | Current Lowest HRL (µg/L) | Proposed Lowest HRL (µg/L) |
|----------------------------------|-----------------|------------------------------|----------------------------|
| 67-64-1 | Acetone | 4000 (chronic) (2011 HRL) | 3000 (chronic) |
| 92-52-4 | Biphenyl | 300 (chronic) | 10 (cancer) |

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.* at 13.

⁴⁹ *Id.* at 13-14.

⁵⁰ *Id.* at 14-15.

⁵¹ *Id.* at 20-21.

| | | | |
|--|---|-----------------------------|------------------|
| | | (1993 HRL) | |
| 75-27-4 | Bromodichloromethane | 6 (cancer) (1993 HRL) | 3 (cancer) |
| 106-46-7 | 1,4-Dichlorobenzene | 10 (cancer) (1994 HRL) | 50 (short-term) |
| 156-60-5 | trans-1,2 Dichloroethene | 40 (chronic) (2013 HRL) | 9 (chronic) |
| 75-35-4 | 1,1- Dichloroethylene | 200 (chronic) (2011 HRL) | 200 (chronic) |
| 78-87-5 | 1,2-Dichloropropane | 5 (cancer) (1994 HRL) | 3 (cancer) |
| 100-41-4 | Ethylbenzene | 50 (short-term) (2011 HRL) | 40 (short-term) |
| 107-21-1 | Ethylene Glycol | 2000 (chronic) (2011 HRL) | 2000 (chronic) |
| 86-73-7 | Fluorene | 300 (chronic) (1993 HRL) | 80 (chronic) |
| 7439-96-5 | Manganese | 100 (chronic) (1993 HRL) | 100 (short-term) |
| 51218-45-2;87392-12-9 | Metolachlor and s-metolachlor | 300 (subchronic) (2011 HRL) | 300 (short-term) |
| 171118-09-5 | Metolachlor ESA | 800 (chronic) (2011 HRL) | 1000 (chronic) |
| 152019-73-3 | Metolachlor OXA | 800 (chronic) (2011 HRL) | 1000 (chronic) |
| 45187-15-3;375-73-5; 29420-49-3; 68259-10-9; 60453-91-4 | Perfluorobutane Sulfonate (PFBS) | 7 (chronic) (2011 HRL) | 0.1 (short-term) |
| 127-18-4 | Tetrachloroethylene | 5 (chronic) (2009) | 4 (cancer) |

| | | HRL _{MCL} | |
|------------------|-------------------------------|--------------------------------|------------------|
| 108-88-3 | Toluene | 200 (short-term) (2011 HRL) | 70 (short-term) |
| 108-67-8 | 1,3,5-Trimethylbenzene | 100 (short-term) (2009 HRL) | 30 (short-term) |
| 1130-20-7 | Xylenes | 300 (short-term) (2011 HRL) | 300 (subchronic) |

23. The Department uses two methods to derive HRL values depending on whether a dose can be found that causes no harm in animals or people. Historically, and consistent with statute, these methods were applied according to the type of health effect that the chemical exposure caused, relying on “non-cancer” and “cancer” outcomes. The scientific community, however, recognizes that chemicals are better assessed based on what is known about finding a dose that causes no harm, regardless of the health effect.⁵²

24. A dose or exposure below which the chemical does no harm or has no effect on the animal tested is called “the threshold.” Many carcinogens - chemicals that cause cancer - only do so after exposure to high doses. Cancer and other health effects will not occur at a dose lower than the threshold dose. Therefore, the threshold is protective of harmful effects, including for cancer. This “threshold method” has been called a “non-linear method” and is used by the Department for any chemical exhibiting a threshold, including many carcinogens.⁵³

25. The Department notes that some carcinogens and neurotoxicants (such as lead) have no apparent threshold because every dose tested shows a potentially harmful effect. Therefore, the Department uses a method for these chemicals which presumes that any exposure carries some risk of harm. This non-threshold method is based on carcinogenic potency and has only been used for carcinogens that do not show a threshold.⁵⁴

26. Twelve chemicals in the proposed HRL amendments are carcinogenic or possibly carcinogenic. Five chemicals (benzophenone, 1,4-dichlorobenzene, 17 alpha-ethinylestradiol, metolachlor, and s-metolachlor) are considered nonlinear (threshold) carcinogens; their chronic non-cancer values are considered protective of public health. The other seven chemicals (benzo[a]pyrene, biphenyl, bromodichloromethane, 1,2-dichloropropane, quinoline, tetrachloroethylene, and tris(1,3-

⁵² *Id.* at 15; See Minn. Stat. § 103H.201, subd. 1.

⁵³ *Id.* at 15-16.

⁵⁴ *Id.* at 16.

dichloroisopropyl)phosphate) do not have thresholds and, therefore, a linear approach was used to derive a cancer guidance value.⁵⁵

27. Contaminants for the proposed amendments were chosen by the Department based on input from several different sources. Internal sources include the Site Assessment and Consultation Unit, Drinking Water Protection Section, and Contaminants of Emerging Concern. The Department also received nominations for contaminants from state agency partners, including the Pollution Control Agency (MPCA) and the Department of Agriculture (MDA). The public can provide input through some of these systems and agencies. The Department also systematically evaluates HRLs to determine whether they remain up to date.⁵⁶

II. Rulemaking Legal Standards

28. In a rulemaking proceeding, the agency must establish the need for and reasonableness of the proposed rules by an affirmative presentation of facts.⁵⁷ To support a rule, an agency may rely on legislative facts, including general facts concerning questions of law, policy, and discretion, or it may simply rely on interpretation of a statute or stated policy preferences.⁵⁸

29. The Department prepared a Statement of Need and Reasonableness (SONAR) in support of the proposed rules. At the hearing, the Department primarily relied on the SONAR for the affirmative presentation of facts in support of the proposed rules.⁵⁹ The SONAR was supplemented by the Department's written post-hearing submissions.

30. A rule must be "rationally related to the objective sought to be achieved."⁶⁰ Thus, any inquiry as to a rule's reasonableness requires "a searching and careful inquiry of the record to ensure that the agency action has a rational basis."⁶¹ The agency must "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."⁶²

31. Although reasonable minds might disagree about the wisdom of a certain course of action, it is not the administrative law judge's role to determine which policy alternative presents the "best" approach, because this would invade the policy-making

⁵⁵ *Id.*

⁵⁶ *Id.* at 120 (Appendix D).

⁵⁷ Minn. Stat. § 14.14, subd. 2 (2022); Minn. R. 1400.2100 (2021).

⁵⁸ See *Mammenga v. Dep't of Human Servs.*, 442 N.W.2d 786, 791-92 (Minn. 1989); *Manufactured Hous. Inst. v. Petterson*, 347 N.W.2d 238, 244 (Minn. 1984).

⁵⁹ Ex. D.

⁶⁰ *Builders Ass'n of Twin Cities v. Minn. Dep't of Labor and Industry*, 872 N.W.2d 263, 268 (Minn. Ct. App. 2015) (quotation omitted).

⁶¹ *Id.*

⁶² *Petterson*, 347 N.W.2d at 244.

discretion of the agency.⁶³ Similarly, “a reviewing court will not substitute its judgment if an agency can demonstrate that it has complied with rulemaking procedures and made a considered and rational decision.”⁶⁴

32. In addition to need and reasonableness, the administrative law judge must also assess whether: (1) the agency complied with the rule-adoption procedures; (2) the proposed rules grant undue discretion to the agency; (3) the agency has statutory authority to adopt the rules; (4) the rules are unconstitutional or illegal; (5) the rules involve an undue delegation of authority to another entity; or (6) the proposed language is a rule.⁶⁵

33. If changes to the proposed rule are made by the agency or suggested by the administrative law judge after original publication of the rule in the *State Register*, the judge must also determine if the new language is substantially different from that which was originally proposed. Minn. Stat. § 14.05, subd. 2 (2022) sets forth the applicable standards to determine whether the changes create a substantially different rule. Under the statute, a modification does not make a proposed rule substantially different if: (1) the differences are within the scope of the matter announced in the notice of hearing and are in character with the issues raised in that notice; (2) the differences are a logical outgrowth of the contents of the notice of hearing and the comments submitted in response to the notice; and (3) the notice of hearing provided fair warning that the outcome of the rulemaking proceeding could be the rule in question.⁶⁶

34. In determining whether modifications result in a rule that is substantially different, the administrative law judge must consider whether: (1) persons who will be affected by the rule should have understood that the rulemaking proceeding could affect their interests; (2) the subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the notice of hearing; and (3) the effects of the rule differ from the effects of the proposed rule contained in the notice of hearing.⁶⁷

III. Procedural Requirements of Minn. R. Ch. 14

A. Publications

35. On January 19, 2021, the Department published a Request for Comments on possible amendments to the current HRL rules in the *State Register*.⁶⁸ That same day, the Department directly notified 12 industry representatives, environmental advocacy

⁶³ See *Minn. Env'tl. Science and Econ. Review Bd. v. Minn. Pollution Control Agency*, 870 N.W.2d 97, 102 (Minn. Ct. App. 2015) (“An agency decision, including rulemaking, enjoys a presumption of correctness and a court should defer to an agency’s expertise and special knowledge.” (quotation omitted)).

⁶⁴ *Id.* at 98.

⁶⁵ Minn. R. 1400.2100.

⁶⁶ Minn. Stat. § 14.05, subd. 2(b) (2022).

⁶⁷ *Id.*, subd. 2(c).

⁶⁸ 45 Minn. Reg. 29, 792-93 (Jan. 19, 2021).

organization staff, or trade organization staff who had requested notification of HRL rulemaking activity, as well as 11 interested staff members from other state agencies.⁶⁹ The Department also notified, via GovDelivery email, 4,169 subscribers of the Water Rules, Guidance and Chemical Review. The email contained the Request for Comments, as published in the *State Register*, a listing of the contaminants under consideration, and links to the Department's HRL Rules webpage.⁷⁰

36. In February 2021, the Department published an article about the HRL Request for Comments in the Spring 2021 issue of the Department's *Waterline* newsletter, which is sent to 5,700 email subscribers and 5,200 subscribers by U.S. mail.⁷¹

37. On January 10, 2022, the Department provided notice to 27 parties concerning a meeting on the possible amendments to the HRL rules, which was scheduled for February 2, 2022.⁷² The Department also emailed notice about the public meeting to 4,723 subscribers to its GovDelivery service on January 10, 2022.⁷³

38. On January 12, 2023, the Department requested review and approval of its Additional Notice Plan and Notice of Hearing from the Judge. On January 19, 2023, the Judge issued an Order Approving the Additional Notice Plan and Notice of Hearing. The Notice of Hearing was approved contingent on the addition of the signature of the person authorized to give notice of the intent to adopt rules and notice of hearing, and the date the person signed the notice.⁷⁴

39. On January 12, 2023, the Department also requested authorization to omit the text of the proposed rule from the Notice of Hearing, pursuant to Minn. Stat. § 14.14, subd. 1a(b) (2022). On January 20, 2023, the Chief Administrative Law Judge issued an order approving the requested omission.⁷⁵

40. On February 1, 2023, the Department mailed and emailed a copy of the SONAR to the Legislative Reference Library, as required by Minn. Stat. §§ 14.131, .23.⁷⁶

41. On February 1, 2023, the Department provided notice of the rulemaking to legislative chairs and minority leaders, as required by Minn. Stat. § 14.116 (2022).⁷⁷

⁶⁹ Ex. D at 83; Ex. H.1.a.

⁷⁰ Ex. D at 83; Ex. H.1.b.

⁷¹ Ex. H.1.c. The Department noted that there may be some overlap between the two lists.

⁷² Ex. H.2.a.

⁷³ Ex. H.2.b.

⁷⁴ Order on Review of Additional Notice Plan and Notice of Hearing (Jan. 19, 2023).

⁷⁵ Order on Request to Omit from the Notice the Text of Proposed Rules (Jan. 20, 2023).

⁷⁶ Ex. E (Certificate of Mailing the SONAR to the Legislative Reference Library and letter to the Legislative Reference Library).

⁷⁷ Ex. K.1.

42. Also on February 1, 2023, the Department mailed the Notice of Hearing to the people on the Department's mailing list and emailed the Notice to people on the Department's mailing list who requested notification by email.⁷⁸ Cretia Weaver, legal secretary, certified that the mailing list was accurate as of January 10, 2023.⁷⁹

43. The Department certified that on February 1 and 2, 2023, notice was provided in accordance with the Additional Notice Plan approved on January 19, 2023. The notice advised that a Notice of Hearing would be published in the *State Register* on February 6, 2023; that a prehearing comment period would be open from February 6 through March 8, 2023; that public hearings would be held on April 5 and 6, 2023, at 9:30 a.m.; and that comments could be made at the public hearings or following the public hearings.⁸⁰

44. The Department certified that, on February 3, 2023, it provided additional notification to the 5,636 subscribers of its relevant GovDelivery service. The notice advised that a Notice of Hearing would be published in the *State Register* on February 6, 2023; that a prehearing comment period would be open from February 6 through March 8, 2023; and that public hearings would be held on April 5 and 6, 2023, at 9:30 a.m. The notice also contained a description on how to participate and a link to the Department's website where the public could review all of the rulemaking documents.⁸¹

45. On February 6, 2023, the Department published the Notice of Hearing in the *State Register*.⁸²

46. Two public hearings on the proposed amended rules were held on April 5 and 6, 2023. The hearings were held virtually to enable maximum public participation from diverse locations across the state. During the hearing, the Department submitted the following documents, which the Judge received into the hearing record:⁸³

- Exhibit A: Request for Comments published in the *State Register* on January 19, 2021 (45 Minn. Reg. 29);
- Exhibit C: Proposed rules amending Minnesota Rules Chapter 4717 including the Revisor's approval for publication;
- Exhibit D: SONAR (dated Jan. 26, 2023), including appendices A - F;

⁷⁸ Ex. G.1; Ex. G.2.

⁷⁹ Ex. G.3.

⁸⁰ Ex. H.3.a.

⁸¹ Ex. H.3.b.

⁸² 47 Minn. Reg. 32, 761-63 (Feb. 6, 2023).

⁸³ The list of exhibits appears to be missing exhibits. This is because some exhibit labels (e.g. Exhibit B) were not used; it is not because a proposed exhibit was not admitted into the record.

- Exhibit E: Certificate of Mailing the SONAR to the Legislative Reference Library and copy of the transmittal letter to the Legislative Reference Library (dated Feb. 1, 2023);
- Exhibit F: Dual Notice of Intent to Adopt Rules as mailed on February 1, 2023, and as published in the *State Register* on February 6, 2023;
- Exhibit G: Certificate attesting that the Department mailed and emailed the Notice of Hearing to persons and associations on the Department's mailing list and the certificate of the accuracy of the mailing list;
- Exhibit H: Certificates of giving additional notice of the Requests for Comments (Jan. 19, 2021, and Spring 2021), public meeting on Jan. 10, 2022, and Notice of Hearing;
- Exhibit I: All written comments on the proposed rules received by the Department between January 19, 2021, and February 5, 2023, as well as the Department's responses; and written comments received between February 6, 2023, and March 8, 2023;
- Exhibit J: Chief Administrative Law Judge's Order permitting the Department to omit the text of the proposed rule from the Notice (dated Jan. 20, 2023); and
- Exhibit K: The Certificate of Notice to legislators and the Legislative Coordinating Commission (dated Feb. 1, 2023); Response from the Minnesota Management and Budget (MMB) on the fiscal impact of the proposed rules (dated Mar. 20, 2023); and slides from the Department's presentation at the public hearings on April 5 and 6, 2023.

47. The Judge finds that the Department has met the procedural requirements imposed by the applicable above-referenced laws and rules.

B. Additional Notice

48. Minn. Stat. §§ 14.131, .23 require that the SONAR contain a description of an agency's efforts to provide additional notice to persons who may be affected by the proposed rules.

49. On January 12, 2023, the Department requested that the Office of Administrative Hearings give prior approval of its Additional Notice Plan and Notice of Hearing.⁸⁴

50. Under the Additional Notice Plan, the Department stated that it would:

- Notify the 4,045 subscribers enrolled in its GovDelivery Water Rules, Guidance and Chemical Review Account that it was contemplating changes to HRLs. (Subscribers to this account represent interested stakeholders, including trade associations and industry advocates, several state agencies, several advocacy groups, and chemical manufacturers.) This notification would include a webpage link listing the eligible contaminant guidance values.
- Publish a Request for Comments. In addition, the Department stated that it would send emails directly to 12 industry representatives, environmental advocacy organization staff, or trade organization staff who had requested notice about HRL rulemaking activity.
- Publish information about the Request for Comments in the Department publication *Waterline* in the spring of 2021. Paper copies of the *Waterline* would be sent to 5,200 subscribers and would be emailed to 5,700 subscribers. (The Department suspects there is some overlap between the paper and electronic subscribers.)
- Hold a virtual public meeting on February 2, 2022. Notice of the meeting would be sent to 4,667 email subscribers.⁸⁵

51. By Order dated January 19, 2023, the Judge approved the Department's Additional Notice Plan.⁸⁶

52. The Department certified that it provided notice of the proposed rules to all individuals and organizations included on their rulemaking mailing list, as well as to the individuals and entities identified in the Additional Notice Plan that the Judge approved on January 19, 2023.⁸⁷ The Judge finds the requirements of the Additional Notice Plan were met.

53. Fifty-three of the 54 registrants attended the February 2, 2022, meeting. Department staff gave an overview of: (1) the chemical selection and review process;

⁸⁴ Letter from Josh Skaar to Chief Administrative Law Judge Jenny Starr (Jan. 12, 2023) (on file with the Minn. Office Admin. Hearings); see Minn. R. 1400.2060 (2021).

⁸⁵ Ex. D at 83-85.

⁸⁶ Order on Review of Additional Notice Plan and Notice of Hearing (Jan. 19, 2023).

⁸⁷ Ex. H (Certificates of Giving Additional Notice Pursuant to the Additional Notice Plan).

(2) the types of guidance it develops for groundwater contaminants; and (3) the proposed HRL amendments. Following the meeting, the Department posted all of the meeting materials, including answers to questions asked at the public meeting, on its HRL rule amendments webpage.⁸⁸

54. The Judge finds that the Department has met the procedural requirements related to additional notice as imposed by applicable law and rules.

C. Statutory Authority

55. Statutory authority for creation and regulation of HRL values for water contaminants is found at Minn. Stat. § 103H.201.

56. Minn. Stat. § 103H.201, subd. 2(a) provides the authority to adopt HRLs in rule.

57. Minn. Stat. § 103H.201, subd. 3 provides the Commissioner with specific authority to review and revise HRL values at least every four years.

58. The Judge concludes that the Department has the statutory authority to adopt the proposed rules.

D. Notice Practice

1. Notice to Stakeholders

59. On February 1, 2023, the Department mailed the Dual Notice of Intent to Adopt Rules and Notice of Hearing (Notice) to stakeholders in accordance with its Additional Notice Plan.⁸⁹

60. On February 6, 2023, the Notice was published in the *State Register*.⁹⁰

61. Two public hearings on the proposed rules were held on April 5 and 6, 2023.

62. The Judge concludes the Department fulfilled its responsibility to mail the dual Notice “at least 33 days before the . . . start of the hearing.”⁹¹

⁸⁸ Ex. D at 84.

⁸⁹ Ex. F.1.

⁹⁰ Ex. F.2.

⁹¹ Minn. R. 1400.2080, subp. 6 (2021).

2. Notice to Legislators

63. On February 1, 2023, the Department provided notice of the rulemaking, including the SONAR, to legislative chairs and minority leaders, and to the Legislative Coordinating Committee, as required by Minn. Stat. § 14.116.⁹²

64. The Judge concludes that the Department fulfilled the requirements of Minn. Stat. § 14.116(b).

3. Notice to the Legislative Reference Library

65. On February 1, 2023, the Department submitted a copy of the SONAR to the Legislative Reference Library.⁹³

66. Minn. Stat. § 14.23 requires the agency to send a copy of the SONAR to the Legislative Reference Library when the Notice of Intent to Adopt is mailed.

67. The Judge concludes that the Department met the requirement of Minn. Stat. § 14.23.

E. Impact of Farming Operations

68. When rules are proposed that affect farming operations, Minn. Stat. § 14.111 (2022) requires that a copy of the proposed rule amendments be given to the Commissioner of Agriculture at least 30 days prior to publishing the proposed rules in the *State Register*. In addition, Minn. Stat. § 14.14, subd. 1b, requires that at least one public hearing be conducted in an agricultural area of the state.

69. The Department states that it did not provide notice to the Commissioner of Agriculture because the rules do not affect farming operations.⁹⁴ Department of Agriculture staff are, however, included in the direct email notifications the Department of Health sends.⁹⁵

70. It is commonly known that agricultural chemicals and practices can impact groundwater. See, e.g.: <https://www.mda.state.mn.us/segwresources>. Moreover, Minn. Stat. § 103H.151 specifically requires the “commissioner of agriculture, in consultation with local water planning authorities” to “develop best management practices for agricultural chemicals and practices.”⁹⁶

⁹² Ex. K.1.

⁹³ Ex. E.

⁹⁴ Ex. D at 84-85.

⁹⁵ *Id.*

⁹⁶ Minn. Stat. § 103H.151, subd. 2.

71. It was an error for the Department to fail to provide notice to the Commissioner of Agriculture in conformity with Minn. Stat. § 14.111. However, the Department used extensive and additional notice practices, including providing notice of the HRL rulemaking to Department of Agriculture staff. In addition, two public hearings were held virtually, enabling participants from all parts of the state to participate. As a result, the Judge finds this is a harmless error.⁹⁷ The Judge advises the Commissioner to ensure that, in future HRL rulemaking proceedings, the Department complies with the requirements of Section 14.111.

IV. Regulatory Analysis in the SONAR

72. Minn. Stat. § 14.131 requires an agency adopting rules to make a reasonable effort to ascertain eight pieces of information and record that information in the SONAR.⁹⁸ In addition, the SONAR must include the agency's description of efforts to provide additional notice to people or classes who may be affected by the proposed rule, or explain why such notice was not provided.⁹⁹ The Department's analysis of each of these factors are discussed below.

A. A description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.

73. The Department asserts that all persons in Minnesota will be affected by, and benefit from, the proposed rules because the proposed amendments affect the quality of groundwater used as drinking water by all Minnesotans.¹⁰⁰ According to the Department, how the HRL values are applied by the state agencies charged with protecting Minnesota's environment and water resources will determine who is affected.¹⁰¹

74. The Department also asserts that the proposed amendments will safeguard vulnerable populations that are sensitive or "highly exposed" to these contaminants.¹⁰²

75. The Department notes that HRLs "serve as benchmarks in state water-monitoring and contamination response programs that protect all Minnesotans' health."¹⁰³ Additionally, other rules that protect Minnesota's water resources incorporate HRL values and related chemical data, which benefits the entire state.¹⁰⁴

⁹⁷ Minn. Stat. §§ 14.14, subd. 1b, .15, subd. 5 (2022).

⁹⁸ Minn. Stat. § 14.131.

⁹⁹ *Id.*

¹⁰⁰ Ex. D at 76.

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.* Citing MCPA's solid waste and surface water rules as one example.

76. According to the Department, the proposed amendments to HRL values may have an impact on individuals or populations when contamination occurs in a public or private water supply and federal Maximum Containment Limits (MCLs) are not available.¹⁰⁵ In that circumstance, the responding agency utilizes HRL values in assessing risks from consuming contaminated water and advises the regulated party, the responsible governmental unit, the water operator, or the public on ways to eliminate or reduce risks.¹⁰⁶

77. The Department states that monetary costs associated with application of the HRLs could affect those who contaminate or degrade groundwater and communities who publicly fund the remediation of contaminated water.¹⁰⁷

78. The Department maintains that the benefits of the proposed amendments will be for those in human life stages that are sensitive or highly exposed.¹⁰⁸

79. The Judge finds that the Department has fulfilled its obligation to describe the classes of persons who probably will be affected by the proposal, including those classes who will bear the costs of the proposed rule and those classes that will benefit from it.

B. The probable costs to the Department and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

80. The Department states that the proposed rule amendments do not have any direct impact on state revenues, and that there are no fees associated with the rules.¹⁰⁹

81. According to the Department, the proposed rules simply provide health-based limits for specified groundwater contaminants.¹¹⁰ The Department maintains it is up to the state agencies that apply and enforce the HRL values to determine costs on a “case-by-case” basis.¹¹¹

82. These limits are not simply benchmarks intended for guidance. They may trigger regulatory action by the Department or other agencies.

83. The Commissioner has enforcement authority over polluted water pursuant to Minn. Stat. § 144.35. This includes groundwater that comes from wells and springs.¹¹²

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² Minn. Stat. § 144.35.

84. Under Minn. R. 1400.2100(A), a rule must be disapproved if it was not adopted in compliance with the procedural requirements of Minn. Stat. ch. 144 (2022), Minn. R. ch. 1400.2000-.2410 (2021), or other law or rule, unless the error must be disregarded as harmless error. Under the harmless error standard in Minn. Stat. § 14.15, subd. 5, an administrative law judge must disregard a defect in the proceeding due to an agency's failure to satisfy a procedural requirement if the judge finds that: (1) the defect did not deprive a person or entity of an opportunity to meaningfully participate in the proceeding; or (2) the agency took corrective action to cure the defect so that no person or entity was deprived of such an opportunity.

85. When an agency's failure to address a procedural requirement causes actual prejudice to the rulemaking process, however, the rule must be invalidated.¹¹³ A deficient SONAR causes prejudice "when it does not adequately preview the agency's intentions, evidence, and rationale so as to afford parties the opportunity to meaningfully participate in the rulemaking process."¹¹⁴

86. An agency can satisfy its obligation to discuss the probable costs that a proposed rule may impose without providing extensive details.¹¹⁵ In *Builders Ass'n of the Twin Cities v. Bd. of Elec.*,¹¹⁶ the Board of Electricity sufficiently discussed costs of compliance by identifying five rule changes and indicating that the costs would not exceed \$600 per project.¹¹⁷ Similarly, in *Water in Motion, Inc. v. Minn. Dep't of Labor and Industry*, the agency adequately identified probable costs when it discussed certain rule provisions that could increase costs and others that could result in lower costs; the Board also noted that costs were difficult to quantify, but in its judgment the rules were cost "neutral."¹¹⁸

87. The requirement that an agency identify the probable costs of a proposed rule is not onerous. The agency must simply summarize information identifying what the costs are. Here, because the Department did not provide any information about the probable costs of the rule, there is no way for the public or this tribunal to review, understand, or comment on the basis for the Department's assessments that the costs must be determined on a "case-by-case" basis.

¹¹³ See *Minn. League of Credit Unions v. Minn. Dep't of Commerce*, 486 N.W.2d 399, 405-06 (Minn. 1992); *Builders Ass'n of the Twin Cities v. Bd. of Elec.*, 965 N.W.2d 350, 360-61 (Minn. Ct. App. 2021).

¹¹⁴ *Builders Ass'n*, 965 N.W.2d at 361.

¹¹⁵ For examples of discussions of costs, see *In the Matter of the Proposed Rules of the Minnesota Dep't of Health Governing Assisted Living Facilities*, OAH No. 65-9000-37175, REPORT OF THE ADMINISTRATIVE LAW JUDGE at 15-25 (Mar. 29, 2021); *In the Matter of the Proposed Rules of the Dep't of Agriculture Governing Groundwater Protection*, OAH No. 71-9024-35205, REPORT OF THE ADMINISTRATIVE LAW JUDGE at 11-16 (Sept. 21, 2018).

¹¹⁶ 965 N.W.2d 350 (Minn. Ct. App. 2021).

¹¹⁷ *Id.* at 359.

¹¹⁸ *Water in Motion, Inc. v. Minn. Dep't of Labor and Industry*, No. A16-0335, 2016 WL 7041978 at *7-*8 (Minn. Ct. App. 2016) (stating that the agency's analysis of costs "lacks the level of detail we might prefer," but that its articulation of potential higher and lower costs associated with different portions of the rule was sufficient).

88. The Department has not made a reasonable effort to address the probable costs to the agency and other agencies of the implementation and enforcement of the proposed HRL values and anticipated effect on state revenues. This is a requirement of rulemaking and a material defect in the rules that requires disapproval. The law does not provide an exception for this requirement where costs may need to be determined on a case-by-case basis.¹¹⁹ Indeed, in any given regulatory endeavor, probable costs are likely to be derived based on consideration of varying types of cases.

89. HRLs impact how the Department and other agencies handle their duties to protect groundwater.¹²⁰ HRLs may trigger corrective measures, such as best management practices and water resource protection requirements.¹²¹ There are probable costs associated with the detection, correction, and monitoring of polluted groundwater as determined by the HRL of toxicants in such water.¹²² These costs need to be addressed in the SONAR.

C. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

90. The Department addressed both this requirement (C) and requirement D together. Please see requirement D below for the analysis.

D. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

91. The Department asserts that it has derived HRL values through scientifically sound sources and methods that ensure the protection of all Minnesotans. The methodology for carrying out statutory directives related to HRL values for contaminants was established through rulemaking in 2009, which is found in Minn. R. 4717.7820 and .7830. This methodology is not currently under review. The currently proposed amendments add new HRL values or repeal old HRL values by applying the 2009 methodology.¹²³

92. The Department explains that it follows an approximately two- to four-year cycle for developing and adopting updated or new HRL values and repealing outdated values. This process includes a step that informs and engages the public. The two- and four-year review schedule is used to guarantee that the most up-to-date toxicity information is considered in establishing HRL values.¹²⁴

¹¹⁹ Minn. Stat. § 14.127.

¹²⁰ See, e.g., Minn. Stat. §§ 103H.101; .151, .275 (2022).

¹²¹ Minn. Stat. § 103H.275.

¹²² See, e.g., Ex. D. at 76.

¹²³ Ex. D at 77-78.

¹²⁴ *Id.* at 77.

93. The Department notes that, based on the specific nature of the rules, the 2009 rulemaking already established the method for achieving the proposed rules' purpose. The Department maintains that there are no less costly or less intrusive methods for achieving the purpose of the proposed rules. The focus of this proposed rulemaking is solely the selection of specific chemicals subject to revision.¹²⁵

94. The Department explains that proposed HRL values, prior to rule adoption, often originate based on other agencies' requests. This departmental guidance, which is known as a Health-Based Value (HBV), uses the same methodology as an HRL. The Department notes that, "[w]hile all HRL values were initially HBV values, not all HBV values are adopted into rule as HRLs."¹²⁶

95. The Department acknowledges that HBV values may generate less cost to the agency since no resources have been used to adopt them into rule and risk managers may use HBV values as they would HRL values. The Department states that HBV values may be viewed by state agencies and the regulated community as "transient in nature," though, because they have not been formally adopted into rule. Accordingly, HBV values may not carry the same weight as an adopted HRL.¹²⁷ The Department asserts that HRLs adopted through rule are more beneficial to risk managers in their long-term planning due to the permanency, authority, and uniformity of rulemaking. In addition, HRLs provide standardization of water guidance statewide.¹²⁸

96. The Department rejects the possibility that the proposed chemicals be left in their outdated or HBV status, instead asserting that HBVs for groundwater contaminants derived through HRL standard methodology are eligible for rule adoption.¹²⁹

97. The Judge finds the Department determined there are not less intrusive methods for achieving the purpose of the proposed rule as required by Minn. Stat. § 14.131 (3).

98. The Judge finds the Department adequately described alternative methods for achieving the purpose of the rule and why each alternative method was rejected. In short, the legislature requires the Department to formulate the HRLs.

¹²⁵ *Id.*

¹²⁶ *Id.* at 78.

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

E. The probable costs of complying with the proposed rules, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals.

99. Minn. Stat. § 14.131 requires the Department to make a reasonable effort to ascertain “the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals.”¹³⁰

100. The Department determines limits for contaminants through the amended HRL rules but disavows the application or enforcement of these limits.¹³¹ The Department asserts that the HRLs merely provide guidance for other regulatory authorities. However, the Judge notes that the Commissioner has authority to “order any person to desist from causing such pollution and to comply with such direction as the commissioner may deem proper and expedient in the premises” where pollution is occurring, including to groundwater.¹³²

101. The Department does not quantify the probable cost of compliance with the proposed amendments. Instead, the Department provides an overview of how application of the proposed HRL amendments could lead to costs for parties regulated by other agencies.¹³³ Specifically, the Department states that agency risk managers use various criteria, including HRL values, to evaluate whether a contaminant’s concentration in groundwater poses a health risk. According to the Department, the HRL values “are not intended to be bright lines between ‘acceptable’ and ‘unacceptable’ concentrations.”¹³⁴ The Department states that the HRL values are derived using conservative methods such that exposure below an HRL value may present only minimal or no risk to human health. Likewise, the Department states that a contaminant concentration above an HRL value, without evaluating other information, may not signal a public health problem. But the authorizing statute does not reflect that the “limits” are anything but just that, and therefore are bright line triggers for action. Moreover, because the lowest proposed HRL values for 11 of the contaminants is lower than previously set values, the Department acknowledges that costs of remediation or prevention of water contamination might increase for some parties regulated by other agencies or entities.¹³⁵ The Department further notes that implementation costs for new values are uncertain and will need to be calculated on a “case-by-case” basis in enforcement circumstances.¹³⁶

¹³⁰ Minn. Stat. § 14.131 (5).

¹³¹ Ex. D at 78.

¹³² Minn. Stat. § 144.35.

¹³³ Ex. D at 78.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

102. As discussed in section B, above, HRLs are triggers for regulatory action to prevent or limit ground water pollution. Thus, “[m]onetary costs for applying the HRLs could affect those found responsible for contaminating or degrading groundwater”¹³⁷ While implementation costs are uncertain, the legislature anticipated this, as reflected in the wording of the statute with the word “probable.” While it is reasonably assumed that such an analysis may require some significant effort in coordinating and discussing with other agencies and regulated entities about what the probable costs of the new HRL limits might be, that is one of the tasks Minn. Stat. § 14.131 requires of the rulemaking agency.

103. The Department has not made a reasonable effort to address the probable costs of complying with the proposed rules as required by Minn. Stat. § 14.131 (5). Therefore, the rules must be disapproved on this basis.

104. To comply with § 14.131, the Department must make a reasonable effort to obtain information to address the probable costs for different categories of parties to comply with the proposed HRL levels and provide that information as part of its rulemaking case.

F. The probable costs or consequences of not adopting the proposed rule, including those costs borne by individual categories of affected parties, such as separate classes of governmental units, businesses, or individuals.

105. The Department contends that not adopting the proposed rules would “impose immeasurable costs or consequences affecting water.”¹³⁸ Because groundwater is a primary source of drinking water for many Minnesotans, protection of this water is crucial. According to the Department, a failure to revise the HRL rules would “ignore legislative directives and leave an outdated set of standards in place,” which would ultimately provide limited options to protect certain populations.¹³⁹

106. The Department states that the proposed amendments do not “in and of themselves” preclude water degradation.¹⁴⁰ Degradation could be the result of unintentional contamination, pre-existing activities prior to a chemical being identified as toxic, or prior chemical releases.¹⁴¹ Authorities can utilize HRL values in risk assessments relating to human health and drinking water. According to the Department, creating a “reliable source of water that is safe for human consumption is essential to a state’s ability to safeguard a high standard of living for its citizens.”¹⁴² This is consistent with the state’s

¹³⁷ Ex. D at 76.

¹³⁸ *Id.* at 79.

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

goal “that groundwater be maintained in its natural condition, free from any degradation caused by human activities.”¹⁴³

107. While it is understood that the costs or consequences of not adopting the proposed HRL revisions cannot be determined exactly, the Department’s failure to address this requirement of Minn. Stat. § 14.131 with more than a general statement that it is “immeasurable” is a critical defect in the rulemaking process. The law requires a more careful inquiry, and this is a matter of important public policy.¹⁴⁴ Indeed, a comparison of the costs of implementation and a failure to implement has a number of purposes: (1) it will better inform the legislature; (2) it will help the Department when it conducts its periodic reviews of the HRLs; and it (3) will assist other agencies with regulatory authority over groundwater when they consider policy concerning groundwater pollution.

108. The Department has not made a reasonable effort to address the probable costs or consequences of not adopting the proposed rules as required by Minn. Stat. § 14.131 (6). Accordingly, the proposed rules are disapproved on this basis.

109. To comply with § 14.131, the Department must address costs related to HRLs. The consequences of not having the proposed HRLs in place must also be more specifically delineated. For example, the Department could provide appropriately specific information about the effects that each toxin may have on the different groups of people the Department uses as groups to establish the HRLs if the proposed HRL is not put in place and complied with. The impact those effects may have on individuals, families, government agencies, and the economy is key information to informed and transparent rulemaking.

G. An assessment of differences between the proposed rule and existing federal regulations and the need for and reasonableness of each difference.

110. The Department explains that the U.S. EPA’s Office of Water publishes several sets of standards and health advisories relating to drinking water, including Maximum Containment Level Goals (MCLGs), Maximum Containment Levels (MCLs), and lifetime Health Advisories (HAs). Though there are similarities, the Department’s HRL values differ from the existing federal regulations and advisory values in numerous ways. First, the Department asserts, HRLs are based strictly on human health. Second, the proposed HRLs are based on guidance for chemicals “that are of high importance specifically to Minnesota.” Third, the Department has additional exposure time durations. Fourth, the Department’s revised HRLs explicitly address risk to sub-populations at higher risk than typical adults, such as infants and children. Finally, the Department asserts it can develop guidance more quickly than the EPA.¹⁴⁵ According to the Department, while

¹⁴³ Minn. Stat. § 103H.001.

¹⁴⁴ See, e.g., Minn. Stat. §§ 103H.001, .101, 144.35.

¹⁴⁵ Ex. D at 79-80.

some federal regulations and advisory values adhere to one or two of these conditions, none adhere to all conditions.¹⁴⁶

111. The Department states that EPA-derived MCLGs are advisory values based solely on considerations of human health. Because the MCLG for any chemical that causes cancer is zero, and because it is highly difficult to restore contaminated groundwater to pristine condition, the Department believes that MCLGs do not provide meaningful values for practical application to groundwater contaminated by carcinogens.¹⁴⁷

112. EPA-derived MCLs are federal standards adopted for the regulation of public drinking water.¹⁴⁸ MCLs incorporate a consideration of the costs required to reduce contaminant concentrations to a given level and technological feasibility of reaching that level. These considerations, according to the Department, may not be relevant to private drinking water wells or other sites impacted by contamination.¹⁴⁹ The Department does not elaborate on why drinking water from a public source is or should be treated differently than drinking water from a private well. Moreover, the costs reckoned by the EPA may be useful to the Department in meeting its rulemaking obligations cited previously at items E and F.

113. EPA-derived Drinking Water Equivalent Levels (DWELs) and Health Advisories (HAs) are estimates of acceptable drinking water levels of non-carcinogens or carcinogens based on health effects information. DWELs and HAs serve as technical guidance for federal, state, and local officials.¹⁵⁰ DWELs assume that all of an individual's exposure to a contaminant is from drinking water, while HAs take into account an individual's exposure by means other than drinking water and allocate to drinking water only a portion of an individual's allowable exposure. The Department asserts that some HAs are not developed based on a relative source contribution (RSC) factor.¹⁵¹ Moreover, HAs may be derived for certain exposure timeframes. One-day and ten-day HAs for children incorporate their intake and body weight, but do not incorporate an RSC factor.¹⁵²

114. Additionally, the Department argues that it focuses its guidance on chemicals that are a priority in Minnesota, whereas at the federal level, the focus is on nationwide priorities. Unlike federal guidance, which may not take into account variations in geography or historical factors, the Department contends that its guidance is generally based on requests from Minnesota risk managers or members of the public who have specific concerns regarding known or potential contaminants in Minnesota waters.¹⁵³

¹⁴⁶ *Id.* at 80.

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

115. The Department also states that it considers and prioritizes the chemical nominations when evaluating which contaminants have the greatest impact on Minnesota’s drinking water. Those with the highest priority and available toxicity information are selected for full review. Nominations are also received from Minnesota agencies for Minnesota groundwater contaminants discovered during monitoring or remediation efforts, which are prioritized during an annual meeting. Based on this additional input, the Department asserts that there are Minnesota HRL values for 142 chemicals found in Minnesota groundwater versus 91 chemicals with MCLs from the EPA. The proposed amendments will the total number of chemicals with HRL values to 162 in Minnesota.¹⁵⁴

116. The Department contends that its water guidance offers more protection for sensitive populations, particularly infants and children, because the Department derives guidance for acute (one day) and short-term (between one and 30 day) durations in addition to subchronic and chronic durations, unlike the EPA, which mainly derives guidance values for subchronic and chronic durations.¹⁵⁵

117. Finally, the Department asserts that its guidance is often available faster than EPA guidance, which can be delayed for a variety of reasons. At the time that Minnesota agencies or the public request HRL guidance values, detection of groundwater contaminants has often already occurred, which increases the potential for human exposure.¹⁵⁶

118. The Judge finds the Department met the requirement of Minn. Stat. § 14.131 (7) to assess the differences between the proposed rules and existing federal regulations, with a specific analysis of the need for and reasonableness of each difference.

H. An assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule.

119. The Department explains that no other state or federal rules are specifically devoted to the purpose of setting allowable water containment values for groundwater, and the proposed amendments supplement the regulatory results already established. The Department emphasizes that instead of proposing enforceable standards, it is adopting further guidance for risk managers and Department partners for utilization in risk evaluations and mitigation.¹⁵⁷

120. The Department contends that the proposed amendments will have “no direct regulatory impact” since the Department’s Health Risk Assessment unit is not

¹⁵⁴ *Id.* at 81.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

tasked with enforcing or regulating the use of health-based guidance. Instead, the Department provided recommended values for risk assessors and risk managers to utilize in making decisions and evaluating health risks. According to the Department, other Department programs or other agencies may choose to adopt these health-based values on their own and add them to enforceable requirements relating to permitting or remediation activities.¹⁵⁸

121. The Department asserts that it is not possible to anticipate every situation where HRL values may provide meaningful guidance, and it cannot anticipate all factors that partners may consider in their application of an HRL value. Rather, each agency or program is responsible for deciding whether to apply an HRL value or whether a deviation from HRL values is appropriate based on site-specific characteristics.¹⁵⁹

122. As noted earlier, the Department explains that health-based guidance is just one set of criteria utilized by state water and environmental protection programs in evaluating water degradation.¹⁶⁰ The Department notes the application of other state and federal health- or environmentally-based rules or law, such as MCL values for public drinking water systems may apply. Moreover, those who consume or work to protect the water from a private well from degradation may seek to comply with an HRL.¹⁶¹

123. The Department asserts that the cumulative effect of these proposed rules is incremental, and the impact will vary “on a case-by-case” basis. The impact varies based upon the type of contamination, the threat level to human health or the environment, and applicable governmental agency requirements.¹⁶² In some situations, the proposed rules may have minimal effect. On the other hand, the Department notes that where a contaminant exceeds the HRL value, the responsible party may be required by an agency to lower the contaminant concentration to a safe level for consumption. The Department explains that the proposed HRL values, like the previously adopted HRL values, will function as an evidence-based resource that agencies may apply in conducting a risk assessment on protecting Minnesota’s drinking water from further degradation.¹⁶³

124. The Judge notes that statute requires the PCA and the MDA to “promote implementation of best management practices to prevent or minimize the source of pollution to the extent practicable.”¹⁶⁴ “[I]f the implementation of best management practices has proven to be ineffective,” those agencies are authorized to “adopt water source protection requirements” which “must be: . . . (2) designed to prevent the pollution

¹⁵⁸ *Id.* at 81-82.

¹⁵⁹ *Id.* at 82.

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ Minn. Stat. § 103H.275, subd. 1.

from exceeding the health risk limits.”¹⁶⁵ Thus, the proposed HRLs, when in effect, are not optional for agencies to follow, as suggested by the Department.

125. Nevertheless, the Judge finds that the Department has adequately assessed the cumulative effect of the rule with other state and federal regulations related to the purpose of protecting groundwater, as required by Minn. Stat. § 14.131.

V. Performance-Based Regulation

126. Minn. Stat. § 14.131 also requires that an agency describe in its SONAR how it has considered and implemented the legislative policy supporting performance-based regulatory systems set forth in Minn. Stat. § 14.002.¹⁶⁶ A performance-based rule is one that emphasizes superior achievement in meeting the agency’s regulatory objectives and provides maximum flexibility for the regulated party and the agency in meeting those goals.¹⁶⁷

127. In its SONAR, the Department asserts that the proposed amendments permit flexibility in assessments made by risk managers and stakeholders regarding the optimal plan for protecting the public from potentially harmful substances in groundwater.¹⁶⁸ The Department explains that the proposed amendments provide a scientific and policy context for a situation-specific risk assessment by risk managers and stakeholders, giving them options about which action to take and how to evaluate the results of those actions.¹⁶⁹

128. The Judge finds that the Department has met the requirements set forth in Minn. Stat. § 14.131 for consideration and implementation of the legislative policy supporting performance-based regulatory systems.

VI. Consultation with Minnesota Management and Budget

129. Under Minn. Stat. § 14.131, an agency is required to “consult with the commissioner of management and budget to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government.”

130. On November 22, 2022, the Department asked the Executive Budget Officer for Minnesota Management and Budget (MMB) to evaluate the fiscal impact and benefits of the proposed rules on local units of government, as required by Minn. Stat. § 14.131.¹⁷⁰

¹⁶⁵ *Id.*

¹⁶⁶ Minn. Stat. § 14.131.

¹⁶⁷ Minn. Stat. § 14.002.

¹⁶⁸ Ex. D at 82.

¹⁶⁹ *Id.*

¹⁷⁰ Ex. F.

131. The Department received a reply from MMB on March 20, 2023.¹⁷¹

132. MMB indicated that it had reviewed the Department's proposed rules and SONAR to evaluate the fiscal impact the proposed amendments may have on local governments. MMB repeated the Department's position on the cost impact of the rules and concluded that the proposed amendments "would not have a material impact on any body in Minnesota, nor on local units of government, and will update MDH's human health-based guidance to protect ground water and public health."¹⁷²

133. The Judge finds that the Department fulfilled its obligation to consult with MMB as required by Minn. Stat. § 14.131.¹⁷³

VII. Compliance Costs for Small Businesses and Cities

134. Under Minn. Stat. § 14.127, an agency must "determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed \$25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees." The agency must make this determination before the close of the hearing record, and the administrative law judge must review the determination and approve or disapprove it. If the agency fails to make the determination, it violates the rulemaking procedures, and the defect is fatal to the rule.¹⁷⁴

135. The Department repeats its prior contention that compliance costs for the proposed amendments cannot be determined because the rules "do not have any implementation, regulation, or enforcement requirements."¹⁷⁵ The Department explains that the rules simply provide health-based guidance for water contaminants and do not address application or use. According to the Department, risk managers use this guidance as one set of criteria in evaluating potential health risks from contaminated groundwater. The Department notes that risk managers "have the flexibility in determining if and when to apply the HRL values and how costs should be considered."¹⁷⁶ Therefore, the Department contends that it has no control over and cannot predict the cost of compliance for other agencies or for regulated parties.

¹⁷¹ Ex. K.2 (letter from Hannah Millang, Executive Budget Officer, MMB to J. Skaar).

¹⁷² *Id.*

¹⁷³ If the Department follows the suggestions herein to correct identified defects, it may need to consult with MMB again.

¹⁷⁴ *Builders Ass'n of Twin Cities v. Minnesota Dept. of Labor and Industry*, 872 N.W.2d 263, 274 (Minn. Ct. App. 2015).

¹⁷⁵ SONAR at 70.

¹⁷⁶ *Id.*

136. As noted above, MMB does not anticipate a fiscal impact to local units of government due to the Department's statements of lack of enforcement authority and lack of fees associated with the proposed amendments.¹⁷⁷

137. The Judge understands that the proposed rules are not the same as, for example, the water resource protection requirements the Pollution Control Agency and the Department of Agriculture may adopt by rule.¹⁷⁸ The HRLs may, however, trigger regulatory action to limit pollution, which may in turn result in costs to a small business or small city. For example, the Department may issue an order requiring contamination to stop pursuant to its authority at Minn. Stat. § 144.35. Other agencies, such as the Department of Agriculture and the Pollution Control Agency, may adopt best management practices or water resource protection requirements based on the HRLs to prevent or minimize groundwater degradation.¹⁷⁹ Thus, in the view of the Judge, possible costs resulting from the HRLs must be determined by the Department under Minn. Stat. § 14.127. These costs may include, for example, conservation easements.¹⁸⁰ The impact of the HRLs on soil and water conservation district plans which, in turn, impact small businesses or small cities, may also have a cost.¹⁸¹ Without an HRL for a given pollutant, the mitigation cost would be even more difficult to quantify. Thus, because there may be costs resulting from the proposed HRLs which trigger a pollution mitigation action, the Department has not met the requirement to address such costs.

138. Notably, the Department has failed to make a cost threshold determination in at least three prior revisions of these rules.¹⁸² In 2008, Judge Heydinger found the omission of a cost determination to be a defect, but gave the Department the opportunity to correct it, which the Chief Judge approved.¹⁸³ In 2015, Judge Cochrane recommended that the Department add language clarifying its rule order where it had said both that it could not make the determination required by Minn. Stat. § 14.127, subd. 1, and that it had made the determination.¹⁸⁴ This was in light of the Court of Appeals' decision in *Builders Association of the Twin Cities v. Minnesota Dept. of Labor and Industry*, 872 N.W. 2d 263 (Minn. Ct. App. Oct. 13, 2015). In 2018, Judge Case recommended, without

¹⁷⁷ MMB's finding is based on the Department's position on costs stated in the SONAR and rejected here.

¹⁷⁸ Minn. Stat. §§ 103H.005, subd. 15; .275.

¹⁷⁹ Minn. Stat. §§ 103H.101; .151, .275. Best management practices are voluntary, pursuant to Minn. Stat. § 103H.005, subd. 4. Water resource protection requirements are not, and include: "design criteria, standards, operation and maintenance procedures, practices to prevent releases, spills, leaks, and incidents, restrictions on use and practices, and treatment requirements." *Id.* at subd. 15.

¹⁸⁰ Minn. Stat. § 103H.105.

¹⁸¹ Minn. Stat. § 103H.111.

¹⁸² *In re Proposed Rules Governing Health Risk Limits for Groundwater*, OAH No. 15-0900-19846-1 Report of the Administrative Law Judge at 18, 51-52 (Dec. 11, 2008), Chief Judge's Order (Dec. 15, 2008); *In re the Proposed Rules on the Health Risk Limits for Groundwater*, 2015 WL 4518139, OAH No. 68-0900-32663, Order on Review of Rules Under Minn. Stat. § 14.26 at 3 (Nov. 19, 2015); *In re the Proposed Rules Relating to Health Risk Limits in Groundwater*, OAH No. 82-9000-34834 Report of the Administrative Law Judge at 18 (May 29, 2018).

¹⁸³ 15-0900-19846-1 at 18 (Dec. 11, 2008 & Dec. 15, 2008).

¹⁸⁴ 2015 WL 4518139 *3.

finding a defect, that the Department “explicitly make the determination required by Minn. Stat. § 14.127 in its proposed order adopting the rules.”¹⁸⁵

139. Because the Department failed to make the determination required by Minn. Stat. § 14.127, the Judge disapproves the rule.

140. To correct this defect, the Department must make a clear determination under Minn. Stat. § 14.127.

VIII. Adoption or Amendment of Local Ordinances

141. Under Minn. Stat. § 14.128, an agency must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule. The agency must make this determination before the close of the hearing record, and the Judge must review the determination and approve or disapprove it.¹⁸⁶

142. The Department determined that local governments will not be required to adopt or amend an ordinance or other regulation to comply with the proposed amendments. The Department points out that local units of government do not have authority to establish HRLs for ground water quality, as this authority is held exclusively by the Commissioner of Health. Groundwater quality standards are not developed or enforced by local governments through ordinances or regulations. The Department notes that local governments have utilized HRL values in consultation with the Department to interpret the results of well monitoring.¹⁸⁷

143. The Judge approves the Department’s determination that the proposed HRLs will not require local governments to adopt or amend ordinances or regulations.

IX. Analysis of the Proposed Rules

144. The remainder of this Report focuses on the portions of the proposed rules that received significant critical comment or otherwise require examination. The Report will not discuss each proposed rule and rule subpart in equal depth. Proposed rules that provoked no controversy were reviewed by the Judge and found to be needed, reasonable, and supported by an affirmative presentation of the facts in the record. These noncontroversial proposed rules are not discussed in this Report. The Judge has read and considered every comment made by a member of the public. After addressing general comments about the rulemaking, the Report turns to a part-by-part analysis of those proposed rules that attracted public comment.

¹⁸⁵ OAH No. 82-9000-34834 at 27-28.

¹⁸⁶ Minn. Stat. § 14.128, subd. 1.

¹⁸⁷ Ex. D at 86.

A. General Need and Reasonableness Analysis

145. Approximately 75 percent of Minnesota's drinking water is from groundwater, making it an important resource for the state.¹⁸⁸ The Groundwater Protection Act authorizes the Department to adopt rules that set HRLs for contaminants found in groundwater that might be used for drinking.¹⁸⁹ Through the SONAR and hearing presentation for these proposed rules, notwithstanding the defects noted above, the Department supported the need and reasonableness its proposed HRLs for water contaminants to protect public health, including the most vulnerable populations.

146. The proposed rules will amend Minnesota Rules, chapter 4717, by revising or adding HRLs for 37 groundwater contaminants.¹⁹⁰ Seventeen contaminants are added, one HRL value is repealed, and 19 other HRLs are updated.¹⁹¹ The proposed amendments build on the Department's 2009 rule revisions and subsequent rulemaking.¹⁹² The amended HRL values are based on the methods the Department adopted in 2009.¹⁹³

B. Overview of the Rules

147. HRLs are defined as "a concentration of a substance or chemical adopted by rule of the commissioner of health that is a potential drinking water contaminant because of a systemic or carcinogenic toxicological result from consumption."¹⁹⁴ The Department explains that an HRL is a concentration of a groundwater contaminant, or a mixture of contaminants, that is likely to pose little or no health risk to humans, including vulnerable subpopulations, and has been adopted into rule. An HRL is expressed as micrograms of a chemical per liter of water.¹⁹⁵

148. These rules are proposed in accordance with the legislative direction that the commissioner shall review each adopted HRL at least every four years¹⁹⁶ and, except in an emergency, shall adopt HRLs through the rulemaking process.¹⁹⁷

149. The process by which the Department chooses toxicants for review is described above in the Nature of the Proposed Rules section.

¹⁸⁸ *Id.* at 1.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.* at 5, 6.

¹⁹² *Id.* at 1.

¹⁹³ *Id.* at 12.

¹⁹⁴ Minn. Stat. § 103H.005, subd. 3.

¹⁹⁵ Ex. D at 6-7.

¹⁹⁶ Minn. Stat. § 103H.201, subd. 3.

¹⁹⁷ Minn. Stat. § 103H.201, subd. 2(a).

150. HRLs are determined by two methods depending on their toxicological endpoint and as specified by the statute as follows:

- For systemic toxicants that are not carcinogens, the adopted health risk limits shall be derived using United States Environmental Protection Agency risk assessment methods using a reference dose, a drinking water equivalent, and a relative source contribution factor.¹⁹⁸
- For toxicants that are known or probable carcinogens, the adopted health risk limits shall be derived from a quantitative estimate of the chemical's carcinogenic potency published by the United States Environmental Protection Agency and determined by the commissioner to have undergone thorough scientific review.¹⁹⁹

151. In the proposed rules, the Department proposes to adopt new or updated HRL values for 36 contaminants and repeal one HRL value.²⁰⁰

X. Rule-by-Rule Analysis

152. The majority of the proposed rules were not opposed by any member of the public and were adequately supported by the SONAR. Accordingly, this Report will not address each proposed HRL amendment. Rather, the following discussion focuses on those proposed HRL amendments about which commentators raised a genuine dispute as to the reasonableness of the Department's regulatory choice or that otherwise require closer examination.

153. The proposed HRLs for the following six chemicals garnered comments:

- a. Ethylene glycol, which received comments from the American Chemistry Council (ACC);²⁰¹
- b. Imidacloprid, which received comments from Bayer US, LLC;²⁰²
- c. Nonylphenol, which received comments from the Alkylphenols & Ethoxylates Research Council (APERC);²⁰³

¹⁹⁸ Minn. Stat. § 103H.201, subd. 1.

¹⁹⁹ *Id.*

²⁰⁰ *Id.* at 5-6.

²⁰¹ Ex. I.2.f.i.

²⁰² Ex. I.2.e.i.

²⁰³ Ex. I.2.d.ii; Comments of the APERC, Apr. 26, 2023.

- d. Perfluorobutane sulfonate (PFBS), which received comments from the ACC;²⁰⁴
- e. Perfluorohexane sulfonate (PFHxS), which received comments from the ACC;²⁰⁵ and
- f. Perfluorohexanoate (PFHxA), which received comments from the ACC.²⁰⁶

154. The Department also received comments on chemicals not part of this rulemaking. Jean Wagenius submitted comments about nitrates. The Metropolitan Council submitted comments on perfluorooctanic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).²⁰⁷

A. Wagenius Comments on Nitrates

155. Prior to the hearing, Jean Wagenius provided written comments concerning nitrates in ground water.²⁰⁸ Wagenius recommends updating the nitrate HRL.²⁰⁹ According to Wagenius, an update is necessary because many wells in Minnesota are contaminated by nitrates.²¹⁰ In addition, according to Wagenius's review of information, the current HRL for nitrates shows a higher risk for colorectal cancer and adverse birth outcomes.²¹¹ Wagenius also states that the current HRL for nitrates is based on outdated standards which are not as stringent as state law requires.²¹²

156. The Department responded to Wagenius's comments in writing on March 31, 2023.²¹³ The Department stated that it is willing to reassess the nitrate HRL when the scientific literature includes data that can be used for a revision of the HRL.²¹⁴ According to the Department, the current nitrate HRL is designed to protect against methemoglobinemia in infants.²¹⁵ Methemoglobinemia is the most well-documented effect of nitrates on humans, and the data is based on epidemiological data – albeit from between 60 and 80 years ago – as opposed to lab animal data.²¹⁶ Moreover, according

²⁰⁴ Ex. I.2.c.i.

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ Ex. I.2.a.i; Comments of Metropolitan Council, Mar. 22, 2023.

²⁰⁸ Ex. I.2.a.i.

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ *Id.*

²¹² *Id.*

²¹³ Ex. I.2.a.ii.

²¹⁴ *Id.*

²¹⁵ *Id.*

²¹⁶ *Id.*

to the Department, in the last two decades, only five cases of methemoglobinemia in infants in Minnesota was related to nitrates in drinking water.²¹⁷ Finally, the Department stated that current ecological studies on nitrates lack sufficient data to demonstrate the impact of toxicity from human exposure to chemicals and, therefore, to amend the current HRL.²¹⁸

157. The Department did not amend the proposed rules based on Wagenius's comments on nitrates. The Judge finds the Department's position reasonable.

B. Metropolitan Council Comments on PFOA and PFOS

158. The Metropolitan Council (Met Council) provided written comments to the Department regarding changing federal standards concerning per- and polyfluoroalkyl substances (PFAS).²¹⁹ The Met Council noted that the Department's HRL revisions did not address three PFASs, including PFOA and PFOS.²²⁰ The Met Council stated that changes to federal water contamination requirements may render the Department's current HRLs on PFOA and PFOS significantly out-of-line with potentially more stringent federal requirements.²²¹ The Met Council also noted that such changes may significantly impact regional water suppliers and communities.²²² The Met Council took no specific position, other than stating it stood ready to partner with the Department and other agencies and stakeholders to address PFAS contamination.²²³

159. The Department responded to the Met Council's comments on April 24, 2023.²²⁴ The Department stated that it withdrew proposed changes to the HRLs for PFOA and PFOS in the fall of 2022 and focused on assessing human epidemiological study data.²²⁵ This approach was employed to examine several recent reviews, including information from the U.S. EPA.²²⁶ The Department expects PFOA and PFOS to be part of the next review of the HRLs.²²⁷

160. Because the Department was not asked by the Met Council to do anything, no further analysis is required here.

161. The remainder of this report will address comments and responses concerning six proposed HRL changes. The details of the Department's proposals to

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ Comments of Metropolitan Council.

²²⁰ *Id.*

²²¹ *Id.*

²²² *Id.*

²²³ *Id.*

²²⁴ Letter from Fossen Johnson to Paske, Apr. 24, 2023.

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ *Id.*

amend the HRLs are located in the SONAR, Section V, and will be cited below, and not reproduced. While written comments and responses were made throughout the rule-making process, this Report only addresses those comments and responses made during the comment period immediately prior to the public hearing and immediately following it. The comments and responses will be summarized to their most pertinent points.

C. Rule 4717.7860, subp. 12d: Ethylene Glycol

162. The details of the Department's proposal to amend the HRL for ethylene glycol are located in the SONAR, Section V,²²⁸ (see Ex. D at 40-42) and need not be reproduced here.

163. The Department received a written comment on its proposed amendment to the HRL for ethylene glycol from the American Chemistry Council Ethylene Glycol Panel (Panel) on March 8, 2023.²²⁹

164. The Panel challenged the study the Department used to determine the point of departure (POD) for making its risk determination for ethylene glycol exposure from drinking water over a period of time.²³⁰ The Panel encouraged the Department to rely on a set of experiments published by Dr. Ed Carney which, according to the Panel, emphasized the importance of dose rate on the toxicity of ethylene glycol in human development.²³¹ The Panel summarized the findings as follows:

when large doses of EG [ethylene glycol] are given by a fast dose rate as in gavage, the saturation of the oxidative enzyme systems for EG occurs, and developmental toxicity can occur. This fast rate of gavage would represent a suicide attempt and does not 'represent a similar exposure as a person consuming ethylene glycol in their drinking water daily over a period of time.'²³²

165. The Panel also challenged the reliance on studies using mice and rats due to the difference in how those animals metabolize ethylene glycol. According to the Panel, such reliance is in error because "there is a clear species difference in the active disposition facilitated by opposite polarity of rodent MCT [monocarboxylate transporters] vs. that of rabbits and humans."²³³ The Panel also stated that "[a] clear argument has been made that the major, active pathway of glycolic acid (GA) disposition into the rat and mouse developing embryo is via the MCT[s] located in the placenta."²³⁴ Thus, the

²²⁸ Ex. D at 40-42.

²²⁹ Ex. I.2.f.i.

²³⁰ *Id.*

²³¹ *Id.*

²³² *Id.* at 6.

²³³ *Id.* at 8.

²³⁴ *Id.* at 9.

effects of ethylene glycol on rat and mouse development is not appropriate to model the chemical's impact on human development.²³⁵

166. The Panel commented that there is strong evidence that renal toxicity is the best POD for a risk assessment.²³⁶

167. The Panel encouraged the Department to consider all of the 21 new peer reviewed studies concerning ethylene glycol, not only the 1985 Neeper-Bradley study upon which the Department largely relies.²³⁷ The studies consider, among other things, metabolism, pharmacokinetics, and pharmacodynamics, all of which are pertinent to risk assessment of the chemical.²³⁸

168. According to the Panel, "ethylene glycol exposures resulting in blood levels below the level of saturation should not result in hazard associated with developmental toxicity in humans."²³⁹ The Panel states that hazardous exposure levels are much lower than the Department's proposed HRL.²⁴⁰

169. The Department responded to the Panel's comments on March 31, 2023.²⁴¹ The Department disagreed with the Panel's position "that the gavage route of exposure used in the Neeper-Bradley (1995) developmental mouse study is inappropriate to use in deriving drinking water guidance."²⁴² While the Department takes all available data into consideration, it's fundamental assumption is that "humans are at least as sensitive as the most sensitive mammalian species for which there are toxicological data."²⁴³ This assumption is overcome, however, when there is "[s]ubstantial evidence that the response seen in laboratory animals is due to a mechanism that does not exist in humans."²⁴⁴ The Department pointed out that the Panel did not provide evidence "that a developing child would be less sensitive to [exposure to ethylene glycol's] adverse developmental effects than other species."²⁴⁵

170. The Department noted that it had reviewed six of the 21 studies the Panel advised should be reviewed as part of the HRL assessment. The Department stated that it subsequently reviewed the remaining 15 studies, and determined they contained no data that would have altered the proposed HRL for ethylene glycol.²⁴⁶

²³⁵ *Id.*

²³⁶ *Id.* at 9, 11.

²³⁷ *Id.* at 10.

²³⁸ *Id.*

²³⁹ *Id.*

²⁴⁰ *Id.* at 10-11.

²⁴¹ Ex. I.2.f.ii.

²⁴² *Id.* at 1.

²⁴³ *Id.* at 1-2.

²⁴⁴ *Id.* at 2.

²⁴⁵ *Id.*

²⁴⁶ *Id.*

171. The Department noted its disagreement with the Panel that relying on a published physiologically based pharmacokinetic (PBPK) model is appropriate for developing the HRL for ethylene glycol.²⁴⁷ According to the Department, relying on such a study “with unresolved uncertainty around human glycolic acid metabolism, especially for glycolic acid kinetics throughout pregnancy, may result in a guidance value that does not protect the most sensitive lifestage against developmental effects.”²⁴⁸

172. The Department noted the Panel’s disagreement with the Department’s operative fundamental assumption in determining HRLs as it pertains to MCTs in various animals.²⁴⁹ According to the Department, “there is still uncertainty as to whether the differences observed during those specific gestational days are representative of the kinetics for the comparative species during other potentially sensitive windows in gestation.”²⁵⁰ Thus, the Department declined to reject its fundamental assumption in evaluating ethylene glycol’s hazards.²⁵¹

173. The Department acknowledged its disagreement with the Panel about the conclusions reached in a particular study.²⁵² The Department defended its position, noting the study itself stated that more data was necessary “to fully compare rodents and humans,” because of “the complexity of monocarboxylic acid transport across the trophoblast.”²⁵³

174. Finally, the Department notes that it does not use renal toxicity as the critical effect in making its determination on the hazards of ethylene glycol because its risk assessment methodology and analysis “resulted in a final guidance value based on a developmental health endpoint.”²⁵⁴ The Department notes its satisfaction with this approach, the effects of the chemical on the kidneys, and that its proposed HRL value for ethylene glycol will adequately protect infants, children, and adults.²⁵⁵

175. The Judge finds that the Department has affirmatively presented sufficient facts to adequately support the need for, and reasonableness of, the proposed HRL value for ethylene glycol. The Department has fully explained its methods and the reasons for its choices. The Department has demonstrated that the proposed rule amendments are necessary and reasonable in terms of substance.

²⁴⁷ *Id.* at 3.

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ *Id.*

²⁵¹ *Id.* at 4.

²⁵² *Id.*

²⁵³ *Id.*, citing Moore, N.P., Picut, C.A., & Charlap, J.H. (2016). Localisation of Lactate Transporters in Rat and Rabbit Placentae. *International Journal of Cell Biology*, 2016, 2084252.

²⁵⁴ *Id.*

²⁵⁵ *Id.* at 4-5.

D. Rule 4717.7860, subp. 12h: Imidacloprid

176. The details of the Department's proposal to add an HRL for imidacloprid are located in the SONAR, Section V,²⁵⁶ (see Ex. D at 45-46) and need not be reproduced here.

177. On March 8, 2023, the Department received a written comment on its proposed HRL for imidacloprid from the Bayer Crop Sciences, which uses the chemical as an ingredient in insect control products.²⁵⁷

178. Bayer's position is that the Department's proposed HLR of 3 µg/L is too low, based on a different study than that which the Department relied.²⁵⁸ Bayer challenged the Department's reliance on a study of imidacloprid exposed female mice over a 28-day period.²⁵⁹ That 2013 study, according to Bayer, is missing key information which would permit the Department to make a quantitative risk assessment.²⁶⁰ Bayer claimed this was in violation of Minn. Stat. §§ 144.0751 and 103H.201.²⁶¹

179. Bayer also noted that the EPA twice specifically considered the 2013 study and rejected it for use in quantitative risk assessments.²⁶² The EPA, according to Bayer, rejected the study because: (1) there was a lack of information about the imidacloprid sample used; (2) there was an absence of raw data to confirm the findings and statistical analysis; and (3) there was limited information about the test conditions.²⁶³

180. Bayer pointed to a different study, which the EPA used in its quantitative risk assessment of imidacloprid.²⁶⁴ That study was completed in 2010 by Bayer.²⁶⁵ In that study, the maximum safe dose of the chemical was 186 mg of imidacloprid per kg of body weight per day, or 18.6 times higher than the maximum dose tested in the 2016 study relied upon by the Department.²⁶⁶ Bayer also commented that it used male rats which are more sensitive than female mice.²⁶⁷ Finally, Bayer stated that the EPA relied on its 2010 study in concluding imidacloprid did not cause immunotoxicity at any tested dose.²⁶⁸

²⁵⁶ Ex. D at 40-42.

²⁵⁷ Ex. I.2.e.i.

²⁵⁸ *Id.* at 1, *citing* 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.

²⁵⁹ *Id.*

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² *Id.* at 2.

²⁶³ *Id.*

²⁶⁴ *Id.*

²⁶⁵ *Id.*, *citing* Kennel. 2010. Imidacloprid 28-day immunotoxicity study in the male Wister rat by dietary administration. Bayer Crop Science, Study No. SA 09406; MRID 48298701.

²⁶⁶ *Id.*

²⁶⁷ *Id.*

²⁶⁸ *Id.*

181. The Department responded to Bayer’s comments on March 31, 2023.²⁶⁹ The Department explained that its use of the 2013 study was in compliance with the law because the study was scientifically acceptable and peer reviewed, as required by Minn. Stat. § 144.0751.²⁷⁰ In addition, the Department “applied a reference dose, a drinking water equivalent, and a relative contribution factor to develop” the HRL, as required by Minn. Stat. § 103H.201, subd. 1(c).²⁷¹

182. The Department asserted that it is not required “to use the EPA’s critical study, adverse critical effect, or reference dose,” and, instead, used its own risk assessors to reach its own conclusions.²⁷² The Department noted that it “selected an adverse effect (reduced delayed-type hypersensitivity) that occurs at a lower dose than the adverse effect chosen by EPA (tremors in dogs from a different study).²⁷³ This is why the Department’s reference dose is lower than that derived by the EPA.²⁷⁴ The Department also stated that its purpose of risk assessment was different from the EPA’s, which was to register pesticides.²⁷⁵

183. The Department further explained that raw data and minute study details are “unusual in the open literature for academic peer-reviewed studies.”²⁷⁶

184. The Department contends that “EPA’s guidelines on immunotoxicity testing do not consider every facet of the immune system.”²⁷⁷ The Department pointed out that the EPA holds “that both rats and mice are acceptable test subjects for immunotoxicity and that either sex may be used.”²⁷⁸ The Department also cited to a recent study from 2020 in which “female mice had a less effective response in activating the innate immune response after imidacloprid exposure.”²⁷⁹ This provided evidence, according to the Department, that the chemical effects “different facets of the immune system.”²⁸⁰

185. The Department provided examples of limitations to the Bayer study as well. The Bayer study “only tested one functional attribute of the immune system – immunoglobulin M (IgM) titers in the serum after antigen challenge.”²⁸¹ Moreover, according to the Department, questions about differences with the study control group raised “questions about experimental precision and methodology.”²⁸²

²⁶⁹ Ex. I.2.e.ii.

²⁷⁰ *Id.* at 1, 2, 3.

²⁷¹ *Id.* at 1.

²⁷² *Id.*

²⁷³ *Id.*

²⁷⁴ *Id.*

²⁷⁵ *Id.* at 1-2.

²⁷⁶ *Id.* at 2.

²⁷⁷ *Id.* at 3

²⁷⁸ *Id.*

²⁷⁹ *Id.*

²⁸⁰ *Id.*

²⁸¹ *Id.*

²⁸² *Id.*

186. The Judge finds that the Department has presented sufficient facts to adequately support the need for and reasonableness of the proposed HRL value for imidacloprid. The Department has fully explained its methods and the reasons for its choices. The Department has demonstrated that the proposed rule amendments are necessary and reasonable in terms of substance.

E. Rule 4717.7860, subp. 13a: p-Nonylphenol (4-Nonylphenol)

187. The details of the Department's proposal to add an HRL for p-Nonylphenol (pNP) are located in the SONAR, Section V,²⁸³ (see Ex. D at 52-53) and need not be reproduced here.

188. On March 8, 2023, the Department received a written comment on its proposed HRL for pNP from the Alkylphenols & Ethoxylates Research Council (APERC), which opposes the proposed HRL for the chemical.²⁸⁴

189. In general, APERC argues that the subchronic non-cancer health-based-values for pNP calculated by the Department "was not replicated in other high-quality and relevant studies."²⁸⁵ According to APERC, the Department "selected an incorrect POD and Critical Effect (CE)" to make its calculation "and did not consider the weight-of-evidence and the perspective gained from consideration of other high-quality follow-up rat studies that further evaluated the renal effects that were the basis for the POD selected."²⁸⁶

190. Based on APERC's review of its preferred research data, the HRL for pNP should be 293 µg/L subchronic and 144 µg/L chronic non-cancer reference doses, as opposed to the Department's proposal of 40 µg/L and 20 µg/L, respectively.²⁸⁷

191. APERC also took issue with the Department's reliance on a 1999 study (Chapin).²⁸⁸ According to APERC, a better study was completed in 2006 (Tyl), upon which the Department should have relied.²⁸⁹ APERC disagreed with the Department's previously stated position that the Tyl study was incomplete.²⁹⁰ According to APERC, the Tyl study "did not replicate the findings of kidney mineralization at the lowest doses" like

²⁸³ Ex. D at 52-53.

²⁸⁴ Ex. I.2.d.i.

²⁸⁵ *Id.* at 1.

²⁸⁶ *Id.* at 1-2.

²⁸⁷ *Id.*

²⁸⁸ *Id.* at 3, *citing* Chapin, R.E., Delaney, J., Wang, Y., Lanning, L., Davis, B., Collins, B., Mintz, N., & Wolfe, G., (1999). The effects of 4-nonylphenol in rats: a multigeneration reproduction study, *Toxicol Sci.*, 52(1), 80-91.

²⁸⁹ *Id.* at 3, 4, *citing* Tyl, R.W., Myers, C.B., Marr, M.C., Castillo, N.P., Seely, J.C., Sloan, C.S., Veselica, M.M., Joiner, R.L., Van Miller, J.P., & Simon, G.S. (2006). Three generation evaluation of dietary para-nonylphenol in CD (Sprague-Dawley) rats. *Toxicological Sciences*, 92, 295-310.

²⁹⁰ *Id.* at 3.

was found in the Chapin study.²⁹¹ APERC also pointed to another study, completed in 2001, which “reported no kidney effects at similar doses . . . as used in [the Chapin study].”²⁹²

192. APERC maintains that the renal mineralization in the Chapin study was not reproduced in subsequent studies.²⁹³ APERC disagrees with the Department that the selection of the low dose from the Chapin study was an adverse effect.²⁹⁴ According to APERC, “at the lowest dose, the effects seen [in the Chapin study] can be considered non-adverse due to being minimal in severity without accompanying inflammation or significant changes in kidney weights or body weights.”²⁹⁵ Thus, in APERC’s view, the no observed adverse effects level (NOAEL) kidney effects should be 200 parts per million (ppm) or 13 mg/kg-bw/day.²⁹⁶ APERC provided much detail and citations to many reports that it contends demonstrate how common renal mineralization in rats is and, therefore, contends is not an appropriate claimed adverse effect upon which to base the HRL for pNP.²⁹⁷

193. The Department responded to APERC’s comments on March 31, 2023.²⁹⁸ The Department explained its reason for relying on the Chapin study. According to the Department, in the Chapin study, renal mineralization occurred “in three consecutive generations [of] young males at the lowest dose tested – and that is key.”²⁹⁹ The Department asserts that the Tyl study would have been better had it looked at the lower doses that the Chapin study “used so that a full comparison could be made.”³⁰⁰ However, “the weight of evidence from these two studies supports that the observed kidney mineralization may be occurring in tandem with renal degeneration.”³⁰¹

194. The Department disagreed with APERC that the NOAEL in the Chapin study was 200 ppm because renal mineralization was observed in all generations of young male rats studied.³⁰² Moreover, the Department argued, the Chapin study results could not “be ignored because other studies, including [the] Tyl [study], did not match the conditions used” in the Chapin study.³⁰³ In any event, the Department developed a POD using the “benchmark dose (BMD) modeling for the Chapin 1999 study rather than

²⁹¹ *Id.* at 4.

²⁹² *Id.*, citing Nagao, T., Wada, K., Marumo, H., Yoshimura, S., & Ono, H. (2001). Reproductive effects of nonylphenol in rats after gavage administration: A two-generation study. *Reproductive Toxicology*, 15 (3), 293-315.

²⁹³ *Id.* at 4-5.

²⁹⁴ *Id.* at 5.

²⁹⁵ *Id.*

²⁹⁶ *Id.*

²⁹⁷ *Id.* at 5-13.

²⁹⁸ Ex. I.2.d.ii.

²⁹⁹ *Id.* at 1-2.

³⁰⁰ *Id.* at 2.

³⁰¹ *Id.*

³⁰² *Id.*

³⁰³ *Id.*

explicitly defining a NOAEL or [low observed adverse effect level] LOAEL.”³⁰⁴ In this case, the Department “used a BMD of 0.49 mg/kg-d_{HED} based on renal mineralization in the second generation of rats as the POD.”³⁰⁵

195. The Department also held that the mineralization seen in young male rats “may be a marker of more severe effects” and thus was properly viewed as adverse.³⁰⁶ According to the Department, the kidney “is one of the primary targets of nonylphenol toxicity” and that renal degeneration accompanied the renal mineralization in the rats.³⁰⁷ Because the rats were young, and because there was “no conclusive evidence that this effect isn’t relevant to humans,” the Department’s method for determining its HRL for pNP was viewed as appropriate.³⁰⁸

196. The Judge finds that the Department has presented sufficient facts to adequately support the need for, and reasonableness of, the proposed HRL value for pNP. The Department has fully explained its methods and the reasons for its choices. Accordingly, the Department has demonstrated that the proposed rule amendments are necessary and reasonable in terms of substance.

F. Rule 4717.7860, subp. 14a: Perfluorobutane sulfonate (PFBS)

197. The details of the Department’s proposal to add an HRL for perfluorobutane sulfonate (PFBS) are located in the SONAR, Section V,³⁰⁹ (see Ex. D at 55-56) and need not be reproduced here.

198. On March 8, 2023, the Department received a written comment on its proposed HRL for PFBS from the American Chemistry Council (ACC), which opposes the proposed HRL for the chemical.³¹⁰

199. ACC objects to the study the Department relies on for its proposed HRL value for PFBS (the NTP study). According to ACC, “the biological significance of the Department’s critical effect from that study . . . is unclear in the absence of additional signs of overt thyroid toxicity.”³¹¹ A more appropriate study for the Department to rely on,

³⁰⁴ *Id.*

³⁰⁵ *Id.*

³⁰⁶ *Id.* at 3.

³⁰⁷ *Id.*

³⁰⁸ *Id.* at 3-4.

³⁰⁹ Ex. D at 55-56.

³¹⁰ Ex. I.2.c.i.

³¹¹ *Id.* at 1, *citing* USEPA. Human health toxicity values for perfluorobutane sulfonic acid (CASRN 375-73-5) and related compound potassium perfluorobutane sulfonate (CASRN 29420-49-3). EPA/600/R-20/345F. Office of Research and Development. Washington, DC (2021), at 82.

according to ACC, is a 2017 developmental study by Feng, et al. (the Feng study).³¹² The Feng study, according to ACC, also reported thyroid effects. In particular, a decrease in serum total thyroxine (T4) in newborn mice.³¹³

200. ACC asserts that “[f]or short-chain PFAS like PFBS, use of the default approach of body-weight scaling to estimate the human equivalent dose is consistent with USEPA guidance and the state of the science.”³¹⁴ According to ACC, there is sufficient data about PFBS that “suggests . . . it is eliminated relatively rapidly and thus will not accumulate” in humans.³¹⁵

201. ACC maintains that “a toxicity value that protects against effects on thyroid hormones also will protect against developmental effects.”³¹⁶ ACC also noted that it “is not aware of available data that would suggest that immunotoxicity is a concern for PFBS” which has different properties from previously evaluated PFAS.³¹⁷

202. The Department responded to the ACC’s comments on March 31, 2023.³¹⁸ In general, the Department notes that the Department has been using its methodology for deriving HRLs since 2008.³¹⁹ The Department looks carefully at both long-term and short-term studies.³²⁰ The Department relies on short-term exposures in its process to ensure it protects sensitive groups, such as infants and fetuses, who are only subject to short-term exposures.³²¹ Moreover, to ensure a safe HRL “for short-term exposures that occur during (sub)chronic durations, the short-term reference dose and/or drinking water guidance value are used for the longer durations if the short-term numbers are lower than those calculated from sub(chronic) studies.”³²²

³¹² *Id.* at 2, *citing* Feng X et al. Exposure of Pregnant Mice to Perfluorobutanesulfonate Causes Hypothyroxinemia and Developmental Abnormalities in Female Offspring. *Toxicol Sci* 155(2): 409-419 (2017).

³¹³ *Id.*

³¹⁴ *Id.*, *citing* USEPA. Recommended Use of Body Weight $\frac{3}{4}$ as the Default Method in Derivation of the Oral Reference Dose. Office of the Science Advisor. Risk Assessment Forum. Washington, DC. EPA/100.R11/001 (2011). <https://www.epa.gov/risk/recommended-use-body-weight-34-default-method-derivation-oral-reference-dose> ; and Sharma V and McNeill JH. To scale or not to scale: the principles of dose extrapolation. *Brit J of Pharma* 157(6):907-921 (2009). <https://doi.org/10.1111/j.1476-5381.2009.00267.x>

³¹⁵ *Id.*

³¹⁶ *Id.*

³¹⁷ *Id.*

³¹⁸ Ex. I.2.c.ii.

³¹⁹ *Id.* at 1.

³²⁰ *Id.*

³²¹ *Id.* at 1-2.

³²² *Id.* at 2.

203. The Department used the NTP study to ensure the HRL derived is the most protective.³²³ According to the Department, “[t]he measured decrease in thyroid hormones was much larger in the NTP study conducted in adult rats (~25-75%) compared to the decreases in mice (~10-20%) observed” in the Feng study.³²⁴ Thus, the “dramatic decline would result in more severe effects on developing fetuses at lower doses than was observe in [the Feng study].”³²⁵ The Department also noted that “identifying and using dose-response information from the most sensitive species” is its preferred methodology.³²⁶

204. The Department explained that the EPA “derived a chemical-specific dosimetric adjustment factor (DAF) for PFBS” and that the Department used this approach.³²⁷ The Department states that “[b]ody weight scaling is not a preferred approach and is meant to be used as a default only when the other options are not feasible.”³²⁸

205. The Department asserts that the ACC position comparing thyroid and developmental effects is based on draft language from a 2018 EPA report which did not appear in the final report in 2021.³²⁹ Thus, the Department declined to rely on the draft language.

206. Finally, the Department stated that there was a data gap regarding immunotoxicity of PFBS.³³⁰ Immunotoxicity has, according to the Department, “been consistently observed as a sensitive effect for several other PFAS.”³³¹ Because of the lack of scientific data and the wealth of evidence of immune suppression in children (particularly infants) exposed to PFAS, immune suppression is an important datapoint for the Department in making its determination on the HRL for PFBS.³³²

207. The Judge finds that the Department has presented sufficient facts to adequately support the need for and reasonableness of the proposed HRL value for PFBS. The Department has fully explained its methods and the reasons for its choices. The Department has thus demonstrated that the proposed rule amendments are necessary and reasonable in terms of substance.

³²³ *Id.* at 2, *citing* National Toxicology Program. (2019) Toxicity studies of perfluoroalkyl sulfonates administered by gavage to Sprague Dawley (Hsd:Sprague Dawley CD) rats (TOX-96). Retrieved from <https://cebs.niehs.nih.gov/cebs/publication/TOX-96>

³²⁴ *Id.*

³²⁵ *Id.*

³²⁶ *Id.*

³²⁷ *Id.* at 3.

³²⁸ *Id.*

³²⁹ *Id.* at 3-4.

³³⁰ *Id.* at 4.

³³¹ *Id.*

³³² *Id.*

G. Rule 4717.7860, subp. 14c: Perfluorohexane sulfonate (PFHxS)

208. The details of the Department's proposal to add an HRL for Perfluorohexane sulfonate (PFHxS) are located in the SONAR, Section V,³³³ (see, Ex. D at 57-58) and need not be reproduced here.

209. On March 8, 2023, the Department received a written comment on its proposed HRL for PFHxS from the American Chemistry Council (ACC), which opposes the proposed HRL for the chemical.³³⁴

210. ACC notes that the Department did not provide any “discussion of the available chronic studies conducted by Butenhoff, et al (2009) [(the Butenhoff study)] and Chang, et al. (2018) [(the Chang study)].”³³⁵ According to ACC, the Butenhoff study has been widely used by a number of other states to assess the health effects of PFHxS.³³⁶ ACC states that the Department’s analysis fails to acknowledge that thyroid effects “may be related to hepatocellular hypertrophy caused by activation of the peroxisome proliferator-activated receptor alpha (PARA α) leading to hyperplasia of the thyroid that is likely not relevant to human health risk.”³³⁷

211. As a result, ACC recommends that “the Department should carefully review interspecies differences and human study data on the relevance of thyroid effects and the variability of thyroid hormones across life.”³³⁸ ACC claims that other study data indicate that there is a lack of evidence to support health risks from PFAS exposure in fetuses and children.³³⁹

212. According to ACC, “the calculation on which the Department [relies] inappropriately uses a benchmark response (BMR) of 20 percent rather than a BMR of one standard deviation.”³⁴⁰ Moreover, ACC continues, the Department’s analysis using the 20 percent BMR “has not been made available for review by external scientists and other stakeholders.”³⁴¹

³³³ Ex. D at 57-58.

³³⁴ Ex. I.2.d.i.

³³⁵ *Id.* at 2-3.

³³⁶ *Id.* at 3. See Butenhoff JL *et al.* 2009. Evaluation of potential reproductive and developmental toxicity of potassium perfluorohexanesulfonate in Sprague Dawley rats. *Reprod Toxicol* 27(3-4):331-341 (2009).

³³⁷ *Id.*

³³⁸ *Id.*

³³⁹ *Id.* at 3-4, *citing* Inoue K *et al.* Perfluoroalkyl substances and maternal thyroid hormones in early pregnancy: Findings in the Danish National Birth Cohort. *Environ Health Persp* 127(11):117002 (2019). <https://doi.org/10.1289/EHP5482>; and Butenhoff study.

³⁴⁰ *Id.* at 4.

³⁴¹ *Id.*

213. ACC thus recommends that the Department “defer establishing standards [for PFHxS] until more data on chronic effects are available.”³⁴²

214. The Department responded the ACC’s comments on March 31, 2023.³⁴³ (See finding of fact 202 for the Department’s general comments.)

215. The Department notes that it evaluated the Butenhoff and Chang studies as part of the PFHxS review process.³⁴⁴ However, the Department relied on the NTP study because thyroid hormone was examined in that study, whereas it was not examined in either the Butenhoff or Chang studies.³⁴⁵

216. The Department contends that the Butenhoff study “only examined the thyroid histologically.”³⁴⁶ Thus, it was not possible “to determine the impact of PFHxS on thyroid hormones or overall thyroid function” using that study.³⁴⁷ The Department also noted that “PARA α activation alone is not sufficient to determine whether a health effect is relevant to human health risk.”³⁴⁸ Moreover, there are studies which counter the Butenhoff study conclusion that hepatocellular hypertrophy is a source of thyroid effects.³⁴⁹ According to the Department, other recent studies suggest that PFHxS can disrupt thyroid hormones through non-hepatic interactions.³⁵⁰ Moreover, “approximately 25% of the gene expression changes caused by PFHsX exposure are independent of PARA α activity,” indicating some other mechanism through which PFHsX affects cells.³⁵¹ The Department notes that “[i]nsufficient thyroid hormone levels during critical periods of development can cause irreversible damage.”³⁵²

217. The Department rejects ACC’s suggestion to rely on epidemiological studies because they have mixed results.³⁵³ However, the Department acknowledges that evidence of thyroid toxicity in animals exposed to PFHxS, without data specifically about humans, should continue to be relied on.³⁵⁴ The Department is also interested in data based on pre- and neo-natal immunological and neurological developmental windows which are more susceptible to disruption than in adults.³⁵⁵

³⁴² *Id.*

³⁴³ Ex. I.2.c.ii

³⁴⁴ *Id.* at 5.

³⁴⁵ *Id.*

³⁴⁶ *Id.*

³⁴⁷ *Id.*

³⁴⁸ *Id.*

³⁴⁹ *Id.*

³⁵⁰ *Id.* at 6.

³⁵¹ *Id.*

³⁵² *Id.*

³⁵³ *Id.*

³⁵⁴ *Id.* at 7.

³⁵⁵ *Id.* at 8.

218. The Department denies ACC's allegation that the Department has withheld information from the public.³⁵⁶ Instead, it claims that its use of the 20 percent BMR is based on "the best available science . . . at the time of [the Department's] review."³⁵⁷

219. The Judge finds that the Department has presented sufficient facts to adequately support the need for, and reasonableness of, the proposed HRL value for PFHxS. The Department has fully explained its methods and the reasons for its choices. The Department has thus demonstrated that the proposed rule amendments are necessary and reasonable in terms of substance.

H. Rule 4717.7860, subp. 14d: Perfluorohexanonate (PFHxA)

220. The details of the Department's proposal to add an HRL for Perfluorohexanonate (PFHxA) are located in the SONAR, Section V,³⁵⁸ (see Ex. D at 58-59) and need not be reproduced here.

221. On March 8, 2023, the Department received a written comment on its proposed HRL for PFHxA from the American Chemistry Council (ACC), which opposes the proposed HRL for the chemical.³⁵⁹

222. The ACC criticized the Department's choice of study to formulate the HRL for PFHxA.³⁶⁰ According to the ACC, the study upon which the Department relied had inconsistent findings on thyroid endpoints that were reported across several study designs.³⁶¹ Thus, there was not as much strength in the Department's relied-upon evidence, and the Department should have relied on a chronic study complete by Klaunig, et al. to derive the HRL.³⁶² Moreover, ACC asserts that the studies available do not show a pattern of immune effects or developmental effects.³⁶³ Thus, the ACC recommended the Department reevaluate the available data before promulgating an HRL for PFHxA.³⁶⁴

223. The Department responded the ACC's comments on March 31, 2023.³⁶⁵ (See Finding of Fact 202 for the Department's general comments.)

³⁵⁶ *Id.* at 9.

³⁵⁷ *Id.*

³⁵⁸ Ex. D at 58-59.

³⁵⁹ Ex. I.2.d.i.

³⁶⁰ *Id.* at 4.

³⁶¹ *Id.*

³⁶² *Id.* at 4-5, *citing* Klaunig JE, *et al.* Evaluation of the chronic toxicity and carcinogenicity of perfluorohexane acid (PFHxA) in Sprague-Dawley rats. *Toxicol Pathol* 43(2), 209-220 (2015).

³⁶³ *Id.* at 5.

³⁶⁴ *Id.*

³⁶⁵ Ex. I.2.c.ii

224. The Department asserts that it reviewed all available data, including the studies cited by ACC.³⁶⁶ The Department also notes that, “to ensure health protections for all populations across all durations,” its methodology relies on a lower guidance value from a shorter duration over a higher value from a longer duration.³⁶⁷ The Department also provided a detailed defense of its reliance on the NTP study, as well as its uncertainly factor of 10.³⁶⁸ The higher uncertainty factor was the result of data gaps that the Department could only account for with a higher uncertainty factor so as to protect the most vulnerable populations.³⁶⁹

225. The Department also noted that decreased post-natal body weight in exposed animals is appropriately considered as an adverse health effect of exposure.³⁷⁰

226. The Judge finds that the Department has presented sufficient facts to adequately support the need for, and reasonableness of, the proposed HRL value for PFHxA. The Department has fully explained its methods and the reasons for its choices. The Department has thus demonstrated that the proposed rule amendments are necessary and reasonable in terms of substance.

227. As noted above, the Department is legally entitled to make choices between possible approaches as long as its choice is rational. It is not the role of the administrative law judge to determine which policy is “best” or to substitute his judgment for that of the agency, for that would invade the policy making discretion of the agency.³⁷¹ The critical question is whether the choice made by the agency is one that a rational person could have made, not whether there is a better option.³⁷²

228. This record evidences that the Department’s proposed rules are based on its expertise, are adequately supported by scientifically acceptable, peer-reviewed information, and are in the realm of the Department’s responsibilities. The Judge finds the Department has affirmatively demonstrated that the scientific methodology underlying its proposed amendments is reasonable and defensible. The Department has shown that its decision to proceed with the proposed amendments was deliberative and rational. The Department’s decision is not arbitrary, capricious, or unreasonable.

³⁶⁶ *Id.* at 10.

³⁶⁷ *Id.*

³⁶⁸ *Id.* at 10, 11.

³⁶⁹ *Id.* at 11.

³⁷⁰ *Id.*

³⁷¹ See generally, *Citizens Advocating Responsible Dev. v. Kandiyohi Cty. Bd. of Comm'rs*, 713 N.W.2d 817, 832 (Minn. 2006) (“Our role when reviewing agency action is to determine whether the agency has taken a ‘hard look’ at the problems involved, and whether it has ‘genuinely engaged in reasoned decision-making’”) (quoting *Reserve Mining Co. v. Herbst*, 256 N.W.2d 808, 825 (Minn. 1977)).

³⁷² *Federal Sec. Adm'r v. Quaker Oat Co.*, 318 U.S. 218, 233 (1943).

CONCLUSIONS OF LAW

1. The Department gave proper notice of the hearing in this matter and has fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule, except as noted in findings 88, 89, 103, 104, 107-109, and 137-140.
2. The Department demonstrated its statutory authority to adopt the proposed rules.
3. The Department demonstrated the need and reasonableness of the proposed rules by an affirmative presentation of facts in the record. The Department did not meet the requirements of Minn. Stat. §§ 14.127 and .131 (2), (5), and (6), however, as noted in findings 88, 89, 103, 104, 107-109, and 137-140.
4. Due to findings of defect and conclusions 1 and 3, this Report has been submitted to the Chief Judge for her approval, pursuant to Minn. Stat. § 14.15, subd. 3.
5. Any findings that might properly be termed conclusions and any conclusions that might properly be termed findings are hereby adopted as such.
6. A finding or conclusion of need and reasonableness with regard to any particular rule subsection does not preclude -- and should not discourage -- the Department from modification of the proposed rules based on this Report and an examination of the public comments, provided that the rule finally adopted is based on facts appearing in this hearing record.

Based on the conclusions of law, the Judge makes the following:

RECOMMENDATION

1. The Judge **DISAPPROVES** the Department's proposed rules for the reasons stated herein, at findings 88, 89, 103, 104, 107-109, and 137-140.
2. This Report and its findings are submitted to the Chief Administrative Law Judge for approval, pursuant to Minn. Stat. § 14.15, subd. 3.

Dated: July 10, 2023



JIM MORTENSON
Administrative Law Judge