Exhibit A. Request for Comments

Minnesota State Register

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Proposed, Adopted, Emergency, Expedited, Withdrawn, Vetoed Rules; Executive Orders; Appointments; Commissioners' Orders; Revenue Notices; Official Notices; State Grants & Loans; State Contracts; Non-State Public Bids, Contracts and Grants

Monday 7 August 2023

Volume 48, Number 6

Pages 123 - 150

Public Comment. Interested persons or groups may submit comments or information on these possible rules in writing until 4:30 p.m. on October 9, 2023. The Board does not plan to appoint a specific advisory committee to comment on the possible rules. However, public meetings of the Board's Legislative and Rules Committee may provide a forum for discussion on these proposed rules. Any meeting of the EMSRB Legislative and Rules Committee will be posted on EMSRB'S publicly available website.

Rules Drafts. The Board is in the process of drafting a possible rules amendment. Individuals wanting to review that draft when it becomes available can review them on the Board's publicly available website once they become available.

Agency Contact Person. Written comments, questions, requests to receive a draft of the rules, and requests for more information on these possible rules should be directed to: Dylan Ferguson at the Emergency Medical Services Regulatory Board, 335 Randolph Ave Suite 220 St Paul, MN 55102, phone 651-201-2806, or ***Dylan.Ferguson@state.mn.us***

Alternative Format. Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request, please contact the agency contact person at the address or telephone number listed above.

NOTE: Comments received in response to this notice will not necessarily be included in the formal rulemaking record submitted to the administrative law judge if and when a proceeding to adopt rules is started. The agency is required to submit to the judge only those written comments received in response to the rules after they are proposed. If you submitted comments during the development of the rules and you want to ensure that the Administrative Law Judge reviews the comments, you should resubmit the comments after the rules are formally proposed.

Dated: August 7, 2023

Dylan Ferguson, Executive Director
Emergency Medical Services Regulatory Board

Minnesota Department of Health (MDH)

Environmental Health Division, Environmental Surveillance and Assessment Section

REQUEST FOR COMMENTS on Possible Amendments to Rules Governing Health Risk Limits, *Minnesota Rules*, Parts 4717.7500 and 4717.7860

Subject of Rules. The Minnesota Department of Health (MDH) requests comments on possible amendments to rules governing Health Risk Limits (HRLs) for groundwater. The amendments will add new HRL values or replace outdated HRL values for groundwater contaminants to the existing Health Risk Limits Tables found in Minnesota Rules, parts 4717.7500 and 4717.7860, plus any related changes necessary to accomplish this. In particular, Minnesota Rules 4717.7860, Subpart 15, for perfluorooctane sulfonate (PFOS) will be updated so that the value does not exceed 0.015 parts per billion, per *Laws of Minnesota 2023*, Chapter 60, Article 3, Section 34.

Persons Affected. The possible amendments to the rules will likely affect risk managers in partner state and local agencies: the Minnesota Department of Agriculture (MDA), the Minnesota Pollution Control Agency (MPCA), the Minnesota Department of Natural Resources (DNR), water system operators, and local public health agencies. Partner agencies rely on HRL values as one standard for environmental assessment and risk management to protect groundwater resources. Industries that manufacture or use the identified chemicals and environmental groups that monitor water quality are also affected. The proposed amendments ultimately could affect drinking water sources for Minnesotans who rely on groundwater as their source of drinking water.

Statutory Authority. *Laws of Minnesota 2023*, Chapter 60, Article 3, Section 34, requires MDH to adopt a rule for PFOS that does not exceed 0.015 parts per billion by July 1, 2026. In addition, the Groundwater Protection Act of 1989 (*Minnesota Statutes,* section 103H.201) and *Minnesota Statutes*, section 144.12, subdivision 1(5), authorize MDH to

adopt and revise health risk limits for substances degrading groundwater. The 2001 Health Standards Statute (*Minnesota Statutes*, section 144.0751) specifies additional requirements for establishing safe drinking water standards.

Public Comment. MDH is now seeking comment on the specific water contaminants and the corresponding values that we are considering for the rule amendment, particularly PFOS. An updated value for PFOS is currently being derived by MDH toxicologists and will be announced when it is finalized. Anyone with interest in this update is encouraged to submit comments. MDH also encourages interested parties to sign up for ***Email Updates (https://public.govdelivery.com/accounts/MNMDH/subscriber/new?topic_id=MNMDH_39)*** through an email subscription service where the updated PFOS value will be announced, along with other updates related to Minnesota water guidance. The updates will also be posted on MDH's website at ***Rules Amendments – Contaminants https://www.health.state.mn.us/communities/environment/risk/rules/water/chemicals.html***. Further, new or updated water guidance values that are eligible for rulemaking will be included in this rule. Links to chemicals currently under consideration for HRLs can be found at on the webpage ***Rules Amendments – Overview and Links https://www.health.state.mn.us/communities/environment/risk/rules/water/overview.html.***

This page will be updated as work progresses.

MDH is also seeking comment on the total regulatory impact that may occur by adding the proposed rule to other state and federal rules related to the same specific purpose.

Interested persons or groups may submit comments or information on these possible rules in writing or orally until MDH publishes a notice of intent to adopt amendments in the *State Register.* MDH will not publish such a notice until more than 60 days have elapsed from the date of this Request for Comments. MDH will make related announcements via its email subscription service. Further information on possible rule amendments, related public meetings, and email subscription is available at ***Rules Amendments – Overview and Links https://www.health.state.mn.us/communities/environment/risk/rules/water/overview.html***.

Rules Drafts. MDH has not yet drafted the possible rules amendments, but it will post them on the webpage ***Rules Amendments – Overview and Links https://www.health.state.mn.us/communities/environment/risk/rules/water/overview.html***.

Agency Contact Person. Written or oral comments, questions, or requests to receive a draft of the rules when available should be directed to:

Nancy Rice
Minnesota Department of Health
625 Robert Street North
P.O. Box 64975
Saint Paul, MN 55164-0975
Phone: (651) 201-4923
E-mail: ***nancy.rice@state.mn.us***

Alternative Format. Upon request, this Request for Comments can be made available in an alternative format, such as large print, braille, or audio. To make such a request, please contact Nancy Rice at the address or telephone number listed above.

NOTE: Comments received in response to this notice will not necessarily be included in the formal rulemaking record submitted to the administrative law judge if and when a proceeding to adopt rules is started. The agency is required to submit to the judge only those written comments received in response to the rules after they are proposed. If you submit comments during the development of the rules and you want to ensure that the administrative law judge reviews the comments, you should resubmit the comments after the rules are formally proposed.

Dated: July 14, 2023

Tom Hogan, Director
Environmental Health Division
Minnesota Department of Health

Exhibit B. Petition for Rulemaking

Not applicable, the rules were not proposed in response to a petition

Exhibit C. Revisor's Office Approved Proposed Rules

Office of the Revisor of Statutes
Administrative Rules

TITLE: Proposed Permanent Rules Related to Health Risk Limits

AGENCY: Department of Health

REVISOR ID: R-4803

MINNESOTA RULES: Chapter 4717

The attached rules are approved for
publication in the State Register

Sandra Glass-Sirany

Sandy Glass-Sirany
Senior Assistant Revisor

Department of Health

Proposed Permanent Rules Related to Health Risk Limits

4717.7860 HEALTH RISK LIMITS TABLE.

[For text of subparts 1 to 7, see Minnesota Rules]

Subp. 7a. [Renumbered subp 7c]

Subp. 7b. **Chlorothalonil.**

CAS number: 1897-45-6

Year Adopted: 2025

Volatility: Nonvolatile

	Acute	**Short-term**	**Subchronic**	**Chronic**	**Cancer**
HRL (µg/L)	ND	20	2	1	6
RfD (mg/kg-day)	--	0.014	0.00067	0.00029	--
RSC	--	0.5	0.2	0.2	--
SF (per mg/kg-day)	--	--	--	--	0.017
ADAF or $AF_{lifetime}$	--	--	--	--	10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)
Intake Rate (L/kg-day)	--	0.290	0.074	0.045	0.155 $_{(<2)}$ 0.040 $_{(2\ to\ <16)}$ 0.042 $_{(16+)}$
Endpoints	--	gastrointestinal system	gastrointestinal system	gastro-intestinal system, hepatic (liver) system, renal (kidney) system	cancer

Subp. ~~7a~~ 7c. **Clothianidin.**

CAS number: 210880-92-5, 205510-53-8

Year Adopted: 2018

Volatility: Nonvolatile

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	ND	200	200 (2)	200 (2)	NA
RfD (mg/kg-day)	--	0.093	(2)	(2)	--
RSC	--	0.5	(2)	(2)	--
SF (per mg/kg-day)	--	--	--	--	--
ADAF or $AF_{lifetime}$	--	--	--	--	--
Intake Rate (L/kg-day)	--	0.285	(2)	(2)	--
Endpoints	--	developmental	developmental	developmental	--

Subp. ~~8~~ 7d. **Cyanazine.**

CAS number: 21725-46-2

Year Adopted: 2018

Volatility: Nonvolatile

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	3	3	3	1	NA
RfD (mg/kg-day)	0.0015	0.0015	0.0012	0.00022	--
RSC	0.5	0.5	0.2	0.2	--
SF (per mg/kg-day)	--	--	--	--	--
ADAF or $AF_{lifetime}$	--	--	--	--	--

Intake Rate (L/kg-day)	0.285	0.285	0.070	0.044	--
Endpoints	developmental, female reproductive system	developmental, female reproductive system	developmental, female reproductive system, hepatic (liver) system, renal (kidney) system	None	--

Subp. 7e. **1,2-Dibromoethane (EDB).**

CAS number: 106-93-4

Year Adopted: 2025

Volatility: High

	Acute	**Short-term**	**Subchronic**	**Chronic**	**Cancer**
HRL (µg/L)	ND	10	10 (2)	9	0.03
RfD (mg/kg-day)	--	0.018	(2)	0.0021	--
RSC	--	0.2	(2)	0.2	--
SF (per mg/kg-day)	--	--	--	--	3.6
ADAF or $AF_{lifetime}$	--	--	--	--	10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)
Intake Rate (L/kg-day)	--	0.290	(2)	0.045	0.155 $_{(<2)}$ 0.040 $_{(2\ to\ <16)}$ 0.042 $_{(16+)}$
Endpoints	--	female reproductive system, hepatic (liver) system, immune	female reproductive system, hepatic (liver) system, immune	female reproductive system, hepatic (liver) system, immune	cancer

		system, male reproductive system, renal (kidney) system, respiratory system, spleen	system, male reproductive system, renal (kidney) system, respiratory system, spleen	system, male reproductive system, respiratory system	

Subp. 8. [Renumbered subp 7d]

[For text of subparts 8a to 8f, see Minnesota Rules]

Subp. 8g. [See repealer.]

[For text of subparts 8h to 14d, see Minnesota Rules]

Subp. 15. **Perfluorooctane sulfonate (PFOS) and salts.**

CAS number: 45298-90-6; 1763-23-1; 29081-56-9; 2795-39-3; 70225-14-8; and 29457-72-5

Year Adopted: ~~2009~~ 2025

Volatility: Nonvolatile

	Acute	**Short-term**	**Subchronic**	**Chronic**	**Cancer**
HRL (µg/L)	ND	~~ND~~ 0.0023	~~ND~~ 0.0023	~~0.3~~ 0.0023	~~NA~~ 0.0076
~~**RfD (mg/kg-day)**~~ RfSC (ng/mL)*	--	~~--~~ 2.6	~~--~~ 2.6	~~0.00008~~ 2.6	--
RSC	--	~~--~~ 0.2	~~--~~ 0.2	0.2	--
SF (per mg/kg-day)	--	--	--	--	~~--~~ 13
ADAF or $AF_{lifetime}$	--	--	--	--	~~--~~ 10 ($ADAF_{<2}$) 3 ($ADAF_{2 \text{ to } <16}$)

					1 (ADAF 16+)
Intake Rate (L/kg-day)	--	~~--~~ #	~~--~~ #	~~0.049~~ #	~~--~~ 0.155 (<2) 0.040 (2 to <16) 0.042 (16+)
Endpoints	--	~~--~~ developmental, hepatic (liver) system, immune system	~~--~~ developmental, hepatic (liver) system, immune system	developmental, hepatic (liver) system, ~~thyroid (E)~~ immune system	~~--~~ cancer

* A reference serum concentration (ng/mL) rather than a reference dose (mg/kg-d) was used in MDH's toxicokinetic model to calculate noncancer guidance values for PFOS.

95th percentile water intake rates (Tables 3-1, 3-3, and 3-5 in the Environmental Protection Agency, Exposure Factors Handbook, 2019), or upper percentile breast milk intake rates (Table 15-1), Environmental Protection Agency Exposure Factors Handbook, 2011.

Subp. 16. **Perfluorooctanoate (PFOA) and salts.**

CAS number: 45285-51-6; 335-67-1; ~~335-66-0;~~ 3825-26-1; 2395-00-8; 335-93-3; and 335-95-5

Year Adopted: ~~2018~~ 2025

Volatility: Nonvolatile

	Acute	**Short-term**	**Subchronic**	**Chronic**	**Cancer**
HRL (µg/L)	ND	~~0.035~~ 0.00024	~~0.035~~ 0.00024	~~0.035~~ 0.00024	~~NA~~ 0.0000079
~~**RfD (mg/kg-day)**~~ **RfSC (ng/mL)***	--	~~0.000018~~ 0.93	~~0.000018~~ 0.93	~~0.000018~~ 0.93	--
RSC	--	~~0.5~~ 0.2	~~0.5~~ 0.2	~~0.5~~ 0.2	--

SF (per ~~mg/kg-day~~ ng/kg-day)	--	--	--	--	~~--~~ 0.0126
ADAF or $AF_{lifetime}$	--	--	--	--	~~--~~ 10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)
Intake Rate (L/kg-day)	--	~~*~~ #	~~*~~ #	~~*~~ #	~~--~~ 0.155 (≤2) 0.040 (2 to ≤16) 0.042 (16+)
Endpoints	--	developmental, hepatic (liver) system, immune system~~, renal (kidney) system~~	developmental, hepatic (liver) system, immune system~~, renal (kidney) system~~	developmental, hepatic (liver) system, immune system~~, renal (kidney) system~~	~~--~~ cancer

~~*~~ A reference serum concentration (ng/mL) rather than a reference dose (mg/kg-d) was used in MDH's toxicokinetic model to calculate noncancer guidance values for PFOA.

~~*~~ # 95th percentile water intake rates (Tables 3-1 ~~and~~, 3-3, and 3-5 in the Environmental Protection Agency, Exposure Factors Handbook, 2019), or upper percentile breast milk intake rates (Table 15-1), Environmental Protection Agency ~~(EPA)~~ Exposure Factors Handbook, 2011.

[For text of subparts 16a to 24, see Minnesota Rules]

REPEALER. Minnesota Rules, parts 4717.7500, subparts 5, 26a, and 31; and 4717.7860, subpart 8g, are repealed.

Exhibit D. Statement of Need and Reasonableness

STATEMENT OF NEED AND REASONABLENESS

In the Matter of Proposed Revisions of
Minnesota Rules, Chapter 4717, Parts 7500 and 7860
Revisor's ID Number: 4803
OAH Docket number: 22-9000-40331

Division of Environmental Health

October 2024

General information

1) Availability: The State Register notice, this Statement of Need and Reasonableness (SONAR), and the proposed rule will be available during the public comment period on the Agency's Public Notices website: Health Risk Limits Rules for Groundwater Rules Amendments -Overview and Links https://www.health.state.mn.us/communities/environment/risk/rules/water/overview.html

2) View older rule records at: Minnesota Rule Statutes https://www.revisor.mn.gov/rules/status/

3) Agency contact for information, documents, or alternative formats: Upon request, this Statement of Need and Reasonableness can be made available in an alternative format, such as large print, braille, or audio. To make a request, contact Nancy Rice, Minnesota Department of Health, 625 North Robert St, St. Paul, MN 55164; telephone 651-201-4923 or 1-800-201-5000; nancy.rice@state.mn.us; or use your preferred telecommunications relay service.

Contents

Acronyms

aci	as cited in (Used when a publication is cited in a second document)
ADAF	Age-Dependent Adjustment Factor
$AF_{lifetime}$	Lifetime Adjustment Factor
APA	Administrative Procedures Act
ALJ	Administrative Law Judge
BMD	Benchmark Dose
BMDL	Benchmark Dose Lower-Confidence Limit
CAS	Chemical Abstract Service Number
CEC	Contaminant of Emerging Concern
CFR	Code of Federal Regulations
cHRL	cancer Health Risk Limit
DAF	Dose Adjustment Factor
DWEL	Drinking Water Equivalent Levels (issued by EPA)
(E)	Endocrine
EPA	U.S. Environmental Protection Agency
HA	Health Advisory
HBV	Health-Based Value
HED	Human Equivalent Dose
HRA	Health Risk Assessment
HRL	Health Risk Limit
IR	Intake Rate
LOAEL	Lowest Observed Adverse Effect Level
MCL	Maximum Contaminant Level (created by EPA)
MCLG	Maximum Contaminant Level Goal (created by EPA)
µg/L	microgram/Liter (also parts per billion)
mg/kg-day	milligrams (of a chemical) per kilogram (of body-weight) per day
MDA	Minnesota Department of Agriculture
MDH	Minnesota Department of Health
MMB	Minnesota Management and Budget

MPCA	Minnesota Pollution Control Agency
Minn. R. pt	Minnesota Rules part
Minn. Stat.	Minnesota Statutes
MN	Minnesota
NA	Not Applicable
ND	Not Derived
nHRL	noncancer Health Risk Limit
NOAEL	No Observed Adverse Effect Level
OAH	Office of Administrative Hearings
PFAS	Per- and Polyfluoroalkyl Substances
PFOA	Perfluorooctanoate
PFOS	Perfluorooctane sulfonate
POD	Point of Departure
RfSC	Reference Serum Concentration
RfD	Reference Dose
RSC	Relative Source Contribution
SF	Slope Factor
SONAR	Statement of Need and Reasonableness
UF	Uncertainty Factor

Introduction and Overview

Introduction

This Statement of Need and Reasonable (SONAR) concerns Health Risk Limit (HRL) Rules amendments. An HRL is the concentration of a groundwater contaminant, or a mixture of contaminants, that can be consumed with little or no risk to health. An HRL can be used to determine if groundwater is acceptable to drink. The value is usually expressed as micrograms of a chemical per liter of water (µg/L) though very low values are expressed as nanograms per liter of water (ng/L). MDH calculates HRL values for specific durations of exposure.

Groundwater provides about 75 percent of Minnesota's drinking water, making it an important resource for the state. In 1989, the Minnesota Groundwater Protection Act proclaimed that it "is the goal of the state that groundwater be maintained in its natural condition, free from degradation caused by human activities." (Minn. Stat. § 103H.001). However, when groundwater quality monitoring shows that the water quality has degraded, the Groundwater Protection Act authorizes the Minnesota Department of Health (MDH) to adopt rules that set health-protective limits, known as Health Risk Limits (HRLs), for contaminants found in groundwater that might be used for drinking (Minn. Stat. § 103H.201).

This project proposes to amend Minnesota Rules, Chapter 4717, by revising and/or repealing HRLs for six groundwater contaminants. Specifically, the amendments repeal six outdated HRL values in Minnesota Rules part 4717.7500 or .7860 and add four updated HRL values to 4717.7860 to replace four of the repealed values (see Proposed Rules: The Health Risk Limits Table below). The two HRL values that will not be replaced are outdated, but there is insufficient data available to create updated water guidance values using methods adopted in 2009. However, using the information that is available, new Risk Assessment Advice (RAA) values (which can be used to develop water guidance but cannot be adopted into rule) have already been published on the MDH website at Human Health-Based Water Guidance Table (https://www.health.state.mn.us/communities/environment/risk/guidance/gw/table.html).

These proposed amendments for the six groundwater contaminants build on MDH's 2009 rule revision and subsequent rulemaking. The current rules on the Health Risk Limits in Minnesota Rules, Chapter 4717 are available on the Minnesota Department of Health's website at Health Risk Limits Rules: (https://www.health.state.mn.us/communities/environment/risk/rules/water/hrlrule.html). MDH will not be amending any other parts of the HRL rules at this time.

The Minnesota Administrative Procedure Act (APA), Minnesota Statutes, chapter 14, requires MDH to justify the need to amend the existing HRL rules and the reasonableness of the amendments in a Statement of Need and Reasonableness (SONAR) (See Minn. Stat. § 14.131). This document fulfills that requirement.

This SONAR is divided into five sections. This Introduction and Overview section contains this introduction, a general scope of the proposed amendments, a description of the contents of the document, and a statement of general need and reasonableness. The Background section briefly describes the definition of HRLs, how they are calculated, past HRL Rule Revisions, and provides detail on MDH's statutory authority for adopting HRLs. The Proposed Rules section includes an overview of the scope of the proposed amendments, as well as detailed information on each proposed amendment in the Rule-by-Rule Analysis subsection. In the Public Participation and Interested Party Involvement section, MDH's process for selecting contaminants for water guidance development is discussed. Additional sections cover the Regulatory Analysis section, a Health Equity Statement, the Additional Notice Plan, the performance-based nature of the rules, consultation with Minnesota Management and Budget (MMB), and the impact of the proposed rules. Appendices A to E provide additional detail regarding term definitions, references cited, concepts used in calculating HRLs, contaminants selected, and a toxicological summary sheet for each contaminant included in this rulemaking.

Statement of General Need and Reasonableness

In general, the agency needs amendments to Minnesota Rules, parts 4717.7500 and .7860 to update outdated HRL values and to add new HRLs for newly detected groundwater contaminants.

In the case of these amendments, the Minnesota Legislature is requiring MDH to "adopt an updated HRL value of no greater than 0.015 ppm for PFOS" under a Session Law passed in 2023 (Laws of Minnesota 2023, Chapter 60, Article 3, Section 34).

Minnesota Statutes, section 103H.201 authorizes MDH to adopt HRLs and provides a general outline of how to derive the HRLs:

1) MDH, in partnership with other State of Minnesota agencies, have detected and identified contaminants in groundwater that cause the degradation of groundwater in some locations where the groundwater is or could be used as a source of drinking water.

2) The contaminants have been evaluated and found to pose potential health risks to humans when they are consumed in groundwater for over defined durations of time.

3) Recent studies of the contaminants have been reviewed by MDH staff and have resulted in updated water guidance values for some contaminants.

4) MDH will use its authority to propose adoption of new or updated HRLs when there is concern about human consumption of contaminated water.

Background

The following section for MDH's guidance on groundwater contaminants covers:

- Defining HRLs
- the MDH-derived HRL algorithm;
- past MDH HRL rule revisions; and
- the statutory authority to review, derive, adopt, and revise HRL values.

Defining Health Risk Limits (HRLs)

HRL values are a type of health-protective guidance MDH develops for groundwater contaminants that pose a potential threat to human health if consumed in drinking water. The 1989 Groundwater Protection Act in Minnesota Statutes, section 103H.005, subdivision 3, defines an HRL 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.

MDH has defined an HRL more precisely as 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 populations, and has been adopted into rule. The purpose of HRLs is described in Minnesota Rules, part 4717.7810, subpart 2, item B, which provides that, "HRLs specify a minimum level of quality for water used for human consumption, such as ingestion of water, and do not imply that allowing degradation of water supplies to HRL levels is acceptable."

MDH first calculates a value called a health-based water guidance value (HBV) for specific durations of exposure which may be later adopted into rule as an HRL. HBVs and HRLs are expressed as micrograms of a chemical per liter of water (µg/L).

In calculating water guidance values, MDH assumes people drink the water containing the contaminant. This assumption comports with the legislature's express policy that "the actual or potential use of the waters of the state for potable water supply is the highest priority use of that water and deserves maximum protection by the state . . . ." (Minn. Stat. § 115.063(a)(2)). This furthers the stated intent of MDH's groundwater protection statutes to prevent degradation of groundwater from contaminants (Minn. Stat. § 103H.001) and the more general legislative intent (Minn. Stat. § 115.063(a)(1)) that the waters of the state are protected.

Risk managers in partner state agencies, such as the Minnesota Department of Agriculture (MDA) and the Minnesota Pollution Control Agency (MPCA), request and apply HRL values in their respective risk-abatement and contamination-response programs. In addition, MDH's Site Assessment and Consultation Unit, Drinking Water Protection, and Well Management programs use HRL values in a context specific to their programs.

Except for the requirements for water resources protection (*See* Minn. Stat. § 103H.275, subd. 1(c)(2)), neither Minnesota statute nor current HRL rules specify how HRL values must be used. In issuing guidance, MDH assumes risk managers consider several principles when applying HRL values. MDH-derived HRL values:

- Specify a water quality level acceptable for human consumption;
- Should not be interpreted as acceptable degradation levels;
- Do not address non-ingestion pathways of exposure to contaminants in water (e.g., dermal or inhalation), except in apportioning exposure through a Relative Source Contribution (RSC) factor;
- Do not account for economic or technological factors such as the cost or feasibility of treatment; and
- Do not account for the potential impact on the environment outside the realm of drinking water, or the health of non-human species.

For more information on RSC, see the 2008/2009 SONAR [Part IV.E.1, page 51] (PDF) at https://www.leg.mn.gov/archive/sonar/SONAR-03733.pdf#page=60 and Minnesota Rules, part 4717.7820, subpart 22.

MDH cannot anticipate all the situations for which HRL values might provide meaningful guidance. Nor can MDH anticipate all the factors that might determine whether applying an HRL value is appropriate. As mentioned above, HRL values are but one of several sets of criteria that state groundwater, drinking water, and environmental protection programs may use to evaluate water contamination. Each program must determine whether to apply an HRL or whether site-specific characteristics justify deviation from HRL values.

MDH-derived HRL Algorithm

The MDH Health Risk Assessment (HRA) Unit derives water guidance values. The HRA Unit does not enforce or regulate the use of health-based guidance but provides recommended values for risk assessors and risk managers to use in making decisions and evaluating health risks. MDH's health-based guidance is only one set of criteria that state groundwater and environmental protection programs use to evaluate contamination. In addition, there are federal requirements

for permissible levels of some drinking-water contaminants called the Maximum Contaminant Levels (MCLs). Legally enforceable under the National Primary Drinking Water Regulations, they apply only to public water systems. More information about MCLs is available in the Regulatory analysis section below.

As stated above, MDH derives HRL values using the methods MDH adopted in 2009 (*See* Minn. R. 4717.7810 –.7900). The calculation used to develop an HRL value is a function of how toxic a chemical is (that is, the minimum quantity that will cause adverse health effects), the duration of exposure, and the amount of water individuals drink (intake rates) during the exposure period.

MDH's approach for developing non-cancer HRL values (nHRL) for effects other than cancer is specified in Minnesota Rules, part 4717.7830, subpart 2. MDH also uses this approach for chemicals that cause cancer only after a known dose level is exceeded (e.g., nonlinear carcinogens, as defined in Minnesota Rules, part 4717.7820). The algorithms and explanation of concepts used to derive HRL values are presented in Appendix C of this SONAR. Additional information is available in MDH's 2008/2009 SONAR (PDF) (Part IV.A at page 30, https://www.leg.mn.gov/archive/sonar/SONAR-03733.pdf#page=30).

Past MDH HRL Rule Revisions

In 1993, MDH adopted methods to calculate HRL values and adopted HRL values for chemicals based on those methods. In 1994, MDH adopted additional HRL values based on the 1993 methods (the 1993-1994 HRL values). The 1993-1994 HRL values were published in Minnesota Rules, part 4717.7500.

In 2001, MDH toxicologists and risk assessors evaluated the adequacy of the 1993 methods to calculate the HRL values. The review spanned seven years during which MDH hosted public meetings and invited interested parties to participate. MDH began formal rulemaking in 2008 by proposing an updated methodology to derive HRL values based on the United States Environmental Protection Agency's (EPA) algorithms and standard practices available at that time. In 2009, MDH adopted the new methods and the HRL values for 21 groundwater contaminants that it derived using the updated methodology. The 2008/2009 SONAR documents additional details on the nature and scope of MDH's 2009 HRL rule revision.

In 2007, Minnesota enacted two laws that required MDH to establish additional HRLs through rule. The first law directed MDH to adopt HRLs for perfluorooctanoic acid (PFOA), (also called perfluorooactanoate [PFOA]), and perfluorooctane sulfonate (PFOS) (Minn. Laws 2007, ch. 37, § 1). MDH did this in August 2007 using the legislation's good-cause exemption authority for rulemaking. MDH adopted the 2007 values via the full rulemaking process in 2009. In 2018, the HRL for PFOA was replaced with an updated value derived from new scientific data.

The second 2007 law required MDH to set HRLs as stringent (i.e., low) as the EPA Maximum Contaminant Levels (MCL) for various commonly detected groundwater contaminants (Minn. Laws 2007, ch. 147, art. 17, § 2). In response, MDH established 11 MCL values as HRLs in 2007, and adopted these HRLs into rule in 2009 along with the MCL for nitrate. Eight of these "MCL-HRLs," as they have been called, plus nitrate, initially appeared in Minnesota Rules, part 4717.7850. MDH updated three of the original eleven MCL-HRLs and adopted them into Minnesota Rules, part 4717.7860 in 2009. Three more MCL-HRLs were updated and adopted into rule in 2015. In 2023, an updated value for tetrachloroethylene was updated and added to part 4717.7860 and removed from part 4717.7850. To date, four of the original 11 MCL values adopted in 2007, plus nitrate, remain unchanged in Minnesota Rules, part 4717.7850, subpart 2.

In 2011, MDH added HRL values for 14 contaminants to Minnesota Rules, part 4717.7860, and updated part 4717.7500 to reflect all repealed or updated values.

In 2013, MDH added HRL values to Minnesota Rules, part 4717.7860, for six chemicals not previously in the HRL rules, and repealed and replaced outdated HRL values for six chemicals. In total, MDH adopted new or updated HRL values for 12 chemicals in 2013.

In 2015, MDH proposed new HRL values for eight chemicals that had not previously appeared in the HRL Rules. MDH also repealed outdated HRL values for three chemicals in Minnesota Rules, part 4717.7500, and replaced the repealed values with updated guidance in part 4717.7860. Outdated HRL values for three additional chemicals already in Minnesota Rules, part 4717.7860, were repealed and replaced with new values. In total, MDH adopted new or updated HRL values for 14 chemicals in 2015.

In 2018, MDH proposed to adopt new or updated HRL values for 22 contaminants. Of these, 18 contaminants had values that were previously adopted in 1993, 2009, or 2011. One of the contaminants, PFOS, was removed from the initial proposed updates, leaving 17 contaminants with update proposals. MDH repealed the 17 outdated values from Minnesota Rules, parts 4717.7500 or 4717.7860, and added the updated values to Minnesota Rules, part 4717.7860. MDH added four additional new values to Minnesota Rules, part 4717.7860.

In 2023, MDH adopted 17 new HRL values and 19 updated HRL values. The 19 updated HRL values replaced values initially adopted in 1993, 1994, 2009, 2011, and 2013. In addition, one 1994 HRL value (n-hexane) was deleted and replaced with Risk Assessment Advice (RAA) which cannot be adopted into rule as they are not established using the same process and information as required under the laws and rules that govern HRL adoption.

For this rulemaking, MDH proposes to adopt an updated HRL value for PFOS. MDH also will propose to update values for three additional HRLs adopted in 1993, 1994, and 2018. In total, there are six contaminants included in this rulemaking (anthracene, chlorothalonil, 1,2-dibromoethane, dichlorodifluoromethane, PFOA, and PFOS), all of which have previous HRL values. MDH is proposing to repeal the HRLs for six contaminants and replace four of them. For

the two HRLs that will not be replaced (anthracene and dichlorodifluoromethane), MDH has already created new RAAs and posted them on the MDH website. This guidance can be used as a water guidance value but cannot be adopted into rule. MDH develops RAA guidance when there is insufficient data to develop a new Health-Based Value using the HRL methodology adopted in 2009.

The table below summarizes the new and updated HRLs adopted into rule since 1993. Some HRLs have been updated more than once.

Table 1. Number of HRL updates by year

Year	Number of new HRLs	Number of updated HRLs	Number of HRLs repealed and not replaced	Total Number of Contaminants with new or updated or repealed HRLs, by year
1993	89	-	-	89
1994	31	-	-	31
2007	2	12	-	14
2009	5	16	-	21
2011	6	8	3	17
2013	6	6	-	12
2015	8	6	-	14
2018	4	17	-	21
2023	17	19	1	37
2024 (Proposed)	0	4	2*	6

*The HRL value for anthracene adopted in 1993 is outdated. A newer RAA value was published on the MDH website in 2019. The HRL value for dichlorodifluoromethane was adopted in 2011, but it is now outdated. A RAA value for dichlorodifluoromethane was published on the MDH website in 2017.

Statutory Authority

MDH derives its authority to propose and adopt HRLs for water contaminants for this rulemaking from the following laws:

Minnesota Session Law

During the 2023 Legislative Session, the Minnesota Legislature passed a session law that requires MDH to adopt a value for perfluorooctane sulfonate (PFOS) into HRL rule that is no greater than 0.015 ppb. Specifically, Laws of Minnesota 2023, Chapter 60, Article 3, Section 34 states:

> By July 1, 2026, the commissioner of health must amend the health risk limit for perfluorooctane sulfonate (PFOS) in Minnesota Rules, part 4717.7860, subpart 15, so that the health risk limit does not exceed 0.015 parts per billion. In amending the health risk limit for PFOS, the commissioner must comply with Minnesota Statutes, section 144.0751, requiring a reasonable margin of safety to adequately protect the health of infants, children, and adults.

The Groundwater Protection Act of 1989

The *Groundwater Protection Act* of 1989—codified at Minnesota Statutes, chapter 103H—created MDH's statutory authority to adopt HRL values for groundwater contaminants. Under these new statutes, "[i]f groundwater quality monitoring results show that there is a degradation of groundwater, the commissioner of health may promulgate health risk limits under subdivision 2 for substances degrading the groundwater." (Minn. Stat. § 103H.201, subd. 1(a)).

An HRL is 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." (Minn. Stat. § 103H.005, subd. 3).

Minnesota Statutes, section 103H.201 authorizes the department to adopt and revise HRL values by rule (subds. 2(a), 3(b)).

MDH uses the following two methods to derive HRLs:

> (1) 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.
>
> (2) 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 or determined by the commissioner to have undergone thorough scientific review.

(Minn. Stat. § 103H.201, subd. 1(c), (d)).

2001 Health Standards Statute

Additional authority is implicit under the 2001 *Health Standards Statute* (Minn. Stat. § 144.0751), which applies to safe drinking water and air quality standards. It provides that safe drinking water standards must:

> (1) be based on scientifically acceptable, peer-reviewed information; and
>
> (2) 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) function, cancer, general infant and child development, and any other important health outcomes identified by the commissioner.

(§ 144.0751(a)).

In cases of water degradation, the Health Standards Statute informs MDH's review, development, and adoption of HRL values for water contaminants based on scientific methods to protect sensitive populations. These above-cited laws clearly establish MDH's authority to adopt the proposed rules.

Proposed Rules

Scope of Amendments

The proposed rule amendments are limited to Minnesota Rules, parts 4717.7500 and 4717.7860, with specific subparts noted below.

Through the proposed rules, MDH intends to:

- Repeal outdated guidance in Minnesota Rules, parts 4717.7500 or 4717.7860 for six contaminants. This includes four values to replace and two values, anthracene and dichlorodifluoromethane, that will only be repealed, as discussed above. Specifically, the values to be repealed from Minnesota Rules parts 4717.7500 or 4717.7860 are:
    - Anthracene (repeal from part 4717.7500, Subp. 5; adopted in 1993)

- Chlorothalonil (repeal from part 4717.7500, Subp. 26a; adopted in 1994)
- 1,2-Dibromoethane (ethylene dibromide, EDB) (repeal from part 4717.7500, Subp. 31; adopted in 1993)
- Dichlorodifluoromethane (repeal from part 4717.7860, Subp. 8g; adopted in 2011)
- Perfluorooctanoate (PFOA) and salts (repeal from part 4717.7860, Subp. 16; adopted in 2018)
- Perfluorooctane Sulfonate (PFOS) and salts (repeal from part 4717.7860, Subp. 15; adopted in 2009)

- Adopt into rule HRL values for four groundwater contaminants with guidance developed using the 2009 methodology and 2019 EPA intake rates. All four contaminants have previously-adopted HRL values in rule. The proposed HRL values, as described in detail in the Rule-by-Rule Analysis section would be added to Minnesota Rules, part 4717.7860:
    - Chlorothalonil (Add updated HRL to renumbered Subp. 7b)
    - 1,2-Dibromoethane (ethylene dibromide, EDB) (Add updated HRL to renumbered Subp. 7e)
    - Perfluorooctane Sulfonate (PFOS) and salts (Add updated HRL to Subp. 15)
    - Perfluorooctanoate (PFOA) and Salts (Add updated HRL to Subp. 16)

More detail about these proposed changes is provided below in the Rule-by-Rule Analysis section.

Table 2. Contaminants included in the proposed HRL amendments

Number	Chemical Abstract Service (CAS) Number	Contaminant Name	Previously adopted values in HRL Rule? (year adopted)
1	120-12-7	Anthracene (Repeal only and not replace. Updated RAA values have already been published.)	Yes (1993)
2	1897-45-6	Chlorothalonil	Yes (1994)
3	106-93-4	1,2-Dibromoethane (ethylene dibromide, EDB)	Yes (1993)
4	75-71-8	Dichlorodifluoromethane (Repeal only and not replace. Updated RAA	Yes (2011)

Number	Chemical Abstract Service (CAS) Number	Contaminant Name	Previously adopted values in HRL Rule? (year adopted)
		values have already been published.)	
5	45285-51-6; 335-67-1; 3825-26-1; 2395-00-8; 335-93-3; 335-95-5	Perfluorooctanoate (PFOA) and salts	Yes (2018)
6	45298-90-6; 1763-23-1; 29081-56-9; 70225-14-8; 2795-39-3; 9457-72-5	Perfluorooctane Sulfonate (PFOS) and salts	Yes (2009)

Rule-by-Rule Analysis

EXPLAINING THE HEALTH RISK LIMITS TABLE (Minnesota Rules, part 4717.7860)

The Health Risk Limits table in Minnesota Rules, part 4717.7860, lists the HRL values derived for chemicals found in Minnesota's groundwater. As noted before, an HRL value represents the health-protective limit of the concentration of a contaminant in groundwater that poses little or no risk to human health, including vulnerable populations, based on current scientific knowledge. HRL values are derived using the methodology specified in Minnesota Rules, parts 4717.7830 and 4717.7840 (see Appendix C for detailed explanations and definitions of the technical terms that follow).

For each chemical and its proposed HRL value, MDH provides the following information in a table:

Heading section:

- The chemical name;
- The CAS Registry Number that uniquely identifies each chemical;
- The year the rule will be adopted; and
- The chemical's volatility classification (nonvolatile, low, moderate, or high).

Row headings:

- **HRL (µg/L):** The Health Risk Limit value shown in micrograms of contaminant per liter of water.
- **RfD (mg/kg-day):** The duration-specific reference dose (RfD) is an estimate of a dose level that is likely to be without an appreciable risk of adverse effects and includes uncertainty factors. See the glossary in Appendix A, chemical summary sheets in

Appendix E, or Minnesota Rules 4717.7820 (https://www.revisor.mn.gov/rules/?id=4717.7820) for more information.

- **RSC:** Relative source contribution (RSC) is a portion of the reference dose that is allocated to drinking water.
- **SF (per mg/kg-day):** Slope factor (SF) is an upper-bound estimate of cancer risk per increment of dose, usually expressed in units of cancer incidence per milligram of chemical per kilogram of body weight per day (per [mg/kg-day] or $[mg/kg\text{-}day]^{-1}$). It reflects increased risks as the dose increases. The steeper the slope, the more potent the carcinogen.
- **Age-Dependent Adjustment Factors (ADAF) or Lifetime Adjustment Factor ($AF_{lifetime}$):** A multiplier of the cancer slope factor that adjusts for the increased susceptibility to cancer from early-life exposures to linear carcinogens.
- **Intake Rate (IR) (L/kg-day):** The amount of water, on a per body weight basis, ingested daily (liters per kg body weight per day or L/kg-day) for a given duration. MDH uses a time-weighted average of the 95^{th} percentile intake rate for the relevant duration.
- **Endpoint:** Endpoint refers to the organ systems that are most susceptible to harm and that should be grouped together for evaluation when more than one chemical is present (additivity endpoint). This can also include endocrine system involvement. (See also Endocrine (E) in the glossary).

Column headings:

Guidance values are developed for specific time durations or cancer endpoints, as follows:

- **Acute:** A period of 24 hours or less.
- **Short-Term:** A period of more than 24 hours, up to 30 days.
- **Subchronic:** A period of more than 30 days, up to approximately 10 percent of the life span in humans (more than 30 days up to approximately 90 days is typically used for mammalian laboratory animal species).
- **Chronic:** A period of more than approximately 10 percent of the life span in humans (more than approximately 90 days to 2 years in typically used mammalian laboratory animal species).
- **Cancer:** The duration used for cancer is 70 years.

In addition, the following notations are used within the tables:

- "--" means not relevant.
- "NA" means not applicable. "NA" in the cancer column means that the chemical has not been classified as a linear (non-threshold) carcinogen.

- "ND" means not derived due to absence or paucity of toxicity information.
- "None" means that the HRL value is based on a general adverse effect (e.g., reduced adult body weight) not attributable to a specific organ system. This endpoint is therefore not included in the calculation of a health risk index, which is used in determining the risk of exposure to multiple chemicals in water.
- Where noted and so that HRL values for longer durations of exposure are adequately protective of shorter durations of exposure, "(2)" indicates the calculated HRL value is greater than the short-term HRL value, so the HRL is set equal to the short-term HRL value.

Terminology

Terms used in the Proposed Rules section are defined below. A full glossary is available in Appendix A:

Additivity endpoint or Health risk index endpoint(s): The general description of critical and co-critical effects used to group chemicals for the purpose of evaluating risks from multiple chemicals. For example, the effect "inhibition of acetyl cholinesterase" is listed as the health risk index endpoint "nervous system," and all chemicals that can affect the nervous system would be considered together.

Benchmark Dose (BMD): Dose or concentration that produces a predetermined change in the response rate of an adverse or biologically meaningful effect. The BMD approach uses mathematical models to statistically determine a dose associated with a predefined effect level (e.g., 10 percent).

Benchmark Dose Level (BMDL): A statistical lower confidence limit on the benchmark dose (BMD).

Co-critical effect(s): Generally, effects that are observed at doses up to or similar to the exposure level of the critical study associated with the critical effect(s).

Critical effect(s): The health effect or health effects from which a non-cancer toxicity value is derived; usually the first adverse effect that occurs to the most sensitive population as the dose increases.

Human Equivalent Dose (HED): The oral human dose of an agent that is believed to induce the same magnitude of toxic effect as the experimental animal species dose. This adjustment may incorporate toxicokinetic information on the particular agent, if available, or use a default procedure, such as assuming that daily oral doses experienced for a lifetime are proportional to body weight raised to the 0.75 power ($BW^{3/4}$).

Point of Departure (POD): The dose-response point that marks the beginning of a low-dose

extrapolation. This point can be the lower bound on a dose-response curve where an effect or change in response is first estimated or observed, using benchmark dose response modeling, or using a No Observed Adverse Effect Level (NOAEL) or Lowest Observed Adverse Effect Level (LOAEL) obtained experimentally.

Reference Dose (RfD): An estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects for a given exposure duration. It is derived from a suitable exposure level at which there are few or no statistically or biologically significant increases in the frequency or severity of an adverse effect between an exposed population and its appropriate control group. The RfD is expressed in units of milligrams of the chemical per kilogram of body weight per day (mg/kg-day).

Toxicodynamics (TD): The determination and quantification of the sequence of events at the cellular and molecular levels leading to a toxic response to an environmental agent (sometimes referred to as pharmacodynamics and also MOA)

Toxicokinetics (TK): The determination and quantification of the time course of absorption, distribution, metabolism, and excretion of chemicals (sometimes referred to as pharmacokinetics).

Uncertainty Factor (UF): One of several factors used in deriving a reference dose from experimental data. UFs are intended to account for:

- **Interspecies UF** - the uncertainty in extrapolating from mammalian laboratory animal data to humans. This uncertainty factor is composed of two subfactors: one for toxicokinetics and one for toxicodynamics.
- **Intraspecies Variability Factor** - the variation in sensitivity among the members of the human population;
- **Subchronic-to-Chronic Factor** (Use of a less-than-chronic study for a chronic duration) - the uncertainty in extrapolating from effects observed in a shorter duration study to potential effects from a longer exposure;
- **LOAEL-to-NOAEL** (Use of a LOAEL rather than a NOAEL) - the uncertainty associated with using a study in which health effects were found at all doses tested; and
- **Database Uncertainty** - the uncertainty associated with deficiencies in available data.

Uncertainty factors (UF) are normally expressed as full or half powers of ten, such as 10^0 (=1), $10^{0.5}$ (»3), and 10^1 (=10). All applicable uncertainty factors are multiplied together to yield a composite uncertainty factor for the RfD. Half-power values such as $10^{0.5}$ are factored as whole numbers when they occur singly but as powers or logs when they occur in tandem (EPA 2002). Therefore, a composite UF using values of 3 and 10 would be expressed as 30 (3×10^1), whereas

a composite UF using values of 3 and 3 would be expressed as 10 ($10^{0.5} \times 10^{0.5} = 10^{1}$).

More information about each parameter can be found in Appendix C and in the 2008/2009 SONAR (PDF) (https://www.leg.mn.gov/archive/sonar/SONAR-03733.pdf#page=2).

PROPOSED RULES: THE HEALTH RISK LIMITS TABLE (Minnesota Rules, part 4717.7860)

Proposed HRL Rules Amendments for Updated Guidance

The following section describes HRL Rules amendments proposed for four substances with updated guidance values: Changes to the current rule are reflected using "[Delete]" for deleted language and "[Add]" for new language.

Subpart. 7b. Chlorothalonil.

Add the chemical name, CAS number, Year Adopted, Volatility and all data in the table below to Minnesota Rules, part 4717.7860, subpart 7b for Chlorothalonil. Repeal Subp. 26a. Chlorothalonil from Minnesota Rules, part 4717.7500.

CAS number: 1897-45-6
Year Adopted: 2025
Volatility: Nonvolatile

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	ND	20	2	1	6
RFD (mg/kg-day)	--	0.014	0.00067	0.00029	--
RSC	--	0.5	0.2	0.2	--
SF (per mg/kg-day)	--	--	--	--	0.017
ADAF or $AF_{lifetime}$	--	--	--	--	10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)
Intake Rate (L/kg-day)	--	0.290	0.074	0.045	$0.155_{(<2)}$ $0.040_{(2\ to\ <16)}$ $0.042_{(16+)}$
Endpoints	--	gastrointestinal system	gastrointestinal system	gastrointestinal system, hepatic (liver) system, renal (kidney) system	cancer

Acute duration
Not derived because of insufficient information.

Short-term duration
The proposed short-term nHRL is 20 µg/L. The RfD is 0.014 mg/kg-d, and the intake rate is 0.290 L/kg-d. The RSC is 0.5. The POD is a $BMDL_{BMR5\%}$ of 6.13 mg/kg-d (Myers, 1995, as cited in EPA, 1995a). The DAF for body weight scaling is 0.22, and the HED is 1.35 mg/kg-d. The total UF is 100 (3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, and 3 for database uncertainty due to suggestive testicular effects reported in other animal studies and human epidemiology studies that have not been thoroughly assessed). The critical effect is forestomach roughening and thickening in F1 pups. There is no co-critical effect. The additivity endpoint is gastrointestinal system.

Subchronic duration
The proposed subchronic nHRL is 2 µg/L. The RfD is 0.00067 mg/kg-d, and the intake rate is 0.074 L/kg-d. The RSC is 0.2. The POD is a $BMDL_{BMR5\%}$ of 0.293 mg/kg-d (Spencer-Briggs, 1994, aci EPA, 1994). The DAF for body weight scaling is 0.23, and the HED is 0.067 mg/kg-d. The total UF is 100 (3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, and 3 for database uncertainty due to suggestive testicular effects reported in other animal studies and human epidemiology studies that have not been thoroughly assessed). The critical effect is epithelial hyperplasia and hyperkeratosis at the limiting ridge of the stomach in female rats. The co-critical effect is epithelial hyperplasia and hyperkeratosis in the nonglandular region of the stomach in female rats. The additivity endpoint is gastrointestinal system.

Chronic duration
The proposed chronic nHRL is 1 µg/L. The RfD is 0.00029 mg/kg-d, and the intake rate is 0.045 L/kg-d. The RSC is 0.2. The POD is a LOAEL of 1.9 mg/kg-d (Spencer-Briggs, 1995, aci EPA, 1995b). The DAF is 0.15 using body weight scaling (US EPA, 2011b; MDH, 2017). Multiplying the DAF by the POD results in an HED of 0.29 mg/kg-d. The UF is 1000 (3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, 10 for using a LOAEL in place of a NOAEL, and 3 for database uncertainty due to suggestive testicular effects reported in other animal studies and human epidemiology studies that have not been thoroughly assessed). The critical effects are epithelial hyperplasia and hyperkeratosis at the limiting ridge and in the nonglandular regions of the stomach in male mice. The co-critical effects are epithelial hyperplasia and hyperkeratosis at the limiting ridge and in the nonglandular regions of the stomach in females, ulceration of the nonglandular region of the stomach, thickened appearance of the forestomach in males, renal uniform cortical scarring, renal karyomegaly in males, and centrilobular hepatocyte enlargement. The additivity endpoints are gastrointestinal system, the hepatic (liver) system, and the renal (kidney) system.

Cancer
The proposed cancer cHRL value is 6 µg/L. EPA's cancer classification is "likely to be a human carcinogen by all routes of exposure" (EPA, 2021b), and the IARC classification is "possibly

carcinogenic to humans (IARC, 1999). The cancer slope factor is 0.017 mg/kg-d^{-1} based on combined renal and forestomach tumors from the male rat (Wilson and Killeen, 1989 aci EPA, 1991; California EPA, 2012)). The age-dependent adjustment factors and intake rates are 10 and 0.155 L/kg-d for an age under 2 years; 3 and 0.040 L/kg-d for an age between 2 years and less than 16 years; and 1 and 0.042 L/kg-d for ages above 16 years. The tumor sites are the forestomach, kidney, liver, and thyroid.

Subpart. 7e. 1,2-Dibromoethane (ethylene dibromide, EDB)

Add the chemical name, CAS number, Year Adopted, Volatility and all data in the table below to Minnesota Rules, part 4717.7860, subpart 7e for 1,2-Dibromoethane. Repeal Subp. 31. 1,2-Dibromoethane (ethylene dibromide, EDB) from Minnesota Rules, part 4717.7500.

CAS number: 106-93-4
Year Adopted: 2025
Volatility: High

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	ND	10	10 (2)	9	0.03
RFD (mg/kg-day)	--	0.018	(2)	0.0021	--
RSC	--	0.2	(2)	0.2	
SF (per mg/kg-day)	--	--	--	--	3.6
ADAF or $AF_{lifetime}$	--	--	--	--	10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)
Intake Rate (L/kg-day)	--	0.290	(2)	0.045	$0.155_{(<2)}$ $0.040_{(2\ to\ <16)}$ $0.042_{(16+)}$
Endpoints	--	female reproductive system, hepatic (liver) system, immune system, male reproductive system, renal (kidney) system, respiratory system, spleen	female reproductive system, hepatic (liver) system, immune system, male reproductive system, renal (kidney) system, respiratory system, spleen	female reproductive system, hepatic (liver) system, immune system, male reproductive system, respiratory system	cancer

Acute duration
Not derived because of insufficient information.

Short-term duration
The proposed short-term nHRL is 10 µg/L. The RfD is 0.018 mg/kg-d, and the intake rate is 0.290 L/kg-d. The RSC is 0.2. The POD is a LOAEL of 125 mg/kg-d (Ratajczak et al., 1994). The DAF for body weight scaling is 0.14, and the HED is 17.5 mg/kg-d. The total UF is 1000 (3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, and 3 for using a LOAEL in place of a NOAEL, and 10 for database uncertainty due to the lack of two-generation reproductive, developmental, and developmental immunotoxicity studies). The critical effects are increased liver weight, increased cholesterol, and reduced T-cell response. The co-critical effects are increased kidney weight, increased neutrophils, decreased immune function in the lung, decreased viable cells in the spleen, increased estrus cycle length, and increased percentage of abnormal sperm. The additivity endpoints are female reproductive system, hepatic (liver) system, immune system, male reproductive system, renal (kidney) system, respiratory system, and spleen.

Subchronic duration
The proposed subchronic nHRL is 10 µg/L. The subchronic nHRL must be protective of the shorter duration exposures that occur within the subchronic period, and, therefore, the subchronic nHRL is set equal to the short-term nHRL of 10 µg/L. The additivity endpoints are female reproductive system, hepatic (liver) system, immune system, male reproductive system, renal (kidney) system, respiratory system, and spleen.

Chronic duration
The proposed chronic nHRL is 9 µg/L. The RfD is 0.0021 mg/kg-d, and the intake rate is 0.045 L/kg-d. The RSC is 0.2. The POD is a NOAEL of 44.6 mg/kg-d (Ratajczak et al., 1995). The DAF is 0.14 using body weight scaling (US EPA, 2011b and MDH, 2017). Multiplying the DAF by the POD results in a HED of 6.24 mg/kg-d. The UF is 3000 (3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, 10 for extrapolation to a chronic duration from a subchronic study, and 10 for database uncertainty for lack of two-generation reproductive, developmental, and developmental immunotoxicity studies). The critical effects are decreased T- and B-cell responses and increased cholesterol and triglycerides. The co-critical effects are increased relative liver weight, increased cholesterol, decreased T-cell response, decreased immune function in the lung, increased estrus cycle length, and increased percentage of abnormal sperm. The additivity endpoints are female reproductive system, hepatic (liver) system, immune system, male reproductive system, and respiratory system.

Cancer
The proposed cancer cHRL value is 0.03 µg/L. EPA's cancer classification is "likely to be carcinogenic to humans" (EPA, 2004), and the IARC classification is "2A - probably carcinogenic to humans" (IARC, 1999). The cancer slope factor is 3.6 $(mg/kg\text{-}d)^{-1}$ based on forestomach tumors in male and female rats and mice (NCI, 1978). The age-dependent adjustment factors

and intake rates are 10 and 0.155 L/kg-d for an age under 2 years; 3 and 0.040 L/kg-d for an age between 2 years and less than 16 years; and 1 and 0.042 L/kg-d for ages above 16 years. The tumor sites are the forestomach, esophagus, blood vessels, liver, lung, thyroid gland, and adrenal gland.

Subpart. 15. Perfluorooctane sulfonate (PFOS) and Salts:

Change the Year Adopted and the data for PFOS to Minnesota Rules, part 4717.7860, subpart 15, as shown in the table below.

CAS numbers: 45298-90-6; 1763-23-1; 29081-56-9; 2795-39-3; 70225-14-8; and 29457-72-5
Year Adopted: [Delete: 2009, Add: 2025]
Volatility: Nonvolatile

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	ND	[Delete: ND; Add: 0.0023]	[Delete: ND; Add: 0.0023]	[Delete: 0.3; Add: 0.0023]	[Delete: NA; Add: 0.0076]
[Delete :RfD Add: RfSC] [Delete: (mg/kg-day) [Add: (ng/mL)*]	--	[Delete:--; Add: 2.6]	[Delete:--; Add: 2.6]	[Delete:0.00008; Add: 2.6]	--
RSC	--	[Delete:--; Add: 0.2]	[Delete:--; Add: 0.2]	0.2	--
SF (per mg/kg-day)	--	--	--	--	[Delete:--; Add: 13]
ADAF or $AF_{lifetime}$	--	--	--	--	[Delete:--; Add: 10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)]
Intake Rate (L/kg-day)	--	[Delete: --; Add: #]	[Delete: --; Add: #]	[Delete:0.049; Add: #]	[Delete: --; Add: $0.155_{(<2)}$ $0.040_{(2\ to\ <16)}$ $0.042_{(16+)}$]

	Acute	Short-term	Subchronic	Chronic	Cancer
Endpoints	--	[Delete: --; Add: developmental, hepatic (liver) system, immune system]	[Delete:--; Add: developmental, hepatic (liver) system, immune system]	[Delete: thyroid (E); Add: immune system]	[Delete: --; Add: cancer]

[Add: *A reference serum concentration (ng/mL) rather than a reference dose (mg/kg-d) was used in MDH's toxicokinetic model to calculate noncancer guidance values for PFOS.

95th percentile water intake rates (Tables 3-1, 3-3, and 3-5 in the Environmental Protection Agency, Exposures Factor Handbook, 2019), or upper percentile breastmilk intake rates (Table 15-1), Environmental Protection Agency Exposure Factors Handbook, 2011.]

Acute duration
Not derived because of insufficient information.

Short-term, Subchronic, and Chronic Durations
The proposed short-term, subchronic, and chronic nHRLs are 0.0023 µg/L. The RfSC for humans is 2.6 ng/mL, determined by MDH in 2023. The POD is a serum concentration of 7.7 ng/mL (equivalent to µg/L) (US EPA 2023a,b), based on a $BMDL_{5\%}$ for decreased birth weight from Wikström, 2020. The DAF and HED are not applicable in this case, as the POD is based on human data. The intake rate is the 95th percentile of water intake rates in Tables 3-1, 3-3, and 3-5 in the EPA's Exposures Factor Handbook (2019), or upper percentile breastmilk intake rates in Table 15-1 from Exposure Factors Handbook (2011). The RSC is 0.2. The total uncertainty factor (UF) is 3, which was applied to account for the remaining database uncertainties regarding potential adverse effects at or near the serum POD concentration. A UF for human toxicodynamics variability was not applied because the POD is based on a sensitive lifestage. Further, differences in human TK were determined to be adequately addressed through the exposure scenario and parameter values selected for use in the TK model. The critical effect is decreased birth weight. The co-critical effects are decreased antibody titers in children and increased cholesterol. The additivity endpoints are developmental system, hepatic (liver) system, and immune system.

Cancer
The proposed cancer cHRL value is 0.0076 µg or (7.6 ng/L) EPA's cancer classification is "likely to be carcinogenic to humans" (US EPA 2023a,b). The California EPA Office of Environmental Health Hazard Assessment (California EPA) (2023) has noted that PFOS "presents a carcinogenic hazard," and the IARC classification is "Group 2B (possibly carcinogenic to humans)" (IARC 2023)). The cancer slope factor is 13 per mg/kg-day for combined hepatocelluar adenomas and carcinomas in female rats (US EPA 2023a,b) and tumor data from Butenhoff et al.,2012. This

was derived from a US EPA cancer slope factor of 39.5 per mg/kg-d (US EPA 2023a,b) converted to 13 per mg/kg-d using a clearance rate of 0.39 mL/kg-d from California EPA, 2023. The age-dependent adjustment factors and intake rates are 10 and 0.155 L/kg-d for an age under 2 years; 3 and 0.040 L/kg-d for an age between 2 years and less than 16 years; and 1 and 0.042 L/kg-d for ages above 16 years. The tumor site is liver.

Subpart. 16. Perfluorooctanoate (PFOA) and salts

CAS numbers: 45285-51-6; 335-67-1; 3825-26-1; [Delete: 335-66-0;]2395-00-8; 335-93-3; 335-95-5

Year Adopted: [Delete: 2018, Add: 2025]

Volatility: Nonvolatile

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	ND	[Delete: 0.035; Add: 0.00024]	[Delete: 0.035; Add 0.00024]	[Delete: 0.035; Add 0.00024]	[Delete: NA; Add 0.0000079]
[Delete :RfD Add: RfSC] [Delete: (mg/kg-day) Add: (ng/mL)*] R	--	[Delete 0.000018; Add: 0.93]	[Delete 0.000018; Add: 0.93]	[Delete 0.000018; Add: 0.93]	--
RSC	--	[Delete: 0.5; Add: 0.2]	[Delete: 0.5; Add: 0.2]	[Delete: 0.5; Add: 0.2]	--
SF (per ng/kg-day)	--	--	--	--	[Delete: --; Add: 0.0126]
ADAF or $AF_{lifetime}$	--	--	--	--	[Delete: --; Add: 10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)]
Intake Rate (L/kg-day)	--	[Delete: *; Add: #]	[Delete: *; Add: #]	[Delete: *; Add: #]	[Delete: --; Add: $0.155_{(<2)}$ $0.040_{(2\ to\ <16)}$ $0.042_{(16+)}$]
Endpoints	--	developmental, hepatic (liver) system, immune system [Delete: renal (kidney) system]	developmental, hepatic (liver) system, immune system [Delete: renal (kidney) system]	developmental, hepatic (liver) system, immune system [Delete: renal (kidney) system]	[Delete: --; Add: cancer]

[Add: * A reference serum concentration (ng/mL) rather than a reference dose (mg/kg-d) was used in MDH's toxicokinetic model to calculate noncancer guidance values for PFOA.]

[#] 95th percentile water intake rates (Tables 3-1 [Delete: and; Add: ,] 3-3 [Add: , and 3-5 in the Environmental Protection Agency, Exposures Factor Handbook, 2019)], or upper percentile breastmilk intake rates (Table 15-1), Environmental Protection Agency[Delete: (EPA)] Exposure Factors Handbook, 2011.

Acute duration
Not derived because of insufficient information.

Short-term, Subchronic, and Chronic Durations
The proposed short-term, subchronic, and chronic nHRLs are 0.00024 µg/L. The RfSC is 0.93 ng/mL, determined by MDH in 2023. The intake rate is the 95th percentile of water intake rates in Tables 3-1, 3-3, and 3-5 in the EPA Exposures Factor Handbook (2019), or upper percentile breastmilk intake rates in Table 15-1 from Exposure Factors Handbook (EPA, 2011). The RSC is 0.2. The POD is 2.8 ng/mL based on a $BMDL_{5\%}$ for decreased haemophilus influenzae Type B (Hib) antibodies (Abraham et al., 2020). There are no DAF or HED values for this calculation because the POD was based on human serum levels. The total UF is 3, which was applied to account for the remaining database uncertainties regarding potential adverse effects at or near the serum POD concentration. A UF for human toxicodynamics variability was not applied because the POD is based on a sensitive lifestage. The critical effect is decreased antibody titers in infants. The co-critical effects are decreased antibody titers in children, decreased birthweight, increased cholesterol, and increased ALT (liver enzyme). The additivity endpoints are developmental, hepatic (liver) system, and immune system.

Cancer
The proposed cancer cHRL value is 0.0000079 ug/L (or 0.0079 ng/L.). EPA's cancer classification is "likely to be carcinogenic to humans" (US EPA 2023 a,b). The California EPA (2023) has noted "strong evidence of carcinogenicity," and the IARC classification is "Group 1 (carcinogenic to humans)" (IARC 2023)). The cancer slope factor is 0.0126 per ng/kg-day based on renal cell carcinoma in humans (Shearer et al., 2021). The source of the cancer slope factor is a serum slope factor of 0.00325 per ng/mL (from US EPA 2023a,b), converted to 0.0126 per ng/kg-d using a clearance rate of 0.28 mL/kg-d (California EPA, 2023). The age-dependent adjustment factors and intake rates are 10 and 0.155 L/kg-d for an age under 2 years; 3 and 0.040 L/kg-d for an age between 2 years and less than 16 years; and 1 and 0.042 L/kg-d for ages above 16 years. The tumor sites for human are kidney, which is the basis of this guidance, and testicle. For animals, the tumor sites are liver and pancreas.

Proposed HRL Rules for Deletion

Proposed Deletion: Health Risk Limit: Minnesota Rules, part 4717.7860)

Subp. 8g. Dichlorodifluoromethane (2011)

The outdated HRL for dichlorodifluoromethane, adopted in 2011, will be repealed only. MDH has replaced the dichlorodifluoromethane HRL with an RAA value.

Proposed Deletions: Health Risk Limits: (Minnesota Rules, part 4717.7500)

Based on MDH's recent review of health-based guidance values listed in Minnesota Rules, part 4717.7500, MDH intends to repeal three outdated HRLs adopted into rule in 1993 or 1994. The specific subparts to be repealed are noted below:

Subp. 5. Anthracene (1993)

Subp. 26a. Chlorothalonil (1993)

Subp. 31. 1,2-Dibromoethane (ethylene dibromide, EDB) (1994)

As discussed above in the Proposed Rules: The Health Risk Limits Table section, updated values for Chlorothalonil and 1,2-Dibromoethane will be added to part 4717.7860 at proposed subparts 7b and 7e. **The outdated HRL for anthracene, adopted in 1993, will be repealed only**. MDH has replaced the Anthracene HRL with Risk Assessment Advice (RAA).

Public participation and interested party involvement

Selection of Contaminants for Review

MDH selected the contaminants for the amendments based on two separate nominating processes, described below. Each year, MDH uses these two processes to create work plans to assess chemicals for health risks and to develop and issue guidance (see Appendix D for more information on selected contaminants).

In one process, MDH holds an annual interagency meeting for representatives of MDA, MPCA, MDH, and other agencies to discuss their concerns about specific contaminants, and to rank a list of chemicals according to each agency's need for new or updated water guidance. A final list of priority chemicals is generated from this process.

In the second process, anyone, including members of the public, may nominate chemicals through the MDH Contaminants of Emerging Concern (CEC) program's website or by contacting MDH. MDH periodically sends emails to the GovDelivery subscribers as reminder that nominations opportunities are available. MDH then screens these nominated chemicals for toxicity and exposure potential and ranks them for review priority.

In addition, MDH aims to periodically re-evaluate post-2009 adopted HRLs to ensure that they incorporate the latest scientific findings and continue to be relevant. Three contaminants that were adopted into rule from 2009 to 2018 were re-evaluated from 2022 to 2023. These HRL re-

evaluations are included in the proposed rule.

As MDH reviewed or re-evaluated each contaminant, it posted the chemical's name, its Chemical Abstracts Service (CAS) Registry Number, and the date the review was started on MDH's Chemicals Under Review webpage, available at: Chemicals Under Review (https://www.health.state.mn.us/communities/environment/risk/review.html). A GovDelivery message is also sent to all interested parties subscribed to this account (8,139 number as of June 25, 2024). MDH invites questions, data submissions or comments throughout the review process.

After completing each review or re-evaluation, MDH posted the guidance values and the chemical-specific summary sheets on the webpage called Human-Health Based Water Guidance Table (https://www.health.state.mn.us/communities/environment/risk/guidance/gw/table.html). MDH also notified subscribers to MDH's Groundwater Rules, Guidance and Chemical Review email notification account about the new or updated guidance. Electronic subscriptions to this account may be requested at Email Updates https://public.govdelivery.com/accounts/MNMDH/subscriber/new?topic_id=MNMDH_39.

Notice Plan

The Minnesota APA has requirements for the publication of official notices in the *State Register* and related procedure, including sending out notifications to the MDH rulemaking list. In addition to these basic notification requirements, MDH has or will complete additional notice activities, as follows:

Notice

MDH will notify all parties listed on the current Minnesota Department of Health Rulemaking Notice List at least three days prior to the publication of Notice of Intent to Adopt Rules in the *State Register*. Further, MDH will complete all the additional activities listed below:

Additional notice plan

MDH attempts to notify as many parties with potential interest in HRLs as possible. Because the HRL Rules affect groundwater, which about 75% of Minnesotans consume for drinking water, there is a potentially a very large audience. However, not all affected parties will have interest in the topic. Therefore, MDH uses an email subscription service to communicate with interested parties about MDH's work on water guidance values and updates to the values. The account is called Groundwater Rules, Guidance, and Chemical Review and is hosted by a commercial service called GovDelivery (offered by the company Granicus). Anyone may sign up for these emails for free on MDH webpages or by phoning or emailing HRA Unit staff.

Another method that MDH uses to communicate detailed information about rulemaking is via its website where there are several pages dedicated to the HRL rulemaking activities. The home page for this collection of webpages is found at Health Risk Limits Rules for Groundwater Rules Amendments - Overview and Links (https://www.health.state.mn.us/communities/environment/risk/rules/water/overview.html).

Moreover, MDH often uses direct communication, via direct email or via phone call, to contact interested parties about developments with the HRL Rules, including announcing opportunities for comment.

Notifications completed or planned for each stage of this rulemaking are as follows:

Request for Comments

The Request for Comments was published on August 7, 2023. The morning of August 7th, MDH sent emails directly to 10 industry representatives or trade organization staff, seven environmental advocacy organization staff, two academic staff, and one corporate public affairs consultant who had requested notice about HRL rulemaking activity. The same day, MDH also sent emails to 14 interested staff members of other State agencies about the open Request for Comments. Further, MDH sent out an email notice to the 6,416 subscribers (as of August 7, 2023) to the Water Rules, Guidance, and Chemical Review email subscription service account. The email notices provided information about publication of the Request for Comments, a link

to the announcement in the State Register, and links to MDH's rules webpages that provide information about each chemical with water guidance eligible for rulemaking.

In an attempt to reach a wider audience that may have interest in the HRL Rules, we also worked with the MDH Drinking Water Protection Section to publish a short announcement called "MDH proposing updates to health risk limits (https://www.health.state.mn.us/communities/environment/water/waterline/winter20232024.html#NaN)" in the Winter 2023-2024 Waterline, an MDH publication that is of interest to water operators and others. As of June 25, 2024, this publication had been viewed 744 times from the MDH website. Paper copies are also sent to 75 subscribers of the Waterline. There is also a GovDelivery account that delivers this information electronically to 7,700 subscribers (as of November 2023), but there might be some overlap among people who subscribe to the paper copies and who view the electronic copy.

Extended outreach

In past HRL rulemaking, many of the parties with comments have been either from large chemical manufacturers, chemical trade associations, chemical manufacturing lobbying groups, community advocacy groups, or state legislators. The PFAS chemicals (sometimes called "forever chemicals") are perhaps more recognizable by the public than some of the chemicals in past HRL rulemaking, and there may be more interest in them from groups with interest in health-equity or environmental justice. Our staff have had meetings with the Tribal Liaison and the Environmental Health's Health Equity Strategist to provide information about the Health Risk Limits Rules and to discuss ways to continue to conduct outreach for comment related to these rules.

Dual Notice of Intent to Adopt Rules

MDH will publish a Dual Notice of Intent to Adopt Rules in the State Register. MDH will mail the proposed rules and the Notice of Intent to Adopt Rules to the parties listed on MDH's rulemaking list under Minnesota Statutes, section 14.14, subdivision 1a. MDH will also send the Notice of Intent to Adopt Rules and a copy of the SONAR to the Legislature and the Legislative Reference Library.

Further, MDH will send a notice to the 8,537 subscribers (as of September 18, 2024) of its Water Rules, Guidance and Chemical Review email subscription service account. Subscribers to this account include most parties known to be interested in this topic, such as trade associations and industry advocates like the American Chemistry Council and the Minnesota Chamber of Commerce, several State agencies, several advocacy groups, state legislators, and chemical manufacturers such as 3M, Bayer, and other companies. Sign-up to the email subscription service is offered on the website or by phoning or emailing MDH staff members. MDH will also send information to the offices of interested parties such as water resource interest groups and industry or commerce organizations to distribute to their members at their discretion. Upon request, copies of the proposed rules and the SONAR will be made available at no charge.

Regulatory analysis

This section discusses the department's consideration and implementation of performance-based rules and the impact of the proposed rules, as required by Minnesota Statutes, section 14.131.

The department's consideration of the eight factors for regulatory analysis that agencies must include in the SONAR under Minnesota Statutes, section 14.131 follows:

1) 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.

Because the subject of these rules is the quality of groundwater used as drinking water in Minnesota, the proposed amendments could potentially affect nearly all persons in Minnesota to some extent. Those who are affected depends more on how state agencies charged with protecting Minnesota's environment and water resources apply HRL values.

Generally, HRLs serve as benchmarks in state water-monitoring and contamination-response programs that protect all Minnesotans' health. In addition, HRL values and related chemical data are incorporated into other state rules that also protect Minnesota's water resources (e.g., MPCA's solid waste and surface water rules), thus benefitting the entire state.

More specifically, the amendments can affect individuals or populations when a public or private water supply becomes contaminated and federal MCLs are unavailable. In these instances, the responding agency chooses to estimate the risks from consuming contaminated water using HRL values, and advises the regulated party, the responsible governmental unit, the water operator, or the public on how to eliminate or reduce risk.

Monetary costs of decisions by third parties applying the HRLs could affect those found responsible for contaminating or degrading groundwater, or communities that use public funds to remediate contaminated water. The proposed amendments provide protection to human life stages that are sensitive or highly exposed. Risk managers have the option of applying HRL values to the general population or adjusting them for smaller groups or "sub-populations." These decisions will impact who is affected by the HRL rules.

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

The proposed amendments *do not* have any direct impact on state revenues, nor are there any costs to any state agencies related to the proposed rules' implementation or enforcement. There are no fees associated with the rules. The amendments simply provide health-based

levels for certain water contaminants. Some programs with enforcement or remediation authorities within MDH or other agencies might choose to implement and enforce their own authorities and rules in response to these amendments. Other programs and agencies that apply HRL values will need to determine costs on a case-by-case basis.

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

AND

4) 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.

Minnesota Rules, parts 4717.7500 and 4717.7860 establish HRL values, which are uniform, science-based values that protect the health of people who drink groundwater.

Unlike other rules that regulate citizen or industry activities, this HRL rules revision applies the previously adopted specific methodology to identified contaminants. The HRA Unit staff calculate the water guidance values for the identified contaminants and the calculated values themselves are proposed for adoption into rule. As described in the section MDH-derived HRL Algorithm above, Minnesota Statutes, section 103H.201, subdivision 1, prescribes the methods that the Commissioner must use in deriving HRL values. In subdivision 1, paragraph (c), the statute requires that the Commissioner establish HRLs for contaminants that are not carcinogens, “using United States Environmental Protection Agency risk assessment methods using a reference dose, a drinking water equivalent, and a relative source contribution factor.”

Likewise, in subdivision 1, paragraph (d), the Commissioner must derive HRL values for contaminants that are known or probable carcinogens “from a quantitative estimate of the chemical's carcinogenic potency published by the United States Environmental Protection Agency or determined by the commissioner to have undergone thorough scientific review.”

In addition, Minnesota Statutes, section 144.0751, provides that safe drinking water standards must “be based on scientifically acceptable, peer-reviewed information” and “include a reasonable margin of safety to adequately protect the health of infants, children, and adults . . . .” The section also lists risks to specific health outcomes that the commissioner must consider.

Thus, the statutes outline how MDH may determine allowable amounts of water contaminants. In 2009, the Commissioner adopted the methodology for carrying these directives out, which is now contained in Minnesota Rules, parts 4717.7820 and 4717.7830. This rulemaking project repeals old values and adds updated values by applying the methodology adopted in 2009, which is not under review at present. MDH regularly adopts the specific HRL values through a process designed to inform and engage the public. MDH currently follows an approximately two

to four-year cycle for developing and adopting updated or new HRL values and repealing outdated values. MDH uses this schedule to ensure the HRL values reflect the most up-to-date toxicity information.

Because of the specific nature of these rules, the method for achieving the proposed rules' purpose has already been established by the 2009 rulemaking. There are no less costly or less intrusive methods for adopting these new chemical values. Similarly, the fact that the method was set in the 2009 rulemaking precludes alternative methods for achieving the purpose of the proposed rule.

HRL values, before being adopted into rule, are often initially derived at other agencies' request. MDH derives this guidance, known as a Health-Based Value (HBV), using the same methodology as an HRL. While all HRL values were initially HBV values, not all HBV values are adopted into rule as HRLs, as all HRLs must have been detected in Minnesota groundwater.

In practice, risk managers may use HBV values in the same way as HRL values. However, because HBV values have not been adopted into rule, state agencies and the regulated community may consider them to be transient in nature and therefore not give them the same weight they would give adopted HRLs. Both regulators and risk managers consider HRL values more useful in long-term planning because they are considered more permanent. Adopting the guidance into rule standardizes the use of guidance statewide and provides the authority and uniformity of rule.

HBVs for groundwater contaminants that MDH has derived through the HRL standard methodology are eligible for rule adoption. MDH rejects the possibility of leaving the proposed chemicals in their outdated or HBV status.

5) 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.

HRL rules establish concentration levels of certain substances or chemicals in groundwater which may present health risks, but do not specify how to apply these health-protective numbers or what one must do in response to them. Neither MDH nor any other government entity can or will enforce compliance with HRLs, and there can be no cost, therefore, of complying with these unenforceable benchmarks.

While MDH cannot quantify the probable costs of complying with other legal requirements that refer to the HRLs proposed to be amended, MDH can describe generally how other regulations that incorporate its HRLs can lead to costs for parties regulated by other agencies.

HRL values are only one set of criteria that agency risk managers use to evaluate whether a

contaminant's concentration in groundwater poses a risk to health. HRL values are not intended to be bright lines between "acceptable" and "unacceptable" concentrations. MDH derives HRL values using conservative methods so that exposures below an HRL value would present minimal, if any, risk to human health. Similarly, a contaminant concentration above an HRL value, without considering other information, might not indicate a public health problem. The values for the four contaminants proposed for rule are lower than the previous HRLs. Treatment of water to lower the concentration below the previous HRL level might increase the cost above the implementation of the previous HRL, but this can only be determined in each case by the enforcing agency.

6) 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.

Not adopting the proposed amendments would impose costs or consequences affecting water safety and quality that cannot be calculated. As stated above, Minnesota's groundwater is a primary source of drinking water for around 75% of Minnesotans, making the need to protect these waters obvious and imperative. A failure to revise the rules would ignore legislative directives and leave an outdated set of standards in place, providing only limited options for protecting some segments of the population.

Though the state's goal is to prevent water degradation, adopting and applying the proposed HRLs alone does prevent degradation. Some water resources have already been unintentionally contaminated by accidental or intentional releases—by activities that occurred before the source waters' vulnerability to contamination was known; by activities that occurred before certain chemicals were identified as toxic; or before regulations prohibiting releases had been implemented. When contamination is discovered, authorities often need a way to provide context to a sample's contaminant concentration and the implication for human health. HRL values allow authorities to evaluate drinking water sources to ensure that there is minimal risk to human health from using the water source for drinking, or to pursue cleanup more quickly if a risk exists. 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.

7) An assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference.

EPA's Office of Water publishes several sets of drinking water-related standards and health advisories such as Maximum Contaminant Level Goals (MCLGs), MCLs, and lifetime Health Advisories (HAs). While these are similar to MDH-derived HRL values in some respects, they differ in important ways noted below. Furthermore, for any given chemical, EPA may have

developed all, several, one, or none of these standards and advisories.

MDH-derived HRL values differ from existing federal regulations and advisory values in several ways:

- HRL values are based strictly on human health;
- MDH derives guidance for chemicals that are of high importance specifically to Minnesota;
- MDH considers more durations than EPA, allowing for protection of critical lifestages;
- MDH derives HRL values explicitly, including a reasonable margin of safety for vulnerable sub-populations (e.g., infants and children, who are potentially at higher risk than adults); and
- MDH can derive guidance more expediently.

While some federal regulations or advisory values might adhere to one or two of the conditions above, none adheres to all conditions.

EPA-derived MCLGs are advisory values based solely on considerations of human health. However, by definition, the MCLG for any chemical that causes cancer is zero. Because restoring contaminated groundwater to a pristine condition might not be possible, MCLGs do not provide meaningful practical values for MDH's partners to apply to groundwater contaminated by carcinogens.

EPA-derived MCLs are federal standards adopted for the regulation of *public* drinking water in Minnesota. However, MCLs consider the costs required to reduce contaminant concentrations to a given level and the technological feasibility of reaching that level. The factors that determine economic and technological feasibility for public drinking water systems might not be relevant to *private* drinking water wells or to other sites affected by contamination. EPA has developed MCLs for 91 chemicals, with the most recent value adopted into federal rule in 2001. While EPA currently has new MCLs proposed for six contaminants, two of which are included in this rulemaking (PFOA and PFOS, as described below), most MCLs were developed using outdated methods based only on adult intakes and body weight.

In April 2024, EPA announced finalized National Primary Drinking Water Regulation for PFOA and PFOS. The new Maximum Contaminant Levels (MCLs) for PFOA and PFOS are 4 ppt, while the Maximum Contaminant Level Goal (MCLG) for each is 0 ppt. As noted above, unlike the Minnesota HRLs, the EPA must consider several factors when deriving an MCL, such as the feasibility of detection, treatment, and cost of treatment. Minnesota Statute defines the mandate that MDH consider only health effects when deriving HRLs for groundwater

contaminants.

EPA-derived Drinking Water Equivalent Levels (DWELs) and HAs are estimates of acceptable drinking water levels of non-carcinogens or carcinogens based on health effects information. DWELs and HAs serve as non-regulatory technical guidance for federal, state, and local officials. DWELs assume that all of an individual's exposure to a contaminant is from drinking water. HRL values and lifetime HAs take into account people's exposure via routes other than drinking water and allocate to drinking water only a portion of an individual's allowable exposure (i.e., incorporate the relative source contribution (RSC) factor). HAs might be derived for exposure durations of one day, ten days, or a lifetime. One-day and ten-day HAs incorporate intake and body-weight parameters appropriate for children but do not incorporate an RSC.

Importantly, the chemicals for which MDH develops guidance are those that MDH and its partners have deemed to be priorities in Minnesota. At the federal level, guidance is developed based on nationwide priorities. At times, because of varying geographic and historical factors, including usage of chemicals at industrial locations, chemicals important nationally may not be as high in priority for Minnesota, and chemicals important to Minnesotans may not be ranked as high nationally. Guidance developed by MDH, however, is often based on requests from Minnesota risk managers who have detected a chemical at locations within the state, or from members of the public who have concerns about specific known or potential contaminants in Minnesota waters. Nominations may be submitted via the MDH website at Nominate Contaminants (https://www.health.state.mn.us/communities/environment/risk/guidance/dwec/nominate.html). Anyone may submit a nomination.

MDH reviews and prioritizes the CEC nominations to determine which nominated contaminants have the highest impact on Minnesota's drinking water. Those with the highest priority and available toxicity information are selected for full review. In addition, the HRL program within the Health Risk Assessment unit receives nominations from Minnesota state agencies for contaminants that staff find in Minnesota groundwater during monitoring or remediation efforts. Staff from several state agencies prioritize these nominations during an annual meeting. As a result of the input from these other agencies, there are Minnesota HRL values for 162 chemicals that have been found in Minnesota groundwater; there are 97 chemicals for which EPA has MCLs. This proposed update for 4 existing HRL values and the repeal of the anthracene HRL and 1,2-Dibromoethane (ethylene dibromide, EDB) HRL (1994) will make a total of 160 HRLs in Minnesota.

Minnesota's water guidance also protects more sensitive populations, especially infants and children, as required by the Health Standards Statute of 2021 and supported by the EPA 2021 Policy of Children's Health, recommends plans to "identify and integrate data to conduct risk assessments of children's health to inform decisions" (EPA, 2021a). EPA currently derives guidance values primarily for subchronic (from 30 days to 10% of a lifetime) and chronic (more than 10% of a lifetime) duration while MDH derives guidance for acute (one day) and short-

term (between one and 30 days) durations in addition to subchronic and chronic durations. Providing guidance for less than subchronic durations helps ensure that risk management decisions protect all exposed individuals.

Further, Minnesota-developed guidance is often available more quickly than guidance developed by EPA. At times, EPA's issuance of new guidance can be delayed for various reasons. When Minnesota state agencies or the public requests an HRL guidance value, groundwater contaminants have often already been detected in the state, with potential for human exposure. This obviously increases the need for timely updated or new guidance.

8) Assessment of the cumulative effect of the rule with other federal and state regulations.

As stated in item 7 above, there are no other state and federal rules devoted to the specific purpose of setting allowable water contaminant values for groundwater. The amendments proposed here only build on the regulatory results already established. MDH is not proposing enforceable standards but adopting further guidance for risk managers and our partners to use in their evaluation and mitigation work.

The amendments have no direct regulatory impact because the HRA Unit at MDH does not enforce or regulate the use of health-based guidance. MDH provides recommended values for use by risk assessors and risk managers in making decisions and evaluating health risks. Other programs within MDH or other agencies may independently adopt these health-based values and incorporate them within enforceable requirements related to permitting or remediation activities.

MDH cannot anticipate all the situations in which HRL values might provide meaningful guidance. Nor can MDH anticipate all the factors that its partners might weigh to determine whether applying an HRL value is appropriate. Each agency or program must decide whether to apply an HRL value or whether site-specific characteristics justify deviation from HRL values.

Health-based guidance is only one set of criteria that state water and environmental protection programs use to evaluate contamination. Other state and federal health or environmentally based rules, laws, or considerations may apply. For example, the federally implemented MCLs for drinking water are applicable to public water systems. MCL values are legally enforceable under the National Primary Drinking Water Regulations. Further, MCLs are not applicable to private water supplies. However, those who consume or work to protect the water from a private well may seek to comply with an HRL value in the interest of protecting health.

Overall, the cumulative effect of these rules is incremental and will vary on a case-by-case basis, depending on the type of contamination present, the level of threat to human health or the environment, and the requirements of the responsible governmental agency. In some situations, the rules may have little or no effect, especially when other laws take precedence or

when contamination is already below the HRL value. In another case where an HRL value is exceeded, an agency might invoke its requirement that the responsible party bring the contaminant concentration down to a safe level for consumption. Thus, the proposed HRL values will work with those HRLs already adopted to serve as another important evidence-based resource for other agencies to apply when assessing how best to protect Minnesota's drinking water from further degradation, thus protecting the health of all its citizens.

Health Equity and Environmental Justice

Clean and safe drinking water is essential for good health for all people. MDH's methodology for assessing the potential health impacts from contaminants is designed to protect those who may be at higher risk for health impacts from potentially greater exposures to chemicals and intrinsic biological factors that potentially increase susceptibility to adverse effects of chemical exposure. MDH acknowledges that communities of color, those in some rural areas, and people with disabilities continue to experience higher rates of environmental contaminant exposure due to systemic polices that result in increased risk for adverse health effects. Further, there is growing awareness that non-chemical stressors associated with socioeconomic status, racism, discrimination associated with sexual orientation or disability status, genetic disposition, and others can converge with environmental exposures, or act on their own, to affect health. MDH strives to include information about socioeconomic and societal factors when developing water guidance.

Currently, within MDH's guidance development, higher exposure concerns are addressed by:

- Using the upper percentile drinking water intake rates in our duration-specific guidance calculations, as opposed to using a mean or median intake rates. This protects most of the population.

- Using intake rates for bottle-fed infants and children to calculate the acute and short-term duration guidance values. These are two of the most vulnerable populations to contaminant toxicity.

- Using a relative source contribution factor (RSC) in our guidance equation. This factor assigns a percentage of exposure that occurs only through water. If a certain population has other exposures to a specific contaminant (dermal, inhalation, food, etc.) the RSC is reduced to allow for these other exposures.

Data that would allow MDH to address potentially increased susceptibility to health effects related to biological/intrinsic factors such as genetics or metabolism is limited, but MDH continues to search for these data and incorporates findings into the guidance when possible. MDH also uses exposure information from communities, when available, to select contaminants for guidance development, particularly for Contaminants of Emerging Concern, and to develop the water guidance with contaminant exposure data incorporated into the calculations.

While there is still work to be done to determine how best to incorporate information about exposures and non-chemical stressors into MDH water guidance, especially as it relates to socioeconomic and societal factors, MDH is committed to working toward health and racial equity and environmental justice for all Minnesotans. This includes committing to thoughtfully calculating water guidance in a way that protects everyone, including those who are in sensitive developmental lifestages and individuals whose communities have been disproportionately impacted by inequities. MDH is also committed to sharing our methods for deriving guidance with communities around Minnesota through GovDelivery and meaningful engagement. MDH's ultimate goal is to ensure that all Minnesotans have access to clean, safe drinking water.

Performance-based rules

Minnesota Statutes, section 14.002, requires state agencies, whenever feasible, to develop rules that are not overly prescriptive and inflexible, and rules that emphasize achievement of the agency's regulatory objectives while allowing maximum flexibility to regulated parties and to the agency in meeting those objectives.

The proposed amendments allow risk managers and stakeholders flexibility in determining how best to protect the public from potentially harmful substances in our groundwater. HRL values provide a scientific and policy context within which the risks posed by a particular situation may be analyzed. Following the risk analysis, risk managers and interested parties, including other regulatory agencies, may examine the options and make decisions on a course of action. After implementation, they may evaluate outcomes.

Consult with MMB on local government impact

As required by Minnesota Statutes, section 14.131, MDH consulted with Minnesota Management and Budget (MMB) about the impact the proposed rules might have on local governments. MDH did this by sending to the MMB Commissioner copies of the proposed rule and SONAR before MDH published the *Notice of Intent to Adopt Rules*. A copy of our correspondence with MMB is attached as Appendix F.

Impact on local government ordinances and rules

As required by Minnesota Statutes, section 14.128, subdivision 1, MDH has considered whether the proposed rules will require a local government to adopt or amend any ordinance or other regulation to comply with these rules. MDH has determined that they *do not* because local governments do not develop or enforce groundwater quality standards through ordinances or regulations. The Commissioner of Health has exclusive authority to establish Health Risk Limits for groundwater quality. Local units of government have consulted with MDH on the use of HRL values for interpreting the results of well monitoring.

Costs of complying for small business or city

Minnesota Statutes, section 14.127, subdivisions 1 and 2, require 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 any one business that has less than 50 full-time employees, or any one statutory or home rule charter city that has less than ten full-time employees."

As described in detail above, there are no enforcement provisions associated with the proposed amendments to Minnesota Rules, parts 4717.7500 and .7860, or those rule parts themselves; thus, there are necessarily no costs associated with compliance with the proposed rule. As required by the plain language of Minnesota Statutes, section 14.127, the Department has determined that the cost of complying with the proposed rule in the first year after the rule takes effect will not 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.

Witnesses and other staff

The agency will publish a Dual Notice of Intent to Adopt Rules, meaning that if 25 or more people request a hearing, a hearing will be held. If less than 25 people request a hearing, a hearing will not be held. If a hearing is necessary, the agency anticipates having no outside witnesses testify.

All witnesses will likely be MDH staff members.

Conclusion

In this SONAR, the agency has established the need for and the reasonableness of each of the proposed amendments to Minnesota Rules, parts 4717.7500 and 4717.7860. The agency has provided the necessary notification documented in this SONAR its compliance with all applicable administrative rulemaking requirements of Minnesota statute and rules.

Based on the forgoing, the proposed amendments are both needed and reasonable.

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Wendy Underwood
Deputy Commissioner, Minnesota Department of Health

/s/ Wendy Underwood

Date 10/28/24

Appendix A: Glossary of Terms Used in Risk Assessment

Acute duration: A period of 24 hours or less.

Additional Lifetime cancer Risk (ALR): The probability that daily exposure to a carcinogen over a lifetime may induce cancer. MDH uses an additional cancer risk of 1×10^{-5} (1 in 100,000) to derive cancer HRL values. One common interpretation of this additional cancer risk is that if a population of 100,000 were exposed over an extended period of time to a concentration of a carcinogen at the level of the HRL, at most one case of cancer would be expected to result from this exposure. Because conservative techniques are used to develop these numbers, they are upper bound risks; the true risk may be as low as zero.

Additivity Endpoint: See *Health risk index endpoint(s).*

Adverse Effect: A biochemical change, functional impairment, or pathologic lesion that affects the performance of the whole organism or reduces an organism's ability to respond to an additional environmental challenge.

$AF_{lifetime}$ or lifetime adjustment factor: An adjustment factor used to adjust the adult-based cancer slope factor for lifetime exposure based on chemical-specific data.

Age-Dependent Adjustment Factor (ADAF): A default adjustment to the cancer slope factor that recognizes the increased susceptibility to cancer from early-life exposures to linear carcinogens in the absence of chemical-specific data. For the default derivation of cancer HRL values the following ADAFs and corresponding age groups are used: $ADAF_{<2} = 10$, for birth until 2 years of age; $ADAF_{2<16} = 3$, for 2 up to 16 years of age; and $ADAF_{16+} = 1$, for 16 years of age and older.

Animal Study: A controlled experiment in which a cohort of test animals, usually mice, rats, or dogs, is exposed to a range of doses of a chemical and assessed for health effects. For the purposes of the HRL rules, only studies of mammalian species were considered; studies relating to fish, amphibians, plants, etc. are not used because of the greater uncertainty involved in extrapolating data for these species to human health effects, as compared to studies involving mammals.

Benchmark Dose (BMD): Dose or concentration that produces a predetermined change in the response rate of an adverse or biologically meaningful effect. The BMD approach uses mathematical models to statistically determine a dose associated with a predefined effect level (e.g., 10 percent).

Benchmark Dose Level (BMDL): A statistical lower confidence limit on the benchmark dose (BMD).

Cancer classification: Most substances are classified under the system put in place in the EPA

Risk Assessment Guidelines of 1986. This system uses the categories:

- A - known human carcinogen;
- B - probable human carcinogen;
- C - possible human carcinogen;
- D - not classifiable as to carcinogenicity; and
- E - evidence of non-carcinogenicity for humans.

In 2005, EPA finalized revised guidelines calling for a "weight of the evidence" narrative, which is a short summary that explains the potential of a substance to cause cancer in humans and the conditions that characterize its expression. The following general descriptors were suggested:

- carcinogenic to humans;
- likely to be carcinogenic to humans;
- suggestive evidence of carcinogenic potential;
- inadequate information to assess carcinogenic potential; and
- not likely to be carcinogenic to humans.

Cancer Slope Factor: See *Slope Factor.*

Carcinogen: Generically, a carcinogen is a chemical agent that causes cancer. For the purposes of these Rules, a carcinogen is a chemical that is:

A) Classified as a human carcinogen (Group A) or a probable human carcinogen (Group B) according to the EPA (1986a) classification system. This system has been replaced by a newer classification scheme (EPA 2005), but many chemicals still have classifications under the 1986 system. Possible human carcinogens (Group C) will be considered carcinogens under these Rules if a cancer slope factor has been published by EPA and that slope factor is supported by the weight of the evidence.

OR

B) Classified pursuant to the Final Guidelines for Carcinogenic Risk Assessment (EPA 2005c) as "Carcinogenic to Humans" or "Likely to be carcinogenic to humans."

See also: *Linear carcinogen, Non-linear carcinogen.*

Chemical Abstract Service (CAS) number: The Chemical Abstract Service (CAS) Registry Number. This number, assigned by the Chemical Abstracts Service, a division of the American Chemical Society, uniquely identifies each chemical.

Chronic duration: A period of more than approximately 10% of the life span in humans (more than approximately 90 days to 2 years in typically used mammalian laboratory animal species).

Co-critical effect(s): Generally, effects that are observed at doses up to or similar to the exposure level of the critical study associated with the critical effect(s).

Conversion Factor (CF): A factor (1,000 µg/mg) used to convert milligrams (mg) to micrograms (µg). There are 1,000 micrograms per milligram.

Critical effect(s): The health effect or health effects from which a non-cancer toxicity value is derived; usually the first adverse effect that occurs to the most sensitive population as the dose increases.

Database Factor: see Uncertainty Factor.

Developmental health endpoint: Adverse effects on the developing organism that may result from exposure before conception (either parent), during prenatal development, or postnatally to the time of sexual maturation. Adverse developmental effects may be detected at any point in the lifespan of the organism. The major manifestations of developmental toxicity include: (1) death of the developing organism, (2) structural abnormality, (3) altered growth, and (4) function deficiency.

Dose-Response Assessment: The determination of the relationship between the magnitude of administered, applied, or internal dose and a specific biological response. Response can be expressed as measured or observed incidence, percent response in groups of subjects (or populations), or the probability of occurrence of a response in a population.

Dosimetric Adjustment Factor (DAF): A mathematical term that is based on body weight scaling that is used to calculate human equivalent exposure concentrations from laboratory animal exposure concentration.

Duration: Duration refers to the length of the exposure period under consideration. The default durations evaluated for non-cancer health effects are acute, short-term, subchronic, and chronic. See individual definitions for more information. These definitions are from “A Review of the Reference Dose and Reference Concentration Processes,” EPA, Risk Assessment Forum (December 2002, https://www.epa.gov/osa/review-reference-dose-and-reference-concentration-processes).

The default durations evaluated for cancer health effects correspond to the age groups upon

which the age dependent adjustment factors (ADAF) are based. These age groups were identified in the "Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens," EPA, Risk Assessment Forum (March 2005, http://www.epa.gov/cancerguidelines/guidelines-carcinogen-supplement.htm). The age groups are: from birth up to 2 years of age; from 2 up to 16 years of age; and 16 years of age and older.

The duration of concern may also be determined by chemical-specific information. For example, the non-cancer health effect may be linked to the time point at which the concentration of the chemical in the blood reaches a level associated with an adverse effect. Another example is if the cancer slope factor is based on a lifetime rather than an adult-only exposure protocol. In this case, a lifetime duration rather than the three age groups identified above would be used.

Endocrine (hormone) system: All the organs, glands, or collections of specialized cells that secrete substances (hormones) that exert regulatory effects on distant tissues and organs through interaction with receptors, as well as the tissues or organs on which these substances exert their effects. The hypothalamus, pituitary, thyroid, parathyroids, adrenal glands, gonads, pancreas, paraganglia, and pineal body are all endocrine organs; the intestines and the lung also secrete hormone-like substances.

Endocrine (E): For the purpose of the HRL revision, "endocrine" or "E" means a change in the circulating hormones or interactions with hormone receptors, regardless of the organ or organ system affected. Because of the many organs and tissues that secrete and/or are affected by hormones, the Department has not considered the endocrine system to be a discrete classification of toxicity. An endpoint is given an "E" designation only if a change in circulating hormones or receptor interactions has been measured. Endpoints with or without the (E) designation are deemed equivalent (e.g., thyroid (E) = thyroid) and should be included in the same Health Risk Index calculation.

Epidemiological Study: Epidemiology is the method used to find the causes of health outcomes and diseases in populations. An epidemiologic study is a way to analyze the community's health using data on risk factors and health outcomes to look for causes of health issues. The community is a population such as the whole state, a county, or another group of people. There are several types of epidemiologic studies. Some examples include: case-control, cohort, and cross-sectional studies.

Exposure Assessment: An identification and evaluation of the human population exposed to a toxic agent that describes its composition and size and the type, magnitude, frequency, route, and duration of exposure.

Groundwater: Water contained below the surface of the earth in the saturated zone including, without limitation, all waters whether under confined, unconfined, or perched conditions, in near-surface unconsolidated sediment or regolith, or in rock formations deeper underground

(*Minnesota Groundwater Protection Act*, Minnesota Statutes, section 103H.005, subdivision 8).

Hazard Assessment: The process of determining whether exposure to an agent can cause an increase in the incidence of a particular adverse health effect (e.g., cancer, birth defect) and whether the adverse health effect is likely to occur in humans.

Health-Based Value (HBV): A health-based value (HBV) is the concentration of a groundwater contaminant that can be consumed daily with little or no risk to health. HBVs are derived using the same algorithm as HRL values but have not yet been as adopted into rule. An HBV is expressed as a concentration in micrograms per liter (µg/L).

Health risk index: A health risk index is a sum of the quotients calculated by identifying all chemicals that share a common health endpoint and dividing the measured or surrogate concentration of each chemical by its HRL. The multiple-chemical health risk index is compared to the cumulative health risk limit of 1 to determine whether an exceedance has occurred.

Health risk index endpoint(s): The general description of critical and co-critical effects used to group chemicals for the purpose of evaluating risks from multiple chemicals. For example, the effect "inhibition of acetyl cholinesterase" is listed as the health risk index endpoint "nervous system," and all chemicals that can affect the nervous system would be considered together.

Health Risk Limit (HRL): A health risk limit (HRL) is the concentration of a groundwater contaminant, or a mixture of contaminants that can be consumed with little or no risk to health, and which has been adopted into rule. An HRL is expressed as a concentration in micrograms per liter (µg/L).

Health Standards Statute: Minnesota Statutes, section 144.0751. This statute requires that drinking water and air quality standards include a reasonable margin of safety to protect infants, children, and adults, taking into consideration the risk of a number of specified health effects, including: "reproductive development and function, respiratory function, immunologic suppression or hypersensitization, development of the brain and nervous system, endocrine (hormonal) function, cancer, and general infant and child development."

Human Equivalent Dose (HED): The oral human dose of an agent that is believed to induce the same magnitude of toxic effect as the experimental animal species dose. This adjustment may incorporate toxicokinetic information on the particular agent, if available, or use a default procedure, such as assuming that daily oral doses experienced for a lifetime are proportional to body weight raised to the 0.75 power ($BW^{3/4}$).

Immunotoxicity: Adverse effects resulting from suppression or stimulation of the body's immune response to a potentially harmful foreign organism or substance. Changes in immune function resulting from immunotoxic agents may include higher rates or more severe cases of disease, increased cancer rates, and auto-immune disease or allergic reactions.

Immune system: A complex system of organs, tissues, cells, and cell products that function to distinguish self from non-self and to defend the body against organisms or substances foreign to the body, including altered cells of the body, and prevent them from harming the body.

Intake Rate (IR): Rate of inhalation, ingestion, and dermal contact, depending on the route of exposure. For ingestion of water, the intake rate is simply the amount of water, on a per body weight basis, ingested on a daily basis (liters per kg body weight per day, L/kg-day) for a specified duration. For the derivation of non-cancer and cancer HRL values, the time-weighted average of the 95th percentile intake rate for the relevant duration was used.

Interspecies Factor: see *Uncertainty Factor.*

Intraspecies Factor: see *Uncertainty Factor.*

Kilogram (kg): One kilogram is equivalent to 2.21 pounds.

Latency Period: The time between exposure to an agent and manifestation or detection of a health effect of interest.

Linear carcinogen: A chemical agent for which the associated cancer risk varies in direct proportion to the extent of exposure, and for which there is no risk-free level of exposure.

Linear Dose Response: A pattern of frequency or severity of biological response that varies directly with the amount of dose of an agent. In other words, more exposure to the substance could produce more of an effect. This linear relationship holds only at low doses in the range of extrapolation.

Liter (L): One liter is equivalent to 1.05671 quarts.

Liters per kilogram per day (L/kg-day): A measure of daily water intake, relative to the individual's body weight.

LOAEL-to-NOAEL: see *Uncertainty Factor.*

Lowest Observed Adverse Effect Level (LOAEL): The lowest exposure level at which a statistically or biologically significant increase in the frequency or severity of adverse effects is observed between the exposed population and its appropriate control group. A LOAEL is expressed as a dose rate in milligrams per kilogram body weight per day (mg/kg-day).

MCL-based HRL: A Health Risk Limit for groundwater adopted by reference to EPA's Maximum Contaminant Level (MCL) rather than through the standard MDH chemical evaluation process.

Mechanism of Action: The complete sequence of biological events (i.e., including toxicokinetic

and toxicodynamic events) from exposure to the chemical to the ultimate cellular and molecular consequences of chemical exposure that is required to produce the toxic effect. However, events that are coincident but not required to produce the toxic outcome are not included.

Microgram (µg): 10^{-6} grams or 10^{-3} milligrams. 1,000 micrograms = 1 milligram

Micrograms per liter (µg/L): A unit of measure of concentration of a dissolved substance in water.

Milligram (mg): 10^{-3} grams. 1,000 milligrams = 1 gram.

Milligrams per kilogram of body weight per day (mg/kg-day or mg/kg-d): A measure of daily exposure to a contaminant, relative to the individual's body weight.

Mode of Action (MOA): The sequence of key event(s) (i.e., toxicokinetics and toxicodynamics) after chemical exposure upon which the toxic outcomes depend.

Neurotoxicity: Any adverse effect on the structure or function of the central and/or peripheral nervous system related to exposure to a chemical.

Non-linear carcinogen: A chemical agent for which, particularly at low doses, the associated cancer risk does not rise in direct proportion to the extent of exposure, and for which there may be a threshold level of exposure below which there is no cancer risk.

Non-linear Dose Response: A pattern of frequency or severity of biological response that does not vary directly with the amount of dose of an agent. When mode of action information indicates that responses may fall more rapidly than dose below the range of the observed data, non-linear methods for determining risk at low dose may be justified.

No Observed Adverse Effect Level (NOAEL): An exposure level at which there is no statistically or biologically significant increase in the frequency or severity of adverse effects between the exposed population and its appropriate control group.

Physiologically Based Toxicokinetic (PBTK) Model (also referred to as physiologically based pharmacokinetic model)**:** A model that estimates the dose to a target tissue or organ by taking into account the rate of absorption into the body, distribution among target organs and tissues, metabolism, and excretion.

Point of Departure (POD): The dose-response point that marks the beginning of a low-dose extrapolation. This point can be the lower bound on a dose-response curve where an effect or change in response is first estimated or observed, using benchmark dose response modeling or using a NOAEL or LOAEL obtained experimentally.

Reference Dose (RfD): An estimate of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects for a given exposure duration. It is derived from a suitable exposure level at which there are few or no statistically or biologically significant increases in the frequency or severity of an adverse effect between an exposed population and its appropriate control group. The RfD is expressed in units of milligrams of the chemical per kilogram of body weight per day (mg/kg-day).

Reference Serum Concentration (RfSC): An estimate of the amount of a chemical in the serum of a human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects for a given exposure duration. It is derived from comparing the serum concentrations of the chemical at which there are few or no statistically or biologically significant increases in the frequency or severity of an adverse effect between an exposed population and its appropriate control group. The RfSC is typically expressed in units of nanograms of the chemical per milliliter of serum (ng/mL).

Relative Source Contribution (RSC): The portion of the RfD that is "allocated" to ingestion of water. Applying this factor acknowledges that non-ingestion exposure pathways (e.g., dermal contact with water, inhalation of volatilized chemicals in water) as well as exposure to other media, such as air, food, and soil may occur. The *Minnesota Groundwater Protection Act*, in Minnesota Statutes, section 103H.201, subdivision 1(d), requires that MDH use a relative source contribution in deriving health risk limits for systemic toxicants. MDH relied upon EPA's Exposure Decision Tree approach contained in Chapter 4 of the Ambient Water Quality Criteria (https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=20003D2R.txt) document (EPA, 2000b) to determine appropriate RSC values.

HRL values are often applied at contaminated sites where media other than groundwater may also be contaminated. The level of media contamination and the populations potentially exposed will vary from site to site and from chemical to chemical. Using a qualitative evaluation and the Exposure Decision Tree, MDH determined the following default RSC values: 0.2 for highly volatile contaminants (chemicals with a Henry's Law Constant greater than 1×10^{-3} atm-m^3/mole) and 0.5 for young infants or 0.2 for older infants, children and adults for chemicals that are not highly volatile. There may be chemical-specific or site-specific exposure information where the Exposure Decision Tree could be used to derive a chemical- or site-specific RSC that is different than the default value.

Reproductive toxicity: Effects on the ability of males or females to reproduce, including effects on endocrine systems involved in reproduction and effects on parents that may affect pregnancy outcomes. Reproductive toxicity may be expressed as alterations in sexual behavior, decreases in fertility, changes in sexual function that do not affect fertility, or fetal loss during pregnancy.

Risk: In the context of human health, the probability of adverse effects resulting from exposure to an environmental agent or mixture of agents.

Risk Assessment: The evaluation of scientific information on the hazardous properties of environmental agents (hazard characterization), the dose-response relationship (dose-response assessment), and the extent of human exposure to those agents (exposure assessment). The product of the risk assessment is a statement regarding the probability that populations or individuals so exposed will be harmed and to what degree (risk characterization).

Risk Assessment Advice (RAA): A type of MDH health-based guidance that evaluates potential health risks to humans from exposures to a chemical. Generally, RAA may contain greater uncertainty than HRL values and HBVs due to limited availability of information or may use novel methods to derive health-based guidance. Based on the information available, RAA may be quantitative (e.g., a concentration of a chemical that is likely to pose little or no health risk to humans expressed in µg/L) or qualitative (e.g., a written description of how toxic a chemical is in comparison to a similar chemical).

Risk Characterization: The integration of information on hazard, exposure, and dose-response to provide an estimate of the likelihood that any of the identified adverse effects will occur in exposed people.

Risk Management: A decision-making process that accounts for political, social, economic, and engineering implications together with risk-related information to develop, analyze, and compare management options and select the appropriate managerial response to a potential health hazard.

Secondary Observation: Notation indicating that although endpoint-specific testing was not conducted, observations regarding effects on the endpoint were reported in a toxicity study.

Short-Term Duration: A period of more than 24 hours, up to 30 days.

Slope Factor (SF): An upper-bound estimate of cancer risk per increment of dose that can be used to estimate risk probabilities for different exposure levels. This estimate is generally used only in the low-dose region of the dose-response relationship; that is, for exposures corresponding to risks less than 1 in 100. A slope factor is usually expressed in units of cancer incidence per milligram of chemical per kilogram of body weight per day (per [mg/kg-day] or $[mg/kg\text{-}day]^{-1}$).

Statistical Significance: This describes the probability that a result is not likely to be due to chance alone. By convention, a difference between two groups is usually considered statistically significant if chance could explain it only 5% of the time or less. Study design considerations may influence the *a priori* choice of a different level of statistical significance.

Subchronic Duration: A period of more than 30 days, up to approximately 10% of the life span in humans (more than 30 days up to approximately 90 days in typically used mammalian laboratory animal species).

Subchronic-to-Chronic Factor: See *Uncertainty Factor*.

Target Organ: The biological organ(s) most adversely affected by exposure to a chemical or physical agent.

Time-Weighted Average (TWA): In quantifying a measurement that varies over time, such as water intake, a time-weighted average takes measured intakes, which may occur at unevenly-spaced intervals, and multiplies each measurement by the length of its interval. These individual weighted values are then summed and divided by the total length of *all* of the individual intervals. The result is an average of all of the measurements, with each measurement carrying more or less weight in proportion to its size.

Threshold: The dose or exposure below which no toxic effect is expected to occur.

Toxicity: Deleterious or adverse biological effects elicited by a chemical, physical, or biological agent.

Toxicodynamics (TD): The determination and quantification of the sequence of events at the cellular and molecular levels leading to a toxic response to an environmental agent (sometimes referred to as pharmacodynamics and also MOA).

Toxicokinetics (TK): The determination and quantification of the time course of absorption, distribution, metabolism, and excretion of chemicals (sometimes referred to as pharmacokinetics).

Uncertainty Factor (UF): One of several factors used in deriving a reference dose from experimental data. UFs are intended to account for:

- **Interspecies UF** - the uncertainty in extrapolating from mammalian laboratory animal data to humans. This uncertainty factor is composed of two subfactors: one for toxicokinetics and one for toxicodynamics.

- **Intraspecies Variability Factor** - the variation in sensitivity among the members of the human population;

- **Subchronic-to-Chronic Factor** (Use of a less-than-chronic study for a chronic duration) - the uncertainty in extrapolating from effects observed in a shorter duration study to potential effects from a longer exposure;

- **LOAEL-to-NOAEL** (Use of a LOAEL rather than a NOAEL) - the uncertainty associated with using a study in which health effects were found at all doses tested; and

- **Database Uncertainty** - the uncertainty associated with deficiencies in available data.

Uncertainty factors are normally expressed as full or half powers of ten, such as 10^0 (=1), $10^{0.5}$ (»3), and 10^1 (=10). All applicable uncertainty factors are multiplied together to yield a composite uncertainty factor for the RfD. Half-power values such as $10^{0.5}$ are factored as whole numbers when they occur singly but as powers or logs when they occur in tandem (EPA 2002). Therefore, a composite UF using values of 3 and 10 would be expressed as 30 (3×10^1), whereas a composite UF using values of 3 and 3 would be expressed as 10 ($10^{0.5} \times 10^{0.5} = 10^1$).

In keeping with the EPA RfC/RfD Technical Panel (EPA, 2002) recommendation and the rationale supporting it, MDH has not derived an HRL for any chemical if the product of all applicable uncertainty factors exceeds 3,000 (Minnesota Rules, part 4717.7820, subpart 21).

Volatile: Volatility is the tendency of a substance to evaporate. Inhalation exposure to volatile chemicals in groundwater may be a health concern. Chemical characteristics that affect volatility include molecular weight, polarity, and water solubility. Typically, a chemical is considered volatile if it has a Henry's law constant greater than 3×10^{-7} atm-m^3/mol. Chemicals are characterized as being nonvolatile, or being of low, medium, or high volatility as follows:

- Henry's Law constant < 3×10^{-7} atm-m^3/mol = nonvolatile
- Henry's Law constant > 3×10^{-7} to 1×10^{-5} atm-m^3/mol = low volatility
- Henry's Law constant >1×10^{-5} to 1×10^{-3} atm-m^3/mol = moderate volatility
- Henry's Law constant >1×10^{-3} atm-m^3/mol = high volatility

Weight of Evidence (WOE): An approach requiring a critical evaluation of the entire body of available data for consistency and biological plausibility. Potentially relevant studies should be judged for quality and studies of high quality given much more weight than those of lower quality.

Appendix B: References

Note: The following references were used to develop an updated methodology and Health Risk Limit values in MDH's effort on revising and updating the rules on Health Risk Limits for Groundwater. These materials are available for review online, at the Minnesota Department of Health, or through an interlibrary loan system.

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Appendix C: Concepts Used in MDH-Derived HRLs

Described below are the basic principles that underlie MDH's risk algorithm adopted in 2009 (Minnesota Rules, part 4717.7830, subpart 2) as stated in MDH-derived HRL Algorithm, MDH used these methods to derive the HRL values that are included in the proposed amendments. Detailed descriptions of these concepts are also available in MDH's 2008/2009 SONAR (MDH, 2008. See Part IV).

HRL rules employ two types of assessments. One assessment is for chemicals for which it is assumed that any dose of that chemical above zero carries some potential increased risk of cancer. These chemicals are identified as "linear" or "non-threshold" carcinogens. The second type of assessment is for evaluating non-cancer effects. This method can also be applied to address chemicals that have the potential to cause cancer through a "non-linear" mechanism. The assessment of a non-carcinogen or a non-linear carcinogen assumes that there is a threshold dose that must be exceeded before adverse health effects (including cancer) will develop.

Toxicity

Toxicity is one of the factors in determining HRL values. In evaluating the dose and response, researchers seek to determine the lowest dose at which adverse effects are observed (the "lowest observed adverse effect level," or LOAEL) and the highest dose at which no adverse effects are observed (the "no observed adverse effect level," or NOAEL). Alternatively, researchers may statistically model the data to determine the dose expected to result in a response in a small percentage of the dosed animals (e.g., the benchmark dose, or BMD). The dose resulting from the dose-response evaluation, also referred to as a point-of-departure (POD) dose, serves as the starting point for deriving health-protective concentrations for air, water and soil, collectively referred to as the "environmental media."

For effects other than cancer, the dose selected from the dose-response evaluation is divided by variability and uncertainty factors (UFs) to account for what is not known about a chemical's toxicity to a human population. The result, called a reference dose (RfD), is an estimate of a dose level that is likely to be without an appreciable risk of adverse effects. An RfD is expressed in milligrams of chemical per kilogram of body weight per day (mg/kg-day).

Understanding the relationship between the timing and duration of exposure and the subsequent adverse effect is essential in deriving criteria that are protective of sensitive life stages (e.g., development early in life) and short periods of high exposure (e.g., infancy). In *A Review of the Reference Dose (RfD) and Reference Concentration (RfC) Processes,* EPA recommends the derivation of acute, short-term, subchronic, and chronic RfDs (EPA, 2002). In cases where sufficient toxicological information is available, MDH derives RfDs for the various time periods as defined by EPA.

In evaluating the proposed nHRL values, MDH staff compiled and assessed the available toxicity information for the following durations of exposure:

- Acute: up to 24 hours
- Short-term: greater than 24 hours and up to 30 days
- Subchronic: greater than 30 days and up to 10% of a lifetime
- Chronic: greater than 10% of a lifetime

The current HRL methods not only list the specific effects occurring at the lowest effect dose, but also effects that occur at doses similar to the Lowest-Observed-Adverse Effect Level (LOAEL), from other available toxicity studies. This provides more information to risk managers and can affect the results of an assessment when multiple chemicals are present (also see Minnesota Rules, part 4717.7880). Within each chemical's toxicology summary (see Appendix E), MDH has also indicated which chemicals are associated with endocrine effects and which chemicals have their greatest effects as a result of exposure *in utero* or during child development. Further, MDH notes whether the information reviewed for each chemical includes assessments of developmental, reproductive, immunological, endocrine, or neurological effects. This information is provided for each chemical in part to meet the stipulations of the *2001 Health Standards Statute*.

For cancer HRLs, as stated in MDH 2008/2009 SONAR, "it is usually assumed that any amount of exposure, no matter how small, potentially carries some risk. Derivations of HRLs based on the endpoint of cancer for chemicals considered to be linear carcinogens do not, therefore, employ an RfD. Instead, Minnesota's long-standing public health policy is to derive values that limit the excess cancer risk to 1 in 100,000. Cancer potency is expressed as an upper bound estimate of cases of cancer expected from a dose of one milligram of substance per kilogram of body weight per day (i.e., cancer incidence per 1 mg/kg-day). From these estimates, a cancer potency slope, or "slope factor" (SF), can be calculated." (MDH, 2008).

In 2021, the Minnesota Legislature passed an amendment to the Groundwater Protection Act that allows MDH to use slope factors published by EPA or determined by the Commissioner to have undergone sufficient scientific review. To derive a cancer HRL, MDH accounts for the potential for increased cancer potency when exposure occurs early in life by using methodology contained in the EPA *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (EPA, 2005b). This approach involves applying age-dependent cancer potency adjustment factors to three life stages. The adjustment factors and corresponding life stages are: a 10-fold adjustment for individuals from birth to 2 years of age; a 3-fold adjustment for individuals from 2 to 16 years of age and no adjustment for individuals 16 years of age and older (MDH, 2008). For additional information about methodology for derivation of cancer HRLs, please see the 2008/2009 SONAR (MDH, 2008).

Examples of sources of toxicity information that MDH considers in deriving HRL values include the following:

- EPA
    - Reregistration Eligibility Decisions (REDs) from the Office of Pesticide Programs. Updates are provided on EPA's Pesticide Chemical Search page at https://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1
    - Health Effects Supporting Documents in The Drinking Water Contaminant Candidate List (CCL) and Regulatory Determination (https://www.epa.gov/ccl) from the Office of Ground Water and Drinking Water
    - The Integrated Risk Information System (IRIS) (https://www.epa.gov/iris)
    - The National Center for Environmental Assessment (NCEA) (https://www.epa.gov/aboutepa/about-national-center-environmental-assessment-ncea) risk assessments
- California EPA
    - The Public Health Goal (http://oehha.ca.gov/water/public-health-goals-phgs) technical supporting documents from the Office of Environmental Health Hazard Assessment (OEHHA)
- Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profiles (https://www.atsdr.cdc.gov/toxprofiles/index.asp);
- National Toxicology Program (https://ntp.niehs.nih.gov/) (NTP) study report and toxicity studies;
- Health Canada's Priority Substances Assessment Program and Screening Assessment Reports (http://www.hc-sc.gc.ca/ewh-semt/pubs/contaminants/index-eng.php#psl)
- European Commission chemical reviews
    - European Chemical Agency Information on Chemicals (https://echa.europa.eu/information-on-chemicals)
    - European Food Safety Authority Scientific Publications (https://www.efsa.europa.eu/en/publications)
    - European Union Pesticides Database (http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN)

- The World Health Organization's (WHO) Concise International Chemical Assessment Documents (https://inchem.org/pages/cicads.html); and
- Other published scientific literature.

Intake Rates

An intake rate (IR) is defined as the rate of ingestion of water (Minnesota Rules, part 4717.7820, subpart 14). In deriving HRL values, the RfD for non-cancer health effects is converted from milligrams per kilogram body weight per day (mg/kg-day) to a water concentration in micrograms per liter of water (µg/L) by dividing by a water intake rate. IR is expressed as the quantity of water consumed in liters per kilogram of body weight per day (L/kg-day).

$$\text{nHRL}\left(\frac{\text{L}}{\text{kg}-\text{d}}\right) = \frac{\text{RfD}\left(\frac{\text{mg}}{\text{kg}-\text{d}}\right) \text{ x } (1000\ \mu\text{g/mg})}{\text{Intake rate}\left(\frac{\text{L}}{\text{kg}-\text{d}}\right)}$$

The initial 2008 default values were time-weighted averages based on the data reported in U.S. EPA's Per Capita Report (EPA, 2004b) and a draft assessment prepared for the Child-Specific Exposure Factors Handbook (EPA, 2008). In 2016, MDH began using the water intake rates from the finalized EPA 2011 Exposure Factors Handbook. In 2019, EPA published another update to water intake rates (Chapter 3, US EPA, 2019). MDH staff calculated and used the following default time-weighted-average intake rates for non-cancer health-based guidance from the 2019 EPA values. MDH began using those rates in 2020 and updated all guidance prepared for rulemaking, using the intake rates, shown below:

- Acute: 0.290 L/kg-day
- Short-term: 0.290 L/kg-day
- Subchronic: 0.074 L/kg-day
- Chronic: 0.045 L/kg-day
- Pregnant Women: 0.038 L/kg-day
- Lactating Women: 0.047 L/kg-d

For linear carcinogens HRLs, as noted in the 2008/2009 SONAR:

> MDH has adopted EPA's approach for integrating age-dependent sensitivity adjustment factors and exposure information. The default intake rates corresponding to the age-dependent adjustment factor (ADAF) age groups used in deriving cancer HRLs are based on the [Time Weighted Average] TWA of the 95th percentile intake rate for each age range. MDH staff calculated and used the following default time-weighted-average intake rates, based on the 2019 EPA values, for cancer health-based guidance: 0.155 L/kg-day (up to 2 years of age), 0.040 L/kg-day (2 to up to 16 years of age), and 0.042 L/kg-day (16 years of age and older).

The duration used to characterize lifetime cancer risk is 70 years, per EPA's practices (MDH, 2008).

The RSC was used to allocate a portion of the total daily RfD to exposure from ingestion of water. This apportionment is to ensure that exposure from ingestion of water combined with other exposures, such as exposures from non-ingestion routes of exposure to water (e.g., inhalation of volatilized chemicals, dermal absorption) as well as exposures via other contaminated media such as food, air, and soil will not result in exceeding the RfD. Minnesota Statutes, section 103H.201, subdivision (1)(c), which establishes methods for deriving HRL values for chemicals other than linear (non-threshold) carcinogens, requires that an RSC be used. The RSC values used are based on an Exposure Decision Tree from the EPA Ambient Water Quality Criteria document (EPA, 2000b) and the consideration of chemical and physical properties of each chemical (e.g., volatility) as well as other potential sources of exposure.

Based on qualitative evaluation and EPA's Exposure Decision Tree (EPA, 2000b), MDH used the following default RSC values: for nonvolatile, low and moderately volatile chemicals, an RSC of 50 percent (0.5) is used for the acute and short-term durations that use the intake rate for young infants; for subchronic and chronic durations, 20 percent (0.2) is used. In contrast, for all durations for highly volatile chemicals, an RSC of 20 percent (0.2) is used for all durations because inhalation exposure is a concern for any duration or age of exposure, including infancy. The volatility classification for each chemical is determined by the following definition (Minnesota Rules, part 4717.7820, subpart 25):

Nonvolatile – Henry's Law constant $<3 \times 10^{-7}$ atm-m^3/mol

- Low volatility – Henry's Law constant $>3 \times 10^{-7}$ to 1×10^{-5} atm-m^3/mol
- Moderate volatility – Henry's Law constant $>1 \times 10^{-5}$ to 1×10^{-3} atm-m^3/mol
- High volatility – Henry's Law constant $> 1 \times 10^{-3}$ atm-m^3/mol

Uncertainty Factors (UFs)

To account for what is not known about a chemical's toxicity to a human population, uncertainty and variability factors are applied to threshold (non-linear) toxicants when deriving HRL values for non-cancer and non-linear carcinogens. Once the dose level (e.g., NOAEL, LOAEL or BMD) has been selected as the point of departure (POD), it is then divided by uncertainty and/or variability factors to derive the RfD:

$$\frac{\text{Point of Departure (POD)}}{\text{Uncertainty and Variability Factors (UFs)}} = \text{Reference Dose (RfD)}$$

As risk-assessment methods have evolved, risk assessors consider the applying five uncertainty and variability factors. Each of these factors and guidelines for application are explained below:

- Interspecies Extrapolation Factor – This factor accounts for the uncertainty or the difference between animals and humans when laboratory animal data are used as the source of the point of departure (POD). It is composed of two subfactors: 1) toxicokinetics (absorption, distribution, metabolism and elimination of the chemical) and 2) toxicodynamics (the body's response to the chemical). The current practice is to use either chemical-specific toxicokinetic data or a data-based adjustment for toxicokinetics rather than an uncertainty factor for toxicokinetics. If there is no chemical-specific information regarding quantitative differences between laboratory animals and humans, a body-weight scaling adjustment based on EPA guidance (EPA, 2011b) is used to calculate the Human Equivalent Dose or HED. Less information is typically available concerning the toxicodynamic portion of this factor. If no chemical-specific toxicodynamic information is available, a default uncertainty factor of 3 is applied for the toxicodynamics. Chemical-specific information for either or both subparts may lead to a combined factor of greater than 10. If human data is the source of the POD then a factor of 1 may be used.

- Intraspecies Variability Factor – This factor accounts for the variation in sensitivity between individuals in the human populations (including life stages) and for the fact that some subpopulations might be more sensitive to the toxicological effects than the average population. As with the interspecies extrapolation factor, this factor is also composed of two subfactors: toxicokinetics and toxicodynamics. If no information on human variability is available then a default value of 10 is used. If adequate information is available for either subfactor then this information is used along with a default factor of 3 for the remaining subfactor. If the POD is based on human data gathered in the known sensitive populations, a value of less than 10 (including 1) may be chosen.

- Subchronic-to-Chronic Extrapolation Factor – This factor accounts for the uncertainty in extrapolating from the effects observed in a shorter-duration study to potential effects of longer-duration exposure due to lack of adequate information in the dataset. In determining whether to apply this factor, MDH considers: 1) data indicating other, more

sensitive, health effects as the duration of exposure increases, 2) data indicating that the critical effect(s) progress in severity as exposure duration increases, or 3) data indicating that the POD decreases in value as exposure duration increases. A default value of 10 is often applied to shorter-duration PODs to derive chronic values unless data suggest a lack of progression with increasing exposure duration. If data addresses only some of the considerations, a value of less than 10 (e.g., 3) may be used.

- LOAEL-to-NOAEL Extrapolation Factor – This factor accounts for the uncertainty in using a study in which even the lowest dose tested causes some adverse effect(s), and is in contrast to the preferred case where at least one of the administered doses caused no adverse effects. Since the RfD is considered to be a threshold value that protects against any adverse health effects, the LOAEL-to-NOAEL factor is applied when the critical study(s) lacks information or the threshold/NOAEL cannot be determined with confidence (e.g., when LOAEL is used as a POD). The default value is 10, however, if the adverse effect observed is considered to be of minimal severity a default value of 3 may be appropriate.

- Database Uncertainty Factor – This factor accounts for uncertainty based on existing data or deficiencies in the available dataset, resulting in the potential for additional data to yield a lower reference value (EPA, 2004a) (i.e., additional studies may show the chemical to be more harmful). A high-confidence database would contain a minimum of two chronic bioassays testing system toxicity by the appropriate route of exposure in different species, one 2-generation reproductive toxicity study, and two developmental toxicity studies in different species. A database UF is used when a potentially more sensitive health effect cannot be identified because the database is missing a particular type of study or the existing data suggest the potential for a health effect but the effect has not been adequately assessed. In general, a default factor of 10 is used if more than one particular type of study is missing. A value of 3 has been used if one particular type of study is missing (e.g., no 2-generation reproductive or developmental study).

In the absence of chemical-specific information, each of the five factors is typically assigned a value between 1 and 10. Uncertainty factors are normally expressed as full or half powers of ten, such as 10^0 (=1), $10^{0.5}$ (»3), and 10^1 (=10). All applicable uncertainty factors are multiplied together to yield a composite uncertainty factor for the RfD. Half-power values such as $10^{0.5}$ are factored as whole numbers when they occur singly but as powers or logs when they occur in tandem (EPA, 2002). Therefore, a composite UF using values of 3 and 10 would be expressed as 30 (3×10^1), whereas a composite UF using values of 3 and 3 would be expressed as 10 ($10^{0.5} \times 10^{0.5} = 10^1$).

In keeping with the EPA RfC/RfD Technical Panel (EPA, 2002) recommendation and the rationale supporting it, MDH has not derived an HRL for any chemical if the product of all applicable uncertainty factors exceeds 3,000 (Minnesota Rules, part 4717.7820, subpart 21). Chemicals with higher total uncertainty factors are not necessarily more toxic than chemicals

with lower total uncertainty factors. The use of a larger total uncertainty factor only means that there is less information available about the toxicity of the chemical.

MDH Health Risk Limit Algorithms

As noted in MDH-derived HRL Algorithm, MDH uses formulas called "algorithms," to derive HRL values. The formulae and explanation of components are described below:

Non Cancer HRLs (nHRLs)

The algorithm for nHRLs is:

$$\mathrm{nHRL_{duration}} = \frac{\mathrm{RfD_{duration}} \times \mathrm{RSC} \times 1000}{\mathrm{IR_{duration}}}$$

Where:

$\mathrm{nHRL_{duration}}$ = the non-cancer health risk limit (nHRL), for a given duration, expressed in units of micrograms of a chemical per liter of water (µg/L) (Minnesota Rules, part 4717.7820, subpart 13).

$\mathrm{RfD_{duration}}$ = the reference dose (RfD) for a given duration, expressed in units of milligrams per kilogram per day (mg/kg-day). The following default durations are used: (i) acute – a period of 24 hours or less; (ii) short-term – a period of more than 24 hours, up to 30 days; (iii) subchronic – a period of more than 30 days, up to approximately 10% of the life span in humans; or (iv) chronic – a period of more than approximately 10% of the life span in humans (Minnesota Rules, part 4717.7820, subpart 9 and 21).

RSC = the relative source contribution (RSC) factor which represents the percentage of total exposure to a substance or chemical that is allocated to ingestion of water. MDH uses the EPA Exposure Decision Tree (EPA, 2000b) to select appropriate RSCs, ranging from 0.2 to 0.8. The default RSC is 20 percent (0.2) for highly volatile chemicals. For other chemicals, the default RSC is 50 percent (0.5) for acute and short-term HRL values and 20 percent (0.2) for subchronic or chronic HRL values (Minnesota Rules, part 4717.7820, subpart 22). In some cases, a chemical-specific RSC is applied. For example a value of 0.8 has been used for pharmaceuticals when, for persons not using the pharmaceutical, no other route of exposure other than drinking water is likely.

1,000 = a factor used to convert milligrams (mg) to micrograms (µg) (Minnesota Rules, part 4717.7830, subpart 2, item D).

$IR_{duration}$ = the intake rate (IR) of ingestion of water, or simply the amount of water, on a per body weight basis, ingested on a daily basis (liters per kg body weight per day or L/kg-day). The default IR corresponds to the time-weighted average (TWA) of the 95th percentile intake rate during the relevant duration: acute and short-term - 0.290 L/kg-day, based on intake for 1 up to 3 months of age; subchronic - 0.074 L/kg-day, based on a TWA up to 8 years of age; and chronic - 0.045 L/kg-day, based on a TWA over a lifetime of approximately 70 years (Minnesota Rules, part 4717.7820, subpart 14).

MDH departed from the above default HRL algorithm and parameter values if sufficient chemical-specific information indicated that a different duration or intake rate was more appropriate. In these cases, a time-weighted intake rate was calculated over the duration specified by the chemical-specific information. The RfD, RSC and IR values used in deriving each nHRL for chemicals included in these proposed rules are presented in Section V.B.

As indicated in the risk algorithm, the magnitude of the HRL value is a function of the RfD and the IR. In general, for a given chemical, the shorter-duration RfD values will be higher than the longer-duration RfD values because the human body can usually tolerate a higher dose when the duration of the dose is short, even if that same dose would be harmful when it occurs over a longer duration. It is possible, however, that the RfD for a shorter duration is similar to, or in rare cases lower, than the RfD for a longer duration. This could occur for various reasons such as if a short duration was sufficient to elicit the same adverse effect found in longer-duration study; or if the health effect assessed only in the shorter-duration study occurred at a lower dose than the effect assessed in the longer-duration study; or if the life stage or species assessed only in the shorter-duration study was more sensitive to the toxicant than the life stage or species assessed in the longer-duration study.

The intake rate also affects the magnitude of the HRL value. As described above, the shorter-duration intake rates are higher than the longer-term intake rates. These higher intake rates combined with the RfD may produce a shorter-duration HRL that is less than the calculated longer-duration HRL. When this occurs, the longer-duration HRL is set equal to the lower, shorter-duration HRL. This ensures that the HRL for a longer duration is protective of higher shorter-term intakes that occur within the longer duration. In instances where the calculated longer-duration HRL value is set at the shorter-duration HRL value, the health endpoints identified will include the health endpoints specified for the shorter-duration, and may include additional health endpoints. These additional health endpoints are included if they are associated with longer-duration exposure to drinking water concentrations similar in magnitude to the shorter-duration HRL.

In accordance with the general rule for calculations involving multiplication or division, HRL values are rounded to the same number of significant figures as the least precise parameter used in their calculation (EPA, 2000c). As a result, the HRL values are rounded to one significant figure. MDH rounded the values as the final step in the calculation (see chemical-specific summary sheets in Appendix E).

The example below shows the derivation of the short-term nHRL value for carbon tetrachloride, using the algorithm for nHRLs:

$$nHRL_{duration} = \frac{(RfD) \times (RSC) \times (Conversion\ Factor)}{(IR_{duration}, L/kg/d)}$$

$$nHRL_{short\ term} = \frac{(0.0037\ mg/kg/d) \times (0.2) \times (1000\ \mu g/mg)}{(0.290\ L/kg\text{-}d)}$$

= 2.55 rounded to 3 µg/L

The next example below shows the derivation of the subchronic nHRL for carbon tetrachloride:

$$nHRL_{subchronic} = \frac{(0.0098\ mg/kg/d) \times (0.2) \times (1000\ \mu g/mg)}{(0.074\ L/kg\text{-}d)}$$

= 26.48 rounded to 26 µg/L

The calculated subchronic nHRL (26 µg/L) is greater than carbon tetrachloride's short-term HRL value of 3 µg/L. Since the subchronic HRL must be protective of the short-term exposures that occur within the subchronic period, the subchronic nHRL is set equal to the short-term nHRL value. Hence, the subchronic nHRL value for carbon tetrachloride is set equal to 3 µg/L. The health endpoint is the hepatic (liver) system. In this case:

$$nHRL_{subchronic} = nHRL_{short\text{-}term} = 3\ \mu g/L$$

Notes

- RfDs and uncertainty adjustments are derived by MDH, unless otherwise noted. The RfDs and the endpoints are usually based on animal studies but may be based on human studies.

- RfDs are based on HED calculated from the point of departure in the selected animal studies. HED is the human dose (for routes other than inhalation) of an agent that is believed to induce the same magnitude of toxic effect as the experimental animal species dose (MDH, 2011).

- A health endpoint designation of "none" is used when a general adverse effect (e.g., decreased adult body weight) cannot be attributed to a specific organ system.

- The duration-specific nHRL value is derived using the following equation as shown above and specified in Minnesota Rules, part 4717.7830, subpart 2:

$$nHRL_{duration} = \frac{RfD_{duration} \times RSC \times 1{,}000}{IR_{duration}}$$

- The terms used in this section are explained in the Glossary (see Appendix A).

Cancer HRLs:

For the derivation of cancer HRLs for linear carcinogens, MDH applied the age-dependent cancer potency adjustment factors and corresponding intake rates to the default HRL algorithm for cancer:

$$cHRL = \frac{(1\times 10^{-5}) \times 1{,}000\ \frac{\mu g}{mg}}{\left[(SF \times ADAF_{<2} \times IR_{<2} \times D_{<2}) + (SF \times ADAF_{2\ to<16} \times IR_{2\ to<16} \times D_{2\ to<16}) + (SF \times ADAF_{16+} \times IR_{16+} \times D_{16+})\right] \div 70\ years}$$

Where:

cHRL = the cancer health risk limit expressed in units of micrograms of chemical per liter of water (µg/L).

(1×10^{-5}) = the additional cancer risk level.

1,000 = a factor used to convert milligrams (mg) to micrograms (µg).

SF = the cancer slope factor for adult exposure, expressed in units of the inverse of milligrams per kilogram of body weight per day ([cancer incidence per mg/kg-day] or $[mg/kg\text{-}day]^{-1}$).

ADAF = the age-dependent adjustment factor for each age group: 10, for up to 2 years of age ($ADAF_{<2}$); 3, for 2 up to 16 years of age ($ADAF_{2<16}$); and 1, for 16 years of age and older ($ADAF_{16+}$). ADAFs are default adjustments to the cancer slope factor that recognize the increased susceptibility to cancer from early life exposures to linear carcinogens. They are incorporated into the denominator of the cancer HRL equation.

IR = the intake rate for each age group: 0.155L/kg-day, for up to 2 years of age ($IR_{<2}$); 0.040 L/kg-day, for 2 up to 16 years of age ($IR_{2<16}$); and 0.042 L/kg-day, for 16 years of age and older (IR_{16+}).

D = the duration for each age group: 2 years, for up to 2 years of age ($D_{<2}$); 14 years, for 2 up to 16 years of age ($D_{2<16}$); and 54, for 16 years of age and older (D_{16+}).

70 years = the standard lifetime duration used by EPA in the characterization of lifetime cancer risk.

MDH departs from the above default HRL algorithm if sufficient information is available to derive a chemical-specific lifetime adjustment factor ($AF_{lifetime}$). In these cases a time-weighted intake rate over a lifetime is applied, resulting in the following equation:

$$\mathrm{cHRL} = \frac{(1 \times 10^{-5}) \times 1{,}000 \frac{\mu g}{mg}}{SF \times AF_{\mathrm{lifetime}} \times 0.044 \frac{L}{kg-day}}$$

Where

(1×10^{-5}) = the additional cancer risk level.

1,000 = a factor used to convert milligrams (mg) to micrograms (µg).

SF = adult-exposure based cancer slope factor.

$AF_{lifetime}$ = the lifetime adjustment factor based on chemical-specific data.

0.045 L/kg-day = 95th percentile water intake rate representative of a lifetime period.

Additional explanations of the concepts used in deriving the HRL values are available in MDH's 2008 SONAR, Part IV (MDH, 2008).

Appendix D: Selection of Contaminants

MDH selected the contaminants for these amendments based on input from several sources. Examples include programs within MDH, such as the Site Assessment and Consultation Unit, Drinking Water Protection Section, and CEC initiative, as well as partner state agencies, such as the Minnesota Pollution Control Agency (MPCA) and the Minnesota Department of Agriculture (MDA). At periodic interagency meetings, representatives from these agencies nominated chemicals for review and discussed their concerns and priorities. Some of the contributing programs and agencies collect input from the public. Further, MDH initiated a system to re-evaluate previously adopted HRLs to ensure that values remain up-to-date. Listed below are chemicals with proposed HRLs and the origin of the guidance requests.

Table D-1. Request for Guidance on Groundwater Contaminants

CAS Numbers	Chemical Name	HBV year	Origin of Request
120-12-7	Anthracene	(RAA 2019 HRL from 1993 to be repealed)	MPCA
1897-45-6	Chlorothalonil	2023	MDA
106-93-4	1,2-Dibromoethane (ethylene dibromide, EDB)	2023	MPCA
75-71-8	Dichlorodifluoromethane	(RAA 2017 HRL from 2011 to be repealed)	Scheduled Re-evaluation
45285-51-6; 335-67-1; 3825-26-1; 2395-00-8; 335-93-3; 335-95-5	Perfluorooctanoate (PFOA) and salts	2024	Scheduled re-evaluation
45298-90-6; 1763-23-1; 29081-56-9; 70225-14-8; 2795-39-3; 9457-72-5	Perfluorooctane sulfonate (PFOS) and salts	2024	Scheduled re-evaluation

Appendix E: Toxicological Summary Sheets

Copies of all four of the Toxicological Summary sheets can be viewed below.

Health-Based Guidance for Water
Health Risk Assessment Unit, Environmental Health Division
651-201-4899

Web Publication Date: January 2023

Toxicological Summary for: Chlorothalonil

CAS: **1897-45-6**
Synonyms: Tetrachloroisophthalonitrile; 1,3-Dicyanotetrachlorobenzene; 2,4,5,6-tetrachlorobenzene-1,3-dicarbonitrile (IUPAC)

Acute Non-Cancer Health-Based Value (nHBVAcute) = Not Derived (Insufficient Data)

Short-term Non-Cancer Health-Based Value ($nHBV_{Short\text{-}term}$) = 20 µg/L

$$\frac{\text{(Reference Dose, mg/kg-d) x (Relative Source Contribution) x (Conversion Factor)}}{\text{(Short-term Intake Rate, L/kg-d)}}$$

$$= \frac{\text{(0.014 mg/kg-d) x (0.5)}^{*} \text{ x (1000 µg/mg)}}{\text{(0.290 L/kg-d)}^{**}}$$

= 24.1 rounded to **20 µg/L**

*Relative Source Contribution: MDH 2008, Section IV.E.1.

**Intake Rate: MDH 2008, Section IV.E.1. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3, and 3-5.

Reference Dose/Concentration:	HED/Total UF = 1.35/100 = 0.014 mg/kg-d (Crl:CD®BR VF/Plus Rat)
Source of toxicity value:	Determined by MDH in 2022
Point of Departure (POD):	6.13 mg/kg-d (administered dose $BMDL_{BMR5\%}$, Myers 1995)
Dose Adjustment Factor (DAF):	0.22 Body weight scaling, default (US EPA 2011 and MDH 2017)
Human Equivalent Dose (HED):	POD x DAF = 6.13 mg/kg-d x 0.22 = 1.35 mg/kg-d
Total uncertainty factor (UF):	100
Uncertainty factor allocation:	3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, and 3 for database uncertainty due to suggestive testicular effects reported in other animal studies and human epidemiology studies that have not been thoroughly assessed
Critical effect(s):	Forestomach roughening and thickening in F1 pups
Co-critical effect(s):	None
Additivity endpoint(s):	Gastrointestinal system

Subchronic Non-Cancer Health-Based Value ($nHBV_{Subchronic}$) = 2 µg/L

$$\frac{\text{(Reference Dose, mg/kg-d) x (Relative Source Contribution) x (Conversion Factor)}}{\text{(Subchronic Intake Rate, L/kg-d)}}$$

$$= \frac{\text{(0.00067 mg/kg-d) x (0.2)}^{*} \text{ x (1000 µg/mg)}}{\text{(0.074 L/kg-d)}^{**}}$$

= 1.8 rounded to **2 µg/L**

*Relative Source Contribution: MDH 2008, Section IV.E.1.

**Intake Rate: MDH 2008, Section IV.E.1. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3, and 3-5.

Reference Dose/Concentration:	HED/Total UF = 0.067/100 = 0.00067 mg/kg-d (Sprague-Dawley rat)
Source of toxicity value:	Determined by MDH in 2022
Point of Departure (POD):	0.293 mg/kg-d (administered dose $BMDL_{BMR5\%}$, Spencer-Briggs 1994)
Dose Adjustment Factor (DAF):	0.23 Body weight scaling, default (US EPA 2011 and MDH 2017)
Human Equivalent Dose (HED):	POD x DAF = 0.293 mg/kg-d x 0.23 = 0.067 mg/kg-d
Total uncertainty factor (UF):	100
Uncertainty factor allocation:	3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, and 3 for database uncertainty due to suggestive testicular effects reported in other animal studies and human epidemiology studies that have not been thoroughly assessed
Critical effect(s):	Epithelial hyperplasia and hyperkeratosis at the limiting ridge of the stomach in female rats
Co-critical effect(s):	Epithelial hyperplasia and hyperkeratosis in the nonglandular region of the stomach in female rats
Additivity endpoint(s):	Gastrointestinal system

Chronic Non-Cancer Health-Based Value ($nHBV_{Chronic}$) = 1 µg/L

$$\frac{\text{(Reference Dose, mg/kg-d) x (Relative Source Contribution) x (Conversion Factor)}}{\text{(Chronic Intake Rate, L/kg-d)}}$$

$$= \frac{\text{(0.00029 mg/kg-d) x (0.2)}^{*} \text{ x (1000 µg/mg)}}{\text{(0.045 L/kg-d)}^{**}}$$

= 1.29 rounded to **1 µg/L**

*Relative Source Contribution: MDH 2008, Section IV.E.1.

**Intake Rate: MDH 2008, Section IV.E.1. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3 and 3-5.

Reference Dose/Concentration:	HED/Total UF = 0.29/1000 = 0.00029 mg/kg-d (Crl:CD(SD)BR mice)
Source of toxicity value:	Determined by MDH in 2022
Point of Departure (POD):	1.9 mg/kg-d (administered dose LOAEL, Spencer-Briggs 1995)
Dose Adjustment Factor (DAF):	0.15 Body weight scaling, default (US EPA 2011 and MDH 2017)
Human Equivalent Dose (HED):	POD x DAF = 1.9 mg/kg-d x 0.15 = 0.29 mg/kg-d
Total uncertainty factor (UF):	1000
Uncertainty factor allocation:	3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, 10 for using a LOAEL in place of a NOAEL, and 3 for database uncertainty due to suggestive testicular effects reported in other animal studies and human epidemiology studies that have not been thoroughly assessed
Critical effect(s):	Epithelial hyperplasia and hyperkeratosis in the nonglandular and limiting ridge regions of the stomach in male mice
Co-critical effect(s):	Epithelial hyperplasia and hyperkeratosis at the limiting ridge and in the nonglandular regions of the stomach in females, ulceration of the nonglandular region of the stomach, thickened appearance of the forestomach in males, renal uniform cortical scarring, renal karyomegaly in males, and centrilobular hepatocyte enlargement
Additivity endpoint(s):	Gastrointestinal system, Hepatic (liver) system, Renal (kidney) system

Cancer Health-Based Value (cHBV) = 6 µg/L

$$\frac{\text{(Additional Lifetime Cancer Risk) x (Conversion Factor)}}{[(SF \times ADAF_{<2\ yr} \times IR_{<2yr} \times 2) + (SF \times ADAF_{2-<16\ yr} \times IR_{2-<16yr} \times 14) + (SF \times ADAF_{16+\ yr} \times IR_{16+yr} \times 54)] / 70}$$

$$\frac{= (1E\text{-}5) \times (1000\ \mu g/mg)}{[(0.017 \times 10^{*} \times 0.155\ L/kg\text{-}d^{**} \times 2) + (0.017 \times 3^{*} \times 0.040\ L/kg\text{-}d^{**} \times 14) + (0.017 \times 1^{*} \times 0.042\ L/kg\text{-}d^{**} \times 54)] / 70}$$

= 5.84 rounded to **6 µg/L**

*ADAF (Age-dependent adjustment factor) and Lifetime Adjustment Factor: MDH 2008, Section IV.E.2.

**Intake Rate: MDH 2008, Section IV.E.2. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3 and 3-5.

Cancer classification:	Likely to be a human carcinogen by all routes of exposure (EPA 2021); Possibly carcinogenic to humans (IARC 1999)
Slope factor (SF):	0.017 mg/kg-d^{-1} (Combined renal and forestomach tumors from the male rat, Wilson and Killeen 1989)

Source of cancer slope factor (SF): (California EPA 2012)
Tumor site(s): Forestomach, Kidney, Liver, Thyroid

Volatile: No

Summary of Guidance Value History:

Guidance for chlorothalonil was first developed by MDH in 1993/1994 with a cancer HRL = 30 µg/L. In 2014, MDH developed a cancer pesticide rapid assessment of 6 µg/L and a noncancer rapid assessment of 50 µg/L. The cancer guidance was lower in the pesticide rapid assessment than the 1993/1994 HRL due to the use of a newer slope factor (California EPA 2012). In 2022 MDH conducted an in-depth full review of chlorothalonil. The cancer guidance in the full review (6 µg/L) and the pesticide rapid assessment cancer value are the same because the slope factor and equation used are identical. The 2022 full review noncancer guidance (short-term, subchronic, and chronic) are lower than the 2014 noncancer rapid assessment as a result of using: 1) updated intake rates; 2) BMD modeling; and 3) selection of a more sensitive health endpoint (gastrointestinal).

Summary of toxicity testing for health effects identified in the Health Standards Statute (144.0751):

Even if testing for a specific health effect was not conducted for this chemical, information about that effect might be available from studies conducted for other purposes. MDH has considered the following information in developing health protective guidance.

	Endocrine	Immunotoxicity	Development	Reproductive	Neurotoxicity
Tested for specific effect?	Yes	Yes	Yes	Yes	Yes
Effects observed?	Yes[1]	No[2]	Yes[3]	Yes[4]	No[5]

Comments on extent of testing or effects:

[1] A provocative but limited study in mice reported changes in the enzymes that make estradiol and progesterone at chlorothalonil levels equal to the short-term RfD, but 19 times higher than the subchronic RfD, and 45 times higher than the chronic RfD. At levels 460 times higher than the short-term RfD, chlorothalonil affected the maturation of ovarian follicles. Fertility in this study was not tested. In rats, increased pituitary gland weight was reported at levels 2,000 times higher than the short-term RfD and a decrease in T4 was reported at levels 3,000 times higher than the short-term RfD. Parathyroid hyperplasia was reported in rats beginning at levels 800 times higher than the short-term RfD. In beagles, increased thyroid weight occurred at chlorothalonil doses 16,000 times higher than the short-term RfD. Also at this dose an enlargement in adrenal cells was reported. In another beagle study, the absolute weight of the adrenal gland and its width were increased at chlorothalonil levels 22,000 times higher than the short-term RfD. Other animal studies also reported adrenal gland

enlargement and hyperplasia. In mice these changes occurred at levels 80 times higher than the short-term RfD. Testicular weight decrease occurred in male rats at levels 13,000 times higher than the short-term RfD while ovarian masses were observed in female rats at levels 1,300 times higher than the short-term RfD.

[2] EPA reported no effects from an immunologic study in laboratory animals. However, in a chronic toxicity study in female rats, a complete involution of the thymus occurred at levels 700 times higher than the short-term RfD.

[3] Early pregnancy resorptions occurred in both rats and mice at levels 7,000 and 4,000 times higher, respectively, than the short-term RfD. Reduced fetal and pup body weights were commonly reported in mouse and rat studies. Fetal mouse and rat pups were both reported to have reduced body weights at chlorothalonil levels beginning at 4,000 and 2,000 times higher, respectively, than the short-term RfD. In the rat, this was accompanied by reduced pup viability at 4,000 times higher than the short-term RfD. Skeletal variations were reported in fetal rats at levels 3,000 times higher than the short-term RfD. Delayed vaginal patency and preputial separation, most likely due to reduced body weights, were reported in developing rats at levels 4,000 times higher than the short-term RfD. In rabbits, reduced fetal bodyweights and skeletal variations were common at doses 700 times higher than the short-term RfD. Fetal malformations were also reported at levels 700 times higher than the short-term RfD. Abortions in rabbits occurred at chlorothalonil levels 300 times higher than the short-term RfD.

[4] The only reproductive effect reported from a sponsored study was reduced uterine weight in one rabbit study at a level of chlorothalonil 100 times higher than the RfD. A recent non-sponsored study in mice reported reduced sperm motility at the same level as the short-term RfD, but at levels 19 times higher than the subchronic RfD, and 45 times higher than the chronic RfD. At a chlorothalonil exposure 100 times higher than the short-term RfD were a reduction in sperm number and slower sperm maturation. The same laboratory reported the hormone and ovarian effects mentioned in the endocrine section, above. Adverse sperm effects have been reported in human epidemiology studies from exposure to chlorinated chemicals. Unfortunately, most of the animal studies in the chlorothalonil database did not test for sperm effects. This resulted in a data base uncertainty factor of "3" added to the chlorothalonil reference doses. Other reproductive effects in rats and mice include a decrease in the number of live fetuses at levels 4,000 times higher than the short-term RfD, and post-implantation loss and early resorptions at levels 4,000 times higher in mice and 7,000 times higher than the short-term RfD in rats.

[5] An acute neurotoxicity study in rats detected no effects at a chlorothalonil dose up to 33,000 times higher than the short-term RfD. In a subchronic neurotoxicity study, no effects were reported in rats up to 4,000 times higher than the short-term RfD. A decrease in brain weight was observed at a level 6,000 times higher than the short-term RfD in rats.

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Health-Based Guidance for Water
Health Risk Assessment Unit, Environmental Health Division
651-201-4899

Web Publication Date: February 2023

Toxicological Summary for: 1,2-Dibromoethane

CAS: **106-93-4**
Synonyms: Ethylene dibromide; ethane, 1,2-dibromo-

Acute Non-Cancer Health-Based Value = Not Derived (Insufficient Data)

Short-term Non-Cancer Health-Based Value ($nHBV_{Short\text{-}term}$) = 10 µg/L

$$\frac{\text{(Reference Dose, mg/kg-d) x (Relative Source Contribution) x (Conversion Factor)}}{\text{(Short-term Intake Rate, L/kg-d)}}$$

$$= \frac{\text{(0.018 mg/kg-d) x (0.2)}^{*} \text{ x (1000 µg/mg)}}{\text{(0.290 L/kg-d)}^{**}}$$

= 12.4 rounded to **10 µg/L**

*Relative Source Contribution: MDH 2008, Section IV.E.1.
**Intake Rate: MDH 2008, Section IV.E.1. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3 and 3-5.

Reference Dose/Concentration:	HED/Total UF = 17.5/1000 = 0.018 mg/kg-d (female B6C3F1 mice)
Source of toxicity value:	Determined by MDH in 2022
Point of Departure (POD):	125 mg/kg-d (LOAEL, Ratajczak, 1994)
Dose Adjustment Factor (DAF):	0.14, Body weight scaling, default (US EPA 2011 and MDH 2017)
Human Equivalent Dose (HED):	POD x DAF = 125 mg/kg-d x 0.14 = 17.5 mg/kg-d
Total uncertainty factor (UF):	1000
Uncertainty factor allocation:	3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, 3 for using a LOAEL in place of a NOAEL, and 10 for database uncertainty due to the lack of two-generation reproductive, developmental, and developmental immunotoxicity studies
Critical effect(s):	Increased liver weight, increased cholesterol, and reduced T-cell response
Co-critical effect(s):	Increased kidney weight, increased neutrophils, decreased immune function in the lung, decreased viable cells in the spleen, increased estrus cycle length, increased percentage of abnormal sperm
Additivity endpoint(s):	Female reproductive system, Hepatic (liver) system, Immune system, Male reproductive system, Renal (kidney) system, Respiratory system, Spleen

Subchronic Non-Cancer Health-Based Value ($nHBV_{Subchronic}$) = $nHBV_{Short\text{-}term}$ = 10 µg/L

$$\frac{\text{(Reference Dose, mg/kg-d) x (Relative Source Contribution) x (Conversion Factor)}}{\text{(Subchronic Intake Rate, L/kg-d)}}$$

$$= \frac{\text{(0.021 mg/kg-d) x (0.2)}^{*} \text{ x (1000 µg/mg)}}{\text{(0.074 L/kg-d)}^{**}}$$

= 56.8 rounded to 60 µg/L

*Relative Source Contribution: MDH 2008, Section IV.E.1.
**Intake Rate: MDH 2008, Section IV.E.1. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3 and 3-5.

Reference Dose/Concentration:	HED/Total UF = 6.24/300 = 0.021 mg/kg-d (female B6C3F1 mice)
Source of toxicity value:	Determined by MDH in 2022
Point of Departure (POD):	44.6 mg/kg-d (NOAEL, Ratajczak, 1995)
Dose Adjustment Factor (DAF):	0.14, Body weight scaling, default (US EPA 2011 and MDH 2017)
Human Equivalent Dose (HED):	POD x DAF = 44.6 mg/kg-d x 0.14 = 6.24 mg/kg-d
Total uncertainty factor (UF):	300
Uncertainty factor allocation:	3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, and 10 for database uncertainty for lack of two-generation reproductive, developmental and developmental immunotoxicity studies
Critical effect(s):	Decreased T- and B-cell responses, increased cholesterol and triglycerides
Co-critical effect(s):	Increased liver weight, increased cholesterol, decreased T-cell response, decreased immune function in the lung, increased estrus cycle length, and increased percentage of abnormal sperm
Additivity endpoint(s):	Female reproductive system, Hepatic (liver) system, Immune system, Male reproductive system, Respiratory system

The Subchronic nHBV must be protective of shorter duration exposures that occur within the subchronic period and therefore, the Subchronic nHBV is set equal to the Short-term nHBV of 10 µg/L. Additivity endpoints: Female reproductive system, Hepatic (liver) system, Immune system, Male reproductive system, Renal (kidney) system, Respiratory system, Spleen

Chronic Non-Cancer Health-Based Value ($nHBV_{Chronic}$) = 9 µg/L

$$\frac{\text{(Reference Dose, mg/kg-d) x (Relative Source Contribution) x (Conversion Factor)}}{\text{(Chronic Intake Rate, L/kg-d)}}$$

$$= \frac{\text{(0.0021 mg/kg-d) x (0.2)}^{*} \text{ x (1000 µg/mg)}}{\text{(0.045 L/kg-d)}^{**}}$$

= 9.33 rounded to **9 µg/L**

*Relative Source Contribution: MDH 2008, Section IV.E.1.
**Intake Rate: MDH 2008, Section IV.E.1. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3 and 3-5.

Reference Dose/Concentration:	HED/Total UF = 6.24/3000 = 0.0021 mg/kg-d (female B6C3F1 mice)
Source of toxicity value:	Determined by MDH in 2022
Point of Departure (POD):	44.6 mg/kg-d (NOAEL, Ratajczak et al. 1995, subchronic exposure)
Dose Adjustment Factor (DAF):	0.14, Body weight scaling, default (US EPA 2011 and MDH 2017)
Human Equivalent Dose (HED):	POD x DAF = 44.6 mg/kg-d x 0.14 = 6.24 mg/kg-d
Total uncertainty factor (UF):	3000
Uncertainty factor allocation:	3 for interspecies differences (for toxicodynamics), 10 for intraspecies variability, 10 for extrapolation to a chronic duration from a subchronic study, and 10 for database uncertainty for lack of two-generation reproductive, developmental, and developmental immunotoxicity studies
Critical effect(s):	Decreased T- and B-cell responses, increased cholesterol and triglycerides
Co-critical effect(s):	Increased relative liver weight, increased cholesterol, decreased T-cell response, decreased immune function in the lung, increased estrus cycle length, increased percentage of abnormal sperm
Additivity endpoint(s):	Female reproductive system, Hepatic (liver) system, Immune system, Male reproductive system, Respiratory system

Cancer Health-Based Value (cHBV) = 0.03 µg/L

$$\frac{\text{(Additional Lifetime Cancer Risk) x (Conversion Factor)}}{[(SF \times ADAF_{<2\ yr} \times IR_{<2yr} \times 2) + (SF \times ADAF_{2-<16\ yr} \times IR_{2-<16yr} \times 14) + (SF \times ADAF_{16+\ yr} \times IR_{16+yr} \times 54)] / 70}$$

$$\frac{= (1E\text{-}5) \times (1000\ \mu g/mg)}{[(3.6 \times 10^{*} \times 0.155\ L/kg\text{-}d^{**} \times 2) + (3.6 \times 3^{*} \times 0.040\ L/kg\text{-}d^{**} \times 14) + (3.6 \times 1^{*} \times 0.042\ L/kg\text{-}d^{**} \times 54)] / 70}$$

= 0.028 rounded to **0.03 µg/L**

*ADAF (Age-dependent adjustment factor) and Lifetime Adjustment Factor: MDH 2008, Section IV.E.2.
**Intake Rate: MDH 2008, Section IV.E.2. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3 and 3-5.

Cancer classification:	2A- probably carcinogenic to humans (IARC, 1999); Likely to be carcinogenic to humans (EPA, 2004)
Slope factor (SF):	3.6 $(mg/kg\text{-}day)^{-1}$ based on forestomach tumors in male and female rats and mice (NCI, 1978)
Source of cancer slope factor (SF):	Cal EPA (2003)

Tumor site(s): Forestomach, esophagus, blood vessels, liver, lung, thyroid gland, and adrenal gland

Volatile: Yes (high)

Summary of Guidance Value History:

A cancer HRL of 0.004 µg/L was promulgated in 1993. The new cancer HBV of 0.03 µg/L is higher than the previous cancer HRL as the result of: 1) use of MDH's most recent risk assessment methodology; 2) the use of a new slope factor derived by Cal EPA 2003; and 3) rounding to one significant digit.

Summary of toxicity testing for health effects identified in the Health Standards Statute (144.0751):
Even if testing for a specific health effect was not conducted for this chemical, information about that effect might be available from studies conducted for other purposes. MDH has considered the following information in developing health protective guidance.

	Endocrine	Immunotoxicity	Development	Reproductive	Neurotoxicity
Tested for specific effect?	Yes	Yes	No	Yes	No
Effects observed?	Yes[1]	Yes[2]	- [3]	Yes [4]	Yes[5]

[1] Testicular atrophy and degenerative changes to the adrenal cortex were observed in rats and mice exposed chronically to oral doses more than 400 times higher than the short-term RfD. An increased estrus cycle length was observed in mice exposed to levels nearly 700 times higher than the short-term RfD and is included as a co-critical effect for all durations.
[2] The short-term, subchronic, and chronic critical effects are based on immunotoxicity in female mice (decreased T- and B-cell response). Dose levels 1,200 times higher than the short-term RfD are associated with increased neutrophils, decreased bactericidal response in the lung, and decreased viable cells in the spleen. Dose levels 1,600 times higher than the short-term RfD are associated with decreased relative thymus weight, increased spleen weight, and decreased natural killer cell function. Chronic exposure in mice at levels 300 times higher than the short-term RfD resulted in increased splenic hematopoiesis.
[3] Developmental effects have not been studied using oral ingestion as a route of exposure. A database uncertainty factor is included in the guidance to account for the lack of developmental studies in the oral database.
[4] An occupational study in men exposed to 1,2-dibromoethane via inhalation and dermally for an average of 5 years found reductions in sperm count, viability, and motility and increases in sperm abnormalities at dose levels 10-fold higher than the short-term RfD. A shorter-duration study in men exposed via inhalation and dermally for 6 weeks reported reductions in sperm velocity and semen volume at a time weighted dose approximately 8 times higher than the short-term RfD.
Testicular atrophy, the male reproductive system chronic co-critical effect, was observed in rats and mice at more than 400 times higher than the short-term RfD. However, a subchronic study evaluating male reproductive toxicity did not observed any changes to fertility and sex organs using doses almost 700 times higher than the short-term RfD. The subchronic and chronic co-critical effect of lengthened estrus cycles in female mice was observed at doses 700 times higher than the short-term RfD. A database uncertainty factor is included in the RfD to account for the lack of a multigeneration or two-generation reproductive toxicity study.

[5] Neurotoxicity has been observed in human case studies involving ingestion, and manifests as confusion, coma, and brain lesions. Oral animal studies did not observe specific indications of neurotoxicity.

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Health-Based Guidance for Water
Health Risk Assessment Unit, Environmental Health Division
651-201-4899

Web Publication Date: February 2024

Toxicological Summary for: Perfluorooctane sulfonate

CAS: **45298-90-6 (anion)**
1763-23-1 (acid)
29081-56-9 (ammonium salt)
70225-14-8 (diethanolamine salt)
2795-39-3 (potassium salt)
29457-72-5 (lithium salt)

DTXSID: DTXSID80108992

Synonyms: PFOS, Perfluorooctane sulfonic acid

In 2024, the Minnesota Department of Health (MDH) completed a re-evaluation of PFOS that focused on epidemiological data. Recent reviews from the European Food Safety Authority, California Environmental Protection Agency, US Environmental Protection Agency, and National Academies of Sciences, Engineering, and Medicine were utilized as resources. Many toxicity studies in laboratory animals also exist; however, the points of departure are significantly higher than those identified in epidemiology studies. MDH also conducted a literature search for epidemiological studies published between 2021 and December 2022, which focused on potential sensitive endpoints (e.g., development, immune, thyroid), to capture information that postdated the reviews by the agencies listed above.

Short-term, Subchronic, and Chronic Noncancer Health-Based Value (nHBV) = 0.0023 µg/L (equivalent to 2.3 ng/L or ppt)*

*Due to the highly bioaccumulative nature of PFOS, serum concentrations are the most appropriate dose metric. PFOS has a half-life of approximately 2.7 years, and the bioaccumulated levels within women of reproductive age can be passed on to fetuses and infants through placental and breastmilk transfer. The standard equation used to derive health-based values (HBVs) is not adequate to address the bioaccumulative nature nor the maternal transfer of PFOS. Since 2017, a single PFOS HBV for all durations has been derived using a toxicokinetic (TK) model developed by MDH (Goeden 2019), which assesses a formula-fed infant scenario as well as a breastfed infant scenario. The TK model accounts for the bioaccumulation and maternal transfer of PFOS and more accurately represents real-world exposure scenarios. MDH typically calculates HBVs at the part per billion level with the final concentration rounded to one significant digit. However, serum concentrations are impacted by changes in water concentrations at the part per trillion (ppt) level. As a result, the PFOS HBV is expressed with two significant digits.

Reference Serum Concentration:	POD/Total UF = 7.7/3 = 2.6 ng/mL (human) *This serum level was developed using population-based data and should not be used for clinical assessment or interpreting serum levels in individuals.*
Source of toxicity value:	Determined by MDH in 2024
Point of Departure (POD):	7.7 ng/mL (equivalent to µg/L) serum concentration (US EPA 2023a,b), $BMDL_{5\%}$ for decreased birth weight from (Wikström 2020)
Dose Adjustment Factor (DAF):	Not applicable (POD is based on human serum level)
Human Equivalent Dose (HED):	Not applicable (POD is based on human serum level)
Total uncertainty factor (UF):	3
Uncertainty factor allocation:	A database UF of 3 was applied to account for remaining database uncertainties regarding potential adverse effects at or near the serum POD concentration (e.g., immune effects, liver effects, thyroid effects). An UF for human toxicodynamic (TD) variability was not applied because the POD is based on a sensitive life stage (i.e., neonates). Differences in human TK were determined to be adequately addressed through the exposure scenario and parameter values selected for use in the TK model.[#]
Critical effect(s):	Decreased birth weight
Co-critical effect(s):	Decreased antibody titers in children, increased cholesterol
Additivity endpoint(s):	Developmental, Hepatic (liver) system, Immune system

[#]The POD is based on birth weights paired with maternal serum levels at median gestation age 10 weeks. Very little information is available regarding PFOS half-life in infants; the half-life used in the TK model is based on a population (age 4-80 years of age) residing in a community with contaminated water (Li 2022). To evaluate the potential impact of TK variability, an upper-bounding scenario, in which all model parameters were set to upper percentile values, was evaluated. The maternal, peak infant, and lifetime steady-state serum levels produced by the upper-bounding scenario were ≤3-fold higher than MDH's selected Reasonable Maximum Exposure (RME) scenario. Since the upper-bounding scenario is considered worst-case and is very unlikely to represent a realistic scenario, the incorporation of an UF to address human TK variability was considered unnecessary. MDH's RME model parameter values used to derive the noncancer water guidance is considered adequately protective of the general population.

Toxicokinetic Model Description (Goeden 2019):

Serum concentrations can be calculated from the dose and clearance rate using the following equation:

$$Serum\ Concentration\left(\frac{\mu g}{L}\right) = \frac{Fluid\ IntakeRate\left(\frac{L}{kg \cdot day}\right) x\ Fluid\ Concentration\left(\frac{\mu g}{L}\right)}{Clearance\ Rate\left(\frac{L}{kg \cdot day}\right)}$$

Where:

Clearance Rate = Volume of Distribution (L/kg body weight) x (Ln2/half-life in days)

Two exposure scenarios were examined: 1) an infant fed with formula reconstituted with contaminated water starting at birth and continuing ingestion of contaminated water throughout life; and 2) an infant exclusively breastfed for 12 months, followed by drinking contaminated water. In both scenarios, the simulated individuals began life with a pre-existing body burden through placental transfer. The serum concentration of the mother was calculated to be at steady state at the time of delivery, using the equation presented above and a time-weighted average (TWA) 95th percentile intake rate from birth to 30 years of age (sufficient time to attain steady-state).

Consistent with MDH methodology, a 95th percentile water and upper percentile (2 standard deviations above mean) breastmilk intake rates were used along with central tendency estimates for half-life, placental transfer, and breastmilk transfer. Breastmilk concentrations are calculated by multiplying the maternal serum concentration by a PFOS breastmilk transfer factor. For the breastfed exposure scenario, a one-year period of breastfeeding is used as representative of an RME scenario.

Daily post-elimination serum concentrations were calculated as:

$$Serum\ Concentration\left(\frac{\mu g}{L}\right) = \left[\frac{Previous\ day + Today's\ Intake(\mu g)}{V_d\left(\frac{L}{kg}\right) \times BW(kg)}\right] \times e^{-k}$$

Where:

V_d = volume of distribution
BW = body weight
e^{-k} = represents clearance

Note: MDH has made several improvements to the TK model published in 2019 (Goeden 2019), including the following:

- The PFOS mass transferred to the infant is now subtracted from the maternal steady-state concentration on day 0 (the day of delivery).
- The daily calculation of the infant's serum concentration is now fully mass-based by adjusting both the current day as well as the previous day's intake by the current day's body weight.
- Maternal lactation was phased in over the first four days of lactation based on data from Neville et al. (1991).
- Water intakes, breastmilk intakes, and body weights were updated with more current information.
- Chemical-specific parameter values (i.e., clearance, half-life, placental transfer, breastmilk transfer, and volume of distribution) were updated to include literature information up to December 2022.

Summary of TK Model Parameter Values Used to Derive Non-Cancer HBV for PFOS

Model Parameter	Value Used
Half-life ($t_{½}$)	Central Tendency = 996 days (2.73 years) (Mean value from (Li 2022) The TK model estimates serum levels from birth to approximately 50 years of age. Critical life-stage is <4 years of age for which serum half-life information is not available. The overall mean was used for the RME scenario. A 95th percentile half-life value of 4.75 years was used in the upper-bounding scenario evaluation.
Placental transfer	Central Tendency = 0.39 (mean of mean values from 27 studies) The mean upper percentile value (0.74) was selected as an upper-end value for the upper-bounding scenario evaluation.

<table>
<tr><th>Model Parameter</th><th>Value Used</th></tr>
<tr><td>Breastmilk transfer</td><td>Central Tendency = 0.03 (95th upper confidence limit (UCL) of the mean from 8 studies). Validation testing of model infant serum predictions indicated that use of the overall mean of the 8 studies (0.020) resulted in underestimating breastfed infant serum levels whereas the 95th UCL did not. A value of 0.065 was used as representative of an upper-end value for the upper-bounding scenario evaluation.</td></tr>
<tr><td>Breastmilk Intake Rate (mL/kg-day) and corresponding Body Weight (kg)</td><td>Upper Percentile intake for exclusively[1] breastfed infants ((US EPA 2019), Table 15-1). Body weight at birth was set at 3.38 kg (Donahue 2010). Remaining body weights (kg) were calculated from data presented in US EPA's Table 15-1 for each age group (i.e., mL/day ÷ mL/kg-day):
<table>
<tr><th>Age Group</th><th>Intake Rate (mL/kg-d)</th><th>Body Weight (kg)</th></tr>
<tr><td>>Birth to <1 month</td><td>220</td><td>4.3</td></tr>
<tr><td>1 to < 3 months</td><td>190</td><td>5.2</td></tr>
<tr><td>3 to < 6 months</td><td>150</td><td>6.7</td></tr>
<tr><td>6 to < 12 months</td><td>130</td><td>7.7</td></tr>
</table></td></tr>
<tr><td>Duration (months) of Breastfeeding</td><td>Upper percentile = 12 months (Breastfeeding Report Card for 2022 (CDC 2022)) reporting that nearly 70 percent of mothers in Minnesota report breastfeeding at six months, with 36.5 percent still exclusively breastfeeding at six months.</td></tr>
<tr><td>Water Intake Rate (mL/kg-day)</td><td>Upper Percentile Intake = Formula-fed infants (up to 2 years old, Table 3-5); for >2 years of age values (Table 3-1); and for lactating women (Table 3-3) (US EPA 2019) were used. Body weights (kg) were calculated from data presented in the aforementioned EPA tables (i.e., mL/day ÷ mL/kg-day):
<table>
<tr><th>Age Group</th><th>Intake Rate (mL/kg-d)</th><th>Body Weight (kg)</th></tr>
<tr><td><1 month</td><td>240</td><td>3.6</td></tr>
<tr><td>1 to < 3 months</td><td>290</td><td>3.8</td></tr>
<tr><td>3 to < 6 months</td><td>186</td><td>7.0</td></tr>
<tr><td>6 to < 12 months</td><td>151</td><td>8.9</td></tr>
<tr><td>1 to < 2 years</td><td>119</td><td>10.5</td></tr>
<tr><td>2 to < 3 years</td><td>67</td><td>13.4</td></tr>
<tr><td>3 to < 6 years</td><td>45</td><td>18.6</td></tr>
<tr><td>6 to < 11 years</td><td>41</td><td>30.7</td></tr>
<tr><td>11 to < 16 years</td><td>31</td><td>56.8</td></tr>
<tr><td>16 to < 21 years</td><td>31</td><td>71.4</td></tr>
<tr><td>21 to < 30 years</td><td>47</td><td>72.5</td></tr>
<tr><td>30 to < 40 years</td><td>44</td><td>74.5</td></tr>
<tr><td>40 to < 50 years</td><td>43</td><td>78.5</td></tr>
<tr><td>50 to < 60 years</td><td>42</td><td>80.7</td></tr>
</table>
For calculation of maternal serum concentration at time of delivery, a time-weighted average water intake rate was calculated from birth to 30 years of age, resulting in a 95th percentile water intake rate of 48 mL/kg-day.</td></tr>
</table>

Model Parameter	Value Used
Volume of Distribution (L/kg)	Central Tendency = 0.56 (calculated from human clearance rate of 0.39 mL/kg-d (California EPA Office of Environmental Health Hazard Assessment 2023)) and the mean half-life of 996 days (Li 2022): CR ÷ (Ln2/half-life) = V_d 0.39 mL/kg-d ÷ (Ln 2/996 d) = 560 mL/kg or rounded to 0.56 L/kg

[1]Note: Exclusively breastfed as defined by (US EPA 2019) refers to infants whose sole source of milk is breastmilk and not formula. Exclusively breastfed infants in the studies underlying these USEPA estimates were not excluded from other foods, typically after six months. This definition differs from other sources, which may define exclusive breastfeeding as breastmilk being the only source of nourishment (solid or liquid).

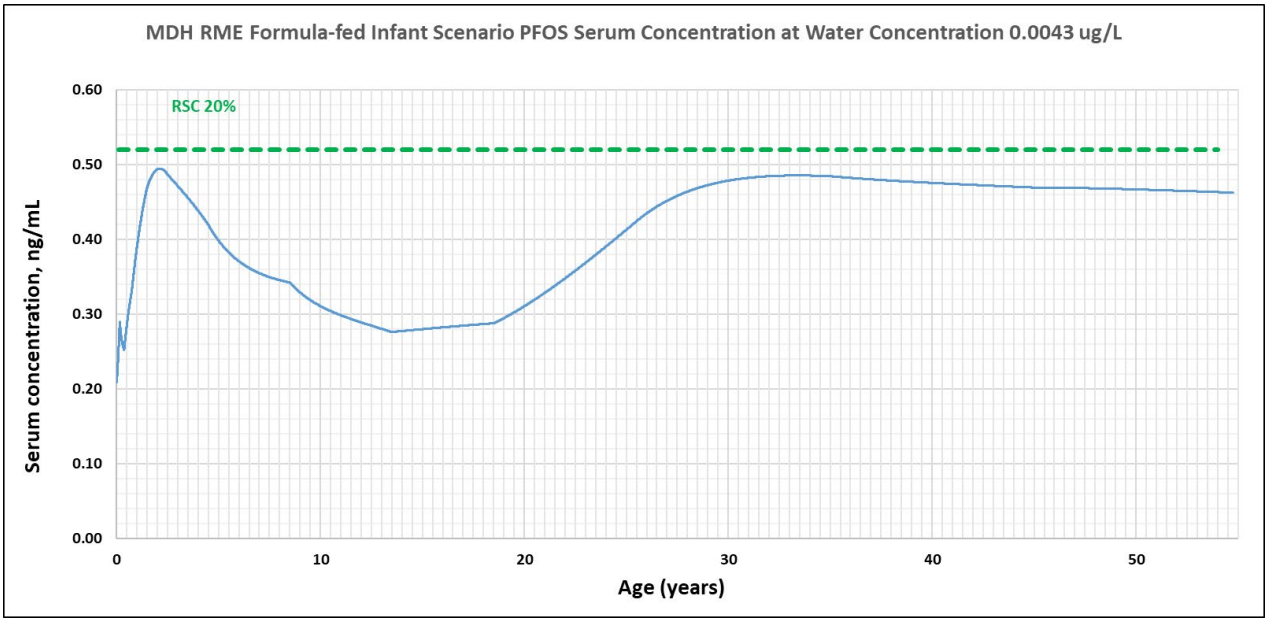
A relative source contribution factor (RSC) is incorporated into the derivation of HBV values to account for exposure sources other than drinking water. MDH utilizes the US EPA 2000 Exposure Decision Tree process to derive appropriate RSCs. The default duration-specific RSCs (0.5, 0.2, and 0.2 for short-term, subchronic and chronic, respectively) are based on the magnitude of contribution of non-drinking water exposures that occur during the relevant exposure duration (Minnesota Department of Health (MDH) 2008). However, in the case of PFOS, application of an RSC needs to account for the long elimination half-life, such that a person's serum concentration at any given age/duration is not only the result of current or recent exposures but also from years past and/or maternal transfer.

Serum concentrations are the best measure of cumulative exposure for PFOS and can be used in place of the reference dose in the Exposure Decision Tree process. Biomonitoring results for the general public reported in the most recent National Report on Human Exposure to Environmental Chemicals (CDC 2021) can be used to represent non-water exposures for older children and adults. The reference serum concentration is 2.6 ng/mL. Both the geometric mean (4.25 ng/mL) and the 95th percentile (14.6 ng/mL) PFOS serum concentration from the most recently available National Report exceed the reference serum concentration. Based on placental transfer data, newborn infants would have PFOS body burdens approximately half that of their mothers. Even at low levels of exposure, PFOS would accumulate in women of reproductive age. Studies assessing young infants (e.g., <6 months of age) who are exclusively breastfed exhibit serum levels that are similar to or slightly higher than their mothers (e.g., (Fromme 2010), (Gyllenhammar 2018)). Consequently, the RSC is set at the floor value of 20% for all life stages.

As mentioned above, two RME scenarios were examined: 1) an infant fed formula reconstituted with contaminated water starting at birth and continuing consumption of contaminated water throughout life; and 2) an infant exclusively breastfed for 12 months by a chronically-exposed mother, followed by consumption of contaminated water throughout life.

For the formula-fed infant, the water concentration that maintains a serum concentration attributable to drinking water below an RSC of 20% throughout life is 0.0043 µg/L (equivalent to 4.3 ng/L or ppt). The infant peak is below the 20% RSC line as the maternal serum concentration was the limiting factor in the formula-fed scenario (Figure 1).

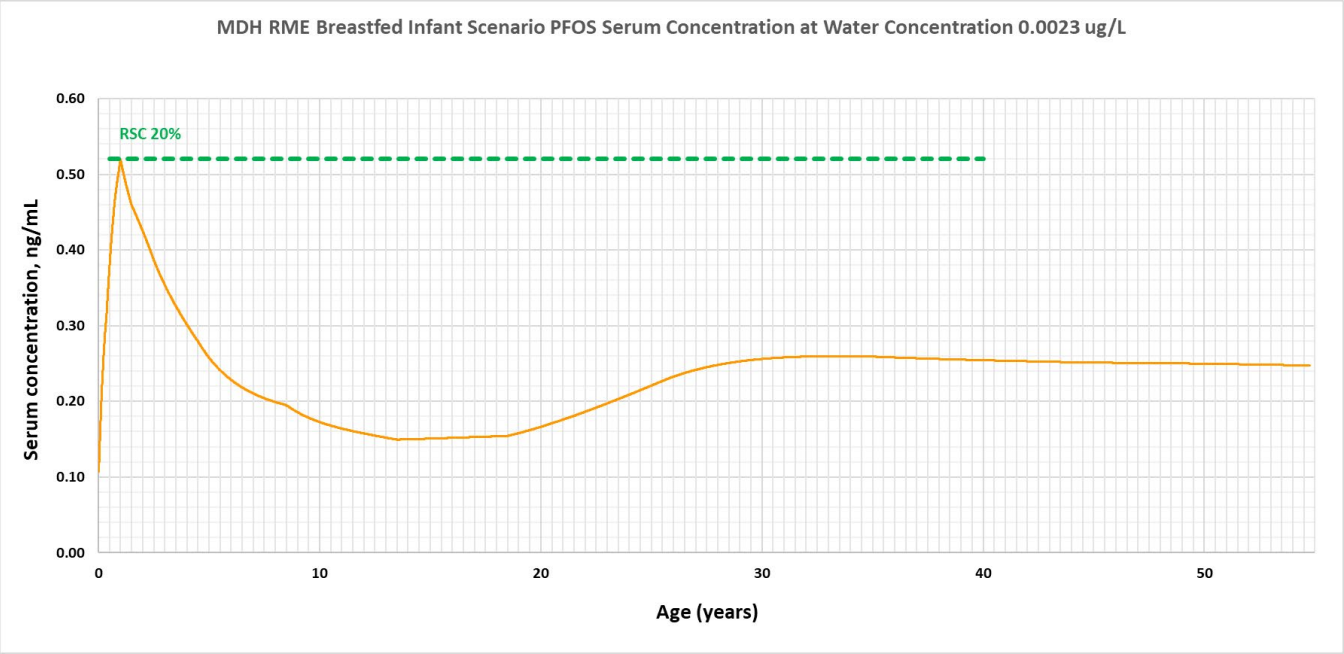
Figure 1. MDH RME Formula-fed Infant Scenario PFOS Serum Concentration at Water Concentration 0.0043 ug/L



A sharp decrease in the formula-fed infant serum levels between the 1 to < 3 month and 3 to <6 months is noted. The formula-fed infant water intake drops from 290 to 186 mL/kg-d as body weight increases from 3.8 to 7 kg across the same time period.

Applying this water concentration (4.3 ng/L) in the context of a breast-fed infant results in peak infant serum concentrations that significantly exceed the RSC of 20%. In order to maintain a serum concentration at or below an RSC of 20% for the breast-fed infant scenario, the water concentration should not exceed 0.0023 µg/L (or 2.3 ng/L or ppt) (Figure 2).

Figure 2. MDH RME Breastfed Infant Scenario PFOS Serum Concentration at Water Concentration 0.0023 µg/L



Due to bioaccumulation in the mother and subsequent transfer to breastmilk, the breast-fed infant exposure scenario produces the lower PFOS water concentration. To ensure protection of all segments of the population, the final noncancer HBV for PFOS is set at 2.3 ng/L (ppt).

Cancer Health-Based Value (cHBV) = 0.0076 µg/L (7.6 ng/L or ppt)

$$\frac{\text{(Additional Lifetime Cancer Risk) x (Conversion Factor)}}{[(\text{SF x ADAF<2 yr x IR<2yr x 2}) + (\text{SF x ADAF2-<16 yr x IR2-<16yr x 14}) + (\text{SF x ADAF16+ yr x IR16+yr x 54})] / 70}$$

$$= \frac{\text{(1E-5) x (1000 µg/mg)}}{[(13 \times 10^{*} \times 0.155 \text{ L/kg-d}^{**} \times 2) + (13 \times 3^{*} \times 0.040 \text{ L/kg-d}^{**} \times 14) + (13 \times 1^{*} \times 0.042 \text{ L/kg-d}^{**} \times 54)] / 70}$$

= 0.0076 µg/L (same as 7.6 ng/L or ppt)

*Age-dependent adjustment factor (ADAF) and Lifetime Adjustment Factor: MDH 2008, Section IV.E.2. ADAFs were maintained because the animals from the critical cancer study did not have early-life exposures to PFOS.
**Intake Rate: MDH 2008, Section IV.E.2. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3, and 3-5.

Cancer classification:	Likely to be carcinogenic to humans (US EPA 2023a,b) (MDH 2023); Presents a carcinogenic hazard (CalEPA Office of Environmental Health Hazard Assessment 2023); Group 2B (possibly carcinogenic to humans) (IARC 2023)
Slope factor (SF):	13 per mg/kg-day (combined hepatocellular adenomas and carcinomas in female rats) (US EPA 2023a,b); tumor data from (Butenhoff 2012)
Source of cancer slope factor (SF):	POD of 19.8 mg/L from (US EPA 2023a,b) converted to 13 per mg/kg-d using a clearance rate

of 0.39 mL/kg-d (CalEPA Office of Environmental Health Hazard Assessment 2023). *[Note: EPA calculated a slope factor of of 39.5 per mg/kg-d from this POD using a clearance rate of 0.128 mL/kg-d].*

Tumor site(s): Liver

Volatile: No

Summary of Guidance Value History:

A chronic nHBV of 1 µg/L was first derived in 2002. A revised chronic nHBV of 0.3 µg/L was derived in 2007 and promulgated as a noncancer HRL (nHRL) in 2009. In 2017, MDH derived a revised nHBV (applicable to all durations) of 0.027 µg/L. In 2018, MDH revised the nHBV (applicable to all durations) to 0.015 µg/L. In 2020 MDH incorporated updated water intake rates (US EPA 2019). Using the updated intake rates did not change the HBV value. The 2024 nHBV of 0.0023 µg/L (2.3 ng/L) is lower than previous values as the result of: 1) utilizing epidemiological data as the basis for the POD; and 2) updating the toxicokinetic model, including more recent data on placental and breastmilk transfer. The 2024 cancer HBV of 0.0076 µg/L (7.6 ng/L) is a new value and MDH has revised their cancer classification to "likely to be carcinogenic".

Summary of toxicity testing for health effects identified in the Health Standards Statute (144.0751):

Even if testing for a specific health effect was not conducted for this chemical, information about that effect might be available from studies conducted for other purposes. MDH has considered the following information in developing health protective guidance.

	Endocrine	Immunotoxicity	Development	Reproductive	Neurotoxicity
Tested for specific effect?	Yes	Yes	Yes	Yes	Yes
Effects observed?	Yes[1]	Yes[2]	Yes[3]	Yes[4]	Yes[5]

Comments on extent of testing or effects:

[Note: MDH conducted a re-evaluation that focused on epidemiological data and sensitive health endpoints.]

[1] Evidence for endocrine effects in humans following PFOS exposure is largely based on increased TSH (thyroid stimulating hormone) and T3 (triiodothyronine) in adults and T4 (thyroxine) in children. However, findings in epidemiology studies were inconsistent, likely due in part to diurnal variations, differential effects across genders and age groups, timing of sampling, and limited number of studies. (US EPA 2023a,b) considers the current level of evidence suggestive but not indicative of adverse endocrine effects due to PFOS exposure due to the uncertainty in results. A database uncertainty factor has been incorporated into the reference serum level to reflect the need for more data regarding thyroid effects.

Studies in laboratory animals have demonstrated clear and consistent alterations in serum thyroid hormone levels, increased thyroid gland weight, and increased follicular cell

hypertrophy in the thyroid gland. Previous MDH guidance was based, in part, on thyroid effects in animals.

[2] In humans, it is widely accepted that PFOS exposure is likely associated with reduced antibody response, especially in infants and children. Immune effects are listed as a co-critical additivity endpoint based on a vaccine response study in young children. Additionally, there is some evidence for increases in asthma and respiratory infections.

In animal models, there is consistent evidence of decreased antibody response, decreased spleen and thymus weight, and alterations in immune cell function after PFOS exposure.

[3] In humans, it is widely accepted that decreased birth weight is likely associated with maternal PFOS serum levels. This likely association is supported by additional epidemiological evidence of related effects such as decreased birth length and postnatal growth. Low birth weight is the basis of the reference serum concentration.

Among the animal studies, decreased postnatal growth leading to developmental effects (e.g., lower pup body weight, delayed eye opening) have been observed.

[4] The evidence for male reproductive effects in humans is limited and largely based on suggestive associations between PFOS exposure and testosterone levels in male children and adults and decreased anogenital distance in children. Considerable uncertainties in these associations exist due to inconsistencies across studies and the limited number of studies available.

The evidence for female reproductive effects in humans is limited and largely based on suggestive associations between PFOS exposure and increased odds of preeclampsia. Considerable uncertainties in these associations exist due to inconsistencies across studies and the limited number of available studies.

Among the animal studies, there is evidence for decreased testicular and epididymal weight, for decreased sperm count, and for hormonal changes in pups, and for increased neonatal mortality.

[5] There is inconsistent evidence for PFOS exposure and neurotoxicity in humans. Most studies focused on neurodevelopment of infants and toddlers; across studies, both negative and positive associations on various developmental assessments were reported.

In a small number of available animal studies, there is limited evidence suggesting neurobehavioral alterations from PFOS exposure.

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Health-Based Guidance for Water
Health Risk Assessment Unit, Environmental Health Division
651-201-4899

Web Publication Date: January 2024

Toxicological Summary for: Perfluorooctanoate

CAS: **45285-51-6 (anion)**
335-67-1 (free acid)
3825-26-1 (ammonium salt, APFO)
2395-00-8 (potassium salt)
335-95-5 (sodium salt)
335-93-3 (silver salt)

DTXSID: DTXSID40892486

Synonyms: PFOA; 2,2,3,3,4,4,5,5,6,6,7,7,8,8,8-pentadecafluorooctanoic acid (IUPAC name); Perfluorooctanoic acid (free acid)

In 2024, the Minnesota Department of Health (MDH) completed a re-evaluation of PFOA that focused on epidemiological data. Recent reviews from the European Food Safety Authority, California Environmental Protection Agency, US Environmental Protection Agency, and National Academies of Sciences, Engineering, and Medicine were utilized as resources. Many toxicity studies in laboratory animals also exist; however, the points of departure are significantly higher than those identified in epidemiology studies. MDH also conducted a literature search for epidemiological studies published between 2021 and December 2022, which focused on potential sensitive endpoints (e.g., development, immune, thyroid), to capture information that postdated the reviews by the agencies listed above.

Short-term, Subchronic, and Chronic Noncancer Health-Based Value (nHBV) = 0.00024 µg/L (equivalent to 0.24 ng/L or ppt)*

*Due to the highly bioaccumulative nature of PFOA, serum concentrations are the most appropriate dose metric. PFOA has a half-life of approximately 2.5 years, and the bioaccumulated levels within women of reproductive age can be passed on to fetuses and infants through placental and breastmilk transfer. The standard equation used to derive health-based values (HBVs) is not adequate to address the bioaccumulative nature nor the maternal transfer of PFOA. Since 2017, a single PFOA HBV for all durations has been derived using a toxicokinetic (TK) model developed by MDH (Goeden 2019), which assesses a formula-fed infant scenario as well as a breastfed infant scenario. The TK model accounts for the bioaccumulation and maternal transfer of PFOA and more accurately represents real-world exposure scenarios. MDH typically calculates HBVs at the part per billion level with the final concentration rounded to one significant digit. However, serum concentrations are impacted by changes in water concentrations at the part per trillion (ppt) level. As a result, the PFOA HBV is expressed with two significant digits.

Reference Serum Concentration:	POD/Total UF = 2.8/3 = 0.93 ng/mL (human) *This serum level was developed using population-based data and should not be used for clinical assessment or interpreting serum levels in individuals.*
Source of toxicity value:	Determined by MDH in 2024
Point of Departure (POD):	2.8 ng/mL (equivalent to µg/L) serum concentration (California EPA Office of Environmental Health Hazard Assessment 2023), $BMDL_{5\%}$ for decreased haemophilus influenzae Type B (Hib) antibodies from (Abraham K 2020)
Dose Adjustment Factor (DAF):	Not applicable (POD is based on human serum level)
Human Equivalent Dose (HED):	Not applicable (POD is based on human serum level)
Total uncertainty factor (UF):	3
Uncertainty factor allocation:	A database UF of 3 was applied to account for remaining database uncertainties regarding potential adverse effects at or near the serum POD concentration (e.g., low birth weight, liver effects, thyroid effects). An UF for human toxicodynamic (TD) variability was not applied because the POD is based on a sensitive lifestage (i.e., young infants). Differences in human TK were determined to be adequately addressed through the exposure scenario and parameter values selected for use in the TK model.[#]
Critical effect(s):	Decreased antibody titers in infants
Co-critical effect(s):	Decreased antibody titers in children, decreased birthweight, increased cholesterol, increased ALT (liver enzyme)
Additivity endpoint(s):	Developmental, Hepatic (liver) system, Immune system

[#]The POD is based on serum levels in one-year old infants, of whom nearly 80% were exclusively breastfed for at least 4 months. Very little information is available regarding PFOA half-life in infants. To evaluate the potential impact of TK variability, an upper-bounding scenario, in which all model parameters were set to upper percentile values, was evaluated. The maternal, peak infant, and lifetime steady-state serum levels produced by the upper-bounding scenario were ≤3-fold higher than MDH's selected Reasonable Maximum Exposure (RME) scenario. Since the upper-bounding scenario is considered worst-case and is very unlikely to represent a realistic scenario, the incorporation of an UF to address human TK variability was considered unnecessary. MDH's RME model parameter values used to derive the noncancer water guidance is considered adequately protective of the general population.

Toxicokinetic Model Description (Goeden 2019):

Serum concentrations can be calculated from the dose and clearance rate using the following equation:

$$Serum\ Concentration\left(\frac{\mu g}{L}\right) = \frac{Fluid\ IntakeRate\left(\frac{L}{kg \cdot day}\right) x\ Fluid\ Concentration\left(\frac{\mu g}{L}\right)}{Clearance\ Rate\left(\frac{L}{kg \cdot day}\right)}$$

Where:

Clearance Rate = Volume of Distribution (L/kg body weight) x (Ln2/half-life in days)

Two exposure scenarios were examined: 1) an infant fed with formula reconstituted with contaminated water starting at birth and continuing ingestion of contaminated water throughout life; and 2) an infant exclusively breastfed for 12 months, followed by drinking contaminated water. In both scenarios, the simulated individuals began life with a pre-existing body burden through placental transfer. The serum concentration of the mother was calculated to be at steady state at the time of delivery, using the equation presented above and a time-weighted average (TWA) 95th percentile intake rate from birth to 30 years of age (sufficient time to attain steady-state).

Consistent with MDH methodology, a 95th percentile water and upper percentile (2 standard deviations above mean) breastmilk intake rates were used along with central tendency estimates for half-life, placental transfer, and breastmilk transfer. Breastmilk concentrations are calculated by multiplying the maternal serum concentration by a PFOA breastmilk transfer factor. For the breast-fed exposure scenario, a one-year period of breastfeeding is used as representative of an RME scenario.

Daily post-elimination serum concentrations were calculated as:

$$Serum\ Concentration\left(\frac{\mu g}{L}\right) = \left[\frac{Previous\ day + Today's\ Intake(\mu g)}{V_d\left(\frac{L}{kg}\right) \times BW(kg)}\right] \times e^{-k}$$

Where:

V_d = volume of distribution
BW = body weight
e^{-k} = represents clearance

Note: MDH has made several improvements to the TK model published in 2019 (Goeden 2019), including the following:

- The PFOA mass transferred to the infant is now subtracted from the maternal steady-state concentration on day 0 (the day of delivery).
- The daily calculation of the infant's serum concentration is now fully mass-based by adjusting both the current day as well as the previous day's intake by the current day's body weight.
- Maternal lactation was phased in over the first four days of lactation based on data from Neville *et al.* (1991).
- Water intakes, breastmilk intakes, and body weights were updated with more current information.
- Chemical-specific parameter values (i.e., clearance, half-life, placental transfer, breastmilk transfer, and volume of distribution) were updated to include literature information up to December 2022.

Summary of TK Model Parameter Values Used to Derive Non-Cancer HBV for PFOA

Model Parameter	Value Used
Half-life ($t_{½}$)	Central Tendency = 902 days (2.47 years) Mean value from (Li 2022) The TK model estimates serum levels from birth to approximately 50 years of age. Critical lifestage is <4 years of age for which serum half-life information is not available. The overall mean was used for the RME scenario. A 95th percentile half-life value of 5.4 years was used in the upper-bounding scenario evaluation.
Placental transfer	Central Tendency = 0.83 (mean of mean values from 25 studies) The mean upper percentile value (1.39) was selected as an upper-end value for the upper-bounding scenario evaluation.
	Central Tendency = 0.068 (95th upper confidence limit (UCL) of the mean from 7 studies). Validation testing of model infant serum predictions indicated that use of the overall mean of

<table>
<tr><th>Model Parameter</th><th>Value Used</th></tr>
<tr><td>Breastmilk transfer</td><td>the 7 studies (0.046) resulted in underestimating breastfed infant serum levels whereas the 95th UCL did not. A value of 0.12 was used as representative of an upper-end value for the upper-bounding scenario evaluation.</td></tr>
<tr><td>Breastmilk Intake Rate (mL/kg-day) and corresponding Body Weight (kg)</td><td>Upper Percentile intake for exclusively[1] breastfed infants ((US EPA 2011), Table 15-1). Body weight at birth was set at 3.38 kg (Donahue 2010). Remaining body weights (kg) were calculated from data presented in US EPA's Table 15-1 for each age group (i.e., mL/day ÷ mL/kg-day):

Age Group — Intake Rate (mL/kg-d) — Body Weight (kg)
>Birth to <1 month — 220 — 4.3
1 to < 3 months — 190 — 5.2
3 to < 6 months — 150 — 6.7
6 to < 12 months — 130 — 7.7</td></tr>
<tr><td>Duration (months) of Breastfeeding</td><td>Upper percentile = 12 months (Breastfeeding Report Card for 2022 (CDC 2022)) reporting that nearly 70 percent of mothers in Minnesota report breastfeeding at six months, with 36.5 percent still exclusively breastfeeding at six months.</td></tr>
<tr><td>Water Intake Rate (mL/kg-day)</td><td>Upper Percentile Intake = Formula-fed infants (up to 2 years old, Table 3-5); for >2 years of age values (Table 3-1); and for lactating women (Table 3-3) (US EPA 2019) were used. Body weights (kg) were calculated from data presented in the aforementioned EPA tables (i.e., mL/day ÷ mL/kg-day):

<table>
<tr><th>Age Group</th><th>Intake Rate (mL/kg-d)</th><th>Body Weight (kg)</th></tr>
<tr><td><1 month</td><td>240</td><td>3.6</td></tr>
<tr><td>1 to < 3 months</td><td>290</td><td>3.8</td></tr>
<tr><td>3 to < 6 months</td><td>186</td><td>7.0</td></tr>
<tr><td>6 to < 12 months</td><td>151</td><td>8.9</td></tr>
<tr><td>1 to < 2 years</td><td>119</td><td>10.5</td></tr>
<tr><td>2 to < 3 years</td><td>67</td><td>13.4</td></tr>
<tr><td>3 to < 6 years</td><td>45</td><td>18.6</td></tr>
<tr><td>6 to < 11 years</td><td>41</td><td>30.7</td></tr>
<tr><td>11 to < 16 years</td><td>31</td><td>56.8</td></tr>
<tr><td>16 to < 21 years</td><td>31</td><td>71.4</td></tr>
<tr><td>21 to < 30 years</td><td>47</td><td>72.5</td></tr>
<tr><td>30 to < 40 years</td><td>44</td><td>74.5</td></tr>
<tr><td>40 to < 50 years</td><td>43</td><td>78.5</td></tr>
<tr><td>50 to < 60 years</td><td>42</td><td>80.7</td></tr>
</table>
For calculation of maternal serum concentration at time of delivery, a time-weighted average water intake rate was calculated from birth to 30 years of age, resulting in a 95th percentile water intake rate of 48 mL/kg-day.</td></tr>
</table>

Model Parameter	Value Used
Volume of Distribution (L/kg)	Central Tendency = 0.36 (calculated from human clearance rate of 0.28 mL/kg-d (California EPA Office of Environmental Health Hazard Assessment 2023)) and the mean half-life of 902 days (Li 2022): $CR \div (Ln2/half\text{-}life) = V_d$ 0.28 mL/kg-d ÷ (Ln2/902 d) = 364 mL/kg or rounded to 0.36 L/kg

[1]Note: Exclusively breastfed as defined by (US EPA 2011) refers to infants whose sole source of milk is breastmilk and not formula. Exclusively breastfed infants in the studies underlying these USEPA estimates were not excluded from other foods, typically after six months. This definition differs from other sources, which may define exclusive breastfeeding as breastmilk being the only source of nourishment (solid or liquid).

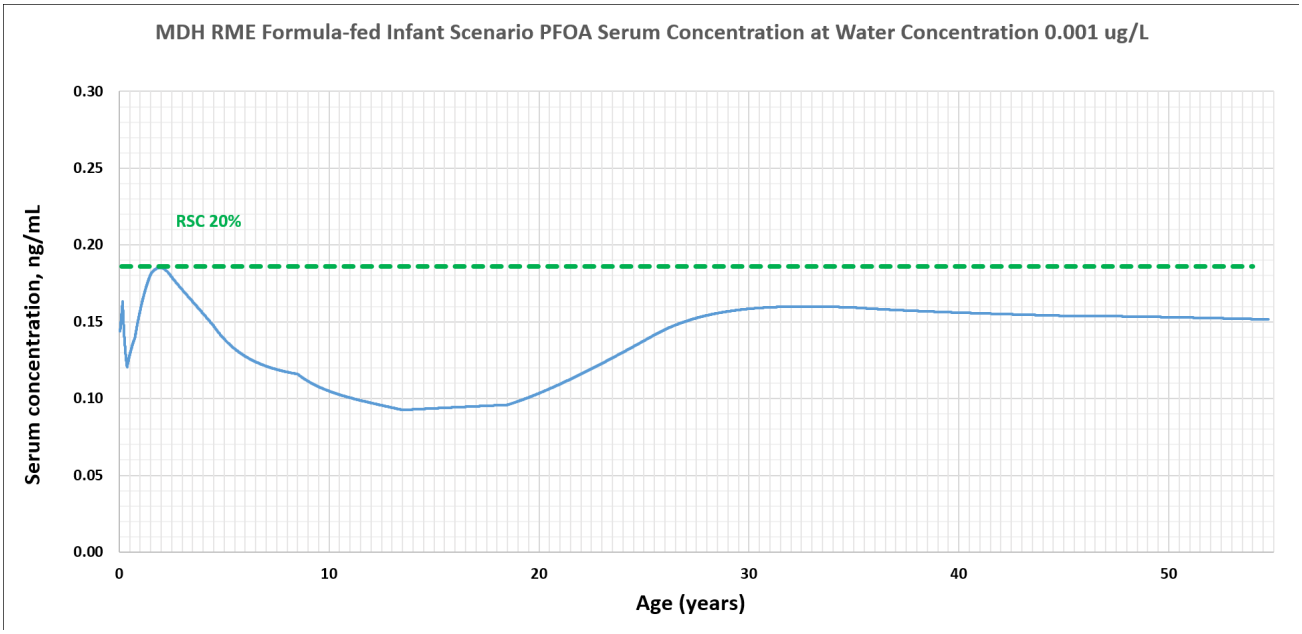
A relative source contribution factor (RSC) is incorporated into the derivation of HBV values to account for exposure sources other than drinking water. MDH utilizes the US EPA 2000 Exposure Decision Tree process to derive appropriate RSCs. The default duration-specific RSCs (0.5, 0.2, and 0.2 for short-term, subchronic and chronic, respectively) are based on the magnitude of contribution of non-drinking water exposures that occur during the relevant exposure duration (Minnesota Department of Health (MDH) 2008). However, in the case of PFOA, application of an RSC needs to account for the long elimination half-life, such that a person's serum concentration at any given age/duration is not only the result of current or recent exposures but also from years past and/or maternal transfer.

Serum concentrations are the best measure of cumulative exposure for PFOA and can be used in place of the reference dose in the Exposure Decision Tree process. Biomonitoring results for the general public reported in the most recent National Report on Human Exposure to Environmental Chemicals (CDC 2021) can be used to represent non-water exposures for older children and adults. The reference serum concentration is 0.93 ng/mL. Both the geometric mean (1.42 ng/mL) and the 95th percentile (3.77 ng/mL) PFOA serum concentration from the most recently available National Report exceed the reference serum concentration. Based on placental transfer data, newborn infants would have PFOA body burdens similar to their mothers. Even at low levels of exposure, PFOA would accumulate in women of reproductive age. Studies assessing young infants (e.g., <6 months of age) who are exclusively breastfed exhibit serum levels that are approximately 3-fold higher than their mothers (e.g., (Fromme 2010), (Gyllenhammar 2018)). It is likely that infants will have similar or, in the case of breastfed infants, higher serum concentrations than their mothers. Consequently, the RSC is set at the floor value of 20% for all life stages.

As mentioned above, two RME scenarios were examined: 1) an infant fed formula reconstituted with contaminated water starting at birth and continuing consumption of contaminated water throughout life; and 2) an infant exclusively breastfed for 12 months by a chronically-exposed mother, followed by consumption of contaminated water throughout life.

For the formula-fed infant, the water concentration that maintains a serum concentration attributable to drinking water below an RSC of 20% throughout life is 0.0010 µg/L (equivalent to 1.0 ng/L or ppt) (Figure 1).

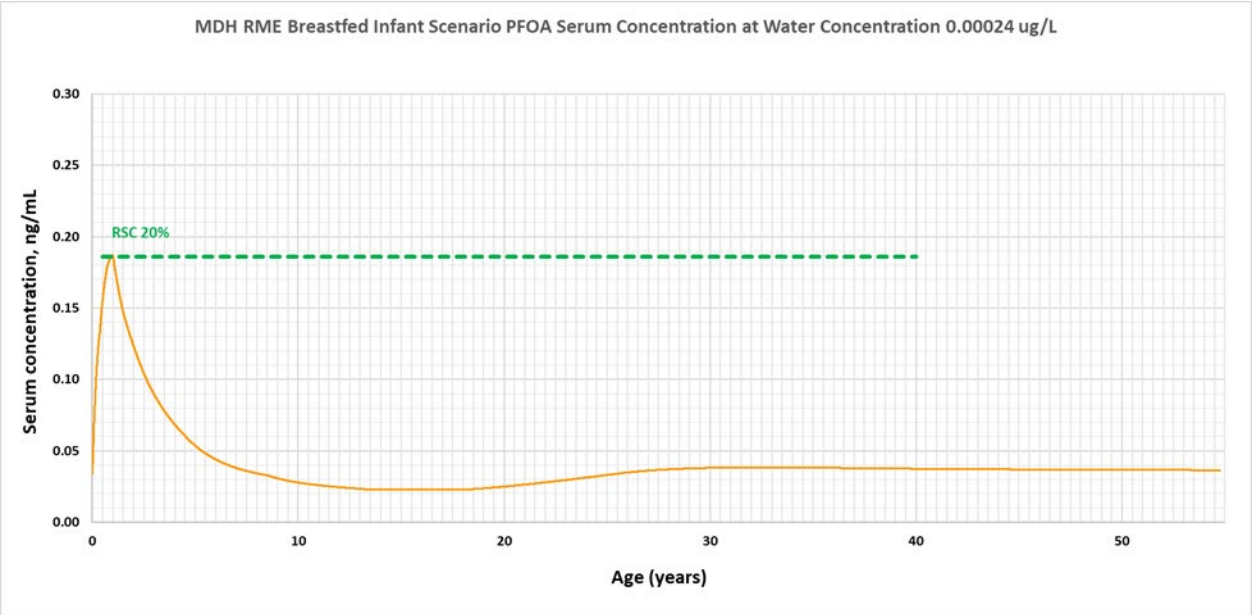
Figure 1. MDH RME Formula-fed Infant Scenario PFOA Serum Concentration at Water Concentration 0.001 ug/L



A sharp decrease in the formula-fed infant serum levels between the 1 to < 3 month and 3 to <6 months is noted. The formula-fed infant water intake drops from 290 to 186 mL/kg-d as body weight increases from 3.8 to 7 kg across the same time period.

Applying this water concentration (1 ng/L) in the context of a breast-fed infant results in peak infant serum concentrations that significantly exceed the RSC of 20%. In order to maintain a serum concentration at or below an RSC of 20% for the breastfed infant scenario, the water concentration should not exceed 0.00024 µg/L (or 0.24 ng/L or ppt) (Figure 2).

Figure 2. MDH RME Breastfed Infant Scenario PFOA Serum Concentration at Water Concentration 0.00024 µg/L



Due to bioaccumulation in the mother and subsequent transfer to breastmilk, the breastfed infant exposure scenario produces the lower PFOA water concentration. To ensure protection of all segments of the population, the final noncancer HBV for PFOA is set at 0.00024 µg/L (0.24 ng/L).

Cancer Health-Based Value (cHBV) = 0.0000079 µg/L (0.0079 ng/L or ppt)

$$\frac{\text{(Additional Lifetime Cancer Risk) x (Conversion Factor)}}{[(SF \times ADAF_{<2\,yr} \times IR_{<2yr} \times 2) + (SF \times ADAF_{2-<16\,yr} \times IR_{2-<16yr} \times 14) + (SF \times ADAF_{16+\,yr} \times IR_{16+yr} \times 54)] / 70}$$

$$= \frac{(1E\text{-}5) \times (1\ \mu g/1000\ ng)}{[(0.0126 \times 10^{*} \times 0.155\ L/kg\text{-}d^{**} \times 2) + (0.0126 \times 3^{*} \times 0.040\ L/kg\text{-}d^{**} \times 14) + (0.0126 \times 1^{*} \times 0.042\ L/kg\text{-}d^{**} \times 54)] / 70}$$

= 0.0000079 µg/L (same as 0.0079 ng/L or ppt)

*Age-dependent adjustment factor (ADAF) and Lifetime Adjustment Factor: MDH 2008, Section IV.E.2. ADAFs were maintained because the cohort from the critical cancer study was unlikely to have early-life exposure to PFOA.

**Intake Rate: MDH 2008, Section IV.E.2. and US EPA 2019, Exposure Factors Handbook, Tables 3-1, 3-3, and 3-5.

Cancer classification:	Likely to be carcinogenic to humans (US EPA 2023a,b) (MDH 2023); Strong evidence of carcinogenicity (CalEPA Office of Environmental Health Hazard Assessment 2023); and Group 1 (carcinogenic to humans) (IARC 2023)
Slope factor (SF):	0.0126 per ng/kg-day (renal cell carcinoma in humans) (Shearer JJ 2021)
Source of cancer slope factor (SF):	Serum slope factor 0.00325 per ng/mL from (US EPA 2023a,b) converted to 0.0126 per ng/kg-d using a clearance rate of 0.28 mL/kg-d (CalEPA Office of Environmental Health Hazard Assessment 2023)
Tumor site(s):	Human: Kidney (basis of guidance), Testicle Animal: Liver, Pancreas

Volatile: No

Summary of Guidance Value History:

A chronic nHBV of 7 µg/L was first derived in 2002. A revised chronic nHBV of 0.3 µg/L was derived in 2007 and promulgated as a noncancer HRL (nHRL) in 2009. In 2016, EPA released a Health Advisory of 0.07 µg/L for PFOA, which MDH recommended on an interim basis while a re-evaluation was conducted. As a result of the re-evaluation, which incorporated the most recent toxicological information and included the application of the TK model, the 2017 nHBV decreased to 0.035 µg/L for all nonacute durations. The 2017 guidance was adopted as a HRL in 2018. In 2020, MDH classified PFOA as "likely to be carcinogenic at high doses" and added Thyroid (E) and Pancreas as Additivity Endpoints. The 2024 nHBV of 0.00024 µg/L (0.24 ng/L) is lower than previous values as the result of: 1) utilizing epidemiological data as the basis for the POD; and 2) updating the toxicokinetic model, including more recent data on placental and breastmilk transfer. The 2024

cancer HBV of 0.0000079 µg/L (0.0079 ng/L) is a new value, and MDH has revised their cancer classification to "likely to be carcinogenic".

Summary of toxicity testing for health effects identified in the Health Standards Statute (144.0751):

Even if testing for a specific health effect was not conducted for this chemical, information about that effect might be available from studies conducted for other purposes. MDH has considered the following information in developing health protective guidance.

	Endocrine	Immunotoxicity	Development	Reproductive	Neurotoxicity
Tested for specific effect?	Yes	Yes	Yes	Yes	Yes
Effects observed?	Yes[1]	Yes[2]	Yes[3]	Yes[4]	Yes[5]

Comments on extent of testing or effects:

[Note: MDH conducted a re-evaluation that focused on epidemiological data and sensitive health endpoints.]

[1] Evidence for endocrine effects in humans following PFOA exposure is largely based on increased TSH (thyroid stimulating hormone) and T3 (triiodothyronine) in adults and T4 (thyroxine) in children. However, findings in epidemiology studies were inconsistent, likely due in part to diurnal variations, differential effects across genders and age groups, timing of sampling, and limited number of studies. US EPA (2023) considers the current level of evidence for thyroid effects to be suggestive due to the uncertainty in results. A database uncertainty factor has been incorporated into the reference serum level to reflect the need for more data regarding thyroid effects.

Studies in laboratory animals have demonstrated clear alterations in serum thyroid hormone levels, increased thyroid gland weight, and increased follicular cell hypertrophy in the thyroid gland. Previous MDH guidance was based, in part, on thyroid effects in animals.

[2] It is widely accepted that PFOA exposure is likely associated with reduced antibody response, especially in infants and children. An immune study in infants forms the basis of the PFOA reference serum concentration used to derive the 2024 nHBV. There is also limited supporting evidence of increased risk of asthma, eczema, and autoimmune disease.

In animal models, there is consistent evidence of decreased antibody response, decreased spleen and thymus weight, and alterations in immune cell function after PFOA exposure.

[3] It is widely accepted that decreased birth weight is likely associated with maternal PFOA serum levels. This likely association is supported by additional epidemiological evidence of related effects such as decreased birth length and postnatal growth. In general, these effects have been reported around similar serum levels as effects on the immune system, which is the basis of the reference serum concentration.

Among the animal studies, decreased postnatal growth leading to developmental effects (e.g., lower pup body weight, delayed eye opening, delayed vaginal opening, and accelerated preputial separation) have been observed. Delayed mammary gland development in female mice exposed in utero has also been reported at low dose levels.

[4] The evidence for male reproductive effects in humans is limited and largely based on suggestive associations between PFOA exposure and testosterone levels in male children and adults and decreased anogenital distance in children. Considerable uncertainties in these associations exist due to inconsistencies across the limited number of studies available.

The evidence for female reproductive effects in humans is limited and largely based on suggestive associations between PFOA exposure and increased odds of preeclampsia, and changes to female reproductive milestones and female reproductive hormonal outcomes. Considerable uncertainties in these associations exist due to inconsistencies across studies and the limited number of available studies. In general, these effects have been reported at doses somewhat higher than effects on the immune system, birth weight, and liver effects.

Among the animal studies, there was no effect of PFOA on reproductive or fertility parameters in female rats. However, it should be noted that female rats have a very high PFOA elimination rate compared to male rats or other species. Increased full litter resorptions and increased stillbirths were observed in pregnant mice exposed to doses resulting in very high serum concentrations. No evidence of altered testicular and sperm structure or function was reported in adult male rats exposed to doses producing high serum concentrations. Increased sperm abnormalities and decreased testosterone were reported at high serum concentrations.

[5] The evidence for effects on the nervous system in humans is limited and largely based on neurodevelopment, including neuropsychological and cognitive development, executive function, and behavioral problems. There are considerable uncertainties due to inconsistency in magnitude and direction of effects across the limited number of studies available.

Information from animal studies is also quite limited. The offspring of mice fed PFOA throughout gestation had detectable levels of PFOA in their brains at birth. Locomotor activity, anxiety-related or depression-like behavior, and muscle strength were not altered. Circadian activity tests revealed sex-related differences in exploratory behavior patterns.

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Exhibit E. Notice of Intent to Adopt Rules as mailed and as published in the State Register

Minnesota Department of Health

Division of Environmental Health

DUAL NOTICE: Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing if 25 or More Requests for Hearing Are Received; Revisor's ID Number: 4803; OAH Docket number: 22-9000-40331

Proposed Amendments to Rules Governing Health Risk Limits for Groundwater, *Minnesota Rules,* Chapter 4717, Part 7500 and Part 7860

Introduction.
The Minnesota Department of Health ("MDH") intends to adopt rules without a public hearing following the procedures set forth in the rules of the Office of Administrative Hearings, Minn. Rules,¶¶ 1400.2300 to 1400.2310, and the Administrative Procedure Act, Minn. Stat. §§ 14.22 to 14.28. If, however, 25 or more persons submit a written request for a hearing on the rules by 4:30 p.m. on Wednesday, December 4, 2024. MDH will hold a public hearing virtually via WebEx. An Administrative Law Judge will conduct the hearing starting at 9:30 a.m. on Tuesday, February 18, 2025, until everyone who wants to comment has had the chance to do so, if possible, but no later than 4:30 p.m. To find out whether MDH will adopt the rules without a hearing or if it will hold the hearing, contact the agency contact person after Wednesday, December 4, 2024, and before Tuesday, February 18, 2025.

You can register to join with video and audio through an internet connection with a computer or mobile device. You also may participate by telephone as follows:

Call: 1-855-282-6330 (US Toll Free)

Meeting link:
https://minnesota.webex.com/minnesota/j.php?MTID=md01cb56d03e1f8f81558d5881acc336a

Access code: 2498 705 8342

All of the information about how to attend the hearing by WebEx or telephone will also be posted on MDH's website: Health Risk Limits Rules for Groundwater Amendments: Overview and Links (https://www.health.state.mn.us/hrlrules.html).

Agency Contact Person.
Submit any comments or questions on the rules or written requests for a public hearing to the agency contact person. The agency contact person is:

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

Phone: (651) 201-4923
Fax: (651) 201-4606
Email: nancy.rice@state.mn.us

You may also review the proposed rule and submit written comments via the Office of Administrative Hearings Rulemaking eComments website https://minnesotaoah.granicusideas.com/discussions.

Subject of Rules and Statutory Authority.
The Groundwater Protection Act of 1989 (Minn. Stat. § 103H.201), authorizes MDH to review, revise, and adopt thresholds for certain substances degrading groundwater in Minnesota. The proposed rule revision is about water guidance values called Health Risk Limits ("HRLs") for contaminants in groundwater used for drinking water, as found in Minnesota Rules, Chapter 4717, parts 7500 and 7860. HRLs provide 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 populations. The current rulemaking is required under Laws of Minnesota 2023, Chapter 60, Article 3, Section 34, where MDH must adopt an updated HRL value of no greater than 0.015 ppm for [Perfluorooctane Sulfonate] PFOS by July 1, 2026.

The proposed amendments to the Health Risk Limit Rules for Groundwater will add or replace HRL values developed by MDH between 2022 and mid-2023, including a value for PFOS. The amendments will add (to Minn. R. ¶ 4717.7860) updated health-based guidance values for four chemicals that have been in Health Risk Limit Rules for Groundwater previously. The outdated HRL values (adopted in 1993, 1994, 2009, or 2018) for these four chemicals will be repealed (in part 4717.7500 or part 4717.7860) and replaced (in part 4717.7860) by new HRL values. In addition, previously adopted HRL values for two chemicals (anthracene, adopted in 1993; and dichlorodifluoromethane, adopted in 2011) will be repealed and not replaced. For these two contaminants, new Risk Assessment Advice has already been posted on MDH's Human Health-Based Water Guidance Table, which is available at www.health.state.mn.us/communities/environment/risk/guidance/gw/table.html.

Additional information about the Health Risk Limits Rules for Groundwater Amendments is available at: https://www.health.state.mn.us/hrlrules.html. You may request a free copy of the proposed rule amendments from the contact person listed above. You may also review the proposed rule and submit written comments via the Office of Administrative Hearings' Rulemaking e-comments website at minnesotaoah.granicusideas.com/discussions.

Comments.
You have until 4:30 p.m. on Wednesday, December 4, 2024, to submit written comment in support of or in opposition to the proposed rules or any part or subpart of the rules. Your comment must be in writing and received by the agency contact person by the due date. Comment is encouraged. Your comments should identify the portion of the proposed rules addressed, the reason for the comment, and any change proposed. You are encouraged to propose any change that you desire. Any comments that you have about the legality of the proposed rules must also be made during this comment period.

Request for a Hearing.
In addition to submitting comments, you may also request that MDH hold a hearing on the rules. You must make your request for a public hearing in writing, which the agency contact person must receive by 4:30 p.m. on Wednesday, December 4, 2024. You must include your name and address in your written request. In addition, you must identify the portion of the proposed rules that you object to or state that you oppose the entire set of rules. Any request that does not comply with these requirements is not valid and the agency cannot count it when determining whether it must hold a public hearing. You are also encouraged to state the reason for the request and any changes you want made to the proposed rules.

Withdrawal of Requests.
If 25 or more persons submit a valid written request for a hearing, MDH will hold a public hearing unless a sufficient number of persons withdraw their requests in writing. If enough requests for hearing are withdrawn to reduce the number below 25, the agency must give written notice of this to all persons who requested a hearing, explain the actions the agency took to effect the withdrawal, and ask for written comments on this action. If a public hearing is required, the agency will follow the procedures in *Minnesota Statutes*, sections 14.131 to 14.20.

Alternative Format/Accommodation.
Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request or if you need an accommodation to make this hearing accessible, please contact the agency contact person at the address or telephone number listed above.

Modifications.
MDH might modify the proposed rules, either as a result of public comment or as a result of the rule hearing process. It must support modifications by data and views submitted to the agency or presented at the hearing. The adopted rules may not be substantially different than these proposed rules unless MDH follows the procedure under *Minnesota Rules*, part 1400.2110. If the proposed rules affect you in any way, MDH encourages you to participate in the rulemaking process.

Cancellation of Hearing.
MDH will cancel the hearing scheduled for February 18, 2025, if the agency does not receive requests for a hearing from 25 or more persons. If you requested a public hearing, the agency will notify you before the scheduled hearing whether the hearing will be held. You may also call the agency contact person at 651-201-4923 after Wednesday, December 4, 2024, to find out whether the hearing will be held or visit the MDH Health Risk Limits Rules for Groundwater Amendments website at https://www.health.state.mn.us/hrlrules.html.

Notice of Hearing.
If 25 or more persons submit valid written requests for a public hearing on the rules, MDH will hold a hearing following the procedures in *Minnesota Statutes*, sections 14.131 to 14.20. MDH will hold the hearing on the date and at the time and place listed above. The hearing will continue until all interested persons have been heard. Administrative Law Judge Christa Moseng is assigned to conduct the hearing. Judge Moseng's Legal Assistant William Moore can be reached at the Office of Administrative Hearings, 600 North Robert Street, P.O. Box 64620,

Saint Paul, Minnesota 55164-0620, telephone 651-361-7900 and fax 651-539-0310 or William.t.moore@state.mn.us

Hearing Procedure.
If MDH holds a hearing, you and all interested or affected persons, including representatives of associations or other interested groups, will have an opportunity to participate. You may present your views either orally at the hearing or in writing at any time before the hearing record closes. All evidence presented should relate to the proposed rules. You may also submit written material to the Administrative Law Judge to be recorded in the hearing record for five working days after the public hearing ends. At the hearing the Administrative Law Judge may order that this five-day comment period is extended for a longer period but not more than 20 calendar days. Following the comment period, there is a five-working-day rebuttal period when the agency and any interested person may respond in writing to any new information submitted. No one may submit new evidence during the five-day rebuttal period.

All post-hearing comments and responses must be submitted to the Administrative Law Judge no later than 4:30 p.m. on the due date. The Office of Administrative Hearings strongly encourages all persons submitting comments and responses to do so using their Rulemaking eComments website minnesotaoah.granicusideas.com/discussions. If you are unable to use the eComments website, you may submit post-hearing comments in person, via United States mail, or by facsimile addressed to Judge Moseng at the address or facsimile number listed in the Notice of Hearing section above.

All comments or responses received will be available for review at the Minnesota Department of Health website at https://www.health.state.mn.us/hrlrules.html. This rule hearing procedure is governed by Minnesota Rules, parts 1400.2000 to 1400.2240, and Minnesota Statutes, sections 14.131 to 14.20. You may direct questions about the procedure to the Administrative Law Judge.

Statement of Need and Reasonableness.
The statement of need and reasonableness summarizes the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. It is now available from the agency contact person. You may review or obtain copies for the cost of reproduction by contacting the agency contact person. A copy of the this document can also be found at www.health.state.mn.us/communities/environment/risk/rules/water/hrlsonar.html

Lobbyist Registration.
Minnesota Statutes, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. Ask any questions about this requirement of the Campaign Finance and Public Disclosure Board at: Suite #190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone (651) 539-1180 or 1-800-657-3889.

Adoption Procedure if No Hearing.
If no hearing is required, the agency may adopt the rules after the end of the comment period. MDH will submit the rules and supporting documents to the Office of Administrative Hearings for a legal review. You may ask to be notified of the date the rules are submitted to the office. If

you want to receive notice of this, to receive a copy of the adopted rules, or to register with the agency to receive notice of future rule proceedings, submit your request to the agency contact person listed above.

Adoption Procedure after a Hearing.
If a hearing is held, after the close of the hearing record, the Administrative Law Judge will issue a report on the proposed rules. You may request to be notified of the date that the Administrative Law Judge's report will become available at the hearing or in writing directly to the Administrative Law Judge. You may also ask to be notified of the date that the agency adopts the rules and the rules are filed with the Secretary of State at the hearing or by writing to the agency contact person stated above.

Order.
I order that the rulemaking hearing be held at the date, time, and location listed above.

10/28/2024

Date

/s/ Wendy Underwood

Wendy Underwood
Deputy Commissioner
Minnesota Department of Health

MINNESOTA STATE REGISTER

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Minnesota State Register

Judicial Notice Shall Be Taken of Material Published in the Minnesota State Register

The Minnesota State Register is the official publication of the State of Minnesota's Executive Branch of government, published weekly to fulfill the legislative mandate set forth in Minnesota Statutes, Chapter 14, and Minnesota Rules, Chapter 1400. It contains:

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Printing Schedule and Submission Deadlines

Vol. 49 Issue Number	Publish Date	Deadline for: all Short Rules, Executive and Commissioner's Orders, Revenue and Official Notices, State Grants, Professional-Technical- Consulting Contracts, Non-State Bids and Public Contracts	Deadline for LONG, Complicated Rules (contact the editor to negotiate a deadline)
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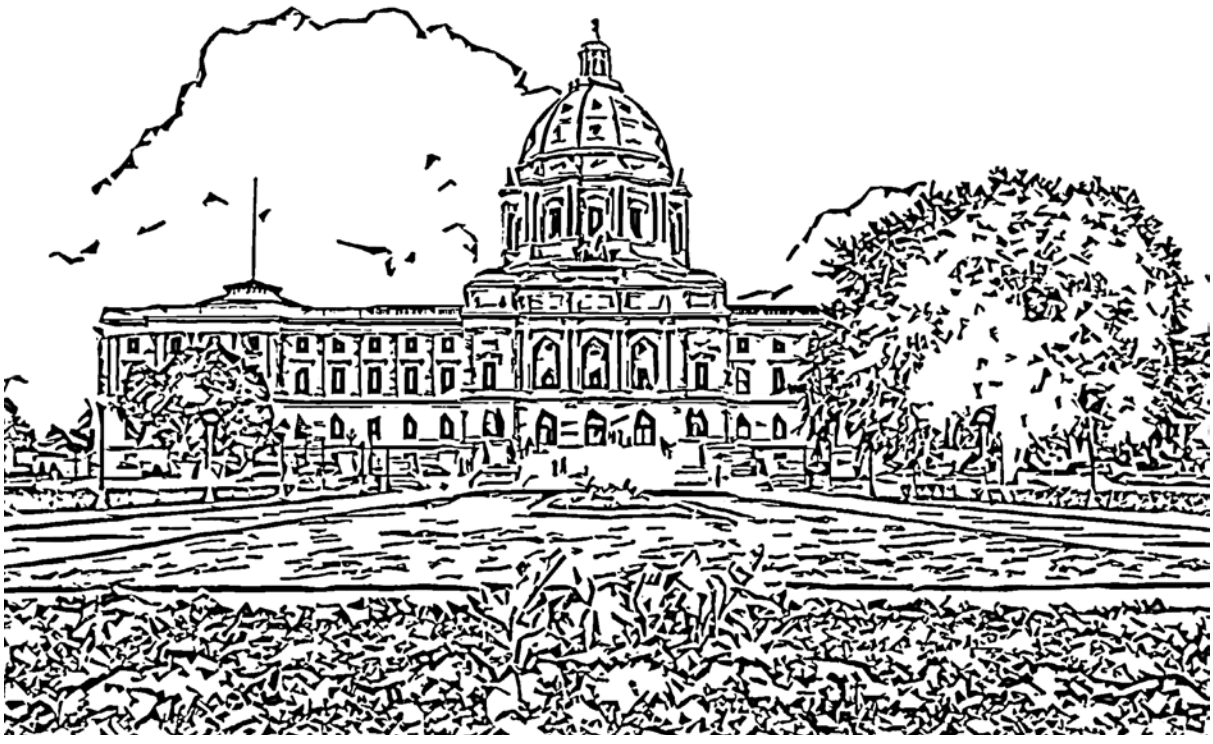


Minnesota Rules: Amendments and Additions

NOTICE: How to Follow State Agency Rulemaking in the State Register

The State Register is the official source, and only complete listing, for all state agency rulemaking in its various stages. State agencies are required to publish notice of their rulemaking action in the State Register. Published every Monday, the State Register makes it easy to follow and participate in the important rulemaking process. Approximately 80 state agencies have the authority to issue rules. Each agency is assigned specific Minnesota Rule chapter numbers. Every odd-numbered year the Minnesota Rules are published. Supplements are published to update this set of rules. Generally speaking, proposed and adopted exempt rules do not appear in this set because of their short-term nature, but are published in the State Register.

An agency must first solicit Comments on Planned Rules or Comments on Planned Rule Amendments from the public on the subject matter of a possible rulemaking proposal under active consideration within the agency (Minnesota Statutes §§ 14.101). It does this by publishing a notice in the State Register at least 60 days before publication of a notice to adopt or a notice of hearing, or within 60 days of the effective date of any new statutory grant of required rulemaking.

When rules are first drafted, state agencies publish them as Proposed Rules, along with a notice of hearing, or a notice of intent to adopt rules without a hearing in the case of noncontroversial rules. This notice asks for comment on the rules as proposed. Proposed emergency rules, and withdrawn proposed rules, are also published in the State Register. After proposed rules have gone through the comment period, and have been rewritten into their final form, they again appear in the State Register as Adopted Rules. These final adopted rules are not printed in their entirety, but only the changes made since their publication as Proposed Rules. To see the full rule, as adopted and in effect, a person simply needs two issues of the State Register, the issue the rule appeared in as proposed, and later as adopted.

The State Register features partial and cumulative listings of rules in this section on the following schedule: issues #1-26 inclusive (issue #26 cumulative for issues #1-26); issues #27-52 inclusive (issue #52, cumulative for issues #27-52 or #53 in some years). A subject matter index is updated weekly and is available upon request from the editor. For copies or subscriptions to the State Register, contact the editor at 651-201-3204 or email at sean.plemmons@state.mn.us

Volume 49 - Minnesota Rules

(Rules Appearing in Vol. 48 Issues #27-52 are in Vol. 48, #52 - Monday 24 June 2024)

Volume 49, #19

Monday 1 July - Monday 4 November

Proposed Rules

Comments on Planned Rules or Rule Amendments. An agency must first solicit Comments on Planned Rules or Comments on Planned Rule Amendments from the public on the subject matter of a possible rulemaking proposal under active consideration within the agency (*Minnesota Statutes* §§ 14.101). It does this by publishing a notice in the *State Register* at least 60 days before publication of a notice to adopt or a notice of hearing, and within 60 days of the effective date of any new statutory grant of required rulemaking.

Rules to be Adopted After a Hearing. After receiving comments and deciding to hold a public hearing on the rule, an agency drafts its rule. It then publishes its rules with a notice of hearing. All persons wishing to make a statement must register at the hearing. Anyone who wishes to submit written comments may do so at the hearing, or within five working days of the close of the hearing. Administrative law judges may, during the hearing, extend the period for receiving comments up to 20 calendar days. For five business days after the submission period the agency and interested persons may respond to any new information submitted during the written submission period and the record then is closed. The administrative law judge prepares a report within 30 days, stating findings of fact, conclusions and recommendations. After receiving the report, the agency decides whether to adopt, withdraw or modify the proposed rule based on consideration of the comments made during the rule hearing procedure and the report of the administrative law judge. The agency must wait five days after receiving the report before taking any action.

Rules to be Adopted Without a Hearing. Pursuant to *Minnesota Statutes* § 14.22, an agency may propose to adopt, amend, suspend or repeal rules without first holding a public hearing. An agency must first solicit **Comments on Planned Rules** or **Comments on Planned Rule Amendments** from the public. The agency then publishes a notice of intent to adopt rules without a public hearing, together with the proposed rules, in the *State Register*. If, during the 30-day comment period, 25 or more persons submit to the agency a written request for a hearing of the proposed rules, the agency must proceed under the provisions of §§ 14.1414.20, which state that if an agency decides to hold a public hearing, it must publish a notice of intent in the *State Register*.

KEY: Proposed Rules - Underlining indicates additions to existing rule language. ~~Strikeouts~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." **Adopted Rules** - Underlining indicates additions to proposed rule language. ~~Strikeout~~ indicates deletions from proposed rule language.

Minnesota Department of Health

Division of Environmental Health

Proposed Amendments to Rules Governing Health Risk Limits for Groundwater; DUAL NOTICE: Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing if 25 or More Requests for Hearing Are Received; Revisor's ID Number: 4803; OAH Docket number: 22-9000-40331

Proposed Amendments to Rules Governing Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Part 7500 and Part 7860

Introduction.

The Minnesota Department of Health ("MDH") intends to adopt rules without a public hearing following the procedures set forth in the rules of the Office of Administrative Hearings, Minn. Rules,¶¶ 1400.2300 to 1400.2310, and the Administrative Procedure Act, Minn. Stat. §§ 14.22 to 14.28. If, however, 25 or more persons submit a written request for a hearing on the rules by 4:30 p.m. on Wednesday, December 4, 2024. MDH will hold a public hearing virtually via WebEx. An Administrative Law Judge will conduct the hearing starting at 9:30 a.m. on Tuesday, February 18, 2025, until everyone who wants to comment has had the chance to do so, if possible, but no later than 4:30 p.m. To find out whether MDH will adopt the rules without a hearing or if it will hold the hearing, contact the agency contact person after Wednesday, December 4, 2024, and before Tuesday, February 18, 2025.

You can register to join with video and audio through an internet connection with a computer or mobile device. You also may participate by telephone as follows:

Call: 1-855-282-6330 (US Toll Free)

Meeting link: ***Webex Meeting Link***

Access code: 2498 705 8342

All of the information about how to attend the hearing by WebEx or telephone will also be posted on MDH's website: Health Risk Limits Rules for Groundwater Amendments: Overview and Links (***https://www.health.state.mn.us/hrlrules.html***).

Agency Contact Person.

Submit any comments or questions on the rules or written requests for a public hearing to the agency contact person. The agency contact person is:

Nancy Rice
Minnesota Department of Health
625 Robert Street North
P.O. Box 64975
St. Paul, MN 55164-0975
Phone: (651) 201-4923
Fax: (651) 201-4606
Email: ***nancy.rice@state.mn.us***

You may also review the proposed rule and submit written comments via the Office of Administrative Hearings Rulemaking eComments website ***https://minnesotaoah.granicusideas.com/discussions***.

Subject of Rules and Statutory Authority.

The Groundwater Protection Act of 1989 (Minn. Stat. § 103H.201), authorizes MDH to review, revise, and adopt thresholds for certain substances degrading groundwater in Minnesota. The proposed rule revision is about water guidance values called Health Risk Limits ("HRLs") for contaminants in groundwater used for drinking water, as found in Minnesota Rules, Chapter 4717, parts 7500 and 7860. HRLs provide 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 populations. The current rulemaking is required under Laws of Minnesota 2023, Chapter 60, Article 3, Section 34, where MDH must adopt an updated HRL value of no greater than 0.015 ppm for [Perfluorooctane Sulfonate] PFOS by July 1, 2026.

The proposed amendments to the Health Risk Limit Rules for Groundwater will add or replace HRL values developed by MDH between 2022 and mid-2023, including a value for PFOS. The amendments will add (to Minn. R. ¶ 4717.7860) updated health-based guidance values for four chemicals that have been in Health Risk Limit Rules for Groundwater previously. The outdated HRL values (adopted in 1993, 1994, 2009, or 2018) for these four chemicals will be repealed (in part 4717.7500 or part 4717.7860) and replaced (in part 4717.7860) by new HRL values. In addition, previously adopted HRL values for two chemicals (anthracene, adopted in 1993; and dichlorodifluoromethane, adopted in 2011) will be repealed and not replaced. For these two contaminants, new Risk Assessment Advice has already been posted on MDH's Human Health-Based Water Guidance Table, which is available at ***www.health.state.mn.us/communities/environment/risk/guidance/gw/table.html.***

Additional information about the Health Risk Limits Rules for Groundwater Amendments is available at: ***https://www.health.state.mn.us/hrlrules.html***. You may request a free copy of the proposed rule amendments from the contact person listed above. You may also review the proposed rule and submit written comments via the Office of Administrative Hearings' Rulemaking e-comments website at ***minnesotaoah.granicusideas.com/discussions***.

Comments.

You have until 4:30 p.m. on Wednesday, December 4, 2024, to submit written comment in support of or in opposition

to the proposed rules or any part or subpart of the rules. Your comment must be in writing and received by the agency contact person by the due date. Comment is encouraged. Your comments should identify the portion of the proposed rules addressed, the reason for the comment, and any change proposed. You are encouraged to propose any change that you desire. Any comments that you have about the legality of the proposed rules must also be made during this comment period.

Request for a Hearing.

In addition to submitting comments, you may also request that MDH hold a hearing on the rules. You must make your request for a public hearing in writing, which the agency contact person must receive by 4:30 p.m. on Wednesday, December 4, 2024. You must include your name and address in your written request. In addition, you must identify the portion of the proposed rules that you object to or state that you oppose the entire set of rules. Any request that does not comply with these requirements is not valid and the agency cannot count it when determining whether it must hold a public hearing. You are also encouraged to state the reason for the request and any changes you want made to the proposed rules.

Withdrawal of Requests.

If 25 or more persons submit a valid written request for a hearing, MDH will hold a public hearing unless a sufficient number of persons withdraw their requests in writing. If enough requests for hearing are withdrawn to reduce the number below 25, the agency must give written notice of this to all persons who requested a hearing, explain the actions the agency took to effect the withdrawal, and ask for written comments on this action. If a public hearing is required, the agency will follow the procedures in *Minnesota Statutes*, sections 14.131 to 14.20.

Alternative Format/Accommodation.

Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request or if you need an accommodation to make this hearing accessible, please contact the agency contact person at the address or telephone number listed above.

Modifications.

MDH might modify the proposed rules, either as a result of public comment or as a result of the rule hearing process. It must support modifications by data and views submitted to the agency or presented at the hearing. The adopted rules may not be substantially different than these proposed rules unless MDH follows the procedure under *Minnesota Rules*, part 1400.2110. If the proposed rules affect you in any way, MDH encourages you to participate in the rulemaking process.

Cancellation of Hearing.

MDH will cancel the hearing scheduled for February 18, 2025, if the agency does not receive requests for a hearing from 25 or more persons. If you requested a public hearing, the agency will notify you before the scheduled hearing whether the hearing will be held. You may also call the agency contact person at 651-201-4923 after Wednesday, December 4, 2024, to find out whether the hearing will be held or visit the MDH Health Risk Limits Rules for Groundwater Amendments website at ***https://www.health.state.mn.us/hrlrules.html***.

Notice of Hearing.

If 25 or more persons submit valid written requests for a public hearing on the rules, MDH will hold a hearing following the procedures in *Minnesota Statutes*, sections 14.131 to 14.20. MDH will hold the hearing on the date and at the time and place listed above. The hearing will continue until all interested persons have been heard. Administrative Law Judge Christa Moseng is assigned to conduct the hearing. Judge Moseng's Legal Assistant William Moore can be reached at the Office of Administrative Hearings, 600 North Robert Street, P.O. Box 64620, Saint Paul, Minnesota 55164-0620, telephone 651-361-7900 and fax 651-539-0310 or ***William.t.moore@state.mn.us***

Hearing Procedure.

If MDH holds a hearing, you and all interested or affected persons, including representatives of associations or other interested groups, will have an opportunity to participate. You may present your views either orally at the hearing or in writing at any time before the hearing record closes. All evidence presented should relate to the proposed rules. You may also submit written material to the Administrative Law Judge to be recorded in the hearing record for five working

days after the public hearing ends. At the hearing the Administrative Law Judge may order that this five-day comment period is extended for a longer period but not more than 20 calendar days. Following the comment period, there is a five-working-day rebuttal period when the agency and any interested person may respond in writing to any new information submitted. No one may submit new evidence during the five-day rebuttal period.

All post-hearing comments and responses must be submitted to the Administrative Law Judge no later than 4:30 p.m. on the due date. The Office of Administrative Hearings strongly encourages all persons submitting comments and responses to do so using their Rulemaking eComments website ***minnesotaoah.granicusideas.com/discussions***. If you are unable to use the eComments website, you may submit post-hearing comments in person, via United States mail, or by facsimile addressed to Judge Moseng at the address or facsimile number listed in the Notice of Hearing section above.

All comments or responses received will be available for review at the Minnesota Department of Health website at ***https://www.health.state.mn.us/hrlrules.html***. This rule hearing procedure is governed by Minnesota Rules, parts 1400.2000 to 1400.2240, and Minnesota Statutes, sections 14.131 to 14.20. You may direct questions about the procedure to the Administrative Law Judge.

Statement of Need and Reasonableness.

The statement of need and reasonableness summarizes the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. It is now available from the agency contact person. You may review or obtain copies for the cost of reproduction by contacting the agency contact person. A copy of the this document can also be found at ***www.health.state.mn.us/communities/environment/risk/rules/water/hrlsonar.html***

Lobbyist Registration.

Minnesota Statutes, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. Ask any questions about this requirement of the Campaign Finance and Public Disclosure Board at: Suite #190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone (651) 539-1180 or 1-800-657-3889.

Adoption Procedure if No Hearing.

If no hearing is required, the agency may adopt the rules after the end of the comment period. MDH will submit the rules and supporting documents to the Office of Administrative Hearings for a legal review. You may ask to be notified of the date the rules are submitted to the office. If you want to receive notice of this, to receive a copy of the adopted rules, or to register with the agency to receive notice of future rule proceedings, submit your request to the agency contact person listed above.

Adoption Procedure after a Hearing.

If a hearing is held, after the close of the hearing record, the Administrative Law Judge will issue a report on the proposed rules. You may request to be notified of the date that the Administrative Law Judge's report will become available at the hearing or in writing directly to the Administrative Law Judge. You may also ask to be notified of the date that the agency adopts the rules and the rules are filed with the Secretary of State at the hearing or by writing to the agency contact person stated above.

Order.

I order that the rulemaking hearing be held at the date, time, and location listed above.

Date: 10/28/2024

Wendy Underwood
Deputy Commissioner
Minnesota Department of Health

Exhibit F. Document Authorizing the Omission of the text of the Proposed Rule in the Notice of Intent to Adopt Rules Published in the State Register

MINNESOTA
OFFICE OF
ADMINISTRATIVE
HEARINGS

PO Box 64620
Saint Paul, MN 55164-0620
mn.gov/oah

PH (651) 361-7900

October 11, 2024

VIA EMAIL ONLY
Justin Kwong
Minnesota Department of Health
625 Robert St N
St. Paul, MN 55101
justin.kwong@state.mn.us

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

Dear Justin Kwong:

Enclosed herewith and served upon you please find the **ORDER ON REVIEW OF ADDITIONAL NOTICE PLAN AND DUAL NOTICE** and **ORDER ON REQUEST TO OMIT FROM THE NOTICE THE TEXT OF PROPOSED RULES, PURSUANT TO MINN. STAT. § 14.14, SUBD. 1a(B)** in the above-entitled matter.

Prior to publishing the DUAL NOTICE in the State Register, please notify the Office of Administrative Hearings (OAH) at william.t.moore@state.mn.us in order to activate the agency's eComments page on OAH's website. **Please note that if you do not notify us of the publication, the eComments site will not be available to receive public comments.**

For the convenience of the Office of Administrative Hearings, the Administrative Law Judge requests the Minnesota Department of Health to change the contact information on page 3 of the Dual Notice, the paragraph titled Notice of Hearing, to read "Judge Moseng's Legal Assistant William Moore can be reached at the Office of Administrative Hearings, 600 North Robert Street, P.O. Box 64620, Saint Paul, Minnesota 55164-0620, telephone 651-361-7900 and fax 651-539-0310 or William.t.moore@state.mn.us."

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,

Nichole Sletten
Legal Assistant

Enclosure

OAH 22-9000-40331
Revisor R-4803

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Minn. R.4717.7500 and 4717.7860 Proposed Amendment to Rules Governing Health Risk Limits, Revisor's ID R-04803	**ORDER ON REQUEST TO OMIT FROM THE NOTICE THE TEXT OF PROPOSED RULES, PURSUANT TO MINN. STAT. § 14.14, SUBD. 1a(B)**

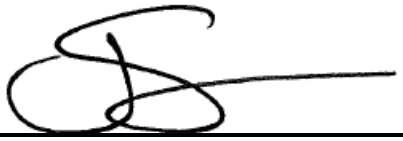
This matter came before Chief Administrative Law Judge Jenny L. Starr on October 7, 2024. The Minnesota Department of Health (Department) seeks an order authorizing the omission of the proposed rule text when it publishes the Notice of Intent to Adopt Rules Without a Hearing (Notice). The Department asserts that publication of the proposed rules in the *State Register* is cost-prohibitive.

As an alternative to publication, the Department pledges that the Notice will state that a free copy of the entire proposed rules will be available upon request to the Department and state how to make that request. The Notice also will identify the website link where a copy may be obtained. Finally, the Notice will state the subject matter of the omitted rules, cite the statutory authority for the proposed rules, and outline the proposed rules' purpose and motivation. In addition, the Department's Statement of Need and Reasonableness (SONAR) will be available free of charge by request and posted on the Department's website.

IT IS HEREBY ORDERED THAT:

Conditioned upon the Department's use of the procedures outlined in its petition of October 7, 2024, the petition to omit the proposed rule text is **GRANTED**.

Dated: October 11, 2024



Jenny L. Starr
Chief Administrative Law Judge

OAH 22-9000-40331
Revisor R-4803

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of Minn. R.4717.7500 and 4717.7860 Proposed Amendment to Rules Governing Health Risk Limits, Revisor's ID R-04803	**ORDER ON REVIEW OF ADDITIONAL NOTICE PLAN AND DUAL NOTICE**

This matter came before Administrative Law Judge Christa L. Moseng upon the Minnesota Department of Health's (Department) request for a legal review under Minn. R. 1400.2060, .2080 (2023) of the Additional Notice Plan and Dual Notice of Intent to Adopt Rules in the above-captioned proceeding.

Under its Additional Notice Plan, the Department plans to notify:

1. the parties listed on MDH's current rulemaking list under Minnesota Statutes, section 14.14, subdivision 1a;

2. the Legislature and the Legislative Reference Library;

3. the 8,537 subscribers (as of September 18, 2024) of MDH's Water Rules, Guidance and Chemical Review GovDelivery email subscription service account, which includes "most parties known to be interested in this topic, such as trade associations and industry advocates like the American Chemistry Council and the Minnesota Chamber of Commerce, several State agencies, several advocacy groups, state legislators, chemical manufacturers such as 3M, Bayer, and other companies, and members of the public; and,

4. other interested parties that the Department has identified, including 34 people in industry, advocacy, and governmental groups known to have an interest in the Rules, as it did during the Request for Comments phase of this rulemaking.

Based upon a review of the written submissions by the Department,

IT IS HEREBY ORDERED THAT:

1. The Additional Notice Plan is **APPROVED**.

2. The Dual Notice is **APPROVED**.

Dated: October 11, 2024

Christa L. Moseng
Administrative Law Judge

[211213/1]

Exhibit G. Certificate of Mailing (or emailing) the Notice of Intent to Adopt Rules and Certificate of Accuracy of the Mailing List

Certificate of Mailing the Dual Notice of Intent to Adopt Rules to the Rulemaking Mailing List

Minnesota Department of Health

Proposed Amendments to Rules Relating to Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID No.4803; OAH Docket No. 22-9000-40331

I certify that on October 29, 2024, at 2:00 p.m., at least 33 days before the end of the comment period, in St. Paul, Ramsey County, Minnesota, I mailed the Dual Notice, SONAR, and proposed rules by depositing a copy in the United States mail with postage prepaid to all persons on the Minnesota Department of Health's rulemaking list who prefer physical mail under Minnesota Statutes, section 14.14, subdivision 1a. Copies of the Notice and the email list are attached to this Certificate.

Nancy Rice Digitally signed by Nancy Rice Date: 2024.11.02 05:21:25 -05'00'

Nancy Rice
Research Scientist

AGENCY NOTIFICATION LIST FOR RULEMAKING

BY MAIL:

Twila Brase
CCHF
161 St. Anthony Ave., Ste. 923 St. Paul, MN
55103

Karen Hermes, CRM
Property Manager
2353 Youngman Ave.
St. Paul, MN 55116

BY EMAIL:

Michael J. Ahern
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402
ahern.michael@dorseyalumni.com

Minnesota Department of Health

CERTIFICATE OF ACCURACY OF THE MAILING LIST

Proposed Rules Governing Health Risk Limits, Minnesota Rules, Parts 4717.7500 and 4717.7860; Revisor's ID Number 4803

I certify that the list of persons and associations who have requested that their names be placed on the Department of Health rulemaking mailing list under Minnesota Statutes, section 14.14, subdivision 1a, is accurate, complete, and current as of November 1, 2024. A copy of the mailing list is attached to this Certificate.

Cretia Weaver
Legal Secretary

From:	Rice, Nancy (MDH)
To:	"ahern.michael@dorseyalumni.com"
Subject:	Health Risk Limit Rules for Groundwater: Notice of Intent to Adopt Rules, Revisor"s ID 4803
Date:	Thursday, October 31, 2024 8:09:00 AM
Attachments:	image002.png image003.png image004.png image005.png image006.png image007.png HRLProposedRules_20241029.pdf HRL-2024-DualNotice.pdf 20241028_HRLSONAR-Final.pdf

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Dear Michael J. Ahern:

The Minnesota Department of Health (MDH) is planning amendments to the existing Health Risk Limits (HRL) rule for Groundwater (Minnesota Rules, Chapter 4717, parts 7500 and 7860). We are contacting you because your name is currently on the Agency Notification List for Rulemaking maintained by MDH.

MDH will publish a Dual Notice of Intent to Adopt Rules in the State Register on Monday, November 4, 2024 (attached; see also the attached Statement of Need and Reasonableness and Draft Rules).

The proposed amendments to the Health Risk Limit Rules for Groundwater will add or replace HRL values developed by MDH between 2022 and mid-2023, including a value for PFOS. The amendments will add (to Minnesota Rules part 4717.7860) updated health-based guidance values for four chemicals that have been in Health Risk Limit Rules for Groundwater previously. The outdated HRL values (adopted in 1993, 1994, 2009, or 2018) for these four chemicals will be repealed (in Minnesota Rules part 4717.7500 or part 4717.7860) and replaced (in part Minnesota Rules part 4717.7860) by new HRL values. In addition, previously adopted HRL values for two chemicals (anthracene, adopted in 1993; and dichlorodifluoromethane, adopted in 2011) will be repealed and not replaced. For these two contaminants, new Risk Assessment Advice has already been posted on MDH's Human Health-Based Water Guidance Table.

More information is available from the MDH webpage Health Risk Limits Rules for Groundwater Rules Amendments - Overview and Links

For questions on the rule amendments, please contact Nancy Rice at (651) 201-4923 or via email at nancy.rice@state.mn.us.

Sincerely,
Nancy Rice

Nancy Rice
Research Scientist|Health Risk Assessment Unit

Minnesota Department of Health
Office: 651-201-4923


DEPARTMENT
OF HEALTH

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

October 29, 2024

Twila Brase
CCHF
161 St. Anthony Ave., Ste. 923
St. Paul, MN 55103

Re: Health Risk Limits Rules Amendments, Minnesota Rules, parts 4717.7500 and 4717.7860

Dear Twila Brase:

The Minnesota Department of Health (MDH) is planning amendments to the existing Health Risk Limits (HRL) rule for Groundwater (Minnesota Rules, Chapter 4717, parts 7500 and 7860). We are contacting you because your name is currently on the Agency Notification List for Rulemaking maintained by MDH.

The proposed amendments to the Health Risk Limit Rules for Groundwater add or replace HRL values with guidance values developed by MDH between 2022 and 2023, including a value for PFOS. The amendments will add health-based guidance values (to Minnesota Rules part 4717.7860) for four chemicals that have been in Health Risk Limit Rules for Groundwater previously. The outdated HRL values (adopted in 1993, 1994, 2009, or 2018) for these four chemicals will be repealed (in part 4717.7500 or part 4717.7860) and replaced (in part 4717.7860) by new HRL values. In addition, previously adopted HRL values for two chemicals (anthracene, adopted in 1993; and dichlorodifluoromethane, adopted in 2011) will be repealed and not replaced. For these two contaminants, new Risk Assessment Advice has already been posted on MDH's Human Health-Based Water Guidance Table, which is available at Human Health-Based Water Guidance Table (https://www.health.state.mn.us/communities/environment/risk/guidance/gw/table.html)

MDH will publish a Notice of Intent to Adopt Rules in the State Register on Monday, November 4, 2024 (enclosed). More information is available from the MDH webpage Rules Amendments - Overview and Links (https://www.health.state.mn.us/communities/environment/risk/rules/water/overview.html).

For additional information on the rule amendment, please contact Nancy Rice at (651) 201-4923 or via email at nancy.rice@state.mn.us.

Sincerely,

Nancy Rice
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975
651-201-4923

Encl: Copy of Notice of Hearing, Statement of Need and Reasonableness, and Proposed Rules

DEPARTMENT OF HEALTH

Protecting, Maintaining and Improving the Health of All Minnesotans

October 29, 2024

Karen Hermes, CRM
Property Manager
2353 Youngman Ave.
St. Paul, MN 55116

Re: Health Risk Limits Rules Amendments, Minnesota Rules, parts 4717.7500 and 4717.7860

Dear Karen Hermes:

The Minnesota Department of Health (MDH) is planning amendments to the existing Health Risk Limits (HRL) rule for Groundwater (Minnesota Rules, Chapter 4717, parts 7500 and 7860). We are contacting you because your name is currently on the Agency Notification List for Rulemaking maintained by MDH.

The proposed amendments to the Health Risk Limit Rules for Groundwater add or replace HRL values with guidance values developed by MDH between 2022 and 2023, including a value for PFOS. The amendments will add health-based guidance values (to Minnesota Rules part 4717.7860) for four chemicals that have been in Health Risk Limit Rules for Groundwater previously. The outdated HRL values (adopted in 1993, 1994, 2009, or 2018) for these four chemicals will be repealed (in part 4717.7500 or part 4717.7860) and replaced (in part 4717.7860) by new HRL values. In addition, previously adopted HRL values for two chemicals (anthracene, adopted in 1993; and dichlorodifluoromethane, adopted in 2011) will be repealed and not replaced. For these two contaminants, new Risk Assessment Advice has already been posted on MDH's Human Health-Based Water Guidance Table, which is available at Human Health-Based Water Guidance Table (https://www.health.state.mn.us/communities/environment/risk/guidance/gw/table.html)

MDH will publish a Notice of Intent to Adopt Rules in the State Register on Monday, November 4, 2024 (enclosed). More information is available from the MDH webpage Rules Amendments - Overview and Links (https://www.health.state.mn.us/communities/environment/risk/rules/water/overview.html).

For additional information on the rule amendment, please contact Nancy Rice at (651) 201-4923 or via email at nancy.rice@state.mn.us.

Sincerely,

Nancy Rice
Minnesota Department of Health
P.O. Box 64975
St. Paul, MN 55164-0975
651-201-4923

Encl: Copy of Notice of Hearing, Statement of Need and Reasonableness, and Proposed Rules

Exhibit H. Certificates of Additional Notice

H.1. Request for Comments

H.1.a. August 7, 2023 (signed January 13, 2025): Certificate of additional notice to 30 parties about the Request for Comments published in the *Minnesota State Register*.

H.1.b. August 7, 2023: Certificate of additional notice to the 6,416 subscribers to the Groundwater Rules, Guidance and Chemical Review account of the email subscription service, GovDelivery, about the Request for Comments published in the *Minnesota State Register* on August 7, 2023.

H.1.c. February 2023: Certificate of publishing an article in the Spring 2021 issues of Minnesota Department of Health's *Waterline*. This newsletter reaches 5,700 subscribers by email and 5,200 subscribers by mailed copy, with some potential overlap. Subscribers include state water operators and others interested in Minnesota's drinking water. See Waterline: Spring 2021 - MN Dept. of Health (state.mn.us) https://www.health.state.mn.us/communities/environment/water/waterline/spring2021.html#hrl.

H.2. Dual Notice

H.2.a. November 4 and 5, 2024: Certificate of additional notice to 48 parties about the Dual Notice of Intent published in the *Minnesota State Register* on November 4, 2024.

H.2.b. November 4, 2024: Certificate of additional notice to the 9,129 subscribers to the Groundwater Rules, Guidance and Chemical Review account of the email subscription service, GovDelivery, about a Dual Notice of Intent to Adopt Rules on the proposed Health Risk Limits Rules Amendments published in the *Minnesota State Register* on November 4, 2024.

H.1. Additional Notice: Request for Comments

H.1.a. August 7, 2023 (signed January 13, 2025): Certificate of additional notice to 30 parties about the Request for Comments published in the *Minnesota State Register*.

H.1.b. August 7, 2023: Certificate of additional notice to the 6,416 subscribers to the Groundwater Rules, Guidance and Chemical Review account of the email subscription service, GovDelivery, about the Request for Comments published in the *Minnesota State Register* on August 7, 2023.

H.1.c. February 2023: Certificate of publishing an article in the Spring 2021 issues of Minnesota Department of Health's *Waterline*. This newsletter reaches 5,700 subscribers by email and 5,200 subscribers by mailed copy, with some potential overlap. Subscribers include state water operators and others interested in Minnesota's drinking water. See Waterline: Spring 2021 - MN Dept. of Health (state.mn.us) https://www.health.state.mn.us/communities/environment/water/waterline/spring2021.html#hrl and story on page 32 below "MDH to Propose Updates to Health Risk Limits Rules."

Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan Via Email to Interested Parties: Request for Comments

Minnesota Department of Health

Division of Environmental Health

Request for Comments on Possible Amendments Relating to Health Risk Limits Rules for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID 4803

I certify that on August 7, 2023, by email through the Minnesota Department of Health's network and email service between approximately 9:00 a.m. and 9:30 a.m., I gave additional notice to 30 interested parties about the Request for Comments on Possible Amendments to Rules Governing Health Risk Limits for Groundwater published in the *State Register* on August 7, 2023. The notification included an email message to the interested party with a link to the State Register document at Request for Comments in the *Minnesota State Register* (https://mn.gov/admin/assets/SR48_06%20-%20Accessible_tcm36-586643.pdf#page=18).

Examples of the notified parties include industry representatives, industry trade organizations, environmental advocacy groups, academicians, and staff at other state and regional agencies who implement the Health Risk Limits. All contacted parties have shown past interest in the Health Risk Limits Rules.

If an email address was not available for the known interested parties, I searched for a different contact method, such as a form on the company's website or a phone number.

An example of an email notification is attached to this Certificate.

Nancy Rice Digitally signed by Nancy Rice
Date: 2025.01.13 16:25:12 -06'00'

Nancy Rice
Research Scientist
Health Risk Assessment Unit
Minnesota Department of Health

From:	Rice, Nancy (MDH)
To:	oataiwo@mmm.com
Subject:	Minnesota Department of Health to begin rulemaking to update the Health Risk Limits rule for PFOS
Date:	Monday, August 7, 2023 9:04:00 AM
Attachments:	image001.gif

Good morning,

3M has expressed past interest in Minnesota Department of Health's (MDH) rulemaking activity for health risk limits (HRLs) for water. This is a courtesy notification to inform you that MDH has been instructed via Session Law from the 2023 Minnesota Legislature to "amend the health risk limit for perfluorooctane sulfonate (PFOS) in Minnesota Rules, part 4717.7860, subpart 15, so that the health risk limit does not exceed 0.015 parts per billion..." (Laws of Minnesota, Chapter 60, Article 3, Section 34) This work must be completed by July 1, 2026.

More information is available on our website at Rules Amendments – Overview and Links (https://www.health.state.mn.us/communities/environment/risk/rules/water/overview.html)

We published a Request for Comments in the *Minnesota State Register* on Monday, August 7, 2023. The Request for Comments is simply the first step in the rulemaking process and an opportunity to obtain input from stakeholders. The Request for Comments will remain open at least until October 7, 2023, and another more formal comment period will be held at a later time. An email notification to subscribers of the MDH Water Rules, Guidance and Chemical Review account will be sent to notify subscribers about input opportunities during the rulemaking process. Subscriptions to this account are available from Minnesota Department of Health (govdelivery.com).

If you have questions, or if this notification should be sent to others at your organization, please contact me at 651-201-4923 or nancy.rice@state.mn.us.

Sincerely,

Nancy Rice

Nancy Rice

Research Scientist | Health Risk Assessment Unit

Minnesota Department of Health

Office: 651-201-4923

Minnesota Department of Health logo

Minnesota Department of Health

CERTIFICATE OF GIVING ADDITIONAL NOTICE PURSUANT TO THE ADDITONAL NOTICE

Proposed Rules Governing Health Risk Limits for Groundwater, Minnesota Rules, Parts 4717.7500 and 4717.7860

I certify that on August 7, 2023, at approximately 10:30 a.m. I sent an electronic mail (email) notification using the Minnesota Department of Health electronic network to the 6,416 subscribers of the Groundwater Rules, Guidance and Chemical Review account of the email subscription service, GovDelivery. The message announced the Request for Comments on Possible Amendments to the Rules Governing Health Risk Limits for Groundwater, Minnesota Rules, Parts 4717.7500 and 4717.7860, published in the *Minnesota State Register* on August 7, 2023. A link to the *State Register* and to the MDH Health Risk Limit Rules website was included in the message. A copy of the notification is attached to this Certificate.

/s/ Azra Thakur
Azra Thakur, MPH
Planner Principal
Health Risk Assessment Unit

From: Minnesota Department of Health
To: Rice, Nancy (MDH)
Subject: Request for Comments on Rules Governing Health Risk Limits
Date: Monday, August 7, 2023 10:32:32 AM

minnesota department of health

Request for Comments on Possible Amendments to Rules Governing Health Risk Limits for Groundwater Minnesota Rules, Parts 4717.7500 and 4717.7680

The Minnesota Department of Health (MDH) is seeking comments for possible amendments to rules on Health Risk Limits (HRLs) in Groundwater and has published a Request for Comments in the Aug. 7, 2023, issue of the *Minnesota State Register*. A copy of the Request for Comments is available at: Request for Comments on Possible Amendments to Rules Governing Health Risk Limits

As required by 2023 Session Law, Chapter 60, Article 3, Section 34, MDH plans to amend the HRLs for perfluorooctane sulfonate (PFOS) in Minnesota Rules, part 4717.7860, subpart 15, so that it does not exceed 0.015 parts per billion. In addition, new or updated water guidance values that are eligible for rulemaking will be included in this rule. The possible amendments include new values for some chemicals and replacement of outdated values for other chemicals. For more information see: Health Risk Limits Rules for Groundwater Rules Amendments - Contaminants.

Additional chemicals may be added to the list if water guidance is derived in time to be included in the proposed HRL rule amendments. MDH will announce any changes to the list via GovDelivery and by posting the update on the above webpage.

For more information about the possible amendments and how to share your comments with MDH, visit: Rules Amendments - Overview and Links.

Minnesota Department of Health

CERTIFICATE OF GIVING ADDITIONAL NOTICE PURSUANT TO THE ADDITIONAL NOTICE PLAN TO PARTIES WITH POTENTIAL INTEREST IN THE HEALTH RISK LIMIT RULES AMENDMENT VIA PUBLICATION IN THE *WATERLINE* NEWSLETTER.

Proposed Rules Governing Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID Number 4587

I certify that in November 2023, at St. Paul, Ramsey County, Minnesota, Minnesota Department of Health (MDH) provided information about the Health Risk Limits Rules via publication in the MDH newsletter called the *Waterline*. Specifically, an article about the Health Risk Limits Rules Amendments Request for Comments was published in the Winter 2023-2024 issue. This newsletter currently reaches about 7,7000 subscribers by email subscription and approximately 75 subscribers by mail, with possibly some overlap. Subscribers include water system operators and others interested in Minnesota drinking water. A copy of the issue that contained the article is online at Waterline:Winter 2023-2024 (https://www.health.state.mn.us/communities/environment/water/waterline/winter20232024.html)

Nancy Rice
Digitally signed by Nancy Rice
Date: 2024.11.06 15:00:50 -06'00'

Nancy Rice
Research Scientist
Health Risk Assessment Unit, MDH

Waterline: Winter 2023 - 2024

Editor:
Stew Thornley

Editor:
Noel Hansen, Erin Culver, Bob Smude

Subscribe to The *Waterline* newsletter. An e-mail notice is sent out each quarter when a new edition is posted to the web site.

On this page:

Minneapolis wins State Fair Tap Water Taste Test

Minneapolis won the Great Minnesota State Fair Tap Water Taste Test, held on the Sustainability Stage of the EcoExperience building at the State Fair August 24. St. Cloud was the runner-up while LeSueur finished third and Moorhead fourth. Past champions of the taste test are Golden Valley, International Falls, Fairmont, St. Cloud, Lake Elmo, Chaska, Crookston, and Saint Peter.

Below, Smiling Bert Tracy (on the right) looks on as WCCO Radio host Jason DeRusha (on the left) talks about the contest and high quality of Minnesota water with a committee member later that day.

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Education in Minneapolis

Minneapolis Water Works hosted educational activities at two of its locations in August. Above, in Columbia Heights, teachers attended the Drinking Water Institute and got to see the old filter plant, which had been used through 1993. The teachers participated in interactive exercises in the lobby of the ultrafiltration plant with the membranes shown behind them. The Drinking Water Institute, in which Minnesota science teachers learn about water and develop ways to incorporate it into their existing curriculum, has been held since 2001. Next year it will be at St. Paul Regional Water Services from July 29 to 31.

Drinking Water Institute

In mid-August Minneapolis held a pair of two-day workshops on filter survelliance for their operators and supervisors. Conducted by Hazen and Sawyer of St. Paul and held at the utility's filter plant in Fridley, the training consisted of classroom presentations and hands-on training to examine filter conditions for the purpose of optimizing operations and backwashing. In the photo below, Ken Funt and Eric Pederson perform turbidity analysis on backwash water.

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SDWA video updated for 50th anniversary

Ten years ago, an anniversary video was made to celebrate 50 years of the federal Safe Drinking Water Act, featuring appearances by Al Quie (shown above) and Walter Mondale, who were in Congress when the act was passed.

50th anniversary Safe Drinking Water Act video

The 40-year anniversary got more than 28,000 views and is still on-line.

40th anniversary Safe Drinking Water Act video

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What's shaking at MDH?

Kylie Jacobsen (above) has joined the Drinking Water Protection (DWP) Section as a strategic initiatives and communications coordinator. She will be working on activities related to source water protection, Clean Water Fund projects, and outreach efforts.

Spouse- and child-free, Kylie has two cats, Bean and Yogi.

She is from the Twin Cities and is back after seven years in Madison, Wisconsin (retaining her fandom for the Vikings and Gophers rather than the Packers and Badgers). Her background is in public health and science communication. Most recently, Kylie was managing nutrition security programs with Second Harvest, a Feeding America foodbank.

She adds, "I love all things outdoors, particularly rock climbing and exploring national parks. I'm also a big foodie who loves cooking, baking, and trying new restaurants."

Janelle Ruth has joined DWP as a management analyst working primarily in the Minnesota Drinking Water Information System. Janelle grew up in Apple Valley and got her degree in earth sciences with an emphasis on hydrogeology at the University of Minnesota. Before joining MDH, she worked for Dakota County's Groundwater Protection Unit, managing the Well

Sealing Grant program. She also has experience working as an environmental consultant and as a hazardous waste laboratory technician. As a huge animal lover, Janelle has also volunteered with multiple animal rehabilitation/wildlife organizations, during which she routinely fed black bears and a variety of baby birds. In her spare time, she enjoys snuggling with her bunny, painting, and playing board games.

Johanna Hayden is the new communications and strategic initiatives specialist in the Minnesota Department of Health DWP Section. A native of Dallas (and a Cowboys fan, of course), she has lived and worked in Germany and Miami in addition to the Texas towns of Dallas and Austin. She loves to travel and has been to 29 countries. With a master's degree in neuroscience/neuropsychology, Johanna was worked in education as a teacher and in corporate communications with FEMA, the Department of Defense, and biotech industries.

Johanna is married to her high school sweetheart, Ian, and they have four children (ages 6 to 19) and one very opinionated Yorkie. Johanna says, "We decided to relocate our family to Minnesota after seeing the incredible natural beauty, the wonderful people, and the way that this state is committed to creating better lives for all its citizens. We have been here just under a year and couldn't be happier. Thank you Minnesota for welcoming us with open arms!"

Sam Swanson is a compliance engineer in the CPWS Unit. Born and raised in St. Paul, he went to college in Rochester, New York, and got a bachelor's degree in chemical engineering. His studies included a Photography in Cuba course, which took him to Cuba for two weeks taking pictures. He also worked his way through the YMCA Camp Menogyn program, which included a six-week canoe and camping trip through the Arctic, all the way up to Nunavut in Canada. Sam also enjoys playing chess and reading science fiction.

David Rindal has returned to the Community Public Water Supply (CPWS) Unit after an absence of more than two years following a serious injury.

Karla Peterson, previously the supervisor of the CPWS Unit at the Minnesota Department of Health (MDH), has become the chief engineer and technical advisor for MDH's Drinking Water Protection Section. She will be the principal technical authority for all aspects of engineering and operations for public water systems.

Andrew Karp is now the engineer for the Metro-South District, succeeding **Jessie Kolar,** who moved to the Infrastructure Unit

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Cold Spring opens first treatment plant in state to treat nitrate biologically

Known for beer and baseball, the central Minnesota city of Cold Spring relies on a steady supply of safe drinking water to keep its businesses humming and its 4,000 residents hydrated. Cold Spring is typical in this regard, its most important resource not being its most prominent. And like other townships and cities in the area, Cold Spring is surrounded by farms and the corresponding challenges agriculture brings to its aquifers, often seen through rising nitrate levels in water.

However, Cold Spring employees note that the issues are a result of more than farming and fertilizers. Public works director Jon Stueve said that agriculture was more of a problem historically than now. “The Department of Ag [Minnesota Department of Agriculture] has done a lot, especially in this area, with the farmers, and they regulate what they do put on the fields. There is a lot of participation from our farmers. They’re doing all they can.”

Tanya Schmidt, the city’s water and wastewater supervisor, echoed Stueve’s sentiments. “When the new generation [of farmers] comes in, you can see it. I grew up on a farm, and I can see the difference when you get the younger generation coming in,” she said before touching on the primary issue they face. “It’s tough geology here.”

Cold Spring has four wells ranging from 63 to 125 feet deep that draw from Quaternary Water Table aquifer. The city has stayed below the maximum contaminant level of 10 parts per million (ppm) for nitrate and was able to keep the level around 5 ppm by blending the wells. Nevertheless, there was a desire to bring the nitrate down even more.

The first approach involved looking for different water sources, according to Ryan Capelle of Stantec, a Minneapolis engineering firm that studied Cold Spring’s options. Quickly determining

that treatment would be necessary, Stantec partnered with the city and AdEdge Water Technologies, LLC of Duluth, Georgia, on a pilot study with input and guidance from the Minnesota Department of Health (MDH).

Ion exchange is a common technique for reducing nitrate, but Capelle cited operational issues, particularly the waste stream it would create, as a drawback. Other technologies have been emerging, including one that has been a staple in wastewater treatment: biological filtration. Bacteria has long been used to consume waste materials in water.

In 2007, Hutchinson became the first Minnesota city to use the process for drinking water. Eric Meester, an engineer on the Hutchinson project, said that the longtime success of chemicals for treating drinking water caused resistance to alternative technologies, adding, “The success of chemical treatment has been documented for a long time. Biological removal has occurred naturally for longer, but no one looked for it or why it existed.”

While Hutchinson chose bacteria to treat for iron and manganese and others have used it to reduce ammonia in the water, Cold Spring became the first in the state to use it for nitrate removal. It was “a willingness of Jon and Tanya to be pioneers that opened the door to look at treatment under a new light,” said Capelle. Timing was a factor, too, with the city getting $4 million in a 2018 state bonding bill. “The technology emerged at the right time,” added Capelle. “People were willing to embrace it.”

The pilot study began in 2018 in the bottling facility of Cold Spring Brewing Company, adjacent to the city’s wells and the site of the new plant, which went on-line in May 2023. A two-stage fixed-bed biological treatment system, the process is efficient operationally in addition to being environmentally friendly.

Above: Jon Stueve and Ryan Capelle in front of the filters.

Below: Capelle points out the direction of the incoming water to Maria Spitael of the Minnesota Department of Health.

The two-stage process starts in a pressure filter with granular activated carbon (GAC) “This is where the magic happens,” said MDH engineer Brian Noma. The filter is where the denitrifying bacteria live in anoxic (low oxygen) conditions. Acetic acid is added as a carbon source and phosphoric acid as a nutrient. “This creates a favorable environment for the microbes to flourish,” explained Capelle. “This makes them hungry, makes them want to eat the nitrate in Stage 1.

“And now the nitrate is all virtually removed. We then add oxygen with peroxide. We are reoxygenating on the way to stage 2.” The second filter, consisting of 30 inches of GAC on top of 20 inches of sand, removes the excess biomass, in essence polishing the water.

Any of the four wells can go directly to the clearwell or through the plant. “It’s about a 50-50 split,” Capelle said, describing it as a header-type system to blend with any given well and produce 500 treated gallons per minute.

Chlorine is available at the front end of the clearwell, fed at a low dose after treatment. “We don’t want to overchlorinate because that is our source for backwash water,” Capelle said. “We don’t want the backwash water to kill the microbes, so we want the chlorine residual to be low, but not nonexistent at this point.”

The $6 million project included a pipe gallery, additional clearwell capacity, a laboratory and control room, and a large chemical room that allows them to buy in bulk, according to Steuve.

The results have been as desired, the finished water coming out with under 5 ppm, less than half of the MCL.

Photos of the pipe gallery and the top of the pressure filters.

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NE Ohio Regional Sewer District provides important election information

The X/Twitter account for the Northeast Ohio Regional Sewer District is always a source of relevant information on important and topical issues.

On November 7, it provided a cogent and inspirational reminder to vote.

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MRWA offers apprenticeship program

The Minnesota Rural Water Association (MRWA) is offering a registered apprenticeship program. Approved by the Minnesota Department of Labor and Industry, the program provides formal training in the industry.

The two-year apprenticeship program, which can be reduced and broken into three six-month periods for those with a Class D water/wastewater license, has been an initiative of the National Rural Water Association for direct entry and training into the workforce. Interested parties may go to the NRWA website.

Those with questions may contact Joel Jasmer of MRWA, 218-671-3475.

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DWRF funds the north shore

From south to north (or more specifically, southwest to northeast), Duluth and Two Harbors are the first two Minnesota cities to draw water from Lake Superior. With an Ojibwe name of Gitche Gumee (just ask Henry Longfellow, or Gordon Lightfoot for that matter, if you don't believe it), Superior is the largest freshwater lake in the world. In addition to Duluth and Two Harbors, it is the water supply for Beaver Bay, Silver Bay, Grand Marais, smaller cities along the north shore. As the two largest cities supplied by the big lake, Duluth (above left) and Two Harbors (above right) have also been regular recipients of money from the state Drinking Water Revolving Fund (DWRF) and both have been putting it to good uses lately.

Duluth - Conquering the city

Nearly $4 million ($3,857,531 to be exact) of DWRF money has helped Duluth install new pumps at its booster station, a structure that goes back to the 19th century and that is flanked by a 14-million-gallon reservoir that is young by comparison, having been rebuilt in 1922.

Duluth has a lake-to-hill geographic profile. The first few inland blocks are flat, but the topography quickly becomes hillside, rising abruptly and steeply. For much of the city's history, an incline served residents needing to go back and forth in an up-and-down manner.

Lake Superior is approximately 600 feet above sea level, the lowest part of Minnesota. The elevation change between the utility's intake and adjacent treatment facility on the lake is about 280 feet to the booster station. From there the water travels upward through two other reservoirs and two other pump stations, eventually climbing 950 feet above Lake Superior to the Highland tower, the highest point in Duluth's water system, supplying Duluthians along the way as well as the consecutive systems of Hermantown and Rice Lake. In all, Duluth has eight major pressure zones and a handful of smaller ones.

Duluth's Aaron Soderlund said the new pumps are only the fourth set in the history of the booster station. The three pumps, he explained, usually run one at a time at 3,300 gallons per minute (gpm). They can get up to 5,000 gpm with two pumps running but rarely do. "The problem with getting up to those flow rates is our pressures," Soderlund added.

The pumps and surge tank in the Duluth booster station.

The pumps are on the same spots as the previous ones although the new pipes are underneath the building. Another change was the addition of a surge vessel with a bladder tank. Soderlund said

they considered the need for a quick shutoff of the pumps in case of a power interruption. “We had some issues in the upper end of this zone, where we would have negative pressure, so the surge vessel is to handle the surge coming back from the stations to alleviate those problems.”

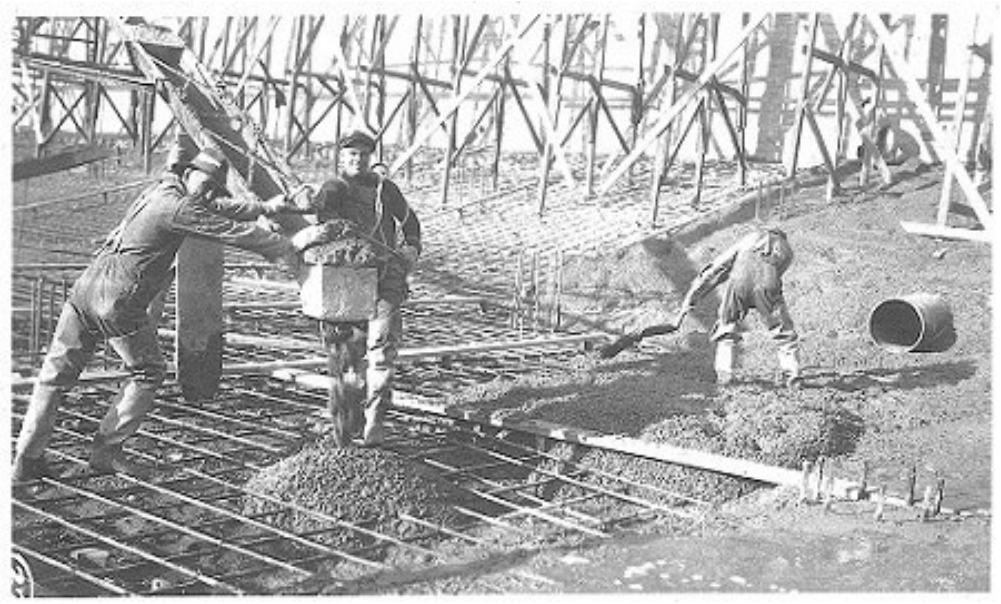
The booster station, shown in the 1930s, had a gas lantern on the front. The mounting is still visible behind Corey Mathisen, Sabrina Sutter, and Chad Kolstad of the Minnesota Department of Health and Aaron Soderlund of Duluth.

The pump project began in early 2022 and went on-line in stages. A challenge encountered along the way was with two suction lines, one coming in off the street and the other directly from the reservoir. Just outside the booster station is an original valve, which hooks up to the station. More than 130 years old, the valve didn't work. A diver from AMI Consulting Engineers of Superior, Wisconsin, went into the reservoir to plug a 20-inch intake line to allow for the installation of a new valve.

"We needed to close the valve to put in our suction piping for the new pump," said Soderlund. "We couldn't close the valve to isolate off the reservoir to do our work within the station." The diver put in a ball to plug the intake line long enough to put in the new valve and then complete the suction piping to a new pump. Soderlund said that during the six-to-eight hours it took, "The only thing we had from emptying the 14 million gallons out of that reservoir was that plug.

"That was nerve wracking to say the least." The challenges surmounted, Duluth completed the work in 2023.

The city's incline to elevate people was phased out with the coming of new-fangled contraptions such as the automobile. But the transport of water upward is still performed with the same methods that have served Duluth well for more than 100 years.



Installation of the 20-inch suction pipe in 1922 and a look at it from within the reservoir a century later.

Two Harbors - The project that keeps on giving

With DWRF money allocated in 2015 with the rehabilitation of a building housing high-service pumps, Two Harbors continued to benefit from the funding in replacing its chlorine contact facility several years later.

Located about 25 miles northeast of Duluth, Two Harbors came together from the communities of Agate Bay and Burlington, each of which has a bay formed by a southern-jutting promontory.

Two Harbors has had water facilities on Burlington Bay for more than 70 years with a power plant existing on the site even before that. A chlorine contact tank was added in 1958 and a filtration plant about 20 years later. High service pumps, which were replaced in 2016, have been around at least as long as the contact tank.

Bolton & Menk, Inc., began working with Two Harbors in 2016 with the rehabilitation of the high-service pump building. During the project, leaking water was discovered from the chlorine contact tank. Brian Guldan of Bolton & Menk said they installed a drain tile as a temporary fix and put a complete replacement of the tank on their to-do list.

It began getting done a few years later, starting with the demolition of the parking lot south of the existing chlorine contact tank. Space restrictions didn't allow for construction of the new tank until at least part of the lot was removed. "They are building half of the new one," said Guldan in the fall of 2023. "The new one will go on-line and get tested, and then the old tank will be demolished and the project completed." Even with one tank at a time during construction, the flow rates can be adjusted to ensure proper contact time.

After the old chlorine contact tank is removed, they will build a second tank next to the new chlorine contact tank, giving the plant two independent tanks with pump chambers to allow for half the tank to be taken out of service for maintenance and still have the capability to produce water at half the capacity.

Above: Dan Foster and Brian Guldan of Bolton & Menk flank Chad Kolstad of the Minnesota Department of Health atop the intake structure on Burlington Bay of Lake Superior. Below: Construction on the chlorine contact tank.

The water treatment facilities have the bay and Lake Superior as a scenic backdrop. The previous contact tank partially blocked the view of the water for nearby residents, who were thrilled to learn that the new structure will be lower, affording an unobstructed vista.

Not just neighbors are enjoying the view. The treatment plant is south of Lakeview Park, which has a trail that is popular with visitors, leading to questions of how to keep people off the new contact tank. One night, Guldan discussed the situation with Chad Kolstad of the Minnesota Department of Health and Luke Heikkila, then the city's water superintendent. Heikkila said, "Why don't we turn it into a lookout?"
After Kolstad said he had no problems with the idea, Heikkila turned to Guldan and said, "Make it happen."

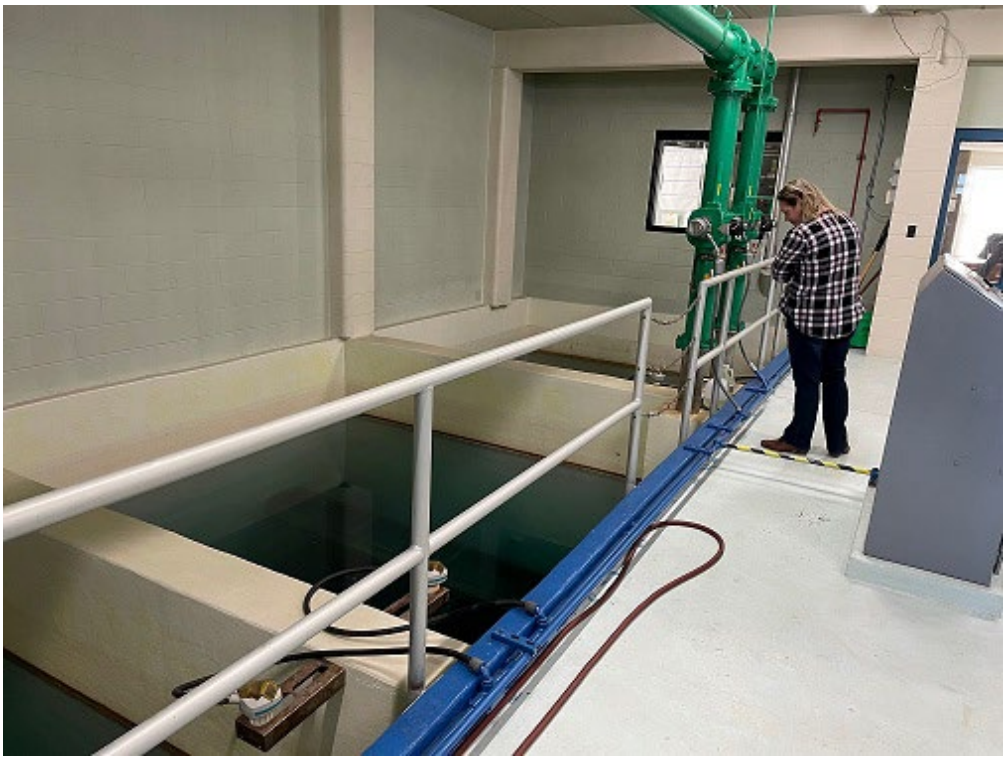
The trio sketched a plan on a napkin for the trail to have access, including a handicapped-accessible ramp, to the top of part of the tank. A railing will separate the lookout from the part of the tank with the hatches. "This way there is a spot to direct people to," said Guldan.

Two Harbors's water treatment plant has three gravity filters with silica sand and anthracite. Chlorine is added to the water coming in from the lake, and then poly aluminum chloride for the rapid mix, although the raw water normally meets turbidity standards even without chemical addition. After flocculation, the water is filtered and sent to the chlorine tanks.

Elevation differences in Two Harbors aren't as dramatic as in Duluth. From the plant the water goes through two booster stations in series to a 1.25-million-gallon tower in the northern part of the city and then to a second tower, this one 100,000 gallons, to the northwest. In addition to the booster stations and towers, Two Harbors has seven pressure reducing stations.

“The project that keeps on giving,” is how Guldan describes the work that began in 2016 and is encompassing the upgrade of the building with the high-service pumps, filter rehabilitation in the treatment plan, the chlorine contact tank, a new maintenance garage, and pipe and valve replacements. “This project will take care of their major needs for 20 years.”

The flocculation basins(above) and filters (below) in Two Harbors.



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When your water tower is down

By Shawn Mulhern and Ben Feldman, KLM Engineering

Do you have a water system that operates with only one tower or ground storage tank in your distribution system? If so, have you considered the impacts to your system if an issue arises and that reservoir needs to be removed from service for an extended period?

Here are some aspects to consider:

Well operations: Has your utility considered the electrical cost impact of operating a well 24/7 compared to normal usage? Operating 24/7 requires the use of at least one pressure relief valve on a hydrant to not exceed normal system pressure. Have you considered the amount of water being dumped or wasted? Have you considered the aquifer impact of significantly increasing the pumping from your well for this time period? Is the static/pumping water level and draw down going to be an issue? Do your wells have the capacity to operate in such a format? If a well were to go down or have maintenance issues during this time, would you be able to handle demand? Has your system been operated in such a manner in the past? Consider that operating outside of typical conditions can potentially lead to watermain breaks.

Treatment chemical usage: Have you considered how water quality will be maintained? Have you factored the increased cost of chemicals and additional treatment being wasted with the high volume of well pumping? If the project takes longer than two weeks, have you considered lead and copper impacts? Have you discussed availability of products with your material supplier?

Water discharge: Have you considered the water-wasting discharge location so you avoid discharge to water bodies and meet wastewater limits? Can the discharge location handle the water? Is dechlorination of the waste stream being performed to prevent the killing of wildlife?

Fire protection: Can your system maintain fire protection during this time? How does it impact utility insurance? What about auxiliary power during a fire or power outage? Is there a back-up system implanted?

Power outage: Does your system have backup power to address and maintain system pressure during an outage if the reservoir is out-of-service?

Project timing: Have you considered timing the project to coincide with low water usage periods? Have you informed stakeholders of ways to avoid system issues, such as not flushing watermains during this time or through water conservation measures by larger customers?

Cross-connection (for multi-tower systems): For multi-tower systems, do you have a cross-connection with another tower, separated with a pressure-reducing valve, that could be put into use?

The Minnesota Department of Health (MDH) has noticed the issuance of boil-water notices tends to occur more often for loss-of-pressure events associated with storage maintenance activities.To better avoid such incidents, MDH has some economical and proven recommendations to maintain distribution pressure and water quality that should be included when planning reservoir projects. These include auxiliary power at the wells, well pumps with variable frequency driven motors, and/or rentable, portable, pressure tanks for the duration the reservoir is out-of-service.

For more information, contact your MDH district engineer.

Can't get enough of water towers?

Water towers can be the most visible landmark in a city and a way to promote municipal pride. During the spring and summer of 2023, KSTP Television in the Twin Cities had a *Water Tower Wednesday* feature. The final installment profiled Kirk and Connie Brown, who created a website on which they have documented more than 1,000 water towers in Minnesota.

The site categorizes towers by city, county, and type. Along with a location of the tower and the year it was built, it has a picture of the tower. Check it out:

Minnesota Water Towers

MDH proposing updates to health risk limits rules

The Minnesota Groundwater Protection Act authorizes the Minnesota Department of Health to develop and review health risk limits (HRLs) in cases of groundwater degradation. In recent years, MDH has been working on a rulemaking process to adopt water guidance values called "Health-Based Values" into Minnesota rules as HRLs. In November 2023, the Minnesota Department of Health adopted two new health risk limits (HRLs) for 17 contaminants and updated for another 19. The HRL for one contaminant, n-Hexane, was repealed.

In addition, in 2023 the Minnesota legislature required MDH to adopt an updated HRL for perfluorooctane sulfonate, a perfluoroalkyl substance, by June 2026. MDH will likely include updated values for perfluorooctanoate and other contaminants. A request for comments was issued in August.

More information:
Human Health-Based Water Guidance Table
Rules Amendments - Overview and Links

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Public Health Priority Points information

Projects submitted to the Drinking Water Revolving Fund are prioritized using rule-defined Public Health Priority Points to ensure that funding priority goes to projects that protect public health, provide adequate water supply, and assist communities with financial needs.

The proposed revisions would allow priority points to be assigned for projects relating to the removal of lead service lines and addressing contaminants of emerging concern when concentrations exceed a health advisory level. The proposed changes would protect public health by reducing the public's exposure to harmful contaminants and assist communities with financial needs to remove or provide treatment to reduce contaminants.

More information:
Public Health Priority Points Rules

Go to top

Professional Operator Development Program announces new course for 2024

Conducted by the Minnesota Section of American Water Works Association in conjunction with utility partners and the Minnesota Department of Health, the Professional Operator Development program is an instructor-led series of lectures, hands-on lessons, and facility tours to enhance an

operator's knowledge of the basic principles needed to operate and manage an advanced public water system.

Open to anyone who has at least a Class C water operator license, the course covers general math, filtration, membrane and ion exchange, disinfection, water quality, regulations, source water, and sampling. The goal of the course is to build competence, confidence, and understanding of public water systems.

The next course will take place on Tuesdays from January 16 to March 19, 2024 from 7:30 a.m. to 2:30 p.m. at the Minneapolis Water Works membrane facility in Columbia Heights. The fee for the course is $300. Each week of attendance earns operators six contact hours toward the renewal of their licenses. An operator certification exam for students will be offered at the conclusion of the course.

Registration information

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Quote of the quarter (and other gems)

A successful person is the one who went ahead and did the thing the rest of us never quite got around to doing.

A truly great library contains something to offend everyone.

We can measure our prosperity not by what we have but by what we take for granted.

Life is not about how fast you run, or how high you climb, but how well you bounce.

It isn't what you know that counts; it's what you can think of in time.

Go to top

Reminder to all water operators

When submitting water samples for analyses, remember to do the following:

- Take coliform samples on the distribution system, not at the wells or entry points.
- Write the Date Collected, Time Collected, and Collector's Name on the lab form.
- Attach the label to each bottle (do not attach labels to the lab form).
- Include laboratory request forms with submitted samples.
- Do not use a rollerball or gel pen (the ink may run).
- Consult your monitoring plan(s) prior to collecting required compliance samples.

Notify your Minnesota Department of Health district engineer of any changes to your systems.

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Calendar

Operator training sponsored by the Minnesota Department of Health and Minnesota AWWA will be held in the coming months.

- Minnesota Water Operators Training Schedule

Register for schools and pay on-line:

- MN AWWA Community Calendar

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Tags

- environment

H.2. Additional Notice: Dual Notice of Intent to Adopt Rules

H.2.a. November 4 and 5, 2024: Certificate of additional notice to 48 parties about the Dual Notice of Intent published in the *Minnesota State Register* on November 4, 2024.

H.2.b. November 4, 2024: Certificate of additional notice to the 9,129 subscribers to the Groundwater Rules, Guidance and Chemical Review account of the email subscription service, GovDelivery, about a Dual Notice of Intent to Adopt Rules on the proposed Health Risk Limits Rules Amendments published in the *Minnesota State Register* on November 4, 2024.

Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan Via Email to Interested Parties: Dual Notice

Minnesota Department of Health

Division of Environmental Health

Proposed Rules Relating to Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860, Revisor's ID 4803; OAH Docket No. 22-9000-40331

I certify that on November 4, 2024, between 7:15 a.m. and 9:07 a.m., I gave notice to 46 interested parties according to the Additional Notice Plan approved by the Office of Administrative Hearings on October 11, 2024. Additionally, on November 5, 2024, between 9:51 a.m. and 9:58 a.m. I gave notice to two additional interested parties for which a correct email or method of contact needed to be identified. Interested parties notified include people who have expressed interest in or participated in the Health Risk Limits rules process in the past, such as representatives for industries that produce chemicals that could be subject to the Health Risk Limits, environmental and health advocacy groups, and government officials that monitor, regulate, or remediate environmental releases of the chemicals.

Specifically, I sent an electronic email notification with a message that announced that a Dual Notice of Intent to Adopt Rules for the Proposed Amendments to the Health Risk Limits for Groundwater in Minnesota Rules, Parts 4717.7500 and 4717.7860, had been published in the *State Register* on November 4, 2024. The Dual Notice, Statement of Need and Reasonableness (SONAR), and Proposed Rules were attached to the message. The message indicated that a comment period would be open from November 4th to December 4th at 4:30 p.m. The announcement also contained links to more information about the proposed amendments and to the OAH's eComments website.

Also included in the email was a copy of an Errata. The Errata noted a typo related to the unit value when citing Laws of Minnesota 2023, Chapter 60, Article 3, Section 34. The units were mistakenly printed as "ppm" in the Notice of Intent but should have been listed as "ppb." The Errata was published in the November 11th version of the *State Register*.

An example of the notification is attached to this Certificate, along with the materials sent.

Nancy Rice Digitally signed by Nancy Rice
Date: 2025.01.14 11:40:47 -06'00'

Nancy Rice
Research Scientist
Health Risk Assessment Unit

From:	Rice, Nancy (MDH)
To:	nels@conservationminnesota.org
Subject:	Health Risk Limit Rules Amendments - Dual Notice to be published on Monday, November 4, 2024
Date:	Monday, November 4, 2024 7:15:00 AM
Attachments:	HRL-2024-DualNotice.pdf HRLProposedRules_20241017.pdf 20241028_HRLSONAR-Final.pdf image002.png image003.png image004.png image005.png image006.png image007.png 20241101_Errata.pdf

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Dear Nels Paulson:

You are being contacted because you or your organization has expressed past interest in the Minnesota Department of Health's Health Risk Limits Rules for Groundwater.

Minnesota Department of Health (MDH) is planning amendments to the existing Health Risk Limits (HRL) rule for Groundwater (Minnesota Rules, Chapter 4717, parts 7500 and 7860). MDH will publish a Dual Notice of Intent to Adopt Rules in the State Register on Monday, November 4, 2024 (see attached Dual Notice, Statement of Need and Reasonableness (SONAR), and Proposed Rules, as well as the attached Errata). MDH will be accepting comments on the proposed amendments from Monday, November 4, 2024, until 4:30 p.m. on Wednesday, December 4, 2024.

The proposed amendments to the Health Risk Limit Rules for Groundwater will add (to Minnesota Rules, part 4717.7860) updated human health-based water guidance values developed by MDH between 2022 and mid-2023 for four chemicals that have had HRL values previously.

These four chemicals include:

- Chlorothalonil
- EDB
- PFOA
- PFOS

The outdated HRL values (adopted in 1993, 1994, 2009, or 2018) for these four chemicals will be repealed (in part 4717.7500 or part 4717.7860) and replaced (in part 4717.7860) by new HRL values. In addition, previously adopted HRL values for two chemicals (anthracene, adopted in 1993; and dichlorodifluoromethane, adopted in 2011) will be repealed and not replaced. For these two contaminants, new Risk Assessment Advice has already been posted on MDH's Human Health-Based Water Guidance Table.

More information is available from the MDH webpage Health Risk Limits Rules for Groundwater Rules Amendments - Overview and Links

For additional information on the rule amendment or questions, please contact Nancy Rice at (651) 201-4923 or via email at nancy.rice@state.mn.us.

Sincerely,

Nancy Rice

Nancy Rice
Research Scientist|Health Risk Assessment Unit

Minnesota Department of Health
Office: 651-201-4923

Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan Via GovDelivery: Dual Notice

Minnesota Department of Health

Division of Environmental Health

Proposed Rules Relating to Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860, Revisor's ID 4803

I certify that on November 4, 2024, at approximately 10:00 a.m., I gave notice according to the Additional Notice Plan approved by the Office of Administrative Hearings on October 11, 2024. Specifically, I sent an electronic email (email) notification to the 9,129 subscribers of the Water Rules, Guidance, and Chemical Review account of the subscription email service, GovDelivery. Subscribers represent a wide variety of interests, such as people associated with businesses, lobby groups, trade associations, government staff, non-governmental organizations, medical staff, Minnesota residents, and others.

The message announced that a Dual Notice of Intent to Adopt Rules for the Proposed Amendments to the Health Risk Limits for Groundwater in Minnesota Rules, Parts 4717.7500 and 4717.7860, was published in the *State Register* on November 4, 2024, and that the comment period would be open from November 4th to December 4th at 4:30 p.m. The announcement contained links to more information about the proposed amendments and to the OAH's eComments website.

A copy of the notification is attached to this Certificate.

Azra Thakur

Digitally signed by Azra Thakur
Date: 2024.11.05 15:39:04 -06'00'

Azra Thakur, MPH
Planner Principal
Health Risk Assessment Unit

From: Minnesota Department of Health
To: Rice, Nancy (MDH)
Subject: MDH Seeks Feedback on Draft Health Risk Limits Rule
Date: Monday, November 4, 2024 10:02:08 AM

minnesota department of health

MDH proposes amendments to health risk limits (HRLs) for six contaminants

The Minnesota Department of Health (MDH) is proposing amendments to the current rules on Health Risk Limits (HRLs) for Groundwater (Minnesota Rules Chapter 4717, parts 7500, 7860). An HRL is the concentration of a chemical (or a mixture of chemicals that affect the same health endpoint) in groundwater that is likely to pose little or no health risk to humans when it is consumed.

A list of the six contaminants included in the proposed rules amendments can be found at Health Risk Limits Rules for Groundwater Rules Amendments - Contaminants.

A Notice of Hearing for the Health Risk Limits Rules Amendments will be published in the Minnesota State Register on Monday, Nov. 4. A link to the Notice, along with the proposed rules, will be available from MDH's webpage Health Risk Limits Rules for Groundwater Notice of Intent to Adopt Rules.

All documents for this rulemaking, including links to the draft rules and Statement of Need and Reasonableness, will be available at Health Risk Limits for: Overview and Links for Groundwater.

MDH will accept written comments on the proposed rules amendments from Monday, Nov. 4, 2024, through Wednesday, Dec. 4, 2024 at 4:30 p.m. To comment, please visit the Office of Administrative Hearings Rulemaking e-comments website or submit comments directly to Nancy Rice.

Nancy Rice
Minnesota Department of Health
625 Robert St. N.
P.O. Box 64975
St. Paul, MN 55164-0975
Phone: 651-201-4923
Email: nancy.rice@state.mn.us

Please also see the associated Errata (PDF) that notes an error in the Dual Notice. In the "Subject of Rules and Statutory Authority," section, the fourth (last) sentence of the first paragraph incorrectly states the units of PFOS referenced in Laws of Minnesota 2023, Chapter 60, Article 3, Section 34 as "ppm," rather than "ppb" or "parts per billion" as shown in the Session Law.

Exhibit I. Copy of the Transmittal Letter or Certificate showing that the agency sent a copy of the Statement of Need and Reasonableness to the Legislative Reference Library

Certificate of Emailing the Statement of Need and Reasonableness to the Legislative Reference Library

Minnesota Department of Health

Division of Environmental Health

Proposed Rules Relating to Amendments to the Health Risk Limits Rules for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID 4803; OAH Docket No. 22-9000-40331

I certify that on October 31, 2024, at St. Paul, Ramsey County, Minnesota, I submitted an electronic copy of the Statement of Need and Reasonableness to the Legislative Reference Library via email to sonars@lrl.leg.mn at the same time when the Notice of Hearing was emailed. I emailed this copy to comply with Minnesota Statutes, sections 14.131 and 14.23. A copy of the cover letter is attached to this Certificate.

Nancy Rice Digitally signed by Nancy Rice Date: 2024.11.02 06:14:11 -05'00'

Nancy Rice
Research Scientist

From:	Rice, Nancy (MDH)
To:	sonars@lrl.leg.mn
Subject:	Health Risk Limits Rules Statement of Need and Reasonableness
Date:	Thursday, October 31, 2024 7:13:00 AM
Attachments:	20241028_HRLSONAR-Final.pdf image002.png image003.png image004.png image005.png image006.png image007.png 20241031_LetterSONARLegLibrary-RD4803.pdf

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In the Matter of the Proposed Permanent Rules Relating to Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID Number 4803; OAH Docket No. 22-9000-40331

Dear Legislative Reference Library:

The Minnesota Department of Health intends to adopt rules relating to Health Risk Limits for Groundwater. We plan to publish a Dual Notice on November 4, 2024, in the *State Register*.

We have prepared a Statement of Need and Reasonableness. As required under Minnesota Statutes, sections 14.131 and 14.23, we are sending the library an electronic copy of the Statement of Need and Reasonableness at the same time that we are sending our Notice of Intent to Adopt Rules.

If you have any questions or concerns, please contact me at nancy.rice@state.mn.us or 651-201-4923.

Sincerely,
Nancy Rice

Nancy Rice
Research Scientist|Health Risk Assessment Unit

Minnesota Department of Health
Office: 651-201-4923

DEPARTMENT OF HEALTH

VIA EMAIL
October 31, 2024

Legislative Reference Library
sonars@lrl.leg.mn

In the Matter of the Proposed Permanent Rules Relating to Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID Number 4803

Dear Legislative Reference Library:

The Minnesota Department of Health intends to adopt rules relating to Health Risk Limits for Groundwater. We plan to publish a Dual Notice on November 4, 2024, in the *State Register*.

We have prepared a Statement of Need and Reasonableness. As required under Minnesota Statutes, sections 14.131 and 14.23, we are sending the library an electronic copy of the Statement of Need and Reasonableness at the same time that we are sending our Notice of Intent to Adopt Rules.

If you have any questions or concerns, please contact me at nancy.rice@state.mn.us or 651-201-4923.

Sincerely,

Nancy Rice Digitally signed by Nancy Rice Date: 2024.10.31 07:04:06 -05'00'

Nancy Rice
Research Scientist
Health Risk Assessment Unit

Enclosure: Statement of Need and Reasonableness

Exhibit J. All written comments and submissions on the proposed rule received during the comment period, requests for hearing, and withdrawals of requests for hearing received by the agency, except those that only requested copies of documents

One comment was received from American Chemistry Council.
The comment and MDH's response are included in the following pages.

December 4, 2024

RE: Proposed Amendments to Rules Governing Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Part 7500 and Part 7860; Revisor's ID Number R-4803

OAH Docket No. 22-9000-40331

Submitted electronically to the Minnesota Department of Health website here.

Dear Commissioner Brooke Cunningham:

The American Chemistry Council (ACC) respectfully submits the following comments on behalf of its membership on the proposed amendments to Rules Governing Health Risk Limits for Groundwater.

ACC represents over 190 companies engaged in the business of chemistry—an innovative, $639 billion enterprise that is helping solve the biggest challenges facing our nation and the world. The business of chemistry drives innovations that enable a more sustainable future, creates approximately 555,000 manufacturing and high-tech jobs—plus over four million related jobs—that support families and communities, and enhances safety through the products of chemistry and investment in research.

We offer these comments to further inform the Minnesota Department of Health's evaluation and to strengthen the underlying scientific information for the proposal.

Should you have any questions or would like additional information, please contact me at robert_simon@americanchemistry.com or 202-249-6700.

Sincerely,

Robert J. Simon
Vice President
Chemical Products and Technology

Technical Comments on Proposed Amendments to Rules Governing Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Part 7500 and Part 7860; Revisor's ID Number R-4803

I. Overview

In October 2024, Minnesota Department of Health (MDH) proposed permanent rules on PFOS and PFOA, from advisory health-based values (HBV) into promulgated Health Risk Limits (HRL). For each compound, there are two types of HRL values derived: noncancer-based and cancer-based.

A. For the derivation of noncancer-based HRL (nHRL), similar to the recent actions taken by several regulatory agencies (e.g. US EPA and the European Food Safety Authority) in which human epidemiology studies are being considered over experimental animal data for the purpose of risk assessment, MDH took human epidemiology data to derive the nHRLs for PFOA and PFOS. MDH also utilized its breastmilk model where upper-bound water consumption scenarios were incorporated, but the model has not been validated.

PFOA nHRL

MDH derived a nHRL for PFOA based on decreased H. influenza type B (Hib) antibodies in children (Abraham et al. 2020). The study used for the basis of the nHRL was a small cross-sectional study, which due to the nature of its design, cannot determine causality. To date, there is only one other human epidemiological (a longitudinal cohort) study that evaluated the antibody titer to Hib in relationship to PFOA in children and it did not observe an association (Granum et al. 2013). There are two international expert working groups that have independently expressed their opinions in that human epidemiology studies on antibody titers to Hib vaccines were not adequate for risk evaluations in the regulatory setting (Garvey et al. 2023; Burgoon et al. 2023).

PFOS nHRL

MDH (via EPA) selected the study by Wikstrom et al. (2020) for the observation of lower birth weight on the basis of having the lowest point-of-departure estimate (among all other studies that evaluated birth weight). Even though EPA Scientific Advisory Board (SAB) explicitly questioned the scientific rationale of selecting this study beyond having the lowest point of departure (POD), EPA did not follow SAB's recommendation to provide additional detail and justification in selecting the study by Wikstrom et al. for the assessment of serum PFOS and lower birth weight. Wikstrom et al. reported a statistically significant association between maternal PFOS (obtained during first trimester) and birth weight that was only observed in female infants but not male infants. In addition, Wikstrom et al. acknowledged the uncertainty in data interpretation with regard to gender-based difference. Further, use of lower birthweight as a critical effect for deriving the nHRL for PFOS is not appropriate given strong evidence that observed associations are confounded by physiological factors associated with pregnancy, such as plasma volume expansion and changes in maternal GFR which impact the measured PFOS serum levels.

Breastmilk model and water consumption estimation in nHRL

The proposed nHRLs inherit several assumption-based biases and uncertainties with MDH's breastmilk model. Even though the model has not been fully validated, it has been used to estimate an individual's water consumption for several PFAS compounds throughout the entire life stages instead of the traditional water consumption rates that EPA relied on. Recently, a joint commentary by various agencies (including MDH) acknowledged several major limitations in the breastmilk model, including 1) small sample size which precluded a precise estimation of PFAS distribution in breastmilk relative to serum concentration; 2) over-estimation of breastmilk concentration based on (primarily men's) serum PFAS levels from community studies because few women of reproductive age participated; 3) unknown breastmilk concentrations over time during lactation period; and 4) non-breastmilk source may also contribute to actual PFAS exposure (LaKind et al. 2022). Therefore, these uncertainties and the subsequent breastmilk estimates need to be addressed and validated.

B. For cancer-based HRL (cHRL), MDH revised its cancer classifications on both compounds to "likely to be carcinogenic to humans," which are in parallel with the recent changes (upgrades) in cancer classifications by the US EPA (2024) and IARC (2023).

PFOA cHRL

MDH derived a cHRL for PFOA based on renal cell carcinomas in humans (Shearer et al. 2021). A major limitation of this study was that it analyzed only a single PFOA blood measurement taken anywhere between 2 – 18 years prior to kidney cancer diagnosis, which calls into question the reliability of blood measurement. Further, these results were inconsistent with the results obtained in a larger and more ethnically diverse cohort that used a similar study design (Rhee et al. 2023), which found no association between PFOA kidney cancer. Burgoon et al. (2023) also evaluated the study by Shearer et al. (2021) and determined that this human cancer epidemiology study was not appropriate for human risk evaluation. MDH did not take full dose response into consideration given that there are also occupationally exposed data available on kidney cancer. The highest exposed group in the study (chosen by MDH) had serum PFOA levels that were substantially lower than the occupational workers during the same timeframe (1993 – 2001), by at least a hundred-fold lower when compared to the geometric means (Raleigh et al. 2014; Steenland and Woskie 2012; Barry et al. 2013). There were two occupational worker studies that reported null findings between PFOA and kidney cancer (Raleigh et al. 2014; Barry et al. 2013) while the third reported a positive association between serum PFOA and kidney cancer, but it did not adjust for a known confounder, tetrafluoroethylene (TFE), that was present in the workplace (Steenland and Woskie 2012). In addition, the study by Shearer et al. did not adequately address the potential of reverse causation.

PFOS cHRL

MDH (via EPA) selected the 2-year bioassay rat data, as reported by Butenhoff et al. (2012), for the derivation of PFOS cHRL. The point of departure was the observation of a statistically significant increase in the incidence of combined hepatocellular adenoma and carcinoma in rats, even though there was only one rat in which hepatocellular carcinoma was found (and the finding was not statistically significant). Even though there is some general agreement in

certain tumor types where carcinomas can potentially develop from adenomas via the adenoma-carcinoma-sequence, specific mode-of-action (MOA) and key events need to be clearly demonstrated in order to apply such inference (EPA 2005). In the current assessment, the weight of evidence on the supporting MOAs and key events lack consistency or concordance, especially when taking human biological relevance into consideration. Using EPA's guidance as well as other studies that focused on species-specific liver tumor MOAs (Corton et al. 2014; Elcombe et al. 2014; Goettel et al. 2024; Haines et al. 2018; Hall et al. 2012), the biological relevance of hepatocellular tumor observed in rodents is called into question given the known (different) mode of actions that exist between rodents and humans.

For further details pertaining to the high-level summary provided above, more in-depth discussions and supporting information for each topic area are included below.

II. Supporting Technical Comments

Analytical Considerations & Implications

Three of the four HRLs are lower than the current US EPA (USEPA 2024) MCLs in drinking water of 4 ppt for PFOS and PFOA (which was set based on analytical feasibility). Per US EPA's Methods 533 ((USEPA 2019) and 537.1 ((USEPA 2020) (the approved analytical methods developed and validated by the US EPA to support the analysis of 29 PFAS in drinking water), the majority of the HRLs set by MDH are lower than the LCMRL (lowest concentration minimum reporting level), which implies that the guidance values proposed by MDH will be difficult to achieve.

	2024 MDH Health Risk Level (HRL) in Drinking Water, ng/L or ppt		LCMRL (lowest concentration minimum reporting level), ng/L or ppt	
	Noncancer-based HRL	Cancer-based HRL	US EPA Method 533	US EPA Method 537.1
PFOA	0.24	0.0079	3.4	0.82
PFOS	2.3	7.6	4.4	2.7

PFOA nHRL

Selection of the critical study (Abraham et al. 2020) for PFOA nHRL

MDH derived a nHRL of 0.24 ppt for PFOA based on decreased *H. influenza* type B (Hib) antibodies in children (Abraham et al. 2020). This study was a small, cross-sectional study of 101 1-year old infants living in Germany whose blood was measured for levels of PFOA, PFOS and 7 other PFAS and vaccine antibodies against HiB, tetanus and diphtheria between 1997 and 1999. The mean PFOA serum concentration for breast-fed babies was 16.8 ng/mL and 3.8 ng/mL for formula-fed babies. A significant correlation between adjusted Hib antibody levels and PFOA (r=-0.32, p=0.001) was observed. No significant association was observed between Hib antibody levels and PFOS. Additionally, Abraham et al. 2020 reported no influence of PFOA on infections during the first year of life. Although the authors conclude that "*the study results contribute to the cumulative evidence of a causally related effect of PFASs in humans at relatively low internal exposures,"* the authors also acknowledge that "*...since most studies in this field are cross-sectional, data need to be interpreted with caution. More insight is needed into possible mechanisms of action, dose-response relationships and clinical relevance."*

Only one other epidemiologic study has examined the relationship between PFOA and Hib antibodies in children (Granum et al. 2013). This longitudinal cohort study examined, in a subset (n = 51) of children from the Norwegian Mother and Child Cohort study, the associations between maternal serum concentrations of PFOA (median = 1.1 ng/mL) measured at delivery with serum antibody concentrations in offspring who had followed a routine vaccination program, where vaccines against Hib were administered at ages 3, 5, and 12 months. The authors reported a non-significant association between pre-natal exposure to PFOA and Hib antibodies (β = -0.05, p=0.978). These findings are inconsistent with the findings reported in Abraham et al. 2020.

An international working group of scientific experts collaborated on a project entitled "The Perfluorooctanoate (PFOA) Safe Dose" in 2022 (Burgoon et al. 2023). This project, supported by the Alliance for Risk Assessment, included three independent technical teams with a total of 24 scientists from 8 countries who were tasked with reviewing the relevant information and the positions of various national authorities and other authoritative sources to determine their safe dose ranges. The scientific teams then developed consensus statements on the mode of action, critical effect, and extrapolation method. Regarding the observed associations between PFOA blood concentrations and antibody responses to vaccines, the working group concluded that the existing epidemiological data were not suitable for developing a safe dose since these assessments were based on a secondary immune response (i.e. response to vaccines) rather than a primary immune response. Working group members also questioned the clinical relevance of small decreases in antibody responses to vaccines because of the vast inter- and intra-individual human variability. It was concluded that "this variability precludes any definitive statement in the choice of this endpoint as the critical effect" (Burgoon et al. 2023).

In 2022, a systematic review and meta-analysis was published on epidemiological studies that examined the effects of PFAS on vaccine antibodies in healthy children (Zhang et al. 2022). Authors used the Grading of Recommendations Assessment, Development, and Evaluation system (GRADE) to evaluate the quality of all the results found in each study, which was expressed by four levels of certainty rating (i.e. "high", "moderate", "low", or "very low"). Based on the only two existing studies (Abraham et al. 2020; Granum et al. 2013) that specifically analyzed PFOA and Hib in children, the authors concluded that the overall judgement was "low" in their GRADE assessment for the association between exposure to PFOA and Hib antibody levels.

In 2023, a systematic review and meta-analysis was conducted to determine, in people of all ages, the magnitude of the association between PFAS serum concentration and the difference in antibody concentration following a vaccine (Crawford et al. 2023). The study included 4830 unique participants across 14 reports. Overall, the authors concluded that data on diphtheria, rubella and tetanus were most supportive of an association than for other antibodies (including Hib antibodies); however, the data on any specific antibody were scarce and confounding factors that might account for the relation were not identified.

In sum, the study by Abraham et al. 2020 should not be used as the basis for the nHRL for PFOA given the inherent limitations of the cross-sectional study design, small sample size, potential for confounding, limited and inconsistent evidence of the association between PFOA levels and Hib antibodies, and the lack of human relevance.

PFOS nHRL

Selection of the critical study (Wikstrom et al. 2020) for PFOS nHRL

MDH derived a nHRL of 2.3 ppt for PFOS based on decreased birthweight in infants (Wikstrom et al. 2020). This study measured maternal serum levels of PFOS (and other PFAS) in early pregnancy and birthweight in 1533 infants enrolled in the Swedish Environmental, Longitudinal, Mother and child, Asthma and allergy (SELMA) study. Given that serum sampling later in pregnancy may be related to issues of confounding and reverse causation (a type of bias and occurs when measurement of the physiological outcome has been *moderated by the health outcome itself)*, this study measured

serum PFOS during the first trimester (at a median of 10 weeks gestation) with 96% during the first trimester and the remaining samples collected early during the second trimester.

The authors reported a statistically significant association between lower birthweight and maternal PFOS (142-gram lower birthweight in the highest PFOS exposure category of >7.6 ppb relative to the lowest PFOS exposure category); however, this statistical association was only observed in female infants – not male infants, which makes the finding difficult to interpret. The authors acknowledged that the mechanisms behind the influence of PFAS on fetal growth and suggested sex-differences are largely unknown.

In selecting Wikstrom et al. 2020 as the basis for its nHRL for decreased birthweight, MDH did not consider the best available peer-reviewed science which suggests that the observed association between PFOS and lower birthweight is an artifact of pharmacokinetic bias. Specifically, meta-analyses support that the timing of serum measurements during pregnancy (late vs. early) confounds the observed relationship between PFOS and lower birthweight (Dzierlenga et al. 2020; Negri et al. 2017; Verner et al. 2015) and modeling to attempt to control for this confounding results in virtually no effect attributable to PFOS at all (Dzierlenga et al. 2020).

The most recent meta-analysis (Dzierlenga et al. 2020) examining the association between birthweight and PFOS concentrations, included observations from 29 studies. When observations were stratified by the timing of PFOS measurements during pregnancy (i.e. before or early in pregnancy and later in pregnancy), the random effects summary for the early group was -1.35 (95% CI: -2.33, -0.37) and -7.17 (95% CI: -10.93, -3.41) for the latter group. When the authors included a term for timing of blood draw in a meta-regression model, the intercept was essentially zero (0.59 g/ng/ml; 95% CI: -1.94, 3.11) indicating that when blood samples were drawn very early in pregnancy, there was no association between birthweight and PFOS. The authors concluded that "the time of blood draw was a key factor in the association and that there was no significant association present when PFOS is measured at the beginning of pregnancy, which supports the possibility of confounding related to timing of specimen sampling."

The results of the meta-analyses conducted to date indicate that associations between PFOS serum measurements and birthweight are driven almost entirely by physiological aspects of pregnancy, including plasma volume expansion, maternal GFR, and when the maternal PFAS measurement was made during gestation. These are critical points to evaluate.

A new study was published in 2024 that examined pregnancy complications and birth outcomes (including birthweight) following low-level exposure to PFAS (Begum et al. 2024). This study included a racially diverse cohort of 459 pregnant mothers across the U.S. which was weighted towards minority populations (black, 44%, white, 38% and other, 17%). PFOS (and other PFAS) were measured between 32-38 weeks' gestation. The median PFOS serum concentration for the 459 pregnant mothers was 2.7 ng/mL. In the adjusted multivariate linear regression analysis, the study reported a non-significant *increase* in birthweight in relation to PFOS levels ($\beta = 0.04$; 95% CI: -0.20-0.28).

In sum, Wikstrom et al. (2020) should not be selected as the critical study for its PFOS nHRL based on the findings of meta-analyses that indicate that pharmacokinetic bias resulting from the timing for serum measurements during pregnancy explains the observed association between serum

levels of PFOS and lower birthweight. Moreover, the study by Wikstrom et al. (2020) showed sex-differences (i.e. no association observed in male infants) in the relationship between PFOS and lower birthweight and the mechanisms behind the influence of PFAS on fetal growth and sex are not known.

Breastmilk model and water consumption estimation in nHRL

Starting around 2018, MDH began using the breastmilk model to estimate an individual's water consumption in its risk assessment process when developing PFAS water guidance values. To our best knowledge, the MDH breastmilk model has never been validated (against empirical data). When compared to the standard water consumption factors (from EPA's exposure handbook) on which other federal agencies relied, the breastmilk model incorporated excessive water-consumption scenarios for the child-bearing women (pre-, during-, and post-pregnancy) as well as the offsprings (from developing fetuses and continuously into adulthood). These assumption-based scenarios contributed to many uncertainties in the risk assessment process.

In 2022, a joint commentary authored by various entities and agencies, including MDH, acknowledged several major shortcomings of the breastmilk model (LaKind et al. 2022). They include:

1) small sample size (of paired serum and breastmilk samples) which precluded a precise estimation of PFAS distribution in breastmilk relative to serum concentration and subsequently, a reliable estimation of breastmilk: serum partition coefficient for different PFAS compounds;

2) very limited breastmilk PFAS data in the US and Canada do not allow for good estimation of breastmilk PFAS concentration in general; the inferred breastmilk data from community studies were especially vulnerable for over-estimation bias because there were limited participants that were of reproductive age;

3) while the MDH breastmilk model intends to capture one's PFAS exposure via breastmilk consumption throughout the entire lactation period, there has not been a study evaluating the breastmilk PFAS concentrations over time during lactation period; as such, the current MDH breastmilk model may have either over- or underestimated the actual PFAS concentration present in the breastmilk;

4) non-breastmilk source (e.g. infant formula and dietary food source) may also contribute to actual PFAS exposure; these were not taken into account by the MDH breastmilk model.

Therefore, it is important for these uncertainties to be addressed, and the reported breastmilk estimates to be validated.

PFOA cHRL

Selection of the critical study (Shearer et al. 2021) for PFOA cHRL

MDH derived a cHRL of 0.0079 ppt for PFOA based on renal cell carcinomas in humans (Shearer et al. 2021). This case-control study identified 324 cases of renal cell carcinoma (RCC) and 324

matched controls among 75,000 participants of a multi-site study from medical centers in 10 US cities. The subjects had a single blood (serum) measurement taken upon entry into the trial. Archived samples were measured for PFOA and, on average, were collected approximately 8 years prior to the diagnosis of kidney cancer (range 2 – 18 years) which is an important limitation of the study. Shearer et al. states the long half-life of elimination of PFOA indicates that a single serum measurement could be sufficient to provide an accurate and precise measurement of a person's long-term PFOA exposure. This assertion ignores the considerable uncertainty regarding the distribution, calculation, and measurement biases associated with the serum elimination half-lives of PFOA in humans. Shearer et al.'s (2021) conclusion that a single PFOA measurement is sufficient based on PFOA's long-half life in humans contradicts fundamental considerations of the connection between toxicodynamics, toxicokinetics, and time. This highlights the limitations of using serum concentrations measured 2 to 18 years prior to the diagnosis of the disease. This discrepancy limits the accuracy of the reported serum concentrations in Shearer et al. (2021). In a recent study examining the reliability of a single blood sample to represent long-term exposure of PFOA among men, the authors reported that a single baseline serum sample represented "rather well" the mean of repeated samples collected up to 13 years apart (Bartell et al. 2024). However, the study did observe lower correlations over time with strong biases towards the null when using single serum samples further back in time. The authors concluded that "More research is needed to evaluate the reliability of single blood sample for representing long-term exposure for epidemiological studies of PFOA among women and children."

Shearer et al. (2021) reported a statistically significant positive association with RCC risk and a doubling in PFOA serum concentration (adjusted odds ratio, OR = 1.68; 95% CI: 1.07 to 2.63) and a greater than twofold increased risk among those in the highest PFOA exposure group compared with the lowest exposure group (adjusted OR = 2.19; 95% CI: 0.86 to 5.61). It is important to note that the highest exposure group in this study had serum concentrations ranging from 7.3 – 27.2 ppb which was substantially lower than serum concentrations observed in occupational populations during the same timeframe. MDH did not consider any of the three occupational studies that have been published (Barry et al. 2013; Raleigh et al. 2014; Steenland and Woskie 2012), which likely represent the highest exposed individuals based on overall reported biomonitoring data. And of these three studies, only one analysis showed a statistically significant association with kidney cancer (mortality); however, this finding was likely confounded by the authors' decision to not adjust for TFE exposure – a known renal carcinogen in rodents (Steenland and Woskie 2012). For Barry et al. (2013), overall, they did not find an association between kidney cancer and PFOA in occupational workers nor did they observe a significant trend in increasing risk.

Shearer et al. (2021) also did not adequately address reverse causation, which is a type of pharmacokinetic bias and occurs when measurement of the physiological outcome (e.g. estimated glomerular filtration rate, eGFR) has been *moderated by the health outcome itself*. The pharmacokinetic bias occurs when there is a sufficient window of time for the disease state to influence the measured physiological outcome. EPA's IRIS Handbook recommends evaluating epidemiological studies for reverse causality and if reverse causality is a concern in the observed association of the exposure and health outcome, then a study should be labelled as deficient or critically deficient. In Shearer et al. (2021), the lack of an association between eGFR, PFOA, and kidney cancer does not conclusively demonstrate a lack of reverse causation, but it should have

been considered as a factor because the eGFR was measured, on average, 8.8 years *prior to* the diagnosis of kidney cancer. There is the possibility of pre-diagnostic conditions that result in declining renal function, but such a conclusion is highly speculative. Therefore, it is erroneous for Shearer et al. (2021) to suggest the lack of an association between a single eGFR measurement, and the diagnosis of kidney cancer eliminates the concern about this type of pharmacokinetic bias in the association between the exposure to PFOA and kidney cancer.

Two more recent epidemiological studies have reported no association or inconsistent associations between PFOA and kidney cancer (Rhee et al. 2023; Winquist et al. 2023). Rhee et al (2023) conducted a case-control study including 428 RCC cases and 428 match controls in a racially and ethnically diverse population. Pre-diagnostic serum concentrations were measured for PFOA and other PFAS compounds. Overall, PFOA was not associated with RCC risk (OR = 0.89, 95% CI: 0.67-1.18). Among White participants, a positive but non-statistically significant association was observed for PFOA and RCC risk (OR = 2.12, 95% CI: 0.87-5.18). No associations were observed between PFOA and risk of RCC in other racial and ethnic groups. Moreover, PFOS was statistically significantly associated with a *decreased* risk of RCC among African Americans (OR=0.40, 95%CI: 0.20-0.79) and Whites (OR = 0.36, 95% CI: 0.13-0.95).

In a case-cohort study, within the American Cancer Society's prospective Cancer Prevention Study II, Winquist et al. (2023) observed no association between PFOA and risk of kidney cancer (n=158 kidney cancer cases). However, in a sex-specific analyses, they reported an elevated, but non-statistically significant association between PFOA and kidney cancer (HR = 1.33, 95% CI:0.97-1.83) among women (though there was a statistically significant association in females between PFOA and renal cell carcinoma). No associations between PFOA serum concentrations and kidney cancer were observed among men.

In 2022, an international working group of scientific experts collaborated on a project entitled "The Perfluorooctanoate (PFOA) Safe Dose" (Burgoon et al. 2023). This project, supported by the Alliance for Risk Assessment, included three independent technical teams with a total of 24 scientists from 8 countries who were tasked with reviewing the relevant information and the positions of various national authorities and other authoritative sources to determine their safe dose ranges. The scientific teams then developed consensus statements on the mode of action, critical effect, and extrapolation method. Regarding the Shearer et al. 2021 study, the working group discussed that "While Shearer et al. (2021) adjusted their results for estimated glomerular filtration rate (eGFR), adjusting for eGFR alone would not adequately control for this potential confounding due to the extensive role of renal transporters in the clearance of PFOA." Further, the working group concluded that the available epidemiologic data could not be used as a reliable basis for a PFOA safe-dose assessment considering the lack of information regarding the mode of action (Burgoon et al. 2023).

Given the important limitations of Shearer et al. (2021) including the use of a single serum measurement, potential for confounding and reverse causation, and the findings of inconsistent or no associations reported in recent studies, a ccHRL for PFOA should not be derived based on renal cell carcinomas in humans.

PFOS cHRL

Selection of the critical study (Butenhoff et al. 2012) for PFOS cHRL

MDH proposed to adopt a cHRL of 7.6 ppt for PFOS based on the final assessment done by the US EPA in the derivation of MCLG. The critical study used to determine the upgrade of PFOS cancer classification was based on a 2-year bioassay data in Sprague Dawley rats, in which dietary potassium PFOS was given to rats for up to 20 ppm for two years. The entire dataset was available to the regulatory agencies for risk assessment evaluation since the completion of its final report in 2002 (Thomford 2002). Even though the key data were later published as Butenhoff et al. (2012) in a scientific journal, there has not been any additional data appended to the original dataset. Given the numerous risk assessment evaluations that both EPA and MDH have formally conducted over the last two decades on PFOS, the classification on PFOS had always been "suggestive" or "possibly." In MDH's most recent classification on carcinogenicity potential (via US EPA's MCLG assessment), however, PFOS was upgraded to "likely to be carcinogenic to humans" solely based on a different statistical analysis and not any new data. However, there are compelling scientific data and evidence why the current cancer classification by MDH for PFOS is mis-classified.

First, it is important to note that PFOS treatment did not affect the survival in rats in the 2-year cancer bioassay. In fact, the PFOS-treated rats had higher survival than the control rats. This observation is in direct contrast to other known carcinogens, such as benzene, in which decreased survivals are observed in rodents (IARC 2012).

Second, in the (only) 2-year cancer bioassay data available to date (Butenhoff et al. 2012; Thomford 2002), the only notable neoplastic observation in rats due to potassium PFOS treatment was a statistically significant increase in benign hepatocellular adenomas in both male and female rats when potassium PFOS was administered at the highest dietary dose (20 ppm), see Table 1A (*vide infra*). While there was only one hepatocellular carcinoma observed which was a 20 ppm dose group female rat, the study authors did not consider this single isolated observation of hepatocellular carcinoma in and of itself significant.

Third, while the distinct histological feature and presentation have served as the key anchoring points by which risk assessment and decision processes can differentiate a benign tumor (i.e. adenoma) from a malignant tumor (i.e. carcinoma), in the latest EPA MCLG assessment for PFOS, it combined both hepatocellular adenoma and carcinoma data together. It is not surprising that the statistical significance observed in adenoma data alone can and did contribute to the statistical significance of the combined adenoma/carcinoma incidence (Table 1A, *vide infra*).

Fourth, as a standard and conventional method of calculating liver tumor incidence shown on Table 1A for female rats, the total tumor incidence rate calculated by Butenhoff et al. 2012 was based on the total number of the tissues examined per specific dose group upon study termination at the end of two years. The US EPA, on the other hand, calculated the tumor incidence rate for female rats based on the number of animals alive at the time when the tumor first occurred (Table 1B), which excluded a subset of rats from control (n=10) and the highest dose group (n=10) that were sacrificed at week 52. The latter method done by the US EPA inflated the % incidence even though the dataset remained unchanged, and this difference in statistical analyses contributed to PFOS

being associated with increased incidence in hepatocellular adenoma/carcinoma combined, albeit the statistical association was primarily due to adenoma, not carcinoma.

Table 1A

	From Butenhoff et al. 2012				
	0 ppm	0.5 ppm	2 ppm	5 ppm	20 ppm
Adenoma (% incidence)	0/60 (0%)	1/50 (2%)	1/49 (2%)	1/50 (2%)	5/60* (8%)
Carcinoma (% incidence)	0/60 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	1/60 (2%)
Combined adenoma/carcinoma, (% incidence)	0/60 (0%)	1/50 (2%)	1/49 (2%)	1/50 (2%)	6/60* (10%)

Table 1B

	From US EPA, 2023				
	0 ppm	0.5 ppm	2 ppm	5 ppm	20 ppm
Adenoma (% incidence)	0/28 (0%)	1/26 (4%)	1/15 (7%)	1/28 (4%)	5/31* (16%)
Carcinoma (% incidence)	0/28 (0%)	0/29 (0%)	0/16 (0%)	0/31 (0%)	1/32 (3%)
Combined adenoma/carcinoma, (% incidence)	0/28 (0%)	1/29 (3%)	1/16 (6%)	1/31 (3%)	6/32* (19%)

*statistically significant p <0.05 relative to control

Fifth, it should be noted that the key event data used by EPA to support the relevant MOA lacks consistency. While the nuclear receptor PPARα and its role in liver tumor development has been largely accepted as a rodent-specific event (Corton et al. 2014), in US EPA's MCLG document, it stated the following with regards to the mode of action for hepatic tumors: "Specifically, the available studies provide varying levels of support for the role of several plausible MOAs: nuclear receptor (PPARα and CAR activation), HNF4α suppression, cytotoxicity, genotoxicity, oxidative stress, and immunosuppression".

> *MOA & nuclear receptors:* on the nuclear receptor, the weight of evidence consideration on the key events showed inconsistency and a lack of dose response (see an example of "Table 3.23" below, excerpted from EPA's final MCLG document). Albeit each of the MOA evidence tables was constructed with escalating doses (presumably to show a dose response), the doses listed in the table actually were from several different studies, each with different study design as well as different life stages of the animals (i.e. pups at weaning, young adult rats, and aged geriatric rats), and the latter certainly plays an important role in many of the cell growth-related parameters such as cell signaling (and not surprisingly, accompanying enzyme changes).

"Table 3-23", excerpted from EPA Final MCLG toxicity assessment for PFOS

Table 3-23. Evidence of Key Events Associated With the PPARα Mode of Action for Hepatic Tumors[a] in Male Sprague-Dawley Rats Exposed to PFOS

Canonical MOA	Key Event 1: PPARα Activation	Key Event 2: Altered Cell Growth Signaling	Key Event 3a: Increased Hepatic Cell Proliferation	Key Event 3b: Inhibition of Apoptosis	Key Event 4: Preneoplastic Clonal Expansion	Outcome: Hepatic Tumors
Dose (mg/kg/day)[b]	PPARα Activation[c]	Altered Cell Growth Signaling	Hepatic Cell Proliferation	Apoptosis	Preneoplastic Clonal Expansion	Hepatic Tumors
0.024	– (4, 14w)	– (4w)	– (4, 14w)	– (14, 103w)	NR	– (103w)
0.098	– (4, 14w)	– (4w)	– (4, 14w)	– (14, 103w)	NR	– (103w)
0.242	– (4, 14w)	– (4w)	– (4, 14w)	– (14, 103w)	NR	– (103w)
0.312	↑ (4w)	NR	NR	– (4w)	NR	NR
0.625	↑ (4w)	NR	NR	– (4w)	NR	NR
0.984	↑ (4w) – (14w)	↑ (4w)	↑ (4w) – (14, 53w)	↓ (103w) – (14, 53w)	NR	↑ (103w)
1	↑ (F1 PND 21)	NR	NR	NR	NR	NR
1.25	↑ (4w)	NR	NR	– (4w)	NR	NR
1.33/1.51	– (4, 14w)	NR	– (4w)	NR	NR	NR
1.66	↑ (28d) – (1, 7d)	NR	↑ (7d) – (1, 28d)	↑ (7d) – (1, 28d)	NR	NR
1.93	– (7d)	NR	↑ (7d)	↓ (7d)	NR	NR

Table 2 shown below details the source of the studies where the doses in "Table 3-23" originated from. It is clear that the MOA assessment did not take all these intrinsic factors into account when integrating for the evidence of key events.

Table 2

Doses (mg/kg/day)	Study Duration	Dosing Route	Reference
0.024	2 years	Dietary	Butenhoff et al. 2012
0.098			
0.242			
0.312	28 days	Oral gavage	NTP 2019
0.625			
0.984	2 years	Dietary	Butenhoff et al. 2012
1	21 days	Lactational	Chang et al. 2009
1.25	28 days	Oral gavage	NTP 2019
1.31 / 1.51	4- and 14-weeks	Dietary	Seacat et al. 2003
1.66	1-, 7-, and 28-days	Dietary	Elcombe et al. 2012
1.93			

MOA & HNF4α suppression: in addition to the nuclear receptors, EPA MCLG also cited HNF4α suppression as a plausible MOA for eliciting liver carcinogenicity. Liver HNF4α, a

transcription factor, controls various facets of liver pathways. While it is continued to be studied for its exact role(s), EPA MCLG cited a single study that showed PFOS can lead to HNF4α suppression which corresponded to a downregulation in its target gene CYP7A1 under via both in vitro and in vivo conditions – a finding that was not consistently observed by other published toxicology studies (which some had reported PFOS was associated with increased CYP7A1 levels (Chang et al. 2009; Rosen et al. 2010)).

MOA & genotoxicity, cytotoxicity, and oxidative stress: while there were studies reporting positive findings in genotoxicity and oxidative stress with PFOS, many of these studies were conducted *in vitro* and typically at high and cytotoxic concentrations which reflected the likely consequence of cytotoxic disruption of normal cellular processes and not a specific genotoxic or oxidative stress effect. Under a battery of guideline-driven genotoxicity and mutagenicity tests, PFOS has not been shown to pose a direct mutagenic or genotoxic risk (see USEPA 2024).

MOA & immunosuppression: Albeit there were studies reporting on the potential effect of PFOS and immunotoxicity in mice and a few of them had been used by the regulatory agencies for their risk assessment (Dong et al. 2011; Dong et al. 2009), none of these studies evaluated immune functions in a thorough and comprehensive matter, which is the fundamental principle because immunology is a rather complex process. Using the most up-to-date techniques with an emphasis on the dynamic (non-static) response of immune functions (versus the single measurement other studies had reported), the multi-discipline analyses of both primary[1] and secondary[2] immune marker analyses did not reveal evidence of immune suppression in the mice with PFOS even after 28 daily doses (Pierpont et al. 2023; Torres et al. 2021). The study conclusion was further solidified with a concurrent comparison to mice that were treated with a positive control compound, cyclophosphamide, which is a well- known immune suppressant in mice and has been used widely in tissue transplant medicine in humans. Cyclophosphamide-treated mice exhibited a wide array of biological response such as decreased body weight, reduced overall immune cell populations in thymus, bone marrow, and spleen, as well as reduced serum immunoglobulins.

In sum, MDH's classification on PFOS carcinogenicity potential (via US EPA's assessment) was based on a different statistical analysis and no new data from a 2-year bioassay in rats that has been available for years and repeatedly analyzed previously. There was no excess incidence of hepatocellular carcinoma (only an isolated single hepatocellular carcinoma in one female rat); only benign hepatocellular adenoma was observed with statistical significance (the latter has been well-documented to be a likely rodent-specific response). Furthermore, as documented by EPA's own guidance (*vide supra*) as well as other studies that focused on liver MOA (Corton et al. 2014;

[1] Primary immune markers include fundamental metabolic endpoints such as body weight, hematology data, organ weights, immune cell populations (on thymus, spleen, bone marrow, lymph node, blood, and liver), gross pathology, and histopathology.

[2] Secondary immune markers evaluate the functional aspect of immune cells which include cell-based assays (e.g. NK cell activity or neutralize antibody activity), imunoassays (e.g. antibody levels or cytokine levels), and flow cytometry assays (e.g. receptor binding or surface and cytoplasmic immunophenotyping).

Elcombe et al. 2014; Goettel et al. 2024; Haines et al. 2018; Hall et al. 2012), the biological relevance of nuclear receptor-mediated hepatocellular tumor observed in rodents is further called into question given the known mode of action differences that exist between rodents and humans.

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DEPARTMENT OF HEALTH

February 21, 2025

Mr. Robert J. Simon
Vice President
Chemical Products and Technology
American Chemistry Council

Re: Proposed Amendments to Rules Governing Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Part 7500 and Part 7860; Revisor's ID Number R-4803 OAH Docket No. 22-9000-40331

Dear Mr. Simon,

We thank the American Chemistry Council (ACC) for their comments regarding the Minnesota Department of Health's (MDH) Proposed Amendments to Rules Governing Health Risk Limits (HRLs) for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID Number R-4803, OAH Docket No. 22-9000-40331, submitted on December 4, 2024.

HRLs play a critical role in protecting public health in Minnesota. They represent the amount of a groundwater contaminant that can be consumed with little or no risk to health and which has been promulgated under rule. When MDH derives their proposed HRLs, it does so with the intention and the mandate of protecting Minnesota's most vulnerable and most highly exposed populations. The guiding legislation for MDH in deriving HRLs, the Groundwater Protection Act, Minn. Stat. § 103H.201, and Health Standards Statute, Minn. Stat. § 144.0751, direct MDH to solely consider human health without consideration for technical feasibility or cost of implementation. Accordingly, HRLs are nonregulatory, yet they remain a powerful tool for MDH, other Minnesota state agencies, and public water systems to protect public health.

Please see MDH's responses to ACC's comments below.

ACC Section I. Overview

Comments regarding selection of critical studies for PFOA and PFOS nHRLs

ACC notes that MDH follows similar recent practice as several regulatory agencies, such as the US Environmental Protection Agency (US EPA), the California Environmental Protection Agency (CalEPA), and the European Food Safety Authority (EFSA), by using human epidemiology studies rather than animal experimental data for the purpose of risk assessment for PFOA and PFOS.

This is correct; there has been a worldwide shift in PFAS risk assessment away from animal experimental data towards human epidemiology studies. Over the past several years, sufficient epidemiological data have become available to perform risk assessments and derive human health guidance values.

When deriving these types of values, it is always better if the studies used are done in humans. This is especially true for PFAS, because humans and rodents respond very differently to PFAS. Unlike many chemicals, humans are more sensitive to PFOA and PFOS than laboratory animals, particularly rats. This sensitivity is well-known and well-documented in the scientific community; it is largely due to differences in how long PFOA and PFOS are retained inside the body after an exposure. Rats excrete PFOA and PFOS after days or weeks. Humans retain PFOA and PFOS for years after exposure, leading to an ongoing internal exposure that endures much longer than in rats. This longer exposure results in humans experiencing health impacts at much lower PFOS or PFOA water concentrations than observed in rats.

The chosen studies fulfill MDH's requirement under the Groundwater Protection Act, Minn. Stat. § 103H.201, and Health Standards Statute, Minn. Stat. § 144.0751(a)(1)-(2), to be "based on scientifically acceptable, peer-reviewed information" and to "adequately protect the health of infants, children, and adults by taking into consideration risks to…immunologic suppression or hypersensitization…[and]…general infant and child development." The studies selected by MDH were critically evaluated by MDH toxicologists as well as by federal and state regulatory agencies and represent the best available science. The critical study for the PFOS nHRL (decreased birthweight in Wikstrom *et al.* 2020) formed part of the basis of US EPA's 2024 PFOS Maximum Contaminant Level Goal (MCLG) reference dose (US EPA, 2024a), while the critical study and effect for the PFOA nHRL (anti-Hib antibody level from Abraham *et al.* 2020) was included in the CalEPA 2024 Public Health Goal (PHG) analysis where it was noted "the impacts of these small [antibody] decreases could be much more important in children who already have compromised or borderline-compromised immune systems for other reasons. As such, these small effects could have important implications for the population as a whole, especially given the very widespread nature of PFOA exposure" (page 176) (CalEPA Office of Environmental Health Hazard Assessment, 2024). MCLGs and PHGs are both comparable values to HRLs in that they are strictly human health based. Therefore, these studies and selected endpoints are in accordance with MDH's promulgated methodology directing us to protect the most sensitive and most highly exposed populations (Minnesota Department of Health, 2008).

Comments regarding MDH's breastmilk model

The breastmilk model used by MDH in derivation of the proposed 2025 PFOA and PFOS HRLs has been validated and has undergone multiple rounds of internal and external review. The

MDH breastmilk model was first created to support derivation of the 2018 PFOA nHRL (Minnesota Department of Health, 2020); during development, the model was validated using available relevant empirical data (Fromme, 2010). Model development and validation was documented in a 2019 peer-reviewed journal (Goeden et al., 2019). The model was subsequently used in derivation of the 2019 perfluorohexane sulfonate (PFHxS) noncancer health-based value that was promulgated into rule as an nHRL in 2023 (Minnesota Department of Health, 2023). The 2019 MDH model also has been requested by and shared freely with other states and federal agencies. CalEPA evaluated the 2019 MDH model while developing their PHGs, noting "[t]his model demonstrated good fit of predicted to observed plasma data" (page 48) (CalEPA Office of Environmental Health Hazard Assessment, 2024). The 2019 MDH model was also referenced heavily by the Agency of Toxic Substances and Disease Registry (ATSDR), a division of the Centers for Disease Control and Prevention (CDC), in their development of a web-based PFAS serum modeling tool (Lynch et al., 2023).

For the proposed 2025 PFOA and PFOS nHRLs, MDH developed an updated and refined breastmilk model. The updated model was similarly validated with empirical data and development was documented in a 2024 peer-reviewed publication (Greene et al., 2024).

Comments regarding LaKind et al. 2022 commentary

ACC mischaracterizes the purpose of the LaKind *et al.* 2022 commentary as a critique of the MDH breastmilk model (LaKind et al., 2022). This is incorrect. As stated in the abstract, the commentary has three aims:

- Document published PFAS breast milk concentrations in the United States and Canada;
- Estimate breast milk PFAS levels from maternal serum concentrations in national surveys and communities impacted by PFAS, and;
- Compare measured or estimated milk PFAS concentrations to screening values

The LaKind *et al.* 2022 commentary is not an analysis of various PFAS breastmilk models, which are only mentioned in passing. Rather, the vast majority of the commentary discussed the lack of available data for PFAS concentrations in breastmilk, specifically in the United States and Canada when compared to other countries; indeed, the dataset used to validate the MDH breastmilk model is from Germany. Standard methods for developing water guidance values often underestimate exposures to infants, and understanding chemical exposures through breastmilk are increasingly important to human health risk assessment, especially in the public health setting where there is not an acceptable risk level to infants from chemicals. This commentary was a call for more of these important data to be collected.

Comments regarding PFOA and PFOS cHRLs

The Groundwater Protection Act directs MDH to derive cancer HRLs (cHRLs) for known or probable carcinogens "from a quantitative estimate of the chemical's carcinogenic potency published by the United States Environmental Protection Agency or determined by the commissioner to have undergone thorough scientific review." (Minn. Stat. § 103H.201, subd. 1(d)).

The proposed 2025 cHRLs for PFOA and PFOS were derived using information from US EPA's PFOA and PFOS MCLGs (US EPA, 2024a, 2024b) and CalEPA's PHGs (CalEPA Office of Environmental Health Hazard Assessment, 2024). In addition to intense internal scrutiny by CalEPA and EPA scientists, the MCLGs and PHGs went through multiple rounds of public drafts and public comment periods before final adoption. Additionally, scientific review occurred as part of MDH's standard risk assessment process when MDH's team of toxicologists performed their own review of the information prior to incorporating it into the analysis for cHRL derivation. MDH's review supported use of the calculated cancer slope factors, and all publicly available peer review documents used to derive the CalEPA PHGs and EPA MCLGs. All of this information meets the statutory requirement of thorough scientific review.

ACC Section II. Supporting Technical Comments

Comments regarding Analytical Considerations and Implications

It is inappropriate for ACC to compare HRLs to maximum contaminant levels (MCLs) for several reasons. ACC correctly notes that several proposed 2025 PFOA and PFOS HRLs are below the 2024 US EPA MCLs and states that the "guidance values proposed by MDH will be difficult to achieve." However, HRLs are strictly health-based values and do not consider technical feasibility and cost, as directed in statute under the Groundwater Protection Act and the Health Standards Statute. HRLs are nonregulatory risk-based values that are derived as part of a larger MDH effort to protect public health from contaminants in drinking water, whereas MCLs are meant to represent a maximum level of a contaminant allowable in a public water drinking system. MCLs can be higher than HRLs, as HRLs prioritize the impact of the contaminant on human health and do not take into account the technical feasibility of achieving a certain level of contaminant in water.

Remaining technical comments submitted by ACC

The remaining technical comments submitted by ACC are expansions of issues covered above. In addition to thorough consideration by MDH scientists during the review process, these issues were also included in the analyses by other regulatory agencies consulted during derivation of

the proposed 2025 PFOA and PFOS HRLs. As noted above, these include (but were not limited to) the US EPA PFOA and PFOS MCLGs and CalEPA PHGs, each going through multiyear and multi-round public draft and public comment periods (CalEPA Office of Environmental Health Hazard Assessment, 2024; US EPA, 2024a, 2024b). Accordingly, MDH considers its evaluations supporting the proposed 2025 PFOA and PFOS HRLs as based on the best available science and satisfying all obligations under the Groundwater Protection Act and Health Standards Statute.

We thank ACC for providing additional detail and data and address their comments further below.

PFOA nHRL study selection

Abraham *et al.* 2020 was used by CalEPA to derive its 2024 PFOA PHG (CalEPA Office of Environmental Health Hazard Assessment, 2024) and by EFSA to derive a PFOA tolerable weekly intake (European Food Safety Authority: Panel on Contaminants in the Food Chain, 2020). The US EPA also selected decreased serum antibodies in humans as their critical endpoint for the 2024 PFOA MCL, although they chose this endpoint from a different study (US EPA, 2024b). While the particular study or antibody may vary, decrease of serum antibodies in humans have consistently been deemed relevant to human health outcomes by state, federal, and international public health agencies and is appropriate for use in nHRL derivation.

PFOS nHRL study selection

Decreased birthweight described in Wikstrom *et al.* 2020 was used by the US EPA, in part, as the basis of the 2024 PFOS MCL (US EPA, 2024a). As noted in the US EPA and CalEPA review documents, Wikstrom *et al.* 2020 is not the only study demonstrating associations between PFOS exposure and decreased birthweight; many studies, including epidemiological and controlled laboratory animal, demonstrate an association between PFOS/PFOA exposure and decreased birthweight (CalEPA Office of Environmental Health Hazard Assessment, 2024; US EPA, 2024a, 2024b; USEPA, 2016a, 2016b).

ACC ends their comment stating that Wikstrom *et al.* 2020 showed a sex-specific difference in the association (i.e., there was no association observed in male infants). This finding does not weaken the low birthweight association observed in female infants, and it is ultimately irrelevant to the development of HRLs and to MDH's mission. We protect, maintain, and improve the health of all Minnesotans.

Breastmilk model

Validation of MDH's breastmilk model was thoroughly addressed above. Regarding the issue of water intake rates, ACC is correct that many state and federal agencies rely on the US EPA's

Exposure Factors Handbook for parameters like intake rates (US EPA, 2019). MDH did the same, as noted in our two scientific manuscripts describing model development and validation (Goeden et al., 2019; Greene et al., 2024). Without seeing their calculations, we cannot comment why ACC's analysis resulted in an overestimation.

Regarding LaKind *et al.* 2022, the purpose of the commentary was thoroughly discussed above.

PFOA cHRL

As noted above, Shearer *et al.* 2021 was used by the US EPA and CalEPA as their critical cancer study for PFOA with renal cell carcinoma as the tumor type (CalEPA Office of Environmental Health Hazard Assessment, 2024; US EPA, 2024b). These assessments went through rigorous internal and external peer review and public drafts. MDH performed a thorough review of these assessments and based its own PFOA cancer analysis on them.

PFOS cHRL

ACC questions how MDH and the US EPA can update their PFOS cancer classification to "likely to be carcinogenic to humans" based on a reanalysis of data. Significantly, CalEPA also recognizes PFOS cancer risk based on the same dataset, classifying PFOS as presenting "a carcinogenic hazard" (CalEPA Office of Environmental Health Hazard Assessment, 2024).

First, ACC notes that PFOS treatment did not affect survival of rats in Butenhoff *et al.* 2012. However, the rats in this study still developed hepatocellular tumors, and the PFOS cHRL is a guidance value based on cancer, not mortality.

ACC next implies combining adenomas and carcinomas into total tumor incidence, as EPA did in their calculations, is atypical. That is a standard risk assessment practice, one that the authors of Butenoff *et al.* 2012 themselves did in the study table. Regarding quantifying tumor incidence starting from time-to-first-tumor, EPA states "[e]xpressing incidence in this way quantitatively eliminates animals that died prior to the PFOS treatment duration plausibly required to result in tumor formation in the critical study" (US EPA, 2024a). It is an accepted method of clarifying a chemical's carcinogenic potential by grouping similar outcomes together in an experimental system.

Finally, ACC presents a discussion on the PFOS mode of action (MOA). MDH's default assumption is that a carcinogen's MOA is relevant to humans. Without evidence to the contrary, MDH assumes that a chemical which causes cancer in laboratory animals can also do so in humans. This is the public health-protective position. While there have been several proposed MOAs for PFOS-mediated carcinogenesis in rodents with varying degrees of evidence, there is no consensus on the exact MOA by which PFOS causes liver tumors. This is not

uncommon when studying chemical carcinogenesis and ultimately is irrelevant when creating cHRLs; MOA is not required, only high-quality science establishing a chemical's carcinogenic characteristics, allowing for a quantitative analysis and calculation of a cHRL.

Conclusion

We again thank the ACC for their comments on the 2025 PFOA and PFOS HRLs. As a public health agency, MDH's stated mission is to protect, maintain, and improve the health of all Minnesotans. The proposed 2025 PFOA and PFOS HRLs fulfill this mission.

Sincerely,

Kristine S. Klos Digitally signed by Kristine S. Klos Date: 2025.02.21 17:05:50 -06'00'

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Exhibit K. Notice of withdrawal of hearing request, evidence that the notice of withdrawal was sent to all persons who requested a hearing, and any responsive comments received

Not applicable: There were no requests for hearing for the proposed Health Risk Limits Rules

Exhibit L. Copy of the adopted rule, showing any modifications to the proposed rule and the Revisor's approval of them

Department of Health

Adopted Permanent Rules Related to Health Risk Limits

4717.7860 HEALTH RISK LIMITS TABLE.

[For text of subparts 1 to 7, see Minnesota Rules]

Subp. 7a. [Renumbered subp 7c]

Subp. 7b. **Chlorothalonil.**

CAS number: 1897-45-6

Year Adopted: 2025

Volatility: Nonvolatile

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	ND	20	2	1	6
RfD (mg/kg-day)	--	0.014	0.00067	0.00029	--
RSC	--	0.5	0.2	0.2	--
SF (per mg/kg-day)	--	--	--	--	0.017
ADAF or $AF_{lifetime}$	--	--	--	--	10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)
Intake Rate (L/kg-day)	--	0.290	0.074	0.045	0.155 $_{(<2)}$ 0.040 $_{(2\ to\ <16)}$ 0.042 $_{(16+)}$
Endpoints	--	gastrointestinal system	gastrointestinal system	gastro-intestinal system, hepatic (liver) system, renal (kidney) system	cancer

Subp. 7c. **Clothianidin.**

CAS number: 210880-92-5, 205510-53-8

Year Adopted: 2018

Volatility: Nonvolatile

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	ND	200	200 (2)	200 (2)	NA
RfD (mg/kg-day)	--	0.093	(2)	(2)	--
RSC	--	0.5	(2)	(2)	--
SF (per mg/kg-day)	--	--	--	--	--
ADAF or $AF_{lifetime}$	--	--	--	--	--
Intake Rate (L/kg-day)	--	0.285	(2)	(2)	--
Endpoints	--	developmental	developmental	developmental	--

Subp. 7d. **Cyanazine.**

CAS number: 21725-46-2

Year Adopted: 2018

Volatility: Nonvolatile

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	3	3	3	1	NA
RfD (mg/kg-day)	0.0015	0.0015	0.0012	0.00022	--
RSC	0.5	0.5	0.2	0.2	--
SF (per mg/kg-day)	--	--	--	--	--
ADAF or $AF_{lifetime}$	--	--	--	--	--

Intake Rate (L/kg-day)	0.285	0.285	0.070	0.044	--
Endpoints	developmental, female reproductive system	developmental, female reproductive system	developmental, female reproductive system, hepatic (liver) system, renal (kidney) system	None	--

Subp. 7e. **1,2-Dibromoethane (EDB).**

CAS number: 106-93-4

Year Adopted: 2025

Volatility: High

	Acute	**Short-term**	**Subchronic**	**Chronic**	**Cancer**
HRL (µg/L)	ND	10	10 (2)	9	0.03
RfD (mg/kg-day)	--	0.018	(2)	0.0021	--
RSC	--	0.2	(2)	0.2	--
SF (per mg/kg-day)	--	--	--	--	3.6
ADAF or $AF_{lifetime}$	--	--	--	--	10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)
Intake Rate (L/kg-day)	--	0.290	(2)	0.045	0.155 $_{(<2)}$ 0.040 $_{(2\ to\ <16)}$ 0.042 $_{(16+)}$
Endpoints	--	female reproductive system, hepatic (liver) system, immune	female reproductive system, hepatic (liver) system, immune	female reproductive system, hepatic (liver) system, immune	cancer

		system, male reproductive system, renal (kidney) system, respiratory system, spleen	system, male reproductive system, renal (kidney) system, respiratory system, spleen	system, male reproductive system, respiratory system	

Subp. 8. [Renumbered subp 7d]

[For text of subparts 8a to 8f, see Minnesota Rules]

Subp. 8g. [See repealer.]

[For text of subparts 8h to 14d, see Minnesota Rules]

Subp. 15. **Perfluorooctane sulfonate (PFOS) and salts.**

CAS number: 45298-90-6; 1763-23-1; 29081-56-9; 2795-39-3; 70225-14-8; and 29457-72-5

Year Adopted: 2025

Volatility: Nonvolatile

	Acute	**Short-term**	**Subchronic**	**Chronic**	**Cancer**
HRL (µg/L)	ND	0.0023	0.0023	0.0023	0.0076
RfSC (ng/mL)*	--	2.6	2.6	2.6	--
RSC	--	0.2	0.2	0.2	--
SF (per mg/kg-day)	--	--	--	--	13
ADAF or $AF_{lifetime}$	--	--	--	--	10 ($ADAF_{<2}$) 3 ($ADAF_{2\ to\ <16}$) 1 ($ADAF_{16+}$)

Intake Rate (L/kg-day)	--	#	#	#	0.155 (<2) 0.040 (2 to <16) 0.042 (16+)
Endpoints	--	developmental, hepatic (liver) system, immune system	developmental, hepatic (liver) system, immune system	developmental, hepatic (liver) system, immune system	cancer

* A reference serum concentration (ng/mL) rather than a reference dose (mg/kg-d) was used in MDH's toxicokinetic model to calculate noncancer guidance values for PFOS.

95th percentile water intake rates (Tables 3-1, 3-3, and 3-5 in the Environmental Protection Agency, Exposure Factors Handbook, 2019), or upper percentile breast milk intake rates (Table 15-1), Environmental Protection Agency Exposure Factors Handbook, 2011.

Subp. 16. **Perfluorooctanoate (PFOA) and salts.**

CAS number: 45285-51-6; 335-67-1; 3825-26-1; 2395-00-8; 335-93-3; and 335-95-5

Year Adopted: 2025

Volatility: Nonvolatile

	Acute	Short-term	Subchronic	Chronic	Cancer
HRL (µg/L)	ND	0.00024	0.00024	0.00024	0.0000079
RfSC (ng/mL)*	--	0.93	0.93	0.93	--
RSC	--	0.2	0.2	0.2	--
SF (per ng/kg-day)	--	--	--	--	0.0126
ADAF or $AF_{lifetime}$	--	--	--	--	10 ($ADAF_{<2}$) 3 ($ADAF_{2 to <16}$) 1 ($ADAF_{16+}$)

Intake Rate (L/kg-day)	--	#	#	#	0.155 (<2) 0.040 (2 to <16) 0.042 (16+)
Endpoints	--	developmental, hepatic (liver) system, immune system	developmental, hepatic (liver) system, immune system	developmental, hepatic (liver) system, immune system	cancer

* A reference serum concentration (ng/mL) rather than a reference dose (mg/kg-d) was used in MDH's toxicokinetic model to calculate noncancer guidance values for PFOA.

95th percentile water intake rates (Tables 3-1, 3-3, and 3-5 in the Environmental Protection Agency, Exposure Factors Handbook, 2019), or upper percentile breast milk intake rates (Table 15-1), Environmental Protection Agency Exposure Factors Handbook, 2011.

[For text of subparts 16a to 24, see Minnesota Rules]

REPEALER. Minnesota Rules, parts 4717.7500, subparts 5, 26a, and 31; and 4717.7860, subpart 8g, are repealed.

Exhibit M. Notice of Adoption of Substantially Different Rules

Not applicable, MDH did not adopt substantially different rules

Exhibit O. Notice of Submission of Rules to the Office of Administrative Hearings

Not applicable, no persons requested notification of the submission of the rules to the Office of Administrative Hearings

Exhibit P. Other Documents

P.1. the certificate of sending notice to legislators and a copy of the transmittal letter, dated October 31, 2024, showing the Department sent notice to legislators.

P.2. a copy of the transmittal letter, dated October 8, 2024, showing the Department consulted with Minnesota Management and Budget (MMB) and MMB's response letter dated October 30, 2024.
Note: The SONAR text lists Appendix F as the location of the letter to MMB. The MMB had not responded at the time of the SONAR signature, and so the letter to MMB and MMB's response are included below in Exhibit P2.

P.3. copy of a letter to Administrative Law Judge Moseng, dated November 4, 2024, concerning a typographical error discovered in the Dual Notice of Intent to Adopt rules, and a copy of the Errata to be published in the State Register on November 12, 2024.

P.4. a copy of the certificate or transmittal letters providing notice of the errata describing an error in the Notice of Intent to Adopt Rules, sent November 4, 2024, (unless otherwise noted) to:

a) The three people on MDH rulemaking list;

b) The 48 individual parties interested in the Health Risk Limits Rules (the Errata was included with the email about the Notice of Intent);

c) The GovDelivery subscription email subscribers to 9,129 subscribers (A link to the Errata was included with the email about the Notice of Intent and the Errata was posted on the landing page for other links within the GovDelivery);

d) Minnesota Legislative chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules and chief House and Senate authors of the rulemaking authority on October 31, 2024, and The Legislative Coordinating Commission on October 31, 2024.

P.5. a copy of the errata published in the Minnesota *State Register* on November 12, 2024.

P.1. October 31, 2024: The Certificate of Sending Notice to Legislators and a Copy of the Transmittal Letter Showing the Agency sent Notice to Legislators.

Certificate of Emailing the Dual Notice, Draft Rules, and Statement of Need and Reasonableness to Minnesota Legislators and the Legislative Coordinating Commission

Minnesota Department of Health

Division of Environmental Health

Proposed Rules Relating to Amendments to the Health Risk Limits Rules for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID 4803; OAH Docket No. 22-9000-40331

I certify that on October 31, 2024, when the Department emailed the Dual Notice of Intent to Adopt Rules under Minnesota Statutes, section 14.14 or 14.22 at St. Paul, Ramsey County, Minnesota, I submitted an electronic copy of the Dual Notice, Statement of Need and Reasonableness, and Draft Rules to legislative chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules and chief House and Senate authors of the rulemaking authority. The Legislative Coordinating Commission was also included when I completed this notification by sending an electronic copy via email. I emailed these documents to comply with Minnesota Statutes, section 14.116. A copy of the cover letter is attached to this Certificate.

Nancy Rice Digitally signed by Nancy Rice Date: 2024.11.02 06:06:32 -05'00'

Nancy Rice
Research Scientist

October 31, 2024

Senator Melissa Wiklund, Chair
Senator Paul J. Utke, Ranking Minority Member
Committee Administrator: Anna Burke
Senate Health and Human Services Committee

Senator Nick Frentz, Chair
Senator Andrew Matthews, Ranking Minority Member
Committee Administrator: J.W. Emmerich
Senate Energy, Utilities, Environment, and Climate Committee

Senator Foung Hawj, Chair
Senator Justin D. Eichorn, Ranking Minority Member
Committee Administrator: Kara Josephson
Senate Environment, Climate, and Legacy Committee

Representative Rick Hansen, Chair
Representative Josh Heintzeman, Ranking Minority Member
Committee Administrator: Peter Strohmeier
House Environment and Natural Resources Finance and Policy Committee

Representative Tina Liebling, Chair
Representative Joe Schomacker, Ranking Minority Member
Committee Administrator: Josh Sande
House Health Finance and Policy Committee

Representative Leon Lillie, Chair
Representative Jeff Backer, Ranking Minority Member
Committee Administrator: Mike Molzahn
House Legacy Finance Committee

Legislative Coordinating Commission
lcc@lcc.leg.mn
Executive Director: Michelle Yurich

Senator Foung Hawj
Representative Rick Hansen
Chief Authors of Laws of Minnesota 2023, Chapter 60, Article 3, Section 34

In the Matter of the Proposed Permanent Rules Relating to Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID Number 4803; OAH Docket No. 22-9000-40331

Dear Legislators:

The Minnesota Department of Health (MDH) intends to adopt rule amendments relating to Health Risk Limits for Groundwater. In 2023, the Minnesota Legislature passed a requirement for MDH to "…amend the health risk limit for perfluorooctane sulfonate (PFOS) in Minnesota Rules, part 4717.7860, subpart 15, so that the health risk limit does not exceed 0.015 parts per billion..." (Laws of Minnesota 2023, Chapter 60, Article 3, Section 34). MDH has prepared new health-based guidance for PFOS, as well for Chlorothalonil (a pesticide), Perfluorooctanoate (PFOA), and 1,2-Dibromoethane (ethylene dibromide, EDB) (an industrial chemical).

We plan to publish a Dual Notice of Intent to Adopt Rules in the November 4, 2024, *State Register* and we are now sending the Notice to persons who have registered for the agency's rulemaking list under section 14.14.

As required under section 14.116, we are sending you a copy of the Notice and the Statement of Need and Reasonableness. We are also enclosing a copy of the proposed rules.

If you have any questions or concerns, please contact me at nancy.rice@state.mn.us or 651-201-4923.

Sincerely,

Nancy Rice
Digitally signed by Nancy Rice
Date: 2024.10.31 07:24:52 -05'00'

Nancy Rice
Research Scientist

Enclosures:

- Notice of Intent to Adopt Rules
- Statement of Need and Reasonableness
- Proposed Rules

cc: Legislative Coordinating Commission

From:	Rice, Nancy (MDH)
To:	rep.tina.liebling@house.mn.gov; rep.joe.schomacker@house.mn.gov; rep.rick.hansen@house.mn.gov; rep.josh.heintzeman@house.mn.gov; rep.leon.lillie@house.mn.gov; rep.jeff.backer@house.mn.gov; Melissa Wiklund; sen.justin.eichorn@senate.mn; sen.paul.utke@senate.mn; sen.nick.frentz@senate.mn; sen.andrew.matthews@sentate.mn; sen.foung.hawj@senate.mn
Cc:	michelle.weber@lcc.mn.gov; Josh.Sande@house.mn.gov; Peter.Strohmeier@house.mn.gov; Mike.Molzahn@house.mn.gov; kara.josephson@senate.mn; lcc@lcc.mn.gov; anna.burke@senate.mn; justin.emmerich@senate.mn; Michelle.Yurich@lcc.mn.gov
Subject:	Health Risk Limit Rules for Groundwater, Minnesota Department of Health, Notice of Intent to Adopt Rules; Revisor"s ID 4803 (Corrected Revisor"s ID number); OAH Docket No. 22-9000-40331
Date:	Thursday, October 31, 2024 8:07:00 AM
Attachments:	20241028_HRLSONAR-Final.pdf HRL-2024-DualNotice.pdf HRLProposedRules_20241029.pdf 20241031_NoticetoLegislators_HRLRules.pdf image002.png image003.png image004.png image005.png image006.png image007.png

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*This email, originally sent on 10/31/24 at 7:47 a.m., is being resent to correct the Revisor's ID number to **4803**. Apologies for the error.*

Dear Legislators:

The Minnesota Department of Health (MDH) intends to adopt rule amendments relating to Health Risk Limits for Groundwater.

In 2023, the Minnesota Legislature passed a requirement for MDH to "…amend the health risk limit for perfluorooctane sulfonate (PFOS) in Minnesota Rules, part 4717.7860, subpart 15, so that the health risk limit does not exceed 0.015 parts per billion..." under Laws of Minnesota 2023, Chapter 60, Article 3, Section 34. MDH has prepared new health-based guidance for PFOS, as well for Chlorothalonil (a pesticide), Perfluorooctanoate (PFOA), and 1,2-Dibromoethane (ethylene dibromide, EDB) (an industrial chemical).

We plan to publish a Dual Notice of Intent to Adopt Rules in the November 4, 2024, issue of the *State Register,* and we are now sending the Notice under section 14.14.

As required under section 14.116, we are sending you a copy of the Notice and the Statement of Need and Reasonableness. We are also enclosing a copy of the proposed rules.

If you have any questions or concerns, please contact me at nancy.rice@state.mn.us or 651-201-4923.

Sincerely,
Nancy rice

Nancy Rice
Research Scientist|Health Risk Assessment Unit

Minnesota Department of Health
Office: 651-201-4923

P.2. October 8, 2024: Copy of the Transmittal Letter Showing the Agency Consulted with Minnesota Management and Budget (MMB) (and MMB's response letter from October 30, 2024)

MINNESOTA

October 8, 2024

Garrett Schoonover
Executive Budget Officer
Minnesota Management and Budget
658 Cedar St., Suite 400
St. Paul, MN 55155

Re: Proposed Amendments to Rules Governing Health Risk Limits, Minnesota Rules, Parts 4717.7500, .7860; Revisor's ID Number 4803

Dear Garrett Schoonover:

Minnesota Statutes, section 14.131, requires that an agency engaged in rulemaking consult with the Commissioner of Minnesota Management and Budget, "to help evaluate the fiscal impact and fiscal benefits of the proposed rule on units of local government."

Enclosed for your review are copies of the following documents on proposed rules [relating to/governing] [topic].

1. The Governor's Office Proposed Rule and SONAR Form (signed by Dupty Commissioner Underwood).
2. The July 11, 2024 Revisor's draft of the proposed rule.
3. The October 2024 draft of the SONAR.

I am also delivering copies of these documents to the Governor's Office today.

If you or any other representative of the Commissioner of Minnesota Management & Budget has questions about the proposed rule revisions, please email me at justin.kwong@state.mn.us. If necessary, you can also call me at 651-706-0684.

Sincerely,

Justin Kwong
Senior Associate General Counsel
Rulemaking Coordinator
Minnesota Department of Health
PO Box 64975
St. Paul, MN 55164
www.health.state.mn.us

Date: October 30, 2024

To: Justin Kwong
Senior Associate General Counsel
Minnesota Department of Health

From: Garrett Schoonover
Executive Budget Officer
Minnesota Management and Budget

Subject: M.S. 14.131 Review of Proposed Amendment to Rules Governing Health Risk Limits for Groundwater, Minnesota Rules Chapter 4717, Parts 7500 and 7860

RE: Health Risk Limit Rules

Background

The Minnesota Department of Health (MDH) proposes to amend Minnesota Rules, Chapter 4717, by revising or repealing Health Risk Limits (HRLs) for six groundwater contaminants. Specifically, the proposed amendments update four HRL values in part 7860 and repeals two HRL in part 7500 without replacement. Pursuant to Minnesota Statutes 14.131, MDH has requested Minnesota Management and Budget evaluate the proposed amendments for fiscal impact and/or benefits on units of local government.

Evaluation

On behalf of the Commissioner of Minnesota Management and Budget, I have reviewed the proposed changes and the draft of the Statement of Need and Reasonableness (SONAR) to evaluate the fiscal impact these changes may have on local governments.

HRL values serve as a type of health-protective guidance MDH uses for groundwater contaminants that pose a potential threat to human health if consumed in drinking water, and is defined in the 1989 Groundwater Protection Act in M.S. 103H.005, subdivision 3, 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.

The proposed amendments establish limits for the contaminants and do not apply nor enforce the limits. MDH does not enforce these limits and there are no fees associated with these results. As such, the proposed amendments should have no direct fiscal impact to local units of government. Fiscal costs that may occur would be due to the enforcement of the health risk limits by other state agencies, such as the Department of Natural

Resources, the Minnesota Pollution Control Agency, and the Board of Water and Soil Resources, if a community would need to use public funds to remediate contaminated water. These costs are indeterminate and would not have a direct impact on state revenues. Local governments do not develop or enforce groundwater quality standards through ordinances or regulations and have consulted with MDH on the use of HRL values for interpreting the results of well monitoring. The rule will not require local governments to adopt or amend ordinance to comply.

This rule change 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 groundwater and public health.

Sincerely,

/s/ Garrett Schoonover

Garrett Schoonover
Executive Budget Officer (MMB)

Cc: Josh Riesen, Director of Budget Policy and Analysis

P.3. November 4, 2024: Letter to Administrative Law Judge Moseng concerning a typographical error discovered in the Dual Notice of Intent to Adopt rules, and a copy of the Errata to be published in the State Register on November 12, 2024.

November 4, 2024

The Honorable Judge Moseng
Administrative Law Judge
Office of Administrative Hearings

In the Matter of Proposed Rule Amendments Relating to Health Risk Limits for Groundwater: Errata for Dual Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing if 25 or More Requests for Hearing Are Received; Revisor's ID Number: 4803; OAH Docket number: 22-9000-40331

Dear Judge Moseng:

The Minnesota Department of Health (MDH) is submitting this letter to inform you of a typographical error that we found in the Dual Notice of Intent to Adopt Rule Amendments published in the State Register on Monday, November 4, 2024.

In the section of the Dual Notice titled "Subject of Rules and Statutory Authority," appearing in the *State Register* dated November 4, 2024, the fourth (last) sentence of the first paragraph of this section incorrectly states the units of PFOS referenced in Laws of Minnesota 2023, Chapter 60, Article 3, Section 34 as "ppm," rather than what these units should be shown as, which is "ppb" or "parts per billion." The sentence, if displayed as a redline (with strikethrough for the erroneous text and underline for the correct text), would read as follows: "…MDH must adopt an updated HRL value of no greater than 0.015 ~~ppm~~ppb for [Perfluorooctane Sulfonate] PFOS by July 1, 2026."

MDH does not believe that this error will interfere with the ability of anyone to review and understand the proposed rule amendment or to submit comments on the proposed amendments, as the error is in merely transcribing the text of a session law that is already effective, published, and available to the public.

To inform parties interested in the Health Risk Limits for Groundwater of this error in the Dual Notice, MDH is submitting an Errata (attached) to the State Register, to be published on November 12, 2024, explaining this error. In addition, we will notify the individuals on the MDH rulemaking list, other individual parties, and subscribers to the Water Rules, Guidance, and Chemical Review account GovDelivery , as per our Additional Notice Plan, of this errata**.**

MDH will take any additional steps as needed to remedy this error.

Please contact me if you have any questions or concerns about the approach set forth above.

Sincerely,

Justin Kwong
Rulemaking Coordinator
Minnesota Department of Health
PO Box 64975
St. Paul, MN 55164
www.health.state.mn.us

Errata Notice Regarding the Proposed Permanent Rules Relating to Health Risk Limits for Groundwater: Dual Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing if 25 or More Requests for Hearing Are Received; Revisor's ID Number: 4803; OAH Docket number: 22-9000-40331

November 2024

This Errata Notice addresses the proposed rules governing Health Risk Limits for Groundwater for Minnesota Rules, parts 4717.7500 and .7860.

In the section of the Dual Notice titled "Subject of Rules and Statutory Authority," appearing in the *State Register* dated November 4, 2024, the fourth (last) sentence of the first paragraph of this section incorrectly states the units of PFOS referenced in Laws of Minnesota 2023, Chapter 60, Article 3, Section 34 as "ppm," rather than what these units should be shown as, which is "ppb" or "parts per billion." The sentence, if displayed as a redline (with strikethrough for the erroneous text and underline for the correct text), would read as follows: "…MDH must adopt an updated HRL value of no greater than 0.015 ~~ppm~~ppb for [Perfluorooctane Sulfonate] PFOS by July 1, 2026."

P.4. November 4, 2024: Additional notice of the errata describing an error in the Notice of Intent to Adopt Rules.

The Errata was sent on November 4,2024, (unless otherwise noted) to:

a) The three people on MDH rulemaking list;

b) The 48 individual parties interested in the Health Risk Limits Rules (the Errata was included with the email about the Notice of Intent);

c) The GovDelivery subscription email subscribers to 9,129 subscribers (A link to the Errata was included with the email about the Notice of Intent and the Errata was posted on the landing page for other links within the GovDelivery); and

d) Minnesota Legislative chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules and chief House and Senate authors of the rulemaking authority on October 31, 2024, and The Legislative Coordinating Commission on October 31, 2024.

Certificate of Emailing the Errata Notice Pertaining to the Dual Notice of Intent to Adopt Rules to the Rulemaking Mailing List

Minnesota Department of Health

Proposed Amendments to Rules Relating to Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID No.4803; OAH Docket No. 22-9000-40331

I certify that on November 4, 2024, I emailed the Errata Notice pertaining to the Dual Notice by sending an electronic copy to all persons on the Minnesota Department of Health's rulemaking list who prefer emailed documents under Minnesota Statutes, section 14.14, subdivision 1a. Copies of the sent Errata Notice and the email list are attached to this Certificate.

Nancy Rice

Digitally signed by Nancy Rice
Date: 2024.11.05 05:49:41 -06'00'

Nancy Rice
Research Scientist

Errata Notice Regarding the Proposed Permanent Rules Relating to Health Risk Limits for Groundwater: Dual Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing if 25 or More Requests for Hearing Are Received; Revisor's ID Number: 4803; OAH Docket number: 22-9000-40331

November 2024

This Errata Notice addresses the proposed rules governing Health Risk Limits for Groundwater for Minnesota Rules, parts 4717.7500 and .7860.

In the section of the Dual Notice titled "Subject of Rules and Statutory Authority," appearing in the *State Register* dated November 4, 2024, the fourth (last) sentence of the first paragraph of this section incorrectly states the units of PFOS referenced in Laws of Minnesota 2023, Chapter 60, Article 3, Section 34 as "ppm," rather than what these units should be shown as, which is "ppb" or "parts per billion." The sentence, if displayed as a redline (with strikethrough for the erroneous text and underline for the correct text), would read as follows: "…MDH must adopt an updated HRL value of no greater than 0.015 ~~ppm~~ppb for [Perfluorooctane Sulfonate] PFOS by July 1, 2026."

Certificate of Mailing the Errata Pertaining to the Dual Notice of Intent to Adopt Rules to the Rulemaking Mailing List

Minnesota Department of Health

Proposed Amendments to Rules Relating to Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID No.4803; OAH Docket No. 22-9000-40331

I certify that on November 4, 2024, in St. Paul, Ramsey County, Minnesota, I mailed the Errata Notice pertaining to a typo in the Dual Notice (mailed on October 29, 2024) by depositing a copy in the United States mail with postage prepaid to all persons on the Minnesota Department of Health's rulemaking list who prefer physical mail under Minnesota Statutes, section 14.14, subdivision 1a. Copies of the Errata Notice and the email list are attached to this Certificate.

Nancy Rice Digitally signed by Nancy Rice Date: 2024.11.05 05:46:41 -06'00'

Nancy Rice
Research Scientist

Errata Notice Regarding the Proposed Permanent Rules Relating to Health Risk Limits for Groundwater: Dual Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing if 25 or More Requests for Hearing Are Received; Revisor's ID Number: 4803; OAH Docket number: 22-9000-40331

November 2024

This Errata Notice addresses the proposed rules governing Health Risk Limits for Groundwater for Minnesota Rules, parts 4717.7500 and .7860.

In the section of the Dual Notice titled "Subject of Rules and Statutory Authority," appearing in the *State Register* dated November 4, 2024, the fourth (last) sentence of the first paragraph of this section incorrectly states the units of PFOS referenced in Laws of Minnesota 2023, Chapter 60, Article 3, Section 34 as "ppm," rather than what these units should be shown as, which is "ppb" or "parts per billion." The sentence, if displayed as a redline (with strikethrough for the erroneous text and underline for the correct text), would read as follows: "…MDH must adopt an updated HRL value of no greater than 0.015 ~~ppm~~ppb for [Perfluorooctane Sulfonate] PFOS by July 1, 2026."

Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan Via Email to Interested Parties: Dual Notice

Minnesota Department of Health

Division of Environmental Health

Proposed Rules Relating to Health Risk Limits for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860, Revisor's ID 4803; OAH Docket No. 22-9000-40331

I certify that on November 4, 2024, between 7:15 a.m. and 9:07 a.m., I gave notice to 46 interested parties according to the Additional Notice Plan approved by the Office of Administrative Hearings on October 11, 2024. Additionally, on November 5, 2024, between 9:51 a.m. and 9:58 a.m. I gave notice to two additional interested parties for which a correct email or method of contact needed to be identified. Interested parties notified include people who have expressed interest in or participated in the Health Risk Limits rules process in the past, such as representatives for industries that produce chemicals that could be subject to the Health Risk Limits, environmental and health advocacy groups, and government officials that monitor, regulate, or remediate environmental releases of the chemicals.

Specifically, I sent an electronic email notification with a message that announced that a Dual Notice of Intent to Adopt Rules for the Proposed Amendments to the Health Risk Limits for Groundwater in Minnesota Rules, Parts 4717.7500 and 4717.7860, had been published in the *State Register* on November 4, 2024. The Dual Notice, Statement of Need and Reasonableness (SONAR), and Proposed Rules were attached to the message. The message indicated that a comment period would be open from November 4th to December 4th at 4:30 p.m. The announcement also contained links to more information about the proposed amendments and to the OAH's eComments website.

Also included in the email was a copy of an Errata. The Errata noted a typo related to the unit value when citing Laws of Minnesota 2023, Chapter 60, Article 3, Section 34. The units were mistakenly printed as "ppm" in the Notice of Intent but should have been listed as "ppb." The Errata was published in the November 11th version of the *State Register*.

An example of the notification is attached to this Certificate, along with the materials sent.

Nancy Rice Digitally signed by Nancy Rice
Date: 2025.01.14 11:40:47 -06'00'

Nancy Rice
Research Scientist
Health Risk Assessment Unit

From:	Rice, Nancy (MDH)
To:	JKlapacz@dow.com
Subject:	Health Risk Limit Rules Amendments - Dual Notice to be published on Monday, November 4, 2024
Date:	Monday, November 4, 2024 7:18:00 AM
Attachments:	HRL-2024-DualNotice.pdf HRLProposedRules_20241017.pdf 20241028_HRLSONAR-Final.pdf image002.png image003.png image004.png image005.png image006.png image007.png 20241101_Errata.pdf

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Dear Joanna Klapacz:

You are being contacted because you or your organization has expressed past interest in the Minnesota Department of Health's Health Risk Limits Rules for Groundwater.

Minnesota Department of Health (MDH) is planning amendments to the existing Health Risk Limits (HRL) rule for Groundwater (Minnesota Rules, Chapter 4717, parts 7500 and 7860). MDH will publish a Dual Notice of Intent to Adopt Rules in the State Register on Monday, November 4, 2024 (see attached Dual Notice, Statement of Need and Reasonableness (SONAR), and Proposed Rules, as well as the attached Errata). MDH will be accepting comments on the proposed amendments from Monday, November 4, 2024, until 4:30 p.m. on Wednesday, December 4, 2024.

The proposed amendments to the Health Risk Limit Rules for Groundwater will add (to Minnesota Rules, part 4717.7860) updated human health-based water guidance values developed by MDH between 2022 and mid-2023 for four chemicals that have had HRL values previously.

These four chemicals include:

- Chlorothalonil
- EDB
- PFOA
- PFOS

The outdated HRL values (adopted in 1993, 1994, 2009, or 2018) for these four chemicals will be repealed (in part 4717.7500 or part 4717.7860) and replaced (in part 4717.7860) by new HRL values. In addition, previously adopted HRL values for two chemicals (anthracene, adopted in 1993; and dichlorodifluoromethane, adopted in 2011) will be repealed and not replaced. For these two contaminants, new Risk Assessment Advice has already been posted on MDH's Human Health-Based Water Guidance Table.

More information is available from the MDH webpage Health Risk Limits Rules for Groundwater Rules Amendments - Overview and Links

For additional information on the rule amendment or questions, please contact Nancy Rice at (651) 201-4923 or via email at nancy.rice@state.mn.us.

Sincerely,
Nancy Rice

Nancy Rice
Research Scientist|Health Risk Assessment Unit

Minnesota Department of Health
Office: 651-201-4923

From: Minnesota Department of Health
To: Rice, Nancy (MDH)
Subject: MDH Seeks Feedback on Draft Health Risk Limits Rule
Date: Monday, November 4, 2024 10:02:08 AM

minnesota department of health

MDH proposes amendments to health risk limits (HRLs) for six contaminants

The Minnesota Department of Health (MDH) is proposing amendments to the current rules on Health Risk Limits (HRLs) for Groundwater (Minnesota Rules Chapter 4717, parts 7500, 7860). An HRL is the concentration of a chemical (or a mixture of chemicals that affect the same health endpoint) in groundwater that is likely to pose little or no health risk to humans when it is consumed.

A list of the six contaminants included in the proposed rules amendments can be found at Health Risk Limits Rules for Groundwater Rules Amendments - Contaminants.

A Notice of Hearing for the Health Risk Limits Rules Amendments will be published in the Minnesota State Register on Monday, Nov. 4. A link to the Notice, along with the proposed rules, will be available from MDH's webpage Health Risk Limits Rules for Groundwater Notice of Intent to Adopt Rules.

All documents for this rulemaking, including links to the draft rules and Statement of Need and Reasonableness, will be available at Health Risk Limits for: Overview and Links for Groundwater.

MDH will accept written comments on the proposed rules amendments from Monday, Nov. 4, 2024, through Wednesday, Dec. 4, 2024 at 4:30 p.m. To comment, please visit the Office of Administrative Hearings Rulemaking e-comments website or submit comments directly to Nancy Rice.

Nancy Rice
Minnesota Department of Health
625 Robert St. N.
P.O. Box 64975
St. Paul, MN 55164-0975
Phone: 651-201-4923
Email: nancy.rice@state.mn.us

Please also see the associated Errata (PDF) that notes an error in the Dual Notice. In the "Subject of Rules and Statutory Authority," section, the fourth (last) sentence of the first paragraph incorrectly states the units of PFOS referenced in Laws of Minnesota 2023, Chapter 60, Article 3, Section 34 as "ppm," rather than "ppb" or "parts per billion" as shown in the Session Law.

Certificate of Emailing the Errata for Dual Notice to Minnesota Legislators and the Legislative Coordinating Commission

Minnesota Department of Health

Division of Environmental Health

Proposed Rules Relating to Amendments to the Health Risk Limits Rules for Groundwater, Minnesota Rules, Chapter 4717, Parts 7500 and 7860; Revisor's ID 4803; OAH Docket No. 22-9000-40331

I certify that on November 4, 2024, when the Department posted an Errata for the Dual Notice of Intent to Adopt Health Risk Limits Rule Amendments on its website, I sent the Errata to legislative chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules and chief House and Senate authors of the rulemaking authority. The Legislative Coordinating Commission was also included. A copy of the Errata and email sent are attached to this Certificate.

Nancy Rice

Digitally signed by Nancy Rice
Date: 2024.11.05 07:51:27 -06'00'

Nancy Rice
Research Scientist

From:	Rice, Nancy (MDH)
To:	rep.tina.liebling@house.mn.gov; rep.joe.schomacker@house.mn.gov; rep.rick.hansen@house.mn.gov; rep.josh.heintzeman@house.mn.gov; rep.leon.lillie@house.mn.gov; rep.jeff.backer@house.mn.gov; Melissa Wiklund; sen.justin.eichorn@senate.mn; sen.paul.utke@senate.mn; sen.nick.frentz@senate.mn; sen.andrew.matthews@sentate.mn; sen.foung.hawj@senate.mn
Cc:	michelle.weber@lcc.mn.gov; Josh.Sande@house.mn.gov; Peter.Strohmeier@house.mn.gov; Mike.Molzahn@house.mn.gov; kara.josephson@senate.mn; lcc@lcc.mn.gov; anna.burke@senate.mn; justin.emmerich@senate.mn; Michelle.Yurich@lcc.mn.gov
Subject:	RE: Health Risk Limit Rules for Groundwater, Minnesota Department of Health, Notice of Intent to Adopt Rules; Revisor"s ID 4803, OAH Docket No. 22-9000-40331
Date:	Monday, November 4, 2024 9:52:00 AM
Attachments:	20241028_HRLSONAR-Final.pdf HRL-2024-DualNotice.pdf HRLProposedRules_20241029.pdf 20241031_NoticetoLegislators_HRLRules.pdf 20241101_Errata.pdf image002.png image003.png image004.png image005.png image006.png image007.png

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Dear Legislators:

The Minnesota Department of Health (MDH) intends to adopt rule amendments relating to Health Risk Limits for Groundwater.

In 2023, the Minnesota Legislature passed a requirement for MDH to "…amend the health risk limit for perfluorooctane sulfonate (PFOS) in Minnesota Rules, part 4717.7860, subpart 15, so that the health risk limit does not exceed 0.015 parts per billion..." under Laws of Minnesota 2023, Chapter 60, Article 3, Section 34. MDH has prepared new health-based guidance for PFOS, as well for Chlorothalonil (a pesticide), Perfluorooctanoate (PFOA), and 1,2-Dibromoethane (ethylene dibromide, EDB) (an industrial chemical).

We published a Dual Notice of Intent to Adopt Rules in the November 4, 2024, issue of the *State Register*.

As required under section 14.116, we are sending you a copy of the Notice and the Statement of Need and Reasonableness (SONAR), as well as an Errata for the Dual Notice. We are also enclosing a copy of the proposed rules.

If you have any questions or concerns, please contact me at nancy.rice@state.mn.us or 651-201-4923.

Sincerely,
Nancy Rice

Nancy Rice
Research Scientist|Health Risk Assessment Unit

Minnesota Department of Health

Office: 651-201-4923

DEPARTMENT OF HEALTH

From: Rice, Nancy (MDH)
Sent: Thursday, October 31, 2024 8:07 AM
To: rep.tina.liebling@house.mn.gov; rep.joe.schomacker@house.mn.gov; rep.rick.hansen@house.mn.gov; rep.josh.heintzeman@house.mn.gov; rep.leon.lillie@house.mn.gov; rep.jeff.backer@house.mn.gov; Melissa Wiklund <Sen.Melissa.Wiklund@senate.mn>; sen.justin.eichorn@senate.mn; sen.paul.utke@senate.mn; sen.nick.frentz@senate.mn; sen.andrew.matthews@sentate.mn; sen.foung.hawj@senate.mn
Cc: michelle.weber@lcc.mn.gov; Josh.Sande@house.mn.gov; Peter.Strohmeier@house.mn.gov; Mike.Molzahn@house.mn.gov; kara.josephson@senate.mn; lcc@lcc.mn.gov; anna.burke@senate.mn; justin.emmerich@senate.mn; Michelle.Yurich@lcc.mn.gov
Subject: Health Risk Limit Rules for Groundwater, Minnesota Department of Health, Notice of Intent to Adopt Rules; Revisor's ID 4803 (Corrected Revisor's ID number); OAH Docket No. 22-9000-40331

*This email, originally sent on 10/31/24 at 7:47 a.m., is being resent to correct the Revisor's ID number to **4803**. Apologies for the error.*

Dear Legislators:

The Minnesota Department of Health (MDH) intends to adopt rule amendments relating to Health Risk Limits for Groundwater.

In 2023, the Minnesota Legislature passed a requirement for MDH to "…amend the health risk limit for perfluorooctane sulfonate (PFOS) in Minnesota Rules, part 4717.7860, subpart 15, so that the health risk limit does not exceed 0.015 parts per billion..." under Laws of Minnesota 2023, Chapter 60, Article 3, Section 34. MDH has prepared new health-based guidance for PFOS, as well for Chlorothalonil (a pesticide), Perfluorooctanoate (PFOA), and 1,2-Dibromoethane (ethylene dibromide, EDB) (an industrial chemical).

We plan to publish a Dual Notice of Intent to Adopt Rules in the November 4, 2024, issue of the *State Register,* and we are now sending the Notice under section 14.14.

As required under section 14.116, we are sending you a copy of the Notice and the Statement of Need and Reasonableness. We are also enclosing a copy of the proposed rules.

If you have any questions or concerns, please contact me at nancy.rice@state.mn.us or 651-201-4923.

Sincerely,

Nancy rice

Nancy Rice
Research Scientist|Health Risk Assessment Unit

Minnesota Department of Health
Office: 651-201-4923

P.5. November 12, 2024: The Errata published in the Minnesota State Register

MINNESOTA STATE REGISTER

TUESDAY, NOVEMBER 12, 2024
VOLUME 49, NUMBER 20
PAGES 473 - 524

Minnesota State Register

Judicial Notice Shall Be Taken of Material Published in the Minnesota State Register

The Minnesota State Register is the official publication of the State of Minnesota's Executive Branch of government, published weekly to fulfill the legislative mandate set forth in Minnesota Statutes, Chapter 14, and Minnesota Rules, Chapter 1400. It contains:

- **Proposed Rules**
- **Adopted Rules**
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- **Withdrawn Rules**
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Printing Schedule and Submission Deadlines

Vol. 49 Issue Number	Publish Date	Deadline for: all Short Rules, Executive and Commissioner's Orders, Revenue and Official Notices, State Grants, Professional-Technical- Consulting Contracts, Non-State Bids and Public Contracts	Deadline for LONG, Complicated Rules (contact the editor to negotiate a deadline)
#21	Monday 18 November	Noon Tuesday 12 November	Noon Thursday 7 November
#22	Monday 25 November	Noon Tuesday 19 November	Noon Thursday 14 November
#23	Monday 2 December	Noon MONDAY 25 November	Noon Thursday 21 November
#24	Monday 9 December	Noon Tuesday 3 December	Noon Thursday 28 November

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SUBSCRIPTION SERVICES: E-mail subscriptions are available by contacting the editor at sean.plemmons@state.mn.us. Send address changes to the editor or at the Minnesota State Register, 50 Sherburne Avenue, Suite 309, Saint Paul, MN 55155.

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House Public Information Services
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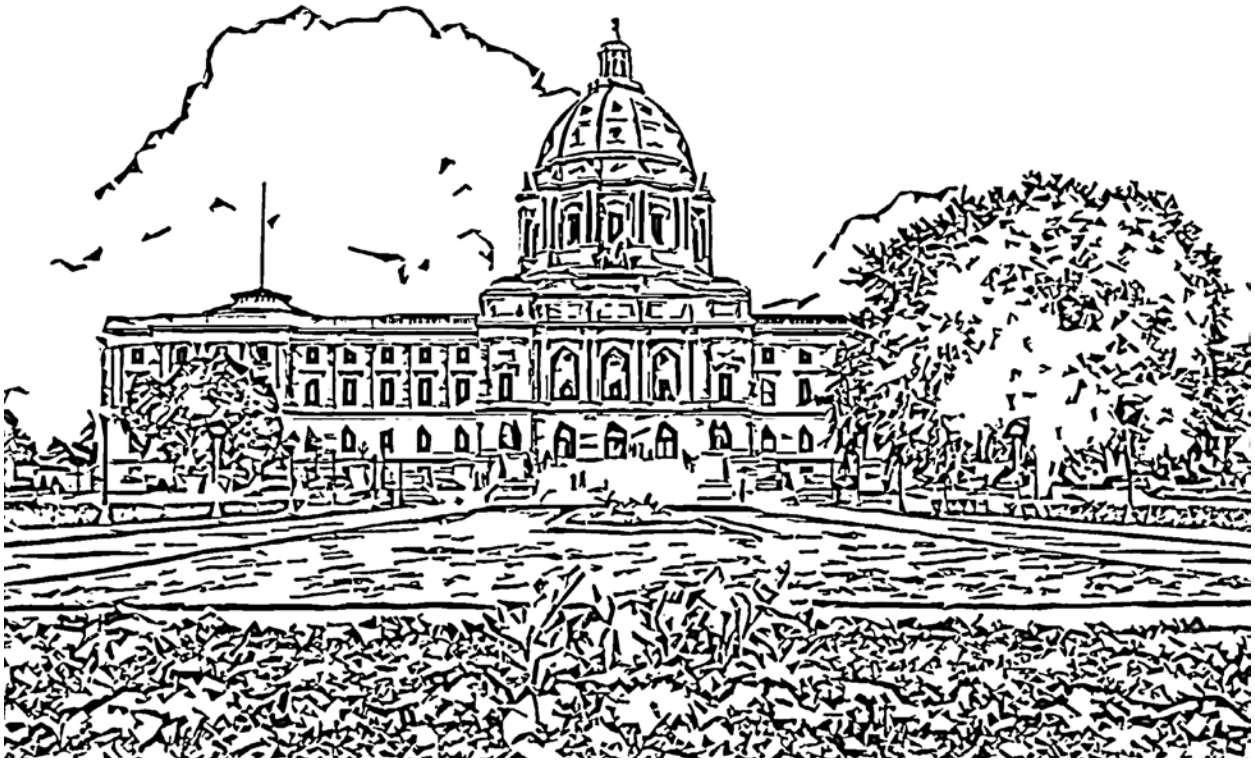
Contents

Front Cover Artwork: *The downtown Saint Paul skyline shows off on a crisp fall day as the Green Line train rolls by State of Minnesota buildings. Photo by Sean Plemmons*



must be provided in the facility's quarterly and annual reporting under item B.

B. Each quarter and annually at the end of the calendar year, a license holder must report to the commissioner the following data:

(1) the number of medical separations, including:

(a) the reason for each medical separation;

(b) the length of each incident, excluding sleeping hours; and

(c) the cumulative time that all residents were removed from their units and programming; and

(2) the number of residents who experienced medical separation, including demographic data disaggregated by age, race, and gender.

REPEALER. Minnesota Rules, parts 2960.0020, subpart 30; and 2960.0710, subpart 8, are repealed.

EFFECTIVE DATE. Minnesota Rules, parts 2960.0020 to 2960.0750, and the repealer are effective 60 calendar days after publication in the State Register.

Errata

Appearing in this section are: corrections to agency or *State Register* rule errors, or in following rulemaking processes, as well as incomplete notices, mislabeled rules, incorrect notices and citations. Whenever an error is corrected in this section, its corresponding rule number(s) will also appear in the *State Register's* index to rulemaking activity: ***Minnesota Rules*: Amendments and Additions.**

KEY: Proposed Rules - Underlining indicates additions to existing rule language. ~~Strikeouts~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." **Adopted Rules** - Underlining indicates additions to proposed rule language. ~~Strikeout~~ indicates deletions from proposed rule language.

Minnesota Department of Health

Errata Notice Regarding the Proposed Permanent Rules Relating to Health Risk Limits for Groundwater: Dual Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing if 25 or More Requests for Hearing Are Received; Revisor's ID Number: 4803; OAH Docket number: 22-9000-40331

November 2024

This Errata Notice addresses the proposed rules governing Health Risk Limits for Groundwater for Minnesota Rules, parts 4717.7500 and .7860.

In the section of the Dual Notice titled "Subject of Rules and Statutory Authority," appearing in the *State Register* dated November 4, 2024, the fourth (last) sentence of the first paragraph of this section incorrectly states the units of PFOS referenced in Laws of Minnesota 2023, Chapter 60, Article 3, Section 34 as "ppm," rather than what these units should be shown as, which is "ppb" or "parts per billion." The sentence, if displayed as a redline (with strikethrough for the erroneous text and underline for the correct text), would read as follows: "…MDH must adopt an updated HRL value of no greater than 0.015 ~~ppm~~ppb for [Perfluorooctane Sulfonate] PFOS by July 1, 2026."