Minnesota Pollution Control Agency

STATEMENT OF NEED AND REASONABLENESS

Proposed Amendments to Minn. R. chs. 7050,
Relating to the Classification and Standards for Waters of the State;
and 7052 Relating to Lake Superior Basin Water Standards
(Human Health Methods and Clarification of Recreational Standards)

Revisor of Statutes # 4177

wq-rule4-08c

Alternative format

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List of frequently used citations, abbreviations and acronyms

ADAF	Age Dependent Adjustment Factor
ADE	Acceptable Daily Exposure
AF	Adjustment Factors
$AF_{Lifetime}$	Adjustment Factor-Lifetime
Agency	State Agency
AWQC	Ambient Water Quality Criteria (EPA)
BAF	Bioaccumulation Factor
BCC	Bioaccumulative Chemical of Concern
BEACH	Beaches Environmental Assessment and Coastal Health Act of 2000 (33 U.S.C. 1346 and 1375a)
Board	MPCA Citizens' Board
C	Carcinogen, Linear
CC	Chronic Criteria
CC_{dev}/CS_{dev}	Chronic Criterion or Standard – Less-than-chronic evaluation of drinking water exposure
CC_{df} /CS_{df}	Chronic Criterion or Standard – Previously used for drinking water, fish consumption, and recreation (1990 methods)
CC_{dfr} /CS_{dfr}	Chronic Criterion or Standard – Revised for drinking water, fish consumption and recreation use classes
CC_f/CS_f	Chronic Criterion or Standard – Previously used for fish consumption and recreation (1990 methods)
CC_{ft}/CS_{ft}	Chronic Criterion or Standard – New for fish tissue-based
CC_{fr}/CS_{fr}	Chronic Criterion or Standard – Revised for fish consumption and recreation use classes
CDC	Center for Disease Control
CFR	Code of Federal Regulations
CR	Cancer Risk Levels
CS	Chronic Standards
CSF	Cancer Slope Factor (same as q1*)
CSFII	Continuing Survey of Food Intakes by Individuals (U.S. Department of Agriculture)
CWA	Clean Water Act (33 U.S.C. § 1251, et seq.)
DOC	Dissolved organic carbon
DC	Domestic Consumption (Class 1 Water Quality Standard)
DDT	Dichlorodiphenyl-trichloroethane
DW	Drinking Water
DWIR	Drinking Water Intake Rate
E. coli	Escherichia coli

EPA	U.S. Environmental Protection Agency – Used in text
FC	Fish Consumption
FCA	Fish Consumption Advice (MDH)
FCR	Fish Consumption Rate
g/d	Grams per day
GWPA	Minnesota Groundwater Protection Act (Minn. Stat. ch. 103H)
GLI	Great Lakes Initiative (Minn. R. ch. 7052)
HH-WQS	Human Health-based Water Quality Standard
HCC	Human Cancer Criterion
HCV	Human Cancer Value
HNC	Human Noncancer Criterion
HNV	Human Noncancer Value
HH-TSD	Human Health Technical Support Document
HRL	Health Risk Limits (drinking water standards MDH)
IR	Intake Rate (drinking water-MDH)
IRIS	Integrated Risk Information System
IW	Incidental Water
IWR	Incidental Water Intake Rate
L	Liter
LOAEL	Lowest Observed Adverse Effect Level
µg/kg	micrograms per kilogram
µg/L	micrograms per liter
mL	milliliters
MCEA	Minnesota Center for Environmental Advocacy
MDH	Minnesota Department of Health
MMB	Minnesota Management and Budget
MPCA	Minnesota Pollution Control Agency
MOA	Mode (or mechanism) of Action
NLC	Nonlinear Carcinogen
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
OAH	Office of Administrative Hearing
OPP	Office of Pesticide Programs
PCB	Polychlorinated biphenyls
POC	Particulate Organic Carbon

q1*	Carcinogen potency factor (slope)(1990)
RFC	Request for Comment
RfD	Reference Dose for noncancer toxicants and nonlinear carcinogens
RSC	Relative Source Contribution factor
SDWA	Safe Drinking Water Act
SONAR	Statement of Need and Reasonableness
TEAM	Total Exposure Assessment Model
TL	Trophic Level
TSR	Triennial Standards Review
USEPA	U.S. Environmental Protection Agency – Used in citations
WQS	Water Quality Standard

I. Introduction

A. Abstract

Water Quality Standards (WQS) provide the foundation for protecting and enhancing the quality of Minnesota's surface waters and are the basis for permitting, assessment of waters, and protection and restoration activities. In this rulemaking the Minnesota Pollution Control Agency (MPCA) addresses methods that are the main basis for protecting human health uses of surface waters (fish consumption, recreation and drinking water source). The following changes to the WQS (Minn. R. chs. 7050 and 7052) are proposed:

- Updates to the methods used to develop numeric WQS that protect human health
- Clarification of the Federal Beaches Environmental Assessment and Coastal Health (BEACH) Act of 2000[1] requirements relating to *E. coli* WQS

The proposed changes to human health-based Water Quality Standards (HH-WQS)[2] include many improvements to both exposure assessments and toxicological evaluations. The proposed improvements include higher intake rates based on newer data and early life-stage protections for infants and children; multi-duration toxicological parameters; and additional evaluation approaches for environmental degradates and mixtures of toxic pollutants. The MPCA is also adding new algorithms to develop fish tissue-based HH-WQS for pollutants accumulating in fish.

The MPCA is incorporating, by reference, the existing Federal BEACH Act requirements that apply in the Lake Superior Basin and is specifically identifying the applicable *E. coli* numeric standards.

The MPCA has conducted extensive public notice and provided opportunities for comment and review of the proposed amendments, including the development of a technical support document which has been available for review on the rulemaking webpage.[3]

B. Executive Summary

1. Updated methods for human health-based water quality standards

Minnesota's WQS in Minn. R. chs. 7050 and 7052 include methods and pollutant-specific numeric standards to protect the beneficial uses of surface waters specific to human health: drinking water, fish consumption, and recreation.[4] The Human Health-based WQS (HH-WQS) center on risk assessment methods. The existing risk assessment methods are out of date and in need of revision to incorporate the latest Federal and State policies and updated science, including additional protection for developmental life stages. The proposed amendments specifically address the important need to

[1] 33 U.S.C. § 1346 and 1375a.

[2] To assist in describing the Chronic Standard (CS) or site-specific Chronic Criterion (CC) based on human health protection, the subject of this SONAR, the alternate term "Human Health-based Water Quality Standard" (HH-WQS) is used.

[3] *Amendments to Human Health Methods for Developing Class 2 Chronic Standards* at http://www.pca.state.mn.us/chdfaa8.

[4] Class 2 surface waters include aquatic life protection as another beneficial use; therefore, toxic pollutants are also evaluated for their acute and chronic effects to aquatic organisms. In the Lake Superior basin, fish-eating wildlife are also considered when developing a CS or CC. MPCA's methods for toxic pollutants address toxicity to all these populations of interest; the final, most stringent CS or CC are identified as being either aquatic toxicity-, human health-, or wildlife-based (Minn. R. 7050.0218, 7050.0222 and 7052.0100).

consider differences in the susceptibility of infants and children to environmental pollutants as compared to adults. Guidance published by the U.S. Environmental Protection Agency (EPA) in 2000 and improved methods for Health Risk Limits (HRL) adopted by the Minnesota Department of Health (MDH) in Minn. R. ch. 4717, provide much of the technical and policy foundation for the revised methods being proposed in this rulemaking.

HH-WQS establish the principal regulatory basis for limiting and managing toxic pollutants present in Minnesota's surface waters that are or may be detrimental to human health. HH-WQS include protection goals (narrative standards) and methods to develop pollutant-specific numeric HH-WQS. The HH-WQS methods are the basis for pollutant-specific Class 2 Chronic Standards (CS) adopted in Minn. R. 7050.0222. The methods (Minn. R. 7050.0217 to 7050.0218, and proposed for Minn. R. 7050.0219, and Minn. R. 7052.0110) are also the basis for site-specific Chronic Criteria (CC) for pollutants that are detected in surface water, but lack adopted CS. Like all WQS, they serve as the basis for protecting the beneficial uses of Minnesota's water resources, setting wastewater discharge effluent limits, assessing water quality, and determining if waters are impaired (i.e., do not meet WQS).

The general algorithms (equations and steps) for developing HH-WQS encompass the toxicological profile of a pollutant and representative exposure rates for people using surface waters as a source of drinking water and for recreating and fishing. This information is incorporated into algorithms based on these beneficial uses to develop pollutant-specific numeric standards or criteria that minimize the risk of adverse effects from long-term (chronic) exposure. The fundamental formula for developing Class 2 HH-WQS is:

Chronic Standard or Criterion (CS or CC) = Toxicological Value / Exposure

The CS or CC is typically expressed in units of pollutant concentration in micrograms per liter (µg/L) of water or micrograms per kilogram (µg/kg) of edible fish tissue.

Toxicological Values characterize a pollutant's noncancer or cancer effects and develop quantitative values for protection from adverse effects. In general, the following quantitative toxicological values are derived: Reference Dose (RfD) for noncancer toxicants and nonlinear carcinogens– the estimated daily exposure likely to prevent adverse impacts – in units of pollutant dose (mg per kg of body weight-day); and Cancer Potency Slope Factor (CSF) – defines upper bound cancer risk per increment of dose – in units of cancer incidence per dose (1/mg of pollutant per kg of body weight-day).

Exposure describes the route and estimated intake rate of a pollutant for a specified population as part of the beneficial uses of surface waters. All HH-WQS intake rates reflect oral routes of exposure, including intake of drinking water, incidental ingestion of water during recreation, or fish consumption. Units are liters of water intake (L) per kg of body weight-day or kilograms of fish consumed (kg) per kg of body weight-day.

The amendments being proposed for the HH-WQS include aspects of the toxicological values, exposure parameters, and their application in revised algorithms for calculating HH-WQS. Under the amendments, the toxicological evaluation of a pollutant will now involve:

- Review and application of toxicity data for shorter duration effects, which may lead to a more restrictive CS than the use of longer duration toxicity data (chronic effects)
- Improvement of methods to address mixtures of pollutants using noncancer Health Risk Index Endpoints
- Inclusion of new cancer potency Adjustment Factors (AF) to account for greater early-life sensitivity to carcinogens

Regarding exposure parameters, the proposed amendments include new intake rates that directly incorporate body weight, newer data, and consideration of different exposure profiles and rates by life stage (e.g., infants and children tend to have higher exposures than adults when calculated based on body weight). In the MDH's latest drinking water Intake Rates (IR) used to develop Health Risk Limits (HRL) or other health-based guidance, additional protection for infants and children was implemented through the use of updated national survey data from the EPA on community drinking water consumption and use of higher percentile values, meaning the use of higher exposure rates than were previously in rule that reflect drinking water intake for more people.

Other proposed improvements in the methods address additional exposure parameters, including Bioaccumulation Factors (BAF), new approaches for evaluating the toxicity of pollutant breakdown products (environmental degradates), and a new Relative Source Contribution (RSC) decision process. Revised BAF methods for statewide use will increase consistency by reflecting those already used for the Lake Superior Basin. To address environmental degradates, a new narrative standard will allow the use of the "parent" pollutant's HH-WQS if insufficient data are available to evaluate the toxicity of the degradate. RSC accounts for other sources of exposure to a pollutant and will now be better estimated using a series of decision steps.

Low concentrations of many surface water pollutants bioaccumulate up the aquatic food chain and reach concentrations of concern in fish tissue. The EPA recognized this issue and published the first national *Ambient Water Quality Criteria* (AWQC) for methylmercury applicable in fish tissue in 2001. The MPCA adopted this fish tissue-based standard for mercury in 2008 and is now proposing to expand this approach by supplementing the current methods with the addition of algorithms specific to developing fish tissue-based HH-WQS for other bioaccumulative pollutants.

Human Health-based Water Quality Standards Technical Support Document (HH-TSD, Exhibit HH-1) provides the details and technical basis for the proposed amendments. References to sections of Exhibit HH-1 are included parenthetically to assist in finding the more detailed topic discussions. Exhibit HH-1 includes complete definitions (Exhibit HH-1, Appendix A1) and full discussion of the existing and proposed algorithms for developing HH-WQS for application in surface water and fish tissue (Exhibit HH-1, Section V.). Exhibit HH-1 also discusses current risk assessment practices and their limitations (Exhibit HH-1, Section VI.). The Appendices B and C of the HH-TSD also provide information on the existing methods, because until future rulemaking projects are initiated to replace the existing pollutant-specific HH-WQS, the numeric CS in Minn. R. chs. 7050 and 7052 will remain as previously established. The revised methods will be the basis for future site-specific CC when adopted.

2. Clarification of applicable Escherichia coli water quality standards in Minn. R. ch. 7052

The MPCA is proposing to clarify which *E. coli* numeric WQS established under the BEACH Act specifically apply in the Lake Superior Basin. The MPCA considers this to be a housekeeping amendment because it is incorporating existing federal WQS that have been in effect since 2004. In addition to incorporating by reference the specific *E. coli* standards that apply to Lake Superior, the MPCA is also proposing a State-only clarification of the federal term "recreation season." For purposes of the *E. coli* standards being proposed, the MPCA is specifying that the "recreation season" is the period from April 1 to October 31, the same timeframe as the existing statewide *E. coli* WQS already in Minn. R. ch. 7050.

II. Background on Human Health-Based Water Quality Standards

As introduced, detailed information about the existing and proposed Human Health-based HH-WQS is provided in the HH-TSD (Exhibit HH-1). Information in this Statement of Need and Reasonableness (SONAR) draws upon the HH-TSD for purposes of need and reasonableness discussion.

The 1987 Clean Water Act (CWA)[5] amendments in Section 303(c)(2)(B)[6] required states and tribes to adopt WQS for toxic pollutants. In response to this mandate, in 1990 the MPCA developed methods and adopted narrative and numeric WQS for aquatic life, human health, and fish-eating wildlife protection in Minn. R. ch. 7050 under the Class 2 designated uses. The rule revision included new numeric WQS for 54 toxic pollutants, revised WQS for five toxic pollutants, and methods for developing site-specific CC for toxic pollutants lacking adopted WQS (Exhibit HH-2). National concerns about bioaccumulative toxics in the Great Lakes led to amendments to Section 118(c)(2)[7] of the CWA in 1990. The new requirements under the *Great Lakes Critical Programs Act* required the EPA to publish, and states to adopt, methods and WQS specific to the Great Lakes. In 1998, the MPCA adopted the Great Lakes Initiative (GLI) methods and AWQC for the Lake Superior Basin in Minn. R. ch. 7052 (Exhibit HH-5). Since those rulemakings, additional WQS for toxics have been adopted or older WQS updated with newer data (Exhibit HH-1, Section I.).

The EPA develops guidance on a national level to assist states in adopting WQS. However, the EPA expects that states incorporate more representative local data when available. The MPCA has always incorporated Minnesota-specific data in HH-WQS. Local data include fish consumption rates and fish lipid values developed by the MPCA in 1990, and toxicological values, RSC factors, and Cancer Risk levels (CR) developed by the MDH in their groundwater protection program (Exhibit HH-1). The MDH has the principal role in Minnesota for toxicological evaluations of environmental pollutants and provides the MPCA with risk assessment support. Therefore, the proposed amendments to the HH-WQS methods are based on the need to incorporate advances in risk assessment approaches used by the EPA, including updated human health methods published in 2000, and the MDH, to ensure the methods in Minn. R. chs. 7050 and 7052 are based on the most recent science, public health practices, and policies for protecting surface water users (Exhibit HH-1, Sections II. and III.).

The purpose of this SONAR is to provide an overview of the current methods used to develop numeric water quality criteria and standards for human health protection and to describe and provide the rationale for the proposed amendments. These methods are specific to elemental and synthetic chemical contaminants characterized as toxic pollutants[8,9]. HH-WQS are the basis for setting *lifetime* protection for humans from toxic pollutants to meet the beneficial uses of drinking water (where

[5] 33 U.S.C. § 1251, et seq.
[6] 33 U.S.C. 1313
[7] 33 U.S.C. 1268
[8] Minn. Stat. § 115.01, subd. 20: "Toxic Pollutant" means those pollutants, or combinations of pollutants, including disease-causing agents, which after discharge and upon exposure, ingestion, inhalation or assimilation into any organism, either directly from the environment or indirectly by ingestion through food chains, will, on the basis of information available to the agency, cause death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions, including malfunctions in reproduction, or physical deformation, in such organisms or their offspring.
[9] The terms *pollutant* and *chemical* are relied on in this document to describe a *toxic pollutant*. Other sources referenced in this document may refer to a *toxic pollutant* interchangeably as a *chemical, element, environmental agent, contaminant,* or *substance.*

designated under Class 1), fish consumption, and recreation in all surface waters. The revision to the HH-WQS will provide the basis for future proposed amendments to numeric HH-WQS that will be adopted into rule as Class 2 CS by subclass or will be used as site-specific CC for pollutants detected in surface water that lack promulgated WQS (Minn. R. 7050.0217 to 7050.0219 and Minn. R. 7052.0110).

A. Existing HH-WQS methods in Minn. R. chs. 7050 and 7052

Minnesota's historical water quality rules that directly relate to Minn. R. chs. 7050 and 7052 were first adopted in 1963 and have been regularly enhanced due to requirements of the CWA. The CWA defines the basis for WQS (40 CFR 131.2). WQS consist of three elements:

- Classification of waters for designated beneficial uses
- Narrative and numeric standards to protect those uses
- Nondegradation policies to maintain and protect existing uses and high quality waters

The WQS proposed for amendments in this rulemaking encompass the first two elements of WQS. The third element, nondegradation (federal antidegradation), is not directly related to the proposed methods and will not be discussed further in the context of these proposed amendments.

1. Use classifications for human health protection

Minn. R. chs. 7050 and 7052 have two beneficial use classifications with relevance to human health protection: Class 1, Domestic Consumption; and Class 2, Aquatic Life and Recreation. The first State water quality rule in 1963 (Water Pollution Control ch. 1) established protection for surface waters used as a source of drinking water. This rule applied federal drinking water standards in ambient waters upstream of Mississippi River public drinking water sources and has served as the basis for Class 1 beneficial use classifications ever since. Based primarily on the CWA and a recognized need to address additional human health uses of surface waters (fish consumption and recreation) the MPCA established the Class 2 beneficial use classification. This use class also includes protection of the aquatic life community as directed under the goals of the CWA (Exhibit HH-1, Section II.).

Minn. R. ch. 7050 addresses drinking water use through the Class 1 Domestic Consumption (DC) designation. Class 1 applies to all groundwater and specified surface waters. Minnesota's Class 1 designation in surface waters precede the requirements of the CWA , by requiring that water pollutants in source water be minimized or eliminated prior to treatment and actual drinking water consumption. The Class 1 designation supports CWA goals, as well as, meeting MPCA policy (Exhibit HH-1; EPA Water Quality Standards Handbook).

Surface waters upstream of Safe Drinking Water Act (SDWA) public drinking water sources designated and administered by the MDH are Class 1, with subclasses (1B or 1C) which categorize general levels of treatment needed prior to actual consumption (Minn. R. 7050.0221).[10] All cold-water aquatic communities (Class 2A) are also protected for drinking water use regardless of if they are actually a source for a SDWA-designated drinking water supply. In some cases, outstanding resource value surface

[10] Unlike groundwater, the actual use of surface waters for drinking is not expected without some level of treatment as indicated in the Class 1 subclasses 1B and 1C. Surface waters used for drinking by municipalities (community) and other entities (non-community and transient) are regulated by the MDH under the comprehensive SDWA requirements. Regulated drinking water quality is evaluated by the MDH at the "tap" or in finished drinking water.

waters, including lakes in the Boundary Waters Canoe Area, also have a Class 1 designation. A complete listing of these waters and their use classifications is found in Minn. R. 7050.0470.

The Human Health-based HH-WQS relevant to this rulemaking are for Class 2 designated surface waters, where State and CWA goals are integrated to define the beneficial uses for this class of waters. As stated in Minn. R. 7050.0140, subp. 3:

> ***Class 2 waters, aquatic life and recreation****. Aquatic life and recreation includes all waters of the state that support or may support fish, other aquatic life, bathing, boating, or other recreational purposes and for which quality control is or may be necessary to protect aquatic or terrestrial life or their habitats or the public health, safety, or welfare.*

Both human consumption of fish and recreational activity are part of the beneficial uses covered in Class 2 waters. And in the context of other uses specific to public health, select surface water are also being used as a source of drinking water as established under the Class 1 designation as previously described. Class 2 HH-WQS for waters also designated Class 1 have to include exposure to pollutants from drinking the water, in addition, to just exposure from fish consumption and recreational ingestion. Therefore, background on the Class 1 designation is helpful for understanding the Class 2 and applicable HH-WQS.

To fully address exposure from fish consumption, Class 2 waters also have subclasses that differentiate their aquatic life communities, including fish species. The subclasses are most relevant to HH-WQS because the presence of different fish species of different trophic levels (place in the food chain) can affect how much a pollutant bioaccumulates in the fish and how much people may be exposed to that pollutant through fish consumption. The degree of bioaccumulation for many pollutants is directly related to the amount of fat (lipids) in a fish. Trout and other *Salmonidae* species are characteristic of Class 2A cold-water communities and have higher lipid content than most other cool and warm water fish. In Lake Superior, Lake Trout have even higher lipid content than other trout species and thus provide the basis for a separate Class 2A Lake Superior subclass. The details on the relevance of the subclasses and BAF used to develop HH-WQS are described later in this SONAR and in the HH-TSD (Exhibit HH-1, Sections II. and IV. C.).

In short, surface waters have multiple use classifications. The Class 1 and 2 subclasses that correspond to the human health-based beneficial uses are:

- Class 2A, 1B (Lake Superior): Drinking water, fish consumption, and recreation
- Class 2A, 1B: Drinking water, fish consumption, and recreation
- Class 2Bd, 1B or 1C: Drinking water, fish consumption, and recreation
- Class 2B (also applied as 2C and 2D as stated in Minn. R. ch. 7050): Fish consumption and recreation

2. Narrative and numeric standards

Narrative and numeric standards work together to provide the protection needed to meet beneficial uses and to define the quantitative basis for pollutant-specific WQS. Numeric standards serve as the measurable values to implement water quality goals (Exhibit HH-1, Sections II. A. and III.).

The Class 1 Use designation is for drinking water protection. As such the Class 1 numeric DC standards incorporate by reference the federal SDWA standards (Maximum Contaminant Levels and Secondary Drinking Water Standards) from 40 CFR 141 and 143. Minn. R. 7050.0221 further describes the application of the SDWA in groundwater and designated surface waters.

Minn. R. 7050.0140, subp. 3, contains the central narrative requirements that comprise the protection level goals for Class 2 HH-WQS. Other supporting statements are made in Minn. R. 7050.0150, subp. 3, relating to preventing "*significant increase in harmful pesticides or other residues in the waters, sediments, and aquatic flora and fauna"*, and are relevant to pollutants that pose health risks when present in surface water or fish tissue. Because there are many pollutants of concern in fish tissue, Minnesota also has a specific narrative standard in Minn. R. 7050.0150, subp. 7, limiting fish-tissue contaminants to levels that allow for consumption of fish at levels below specific health effects as often as one meal per week based on the MDH Fish Consumption Advice (FCA). Concentrations of pollutant that result in more restrictive FCA would exceed the protection goals for HH-WQS.

These and other narrative standards included in Minn. R. chs. 7050 and 7052 provide the framework for developing numeric standards using the methods for HH-WQS. The protection level goals found in Minn. R. 7050.0217, subp. 2. (excerpted below) address and define both Federal and State risk policies and quantifiable measures on the level of human health protection provided by the HH-WQS.

> *Protection of human consumers of fish, other edible aquatic organisms, and water for drinking from surface waters means that exposure from noncarcinogenic chemicals shall be below levels expected to produce known adverse effects; and the incremental cancer risk from exposure to carcinogenic chemicals, singly or in mixtures, shall not exceed one in 100,000. The combined risk from mixtures of carcinogens will be determined as described in part 7050.0222, subpart 7, item D.*

HH-WQS are set at concentrations to protect human users of surface waters. That protection considers the toxicity (deleterious, noxious, or injurious) characteristics of the pollutant and how much a population may be exposed to that pollutant through the three designated beneficial uses of surface waters: drinking water, recreational activities, and fish consumption. In short, HH-WQS encompass a pollutant's toxicity and a population's potential exposure and lead to numeric CS (or site-specific CC) that cannot be exceeded in surface water or fish tissue (Exhibit HH-1, Section III.).

The methods used to develop pollutant-specific numeric HH-WQS (Class 2 CS or CC) for toxic pollutants were first adopted in 1990 for statewide application and in 1998 for the Lake Superior Basin. Currently, Minn. R ch. 7050 contains WQS for 69 toxic substances. Of these, 36 standards are more restrictive to protect human health than aquatic life (Minn. R. 7050.0222). Minnesota R. ch. 7052 contains WQS for 29 pollutants; for 15 of these standards human health is the basis for the most stringent CS (Minn. R. 7052.0100).

3. Existing HH-WQS parameters and algorithms

This section provides an overview of the existing methods for developing the numeric standards or criteria; the methods are fully described in Exhibit HH-1, Section II. C.

The methods for HH-WQS center on three main practices of risk assessment, adapted to the beneficial uses of surface waters: drinking water, fish consumption, and recreation. The practices are:

- Describe the toxicological profile of a pollutant
- Identify the population protected and at what levels
- Evaluate the exposure routes and rates representative of that population

Toxicological Profiles

For HH-WQS, the current algorithms in rule are based on two toxicological outcomes: noncancer adverse health effects (reviewed for all pollutants) and carcinogenicity. Both of these evaluations come principally from animal toxicity studies with, in some cases, human epidemiological information. The

outcome of a noncancer evaluation is a description of the types of observed health effect and derivation of the dose of the most relevant and sensitive adverse outcome, defined as the Point of Departure. That value, when combined with uncertainty factors results in the Reference Dose (RfD). The RfD, as defined in Minn. R. 7050.0218,

> "*means an estimate of daily exposure to the human population, including sensitive subpopulations, that is likely to be without appreciable risk or deleterious effects over a lifetime."*[11]

The basis for the RfD is the dose-response evaluation which identifies the dose below which exposure to the pollutant has no adverse effects (threshold dose). At doses above the threshold, adverse effects are likely. The determination of that "threshold dose" serves as the basis for protecting humans from chronic exposure to the pollutant.

A pollutant is also evaluated for information on its potential to lead to carcinogenic processes or tumor responses. When sufficient data are available to characterize a pollutant as a carcinogen, a secondary review is done to determine the mode of action (MOA) and the most appropriate toxicological value for use in risk assessments. If the carcinogenic action leads to a response more akin to noncancer effects, or in other words, shows a threshold response, a RfD is the basis for the protective standard. These pollutants are called nonlinear carcinogens (NLC).

If available data demonstrate that the pollutant is a direct-acting carcinogen (i.e., DNA mutagen) or is insufficient to determine the MOA, it is termed a linear carcinogen (C) and quantified through the Cancer Potency Factor (q1*, now referenced as CSF). This approach assumes that any exposure to this pollutant can lead to cancer, so the q1* is always paired with a Cancer Risk (CR) Level. The CR level signifies an expected upper bound incremental increase in cancer incidence in a population associated with exposure to the pollutant. The incremental CR level used in HH-WQS is one additional case of cancer in a population of 100,000 (expressed as 1/100,000 or 10^{-5}) resulting from lifetime exposure to the carcinogen.

Historically, if the pollutant was a Group C carcinogen (limited, but insufficient evidence to quantify carcinogenicity with a slope factor), the MDH applied an extra 10-fold UF to the RfD. As described in the full discussion of the revised methods in the HH-TSD, these evaluations have improved with greater scientific understanding of cancer related processes and better risk assessment approaches.

Populations and exposure evaluation

In establishing HH-WQS, the MPCA considers the effect of a toxic pollutant on any person who may drink, eat fish from, or recreate in Minnesota's surface waters. The specifics of how the MPCA estimates exposure for this population depend on the parameter being considered and the availability of data (Exhibit HH-2). When the Drinking Water (DW) and Fish Consumption (FC) intake rates were developed in 1990, exposure centered on adult body weight and exposure data. For body weight the standard value was 70 kg, which generally represented a population average. Most EPA programs also used 2 L per day as a general adult population DW average intake rate. To address exposure to pollutants while recreating (i.e., swimming), the MPCA included an Incidental Water (IW) intake rate of 0.01 L per day. This rate was based on an estimated volume of water representative of a "mouthful" of water ingested during the summer swimming season and adjusted to a year-round daily intake rate.

The exposure data most relevant and specific to a Minnesota population of surface water users relate to fish consumption patterns and rates. Fishing is an important activity in Minnesota and State-based

[11] For Minn. R. ch. 7052, the GLI methods gave this same meaning to the term Acceptable Daily Exposure (ADE).

information on fish consumption by Minnesota anglers is very relevant to HH-WQS. When the MPCA established the existing HH-WQS, instead of adopting the EPA nationally recommended FCR of 6.5 g per day (g/d), the MPCA evaluated regional data on sport fish consumption (Exhibit HH-2). Studies of adult anglers in Wisconsin and Ontario provided the survey data needed for the MPCA to develop an 80th percentile consumption rate of 30 g per day for this population; use of a higher rate than the EPA's national default rate served to recognize the importance of fishing in Minnesota and to provide additional protection to fish consumers from toxic pollutants.

When the CWA required Great Lakes States to work with the EPA to develop consistent WQS for a list of Bioaccumulative Chemicals of Concern (BCC), the results were new AWQC for methods and numeric criteria for 18 pollutants based on human health protection. These Great Lakes Initiative (GLI) methods and criteria served as the foundation for the Lake Superior Basin WQS (Minn. R. ch. 7052)(Exhibit HH-5). Again the MPCA replaced the GLI default for fish consumption with the Minnesota-specific rate; the MPCA replaced the GLI fish consumption rate of 15 g/d with the already promulgated statewide rate of 30 g/d (Exhibit HH-1, Section II. D.).

The other consideration for fish consumption is estimating how much the pollutant partitions and biomagnifies (increases in each level of the aquatic food web) in fish tissue. Bioaccumulation Factors are used to set a water concentration protective of fish consumers. The BAF is the ratio between the concentration of the pollutant in fish tissue and the surrounding water. The MPCA developed BAF methods for statewide use in 1990. The methods included fish lipid values specific to Minnesota's Class 2A trout waters (6%) and Class 2B cool-warm water fisheries (1.5%). The GLI methods included new BAF methods that the MPCA adopted for use in Minn. R. ch. 7052 for the Lake Superior Basin. The GLI methods differed from those previously adopted in Minn. R. ch. 7050 and used a higher fish lipid value representative of Lake Superior Lake Trout of 8.5% (Exhibit HH-5).

The final exposure parameter referenced in the current methods is the RSC. The RSC was assigned to account for other non-water sources of exposure to the pollutant. The purpose of the RSC is to ensure that the level of chemical pollutant allowed in surface waters as expressed by a HH-WQS, when combined with other identified sources of exposure common to the population of interest, will not result in their exposures exceeding the RfD, which could lead to potential adverse health effects. Historically, the MPCA has applied a default RSC of 20%, unless chemical-specific exposure data were sufficient to derive another value. For example, the GLI methods used 80% for bioaccumulative pollutants, because fish consumption was the main source and route of exposure.

Another aspect the MPCA considers in establishing HH-WQS is defining protection for a *lifetime*. The application of the concept of lifetime protection grounds the methods in a 70-year timeframe and the assumption that surface water users are exposed to the same water and pollutants for 70 years. This can be a conservative assumption for many pollutants, but the MPCA considered this assumption reasonable, because some pollutants are found widely in water resources across the State and country (e.g., mercury), where exposure could commonly occur across an individual's lifetime from water or other sources. This assumption is also consistent with the MDH and EPA risk assessment methods for toxic pollutants. The lifetime duration is implemented as a chronic duration, defined as greater than 10% of a human lifespan (rounded up to a minimum duration of 8 years by the MDH and MPCA). This duration is significant for initiating long-term adverse effects or carcinogenic processes.

Example 1990 Algorithms-noncarcinogenic and carcinogenic chemicals

To illustrate application of the toxicological profile and exposure parameters in the 1990 HH-WQS algorithms, the Class 2A and 2Bd noncancer and cancer algorithms are presented below. These algorithms are used to develop site-specific CC or CS for surface waters protected for the beneficial uses of fish consumption, recreation, and drinking water use.

Noncancer Algorithm 1

$$CC_{df}, mg/L = \frac{RfD\ mg/kg\text{–}day \times 70\ kg\ \times RSC}{2\ L/day + (0.030\ kg/day \times BAF\ L/kg)}$$

Where:

CC_{df}	=	drinking water plus fish consumption [recreation exposure, defined by incidental water intake, is considered addressed by drinking water rate] Chronic Standard in mg/L
RfD	=	reference dose in mg/kg/day
70 kg	=	standard weight of an adult
RSC	=	relative source contribution factor
2 L/day	=	two liters of (drinking) water consumed per day (by adults)
0.030 kg/day	=	amount of fish assumed to be consumed per day (by people in Minnesota)
BAF	=	final Bioaccumulation factor in L/kg (liters per kilogram and specific to Class 2 subclass fish lipid values, 6% for 2A and 1.5% for 2Bd)

Cancer Algorithm 1

$$CC_{df}, mg/L = \frac{70\ kg\ \times\ 10^{-5}}{q1^{*}\ (mg/kg\text{–}day)^{-1}\ \times [2\ L/day + (0.030\ kg/day \times BAF\ L/kg)]}$$

Where:

10^{-5}	=	a cancer risk (CR) level of one chance in 100,000
q1*	=	the cancer potency factor in days times kg (body weight) per mg (toxicant)

Other variables as previously identified

The existing methods include four algorithms that cover the following four scenarios based on the pollutant's toxicological profile and surface water use classifications:

1. Noncarcinogenic pollutant and drinking water, fish consumption and recreation use classes (Classes 2A and 2Bd)
2. Noncarcinogenic pollutant and fish consumption and recreation use class (Class 2B)
3. Carcinogenic pollutant and drinking water, fish consumption and recreation use classes (Classes 2A and 2Bd)
4. Carcinogenic pollutant and fish consumption and recreation use class (Class 2B)

Mercury fish tissue chronic standard

In addition to the current HH-WQS algorithms for CS applied in water, the MPCA adopted a fish tissue-based standard for mercury in 2008 based on the EPA AWQC for methylmercury (2001)(Exhibit HH-1, Section II. E.). The mercury HH-WQS served to augment the already listed CS protective of aquatic organisms, humans, and fish-eating wildlife in Minn. R. chs. 7050 and 7052. Mercury is highly bioaccumulative and its presence in fish tissue results in the main source of exposure to humans. Application of a CS in fish tissue more directly protects fish consumers. The CS is listed in Minn. R. ch. 7050 as applicable in edible fish tissue and was based on the following algorithm and parameters:

$$CS_{Fish\ Tissue} = \frac{70\ kg\ x\ (RfD - RSC)}{0.030\ kg/day}$$

$CS_{Fish\ Tissue}$ or CS_{ft} = for total mercury of 0.20 mg/kg or ppm (parts-per-million)

Given:

RfD	=	reference dose in mg/kg-day of 0.0001 mg methylmercury/kg body weight-day
70 kg	=	standard weight of an adult
RSC	=	relative source contribution factor of 2.7×10^{-5} mg methylmercury/kg body weight-day
0.030 kg/day	=	amount of fish assumed to be consumed per day (Minnesota)

Organoleptic standards

Early approaches taken by the EPA to address surface water pollutants included consideration of taste and odor issues, known as organoleptic effects. Both the EPA's AWQC and Safe Drinking Water Act Secondary Standards developed water concentrations to prevent nuisance taste and odor conditions in fish tissue and drinking water. As described in more detail in *Role of EPA Guidance in HH-WQS*, AWQC provide a scientific foundation for WQS. In 1990, the organoleptic criteria for three pollutants (acenaphthene, chlorobenzene, and 2, 4, 6-trichlorophenol) were more stringent than the CS developed based on noncancer effects and were adopted as the final CS in Minn. R. ch. 7050.

4. Summary

The complete history of the data and reasonableness for the methods and parameters existing, and proposed for amendments, in rule are described in Exhibit HH-1, Appendices A1, B1 and B2, and 1989 and 1997 SONARs (Exhibits HH-2 and HH-5). The details of the application of the methods and algorithms currently used for development of site-specific CC are found in Minn. R. 7050.0217, 7050.0218, and 7052.0110, subp. 4.

B. Role of EPA Guidance in HH-WQS

As introduced, the development, adoption, and use of methods for protection of human health for surface water users were originally prompted by the CWA and Federal and State objectives to reduce Priority Pollutants (many defined as such because of toxicity to humans or aquatic communities)[12]. Section 304(a)[13] of the CWA also specifically directs the EPA, as administrator for the Act, to develop methods and pollutant-specific AWQC for use by states and tribes to develop WQS.

AWQC are technical documents covering the latest scientific knowledge of pollutants and are used to implement water quality protection. Since 1976, the EPA has published AWQC for about 160 pollutants, with over 100 having human health-based criteria, including 10 based on organoleptic factors. These criteria documents have formed the basis for many of the MPCA's human health-based numeric CS adopted in 1990 and 1994 in Minn. R. ch. 7050 (Exhibit HH-1, Section III. A.).

In 1995 the EPA published updated methods and new criteria for 29 pollutants as part of the GLI. These criteria focused on BCC – chemicals that accumulate in the food chain to levels of concern in fish. Based on those criteria, the MPCA adopted the methods and 13 new human health-based CS in Minn. R. ch. 7052 for the Lake Superior Basin in 1998 (Exhibit HH-5).

Most recently, in 2000, the EPA published an AWQC Guidance document specific to the methods for developing HH-WQS (Exhibit HH-3). This Guidance includes important risk assessment information, which the MPCA has used for updating the proposed standards.

The AWQC provide valuable scientific evaluations and recommendations to support development of WQS; however, while still supporting the preferred alternative that states and tribes replace or refine the national methods and defaults with more relevant local to regional scientifically defensible data when available. The MPCA initially modified the national AWQC for human health using Minnesota data and environmental risk policies and will continue to modify the national AWQC as appropriate. For example, regional studies of freshwater, caught fish consumption provided the basis for establishing a higher statewide fish consumption rate than the national default (Exhibits HH-1 and HH-2). The MPCA also has evaluated the lipid composition of Lake Superior and inland fish communities for Minnesota-specific fish lipid values for use in developing Minnesota-specific BAFs. In addition, as described in detail in the next section, the parameters (RSC and CR level) and most of the toxicological values used in HH-WQS were developed in collaboration with the MDH. While the MDH's risk assessment methods stem primarily from the EPA Guidance, the MDH also performs its own research to comply with State mandates for human health protection. The MDH's State-specific authority results in important differences in risk assessment approaches and toxicological values from the EPA's AWQC (discussed further in *Consistency with the MDH Drinking Water Programs,* and Exhibit HH-1, Section III. A.).

[12] The 1972 CWA lists 172 *Priority Pollutants* that were deemed a concern in the nation's waters at that time. The EPA, states and tribes were required to address these pollutants in water quality standards (http://www.epa.gov/waterscience/criteria/wqctable/).

[13] 33 U.S.C. 1314

III. Consistency with the MDH Drinking Water Programs

In Minnesota, the MDH serves as the lead for toxicological evaluations and for many environmental human health risk assessments. The MDH's authority for water programs specifically includes the federal SDWA and Minnesota GWPA (Minn. Stat. § 103H). Through its GWPA authority, the MDH adopts health protective drinking water standards, termed HRL, into Minn. R. ch. 4717. HRL are promulgated for chemicals that, because of human activity, have degraded groundwater (Exhibit HH-6). The MDH defines chemical-specific HRL as "*concentrations of a groundwater contaminant, or mixture of contaminants, that can be consumed with little or no health risk to humans, including vulnerable subpopulations"* (Exhibit HH-6). The MDH also follows the HRL methods to develop other health based guidance (e.g., Health Based Values and Risk Assessment Advice) for drinking water pollutants. The MDH guidance values are used for many purposes, such as informing remediation, pesticide management activities, as well as to inform individual well owners.

The MDH's risk assessment expertise and drinking water guidance has been referenced in the MPCA's HH-WQS rulemaking activities (Exhibits HH-2 and HH-7). The MPCA's policy is to maintain consistency between HH-WQS and the MDH's HRL development and other risk assessment protocols. Consistency in risk assessment practices, especially for drinking water protection is important for many reasons:

1. To comply with the intent of the original adoption of methods and standards for human health protection, including references to the MDH's early statewide drinking water guidance values (Recommended Allowable Limits) and FCA in Minn. R. ch. 7050 (Exhibits HH-2 and HH-7);
2. To acknowledge the MDH's role as the lead State Agency for human health toxicological evaluations and consultations (Exhibit HH-1, Section III.), and directed authority of relevant State statutory requirements for the MDH's drinking water and other programs (Exhibit HH-6); and
3. To maintain uniform measures of toxicity, exposure, and risk across State environmental standards that may differ from national defaults. Maintaining statewide consistency is essential, especially in light of the CWA requirement that states base WQS on statewide or local data (Exhibit HH-3).

IV. Public Participation and Stakeholder Involvement

Many of the requirements of the State rulemaking process ensure that adequate notification is provided to all interested or affected persons and entities. These include the general public and affected stakeholders, but also various Agencies and Departments, including the Office of the Governor.

The HH-WQS were originally intended to be adopted as part of a rulemaking effort based on a 2003 Triennial Standards Review. Those amendments, when they were finally adopted in 2008, did not include the HH-WQS. The MPCA then intended to propose the HH-WQS as part of a combined rulemaking that resulted from the 2008 Triennial Standards Review. The rule proposals, including the HH-WQS, were subsequently divided into several separate rulemaking projects. As a result of this long history of rule development and discussion, the HH-WQS being proposed in this rulemaking share many of the same early stage public notice and public participation activities with other WQS rule proposals.

A. Required notifications

The MPCA conducted a number of outreach activities for this rulemaking to comply with the requirements of Minnesota's rulemaking process and the CWA, but also to provide a useful exchange of information between the MPCA rulemaking and technical staff and other parties with knowledge and experience regarding water quality issues and standards. The MPCA extensively communicated with and engaged the regulated community as well as stakeholders who will be affected by this rulemaking. These interested parties, along with the contacts on the list maintained in accordance with Minn. Stat. § 14.14, subd. 1a, and the lists of parties specifically interested in water standards rulemaking, are the basis of the MPCA's public notification process for receiving notices required by the Administrative Procedures Act as well as notices of other opportunities for public engagement.

Minn. Stat. ch. 14 requires that agencies conduct a number of public notification activities and document those activities for review by the Office of Administrative Hearings. In addition, Minn. Stat. § 14.131 requires the Agency to provide in its SONAR a description of its efforts to provide additional notification to persons or classes of person who may be affected by the proposed rule. In this section of the SONAR, the MPCA will identify both the required and additional public notification activities it has conducted regarding:

- *State Register* publication and notification of interested parties
- MPCA Board meetings
- Webpage
- Meetings
- Specific notifications

B. State Register publication

The MPCA published two Requests for Comment (RFC) in the *State Register* to identify and refine the scope of this rulemaking. The first RFC was published on July 28, 2008 (Exhibit A-18)[14] and the public comment period ran from July 28 to September 26, 2008. The first RFC listed the major items under consideration by the MPCA for rulemaking and invited any person to comment on those items or on any other aspect of Minn. R. chs. 7050 and 7052 and provided information about how to participate, including the opportunity to attend a series of public meetings. The meetings were held in accordance with CWA and other federal requirements for hearings. Copies of the RFC were mailed to the MPCA's lists of parties identified as interested in all WQS and was posted on both the MPCA's public notice webpage (http://www.pca.state.mn.us/yrwc6a9) and the triennial rulemaking webpage (http://www.pca.state.mn.us/9arfa9u) during the term of the comment period.

Of the comments received in response to the RFC, only one, from the Minnesota Center for Environmental Advocacy's (MCEA) Water Quality Director, Kris Sigford (Exhibit A-14), discussed the MPCA's plans to revise the human health methods for CS. The MCEA recommended the MPCA revise the methods for consistency with the MDH's methods for Health Risk Limits. As stated in this SONAR, the revisions adopted by the MDH (Minn. R. ch. 4717) are the principal foundation for the proposed revision to the human health-based standards.

[14] The exhibits identified as "Administrative" (A-#) relate to a full set of comments and information received as part of the 2008 Triennial Standards Review. Only the exhibits relevant to this rulemaking are included here.

The second RFC published on March 2, 2009 (Exhibit A-19) more specifically identified the amendments that would be addressed and sought technical advice and comment on those areas of proposed amendment. The comment period associated with this RFC ran from March 2 to April 17, 2009. The MPCA's notification activities for this RFC were the same as for the first RFC; it was mailed to the interested parties list and to persons who were interested in WQS, and it was posted on the MPCA's public notice and triennial rulemaking webpage.

During the winter of 2012, the MPCA conducted a transition to more targeted electronic communication (GovDelivery) and contacted all entities that had previously requested information or expressed an interest in the water standards (e.g., the previously used mailing lists). Entities for which the MPCA already had an e-mail address were automatically registered and others were invited to register to receive future electronic notices through the new system. Information about registering to receive electronic notifications was posted on the webpage for this rulemaking and notices were sent to persons who had already registered to receive electronic notice regarding permits to invite them to register for notice of rule activities. As a result of this effort, more than 1,800 entities have registered their interest in receiving notice of WQS rulemaking.

C. MPCA Board meetings

MPCA staff has briefed the MPCA Citizens' Board (Board) about the proposed rule amendments. Informational briefings that discussed the HH-WQS occurred in September 2003 and August 2004. An informational Board briefing about all the amendments considered in the 2008 Triennial Standards Review (TSR), including the HH-WQS, took place on November 28, 2008 and again on September 24, 2013. MPCA Board meetings are monthly public meetings that are also publicly webcast. The webcast meetings may be viewed during the actual Board meeting and remain permanently available to view by interested parties. Notice of meetings and the agenda are widely distributed prior to each meeting. A briefing memorandum is made publicly available through the MPCA's website.

D. Webpage notification

The use of a topic-specific webpage has become an increasingly popular mechanism for providing information about the MPCA's rulemaking activities. Three webpages are relevant to this rulemaking. The first is the MPCA's general public notice webpage found at http://www.pca.state.mn.us/yrwc6a9. On this webpage the MPCA publishes official notices of rulemaking activity, including RFC and the notices published in the *State Register* when rules are proposed for public comment. The notices published on the public notice webpage remain available for viewing during the entire term of the comment period.

The second relevant webpage is the Planned Amendments to Water Quality Standards page (http://www.pca.state.mn.us/9arfa9u), which provides general information about all of the MPCA's WQS rulemakings and a link to the page that specifically discusses the revisions to HH-WQS methods.

The third relevant webpage is the page developed specifically to inform the public about this rulemaking: http://www.pca.state.mn.us/chdfaa8. MPCA staff periodically updates this HH-WQS rulemaking webpage to include more detailed information about the MPCA's proposed amendments. When the MPCA completed the HH-TSD, it was posted for public review on this page. The MPCA also intends to post the SONAR, the proposed rule language, and subsequent rulemaking documents (e.g., Response to Comments) on the HH-WQS webpage.

E. Meetings

Beginning as early as the spring of 2008, MPCA staff began meeting with interested parties to discuss plans for the revision of multiple WQS. The MPCA held two sets of public meetings specifically to discuss all of the areas of amendment that resulted from the 2008 TSR, including the HH-WQS. In conjunction with the publication of the first RFC, the MPCA hosted a series of public meetings to provide stakeholders and interested members of the public an opportunity to learn about the proposed amendments, provide comments and ask questions. The meetings were held at the MPCA's St. Paul office on September 8, 9 and 15, 2008; to facilitate participation they were also video linked to six of the MPCA's regional offices. The public was informed about the meetings through the RFC published in the July 28, 2008, *State Register,* by the mailings, e-mail notifications and website posting associated with that RFC, and by a news release provided to approximately 1,400 media outlets and interested parties.

A second series of public meetings was held November 29 and 30, 2010. These meetings, presented in the format of individual poster sessions, provided detailed information about each aspect of the MPCA's intended rulemaking activities, including the HH-WQS, and invited public questions and comments. These meetings were held in the MPCA's St. Paul offices, but were also video-linked to each of the MPCA's regional offices. Notice of these public meetings was provided via the MPCA's Triennial Standards Review webpage, a postcard notification to interested parties, and an e-mail notification to the persons who had indicated an interest in WQS rulemaking.

F. Summary of notifications

The activities identified above meet the MPCA's mandatory notification requirements prior to publication of the proposed amendments for public comment. The MPCA will provide additional notice when the proposed amendments are published for public comment. Throughout the rule development process, the MPCA has made efforts to provide opportunities for interested parties to be informed about the MPCA's rulemaking plans and to provide input into the development of the proposed amendments. The MPCA held two series of public meetings at multiple locations throughout the State and on several occasions briefed the MPCA Board. In addition to publishing two RFC in the *State Register*, the MPCA provided mailed and electronic notification to an extensive list of self-registered interested parties.

G. Federal public notification requirements

Section 303(c)(1) of the CWA requires states to hold public hearings at least once every three years for the purpose of reviewing applicable water quality standards, and as appropriate, modify and adopt those standards. The proposed amendments are the result of this TSR process. The MPCA has conducted the rulemaking to comply with the requirements of the State Administrative Procedures Act and also the federal requirements regarding TSR of WQS. The federal definition of a public hearing is different than what is considered to be a public hearing for purposes of rulemaking under Minnesota's Administrative Procedures Act. The MPCA has consulted with the EPA Region 5 staff about the criteria for a public hearing and have determined that the public informational meetings noticed in the RFC published in the July 28, 2008 *State Register* and held on September 8, 9 and 15, 2008, constituted public hearings for the purposes of the CWA. Those meetings, which were widely publicized and recorded for later review by the EPA, met the requirements of 40 Code of Federal Regulations § 131.20 (a) and (b) which states:

40 CFR § 131.20 State review and revision of water quality standards.

"(a) State Review: The State shall from time to time, but at least once every three years, hold public hearings for the purpose of reviewing applicable water quality standards and, as appropriate, modifying and adopting standards. Any water body segment with water quality standards that do not include the uses specified in section 101(a)(2) of the Act shall be re-examined every three years to determine if any new information has become available. If such new information indicates that the uses specified in section 101(a)(2) of the Act are attainable, the State shall revise its standards accordingly. Procedures States establish for identifying and reviewing water bodies for review should be incorporated into their Continuing Planning Process

(b) Public Participation: The State shall hold a public hearing for the purpose of reviewing water quality standards, in accordance with provisions of State law, EPA's water quality management regulation (40 CFR 130.3(b)(6)[15]) and public participation regulation (40 CFR part 25). The proposed water quality standards revision and supporting analyses shall be made available to the public prior to the hearing."

The applicable federal regulations regarding public hearings state:

40 CFR § 25.5 Public hearings: "(a) Applicability. Any non-adjudicatory public hearing, whether mandatory or discretionary, under the three Acts shall meet the following minimum requirements. These requirements are subordinate to any more stringent requirements found elsewhere in this chapter or otherwise imposed by EPA, State, interstate, or substate agencies. Procedures developed for adjudicatory hearings required by this chapter shall be consistent with the public participation objectives of this part, to the extent practicable.

(b) Notice. A notice of each hearing shall be well publicized, and shall also be mailed to the appropriate portions of the list of interested and affected parties required by §25.4(b)(5). Except as otherwise specifically provided elsewhere in this chapter, these actions must occur at least 45 days prior to the date of the hearing. However, where EPA determines that there are no substantial documents which must be reviewed for effective hearing participation and that there are no complex or controversial matters to be addressed by the hearing, the notice requirement may be reduced to no less than 30 days. EPA may further reduce or waive the hearing notice requirement in emergency situations where EPA determines that there is an imminent danger to public health. To the extent not duplicative, the agency holding the hearing shall also provide informal notice to all interested persons or organizations that request it. The notice shall identify the matters to be discussed at the hearing and shall include or be accompanied by a discussion of the agency's tentative determination on major issues (if any), information on the availability of a bibliography of relevant materials (if deemed appropriate), and procedures for obtaining further information. Reports, documents and data relevant to the discussion at the public hearing shall be available to the public at least 30 days before the hearing. Earlier availability of materials relevant to the hearing will further assist public participation and is encouraged where possible.

(c) Locations and time. Hearings must be held at times and places which, to the maximum extent feasible, facilitate attendance by the public. Accessibility of public transportation, and use of evening and weekend hearings, should be considered. In the

[15] An error was noted in this citation by the EPA Region V; the correct citation is 40 CFR 130.5(b)(6).

case of actions with Statewide interest, holding more than one hearing should be considered.
(d) Scheduling presentations. The agency holding the hearing shall schedule witnesses in advance, when necessary, to ensure maximum participation and allotment of adequate time for all speakers. However, the agency shall reserve some time for unscheduled testimony and may consider reserving blocks of time for major categories of witnesses.
(e) Conduct of hearing. The agency holding the hearing shall inform the audience of the issues involved in the decision to be made, the considerations the agency will take into account, the agency's tentative determinations (if any), and the information which is particularly solicited from the public. The agency should consider allowing a question and answer period. Procedures shall not unduly inhibit free expression of views (for example, by onerous written statement requirements or qualification of witnesses beyond minimum identification).
(f) Record. The agency holding the hearing shall prepare a transcript, recording or other complete record of public hearing proceedings and make it available at no more than cost to anyone who requests it. A copy of the record shall be available for public review.

The MPCA has conducted the public information phase of this rulemaking in order to comply with the requirements of the federal TSR process as directed by the EPA.

V. Additional Notice Plan

The MPCA intends to request that the Office of Administrative Hearings review and approve this Additional Notice plan, pursuant to Minn. R. 1400.2060.

The MPCA has conducted extensive public notice activities in order to develop a current mailing list of parties interested in this rulemaking. This GovDelivery list meets the requirements of Minn. Stat. § 14.14, subd. 1a, for maintaining a list of interested parties.

The following activities will occur in addition to publishing the Notice of Intent to Adopt Rules Without a Public Hearing (Notice) and proposed rules in the *State Register*:

1. The MPCA will provide an extended comment period (75 days) when the rules are proposed.
2. The MPCA will hold public hearings on the proposed amendments if there is sufficient interest. If a hearing is held, the hearing process (Minn. R. pt. 1400.2230, subp. 1) allows for an additional 5 to 20 days of post-hearing public comment.
3. The MPCA will send an electronic notification to all the persons that have registered with GovDelivery for the purpose of receiving notice of rule proceedings, as required by Minn. Stat. § 14.14, subd. 1a. The GovDelivery notification will include a hyperlink to the Notice, the proposed rules and SONAR, and will include the name of an MPCA contact person. This email notification will be sent on the date the Notice is published in the *State Register*. At this time the GovDelivery list of persons interested in WQS includes more than 1,800 names.
4. A copy of the Notice, proposed rules, and SONAR will be posted on the MPCA's public notice webpage at: http://www.pca.state.mn.us/yrwc6a9 and also on the webpage established specifically for this rulemaking http://www.pca.state.mn.us/chdfaa8.
5. Individuals and representatives of associations who do not wish to receive an electronic Notice will be mailed a paper copy of the Notice and proposed rules. To accommodate these people, the MPCA has provided the name, address and phone number of a contact person on all of its notices

regarding the proposed amendments and on the website where information about this rulemaking is posted.

6. Minn. Stat. § 115.44, subd. 7 states:

   "For rules authorized under this section, the notices required to be mailed under sections 14.14, subdivision 1a, *and* 14.22 *must also be mailed to the governing body of each municipality bordering or through which the waters for which standards are sought to be adopted flow."*

   The MPCA interprets this statute to broadly apply to any amendments to water standards and not only to specific changes in use classification or site-specific numeric or narrative standards. The proposed amendments are being conducted under authority of Minn. Stat. § 115.44 and will apply statewide so the MPCA affirms that it is appropriate to provide notice on a statewide basis. The MPCA will provide a specific electronic notification to every municipality in Minnesota at the time that the rules are proposed for public comment. The MPCA will purchase a current list of all municipal officials through the League of Minnesota Cities and links to the Notice, proposed rules and SONAR will be provided to more than 850 municipalities. This will ensure that even those officials that had not previously registered with the MPCA's system will have the opportunity to review and comment on the proposed rules.

7. The MPCA will send a cover letter to the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the subject matter of the proposed rules, and to the Legislative Coordinating Commission, as required by Minn. Stat. § 14.116. The letter will include a link to electronic copies of the Notice, proposed rules, and SONAR. This Notice will be sent when the rules are published for public comment . (Minn. Stat. § 14.116 also states that if the mailing of the notice is within two years of the effective date of the law granting the Agency authority to adopt the proposed rules, the Agency must make reasonable efforts to send a copy of the Notice and SONAR to all sitting house and senate legislators who were chief authors of the bill granting the rulemaking. This requirement does not apply because the MPCA is using its general rulemaking authority for these rules, and no bill was authored within the past two years granting special authority for this rulemaking.)
8. The MPCA will send a copy of the SONAR to the Legislative Reference Library in accordance with Minn. Stat. § 14.131 when the Notice required under Minn. Stat. § 14.14, subd. 1a, is sent.
9. The MPCA will notify MDH when the rules are published for comment because of the close association between MDH's work and the HH-WQS. The statutory requirements to provide notice to MnDOT and MDA do not apply to this rulemaking and the MPCA does not intend to provide special notice to either of these agencies.

This Additional Notice Plan, including the early development of an extensive GovDelivery mailing list, publication in the *State Register* and posting on the MPCA's public webpages, will adequately provide additional notice of this rulemaking to persons interested in or regulated by the proposed amendments.

VI. Statutory Authority

Minnesota's water quality rules and standards are based on both State and federal authorities.

Federal authority is found in CWA Section 303(c)(1), which requires states to review and amend as appropriate its WQS every three years in order to maintain federal delegation to administer the water program. The EPA must approve of a state's WQS and any revisions to WQS to ensure they meet the CWA.

State authority for the MPCA to adopt WQS and to classify waters of the state is found in Minn. Stat. § 115.03, specifically subdivisions 1(b) and 1(c).

> *115.03 POWERS AND DUTIES.*
>
> *Subdivision 1.Generally.The agency is hereby given and charged with the following powers and duties:*
>
> *(a) to administer and enforce all laws relating to the pollution of any of the waters of the state;*
> *(b) to investigate the extent, character, and effect of the pollution of the waters of this state and to gather data and information necessary or desirable in the administration or enforcement of pollution laws, and to make such classification of the waters of the state as it may deem advisable;*
> *(c) to establish and alter such reasonable pollution standards for any waters of the state in relation to the public use to which they are or may be put as it shall deem necessary for the purposes of this chapter and, with respect to the pollution of waters of the state, chapter 116;*

Subdivision 1(b) authorizes the MPCA to classify waters, while subdivision 1(c) authorizes the MPCA to establish standards.

Additional authority for adopting standards is established under Minn. Stat. § 115.44, *Classification of Waters; Standards of Quality and Purity*, subd. 2 and 4. Subdivision 2 authorizes the MPCA to:

> *…group the designated waters of the state into classes, and adopt classifications and standards of purity and quality therefor…*

Subdivision 4, with specific relevance to the HH-WQS methods, authorizes the MPCA to:

> *…adopt and design standards of quality and purity for each classification necessary for the public use or benefit contemplated by the classification. The standards shall prescribe what qualities and properties of water indicate a polluted condition of the waters of the state which is actually or potentially deleterious, harmful, detrimental, or injurious to the public health, safety, or welfare; to terrestrial or aquatic life or to its growth and propagation; or to the use of the waters for domestic, commercial and industrial, agricultural, recreational, or other reasonable purposes, with respect to the various classes established…*

Under these federal and State statutory provisions, the MPCA has the necessary authority to adopt the proposed WQS into Minnesota rules.

VII. Statement of Need

A. Publication of updated EPA AWQC methods and pollutant-specific criteria

The EPA has a key role in providing technical guidance and oversight of the MPCA's WQS. Since the MPCA adopted in Minn. R. ch. 7050 human health methods in 1990 for statewide application, the EPA has developed improved risk assessment methods in AWQC and other Guidance documents. The GLI methods and AWQC were promulgated in the Code of Federal Regulations (40 CFR 132) in 1995. The MPCA incorporated the methods by reference in Minn. R. ch. 7052 for the Lake Superior Basin (Exhibit HH-5). The key differences between the newer federal methods and those applied statewide include new procedures used to develop BAFs and toxicological values. In 2000, the EPA published, *Methodology for Deriving Ambient Water Quality Criteria for Human Health* (2000 HH-AWQC, Exhibit HH-3). This Guidance included aspects of the GLI and other newer EPA risk assessment guidance to offer recommendations for states and tribes to improve their human health methods. As with any AWQC, states are expected to review the guidance and update its WQS, preferably incorporating local, state, or regional data. States can also utilize other scientifically defensible data when available (Exhibits HH-1 and HH-3).

The 2000 HH-AWQC methods provide a number of improvements for developing HH-WQS. The 2000 HH-AWQC methods provides the EPA Guidance on risk assessments practices, particularly those relevant to CWA and SDWA that support state and tribal WQS (see sidebar references from Exhibit HH-3). These improvements: standardize development of toxicological values and exposure rates for noncarcinogens and carcinogens; incorporate the latest science; and offer algorithms specific to surface water pollutants and beneficial uses relevant to human health (Exhibit HH-3, Section 1, and Exhibit HH-1).

To enhance the effort by states and tribes to evaluate and incorporate more local data into their HH-WQS in response to the 2000 revised methods, the EPA also

EPA Risk Assessment Guidance Published since 1980 cited in 2000 AWQC Methods for Human Health

1986. Guidelines for Carcinogen Risk Assessment.

1986. Guidelines for Mutagenicity Risk Assessment.

1986. Total Exposure Assessment Model (TEAM) Study: Summary and Analysis, Volume I. Final Report.

1986. Guidelines for Exposure Assessment.

1991. Guidelines for Developmental Toxicity Risk Assessment.

1992. Guidelines for Exposure Assessment.

1995. Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors.

1995. Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values.

1996. Proposed Guidelines for Carcinogen Risk Assessment.

1996. Guidelines for Reproductive Toxicity Risk Assessment.

1997. Exposure Factors Handbook.

1998. Guidelines for Neurotoxicity Risk Assessment.

1998. Guidance for Conducting Fish and Wildlife Consumption Surveys.

1999. Guidelines for Carcinogen Risk Assessment. Review Draft.

1999. Guidance for Conducting Health Risk Assessment of Chemical Mixtures. Final Draft.

2000. Estimated Per Capita Water Ingestion in the United States: Based on Data Collected by the United States Department of Agriculture's 1994-96 Continuing Survey of Food Intakes by Individuals.

2000. Estimated Per Capita Fish Consumption in the United States: Based on Data Collected by the United States Department of Agriculture's 1994-1996 Continuing Survey of Food Intake by Individuals.

published three supplementary technical support documents (TSD): Volume 1: *Risk Assessment* (2000)[16]; Volume 2: *Development of National Bioaccumulation Factors* (2003)(Exhibit HH-4) and Volume 3: *Development of Site-specific Bioaccumulation Factors* (2009)[17]. In the 2000 HH-AWQC, the EPA also stated that a more detailed TSD would be published to address the data and evaluation behind the exposure aspects of the previously published methods. However, as of January 2014, that Guidance has not been published. The unavailability of that information compels states and tribes to make their own interpretation of national defaults and best use of other scientifically defensible data to develop exposure intake rates for fish consumption and recreational exposure as described in Exhibit HH-1, Section IV. C.

Section 304(a) of the CWA, as implemented by the EPA, requires states to consider AWQC as part of its TSR. States are required to adopt standards that are equal to, or "as protective as," the AWQC to ensure protection of the beneficial uses of surface waters. The 2000 HH-AWQC Guidance provides improvements for how HH-WQS are developed.

The following two key areas of the revised methods serve to provide robust technical approaches to improving and amending the current HH-WQS methods in Minn. R. chs. 7050 and 7052.

1. Relative Source Contribution serves as the means to account for other routes and sources of exposure in addition to that portion from surface water included directly in the HH-WQS (oral ingestion from drinking water, fish consumption, and incidental water). The noncancer algorithms for developing HH-WQS include a RSC to ensure exposure from surface water uses would not lead to a person's total exposure to that pollutant exceeding the RfD or adverse effect level. As described later in the SONAR, the RSC Decision Tree developed by the EPA improves upon and standardizes the current RSC approach. The MDH has also referenced the RSC Decision Tree in the HRL methods.
2. The 2000 EPA Guidance also includes the first nationally recommended BAF methods. These methods are founded on those developed from extensive research on BCC as part of the GLI. The Lake Superior HH-WQS (Minn. R. ch. 7052) already incorporate the GLI methods by reference. Therefore, revising the BAF methods currently in Minn. R. ch. 7050 will mean consistency in methods across all HH-WQS.

Adoption of these improved methods for RSC and BAFs for statewide application offers many advantages over the current methods. The proposed methods are needed to reflect the latest science and to maintain consistency with methods used by the EPA, MDH, and MPCA for HH-WQS in the Lake Superior Basin. Other improvements to the methods for human health protection in WQS discussed in the 2000 HH-AWQC Guidance will follow the MDH's risk assessment methods (Exhibit HH-1, Section IV. C.).

B. Advances in risk assessment methods and policies for protecting infants and children

Risk assessment centers on a process to examine health effects to an individual or population from exposure to a hazardous or toxic material or situation (Exhibit HH-6). As discussed in the HH-TSD (Exhibit HH-1), since 1990 there have been significant advances at the federal and State levels in risk assessment methods and the data used to assess exposure and toxicological effects, especially as it relates to infants

[16] USEPA *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*: *Technical Support Document, Volume 1: Risk Assessment*. USEPA EPA-822-B-00-005. October 2000.
[17] USEPA *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*: *Technical Support Document, Volume 3: Development of Site-Specific Bioaccumulation Factors*. USEPA EPA-822-R-09-008, September 2009.

and children (Exhibit HH-1, Section IV. A.). In 1993 the National Research Council published an influential report*, Pesticides in the Diet of Infants and Children,* which declared that infants and children were not sufficiently protected by current risk assessment methods that relied on adult parameters. Infant and childhood exposure and toxicological outcomes are unique and need evaluations specific to these differences. At the federal level, the 1996 amendments to the Food Quality Protection Act and 1997 Presidential Executive Order, *Protection of Children from Environmental Health Risks and Safety Risks* (Exhibit HH-1, Appendix A3 and Exhibit HH-6), solidified the need for the EPA and other federal agencies that deal with environmental risk assessment to develop specific guidance to enhance protection for all developmental life stages.

The resulting research and guidance on infant and childhood exposure and susceptibility to toxicants provide an important foundation for the changes in current risk assessment methods (Exhibit HH-1, Section IV. A.). Key aspects for enhancing HH-WQS to improve protection for infants and children are:

1. Infancy and childhood should be characterized as distinct life stages; infants and children are not subpopulations of adults. Exposures and adverse events that occur during early life stages have bearing on all subsequent stages of a person's life as they age and on future health status. Or in other words, protection from environmental pollutants *for* a lifetime needs to consider differences in risk *across* a lifetime.
2. Protection of infants and children should extend to all developmental life stages from preconception (adult reproduction) through adolescence (Exhibit HH-1, Table 2).
3. Developmental risk related to environmental pollutants has to be evaluated on the basis of measures of exposure (routes and rates of drinking water, food, air, and dermal intake) and toxicological sensitivity specific to the developmental windows of susceptibility as defined by age groupings.
4. Data used to evaluate developmental risk have limitations that will require policy consideration. Those policy considerations must identify and address the gaps for meeting protection level goals (Exhibits HH-1; HH-6; and HH-8).

The methods for HH-WQS adopted in 1990 in Minn. R. ch. 7050 and 1998 in Minn. R. ch. 7052 need to be updated to reflect these newly identified aspects for strengthening *lifetime* risk assessments. The specific aspects of the revisions needed are described fully in the SONAR discussion of *Reasonableness*. Briefly, the MPCA's current methods need to be amended because they:

1. Address only chronic durations and not less-than-chronic durations that have specific relevance for developmental life stages.
2. Use only drinking water and fish consumption rates based on adults.
3. Have deficiencies in accounting for higher early-life sensitivity to carcinogens (Exhibit HH-1, Sections IV. and V.).

C. Revisions to the MDH Health Risk Limits (HRL) in Minn. R. ch. 4717

In 2009 the MDH considerably revised the methods in Minn. R. 4717.7500 to 4717.7900 used to develop protective drinking water standards HRL for groundwater (Exhibit HH-6). The methods that the MDH adopted encompass toxicological characterization and exposure revisions. The MDH's revisions addressed new State requirements and Federal Guidance related to scientific improvements in risk assessment methods. Many of the changes stemmed from the need to better account for differences in exposure and susceptibility of infants and children to environmental contaminants.

The MDH's revisions to their HRL rule lead directly to the need for the MPCA to update our HH-WQS methods. The proposed amendments are needed in order to:

1. Meet the MPCA's commitment to ensure HH-WQS are founded on the MDH risk assessment methods and data in order to maintain a consistent level of human health protection in Minnesota's environmental health standards
2. Update the parameters in HH-WQS based on the newer scientific data and approaches researched and incorporated by the MDH in HRL noncancer and cancer methods
3. Include the improved methods that specifically address protection of infants and children or developmental life stages in surface water standards designed to protect human health

Consistency in public health protection in Minnesota is a key need for the proposed amendments. The MPCA has been tracking the MDH's revision of methods and determining how the changes should be incorporated into HH-WQS for the beneficial uses of surface waters. Described in *Consistency with the MDH Drinking Water Programs*, the MPCA has firmly established the need for consistency with the MDH risk assessment methods and drinking water protection programs. The technical rationale for the proposed amendments needed for HH-WQS to maintain consistency with the MDH is found in the SONAR discussion on *Reasonableness* and Exhibit HH-1.

The MDH's 2009 revisions to Minn. R. ch. 4717 included updates to the HRL algorithms and parameters. The revisions were based on extensive review of newer scientific data, EPA Guidance and other risk assessment experts, State legislative mandates, and citizen comments (Exhibit HH-6). More specifically, the MDH's amendments make substantial gains in protecting infants and children by incorporating specific Guidance published by the EPA. The resulting State rules clearly improve and expand on the approaches presented in the EPA's 2000 HH-AWQC (see sidebar and Exhibit HH-1, Appendix A3). MDH's 2009 HRL rule provides a Minnesota-centered approach to the comprehensive and recent risk assessment foundation for revising HH-WQS.

EPA Risk Assessment Guidance Published since the 2000 Methodology for Deriving Ambient Water Quality Criteria for Human Health (see Exhibit HH-1, Appendix A3)

2000. Toxicological Review of Vinyl Chloride.

2002. Determination of Appropriate FQPA Safety Factor(s) in Tolerance Assessment.

2002. A Review of the Reference Dose and Reference Concentration Process.

2003. Framework for Cumulative Risk Assessment.

2004. Risk Assessment Principles and Practices.

2004. Estimated per Capita Water Ingestion and Body Weight in the United States–An Update:

2005. Supplemental Guidance for Assessing Cancer Susceptibility from Early-life Exposure to Carcinogens.

2005. Final Guidelines for Carcinogenic Risk Assessment.

2005. Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants.

2006. A Framework for Assessing Health Risk of Environmental Exposures to Children (Final).

2007. Framework for Determining a Mutagenic Mode of Action for Carcinogenicity.

2008. Child-specific Exposure Factors Handbook.

The revisions to the MDH HRL rule with specific relevance to HH-WQS include:

1. Defining and evaluating four durations of adverse effects and exposure rates for noncancer or nonlinear carcinogen HRL
2. Identifying *Developmental Toxicity* as a noncancer endpoint (Health Endpoint) to use for enhancing early-life protection from mixtures of pollutants
3. Addressing gaps in developmental and reproductive toxicity studies by applying higher UF in RfD

4. Accounting for known and potentially higher susceptibility in early life stages to carcinogens through the use of cancer potency Adjustment Factors (AF)
5. Using higher intake rates for drinking water. Based on the latest community drinking water data from the EPA's Per Capita Water Ingestion report, the MDH applies the 95th percentile intake rate from "consumers-only" data, resulting in intake rates higher than the previous use of 2 L and 70 kg-body weight for adults. This means greater protection to more drinking water consumers. In addition, the MDH's highest intake rates are based on infants drinking formula mixed with water (Exhibit HH-6)
6. Applying the EPA's new RSC Decision Tree for more standard accounting for total exposure to a pollutant
7. Including specific guidance for evaluating environmental degradates that lack HRL

In this rulemaking the MPCA plans to incorporate the revisions made by the MDH for drinking water protection into the methods for developing HH-WQS, either directly or as modified to reflect the additional beneficial uses of surface water: fish consumption and recreation. The revisions are needed in both Minn. R. chs. 7050 and 7052 and cover both toxicological and exposure aspects of the methods. The amendments to the MPCA's rules to reflect the MDH's 2009 revisions are needed to:

1. Address less-than-chronic (acute to subchronic) duration adverse effects, based on the RfD, when appropriate to ensure the CS is protective for shorter duration health effects. These shorter durations may warrant more stringent CS, because when the RfD are matched with the MDH's higher, shorter duration drinking water intake rates, which are much higher than the chronic intake rate, the concentration of a contaminant in water that will protect consumers from these shorter duration health effects may have to be lower than the chronic standard based on long-term adverse effects. This is reviewed on a pollutant-specific basis.
2. Include enhanced toxicological evaluations by the MDH and EPA, which better characterize a pollutant's adverse effects, including MOA, target organs or systems, and nonlinear or linear carcinogenic profiles.
3. Address conclusions by the MDH that clearly demonstrate that exposure to linear carcinogens in early life leads to higher lifetime cancer risk as measured by a number of variables (e.g., higher incidence, earlier neoplasm formation, etc.). The MPCA plans to apply cancer potency Adjustment Factors (AFs) using the same protocol as the MDH's HRL rule.
4. Incorporate the revised drinking water intake rates as defined by the MDH and fish consumption and incidental water intake rates as developed by the MPCA. When incorporated into the new and revised algorithms, these new rates will improve HH-WQS protection for all life stages.
5. Implement the RSC values as recommended by the EPA's RSC Decision Tree.
6. Include narrative language to address environmental degradates using parent HH-WQS or the MDH health based guidance when available.

D. Improve applicability of HH-WQS for fish tissue pollutants

In 2008, the MPCA expanded on its existing HH-WQS that were developed as water concentrations by adopting a mercury Chronic Standard (CS_{ft}) applicable directly to edible fish tissue (Exhibit HH-1, Section II. E.). The fish tissue-based CS_{ft} was based on the EPA's 2001 *Water Quality Criterion for the Protection of Human Health: Methylmercury*. The MPCA determined that a fish tissue criterion was more accurate and germane than one solely applied in water because 1) the EPA's review of mercury partitioning and bioaccumulation in fish tissue as methylmercury clearly demonstrated that fish consumption is the main

route of human exposure, 2) most monitoring data for mercury were in fish, and 3) there is variability in BAF.

Mercury is not the only pollutant that accumulates to high concentrations in aquatic organisms. Many legacy and *Priority Pollutants* listed in the CWA, including those identified as high concern in the Great Lakes, biomagnify in aquatic food chains. Biomagnification occurs when the concentration of a pollutant increases as it is transferred to higher trophic levels of the food chain.

The GLI specifically defines a (BCC as any chemical having a final BAF greater than 1,000 (40 CFR 132). The BAF is an estimate of the increase in a pollutant between the water and fish concentration. A BAF of 1,000 or higher indicates that the physicochemical properties of the pollutants lead to biomagnification and reliable detection in fish tissue. The use of the BAF threshold for defining a BCC has relevance for identifying bioaccumulative pollutants in need of fish-tissue based standards. When BAFs are 1,000 or greater, the drinking water or incidental ingestion routes of exposure are negligible and the HH-WQS algorithms need only reflect the fish consumption pathway. The GLI also identified the following BCC found in Great Lakes fish at concentrations of concern: polychlorinated biphenyls (PCB), dichlorodiphenyl-trichloroethane (DDT and related forms), dioxins (i.e., 2,3,7.8-TCDD), dieldrin, hexachlorobenzene, and toxaphene (Exhibit HH-5).

With the exception of the mercury standard, which was revised as described above, Minn. R. chs. 7050 and 7052 currently have only water-based HH-WQS for highly bioaccumulative pollutants. This revision proposes new algorithms to develop fish tissue-based CS_{ft} (or CC_{ft}) for toxic pollutants with final BAF greater than 1,000 (based on the BCC definition) to augment the water-based human health CS (or CC).

Including fish tissue-based methods for CS_{ft} (and CC_{ft}) into WQS is needed to:

1. Enhance the usefulness of WQS by addressing the most relevant route–fish consumption – of human exposure to highly bioaccumulative surface water pollutants.
2. Reflect the EPA Guidance and recommendations for states to use fish-tissue data in their WQS program for developing HH-WQS.
3. Enable the MPCA to use more fish-tissue monitoring data to advance the process for assessing WQS.
4. Supplement, and eventually replace, the existing narrative standard in Minn. R. 7050.0150, subp. 7, based on the MDH FCA.

The proposed addition of fish tissue-based methods improves upon having water-based standards only. The EPA has provided Guidance on the benefits of addressing fish pollutants with fish tissue-based criteria and monitoring data (Exhibit HH-1, Section II. E.). This excerpt from the EPA 2001 AWQC states the many benefits of addressing a fish pollutant like mercury with fish-tissue based criteria.

> *A fish tissue residue water quality criterion is more closely tied to the CWA goal of protecting the public health because it is based directly on the dominant human exposure route for methylmercury. The concentration of methylmercury is also generally easier to quantify in fish tissue than in water and is less variable over the time periods in which water quality standards are typically implemented...*

Because a key aspect of HH-WQS is to keep pollutant concentrations in fish tissue below a level that can result in adverse health effects, the addition of CS_{ft} (or CC_{ft}) more directly addresses this goal and better protects fish consumers.

Development of CS in fish-tissue for BCC provides a more accurate HH-WQS than CS in water. CS applied in water is based on an estimate of the average BAF in aquatic organisms (primarily fish) in two trophic

levels. The available data for BAF development can vary, and even when based on field studies, will have some level of variability in each waterbody[18] or site. The uncertainties in this approach to protecting surface water users are well known; the EPA BAF methods have advanced over the years to improve this "translation" of protective fish concentration to protective water concentrations. Water-based standards are needed for assessing water monitoring data, implementing National Pollutant Discharge Elimination System (NPDES) permits and other pollution control activities. However, to recognize the higher accuracy of the CS_{ft} or CC_{ft}, where different impairment determinations are made in an individual waterbody when comparing fish data with respective CS and water data to respective CS, the results of the fish tissue comparison will be the basis for final determination of the HH-WQS being met or impairment determination.

While Minn. R. ch. 7050 has a narrative standard based on the MDH's FCA to support the goals of HH-WQS, there are gaps in this approach when solely relied on for assessing compliance with HH-WQS. One area of potential discrepancy stems from the vital role of FCA in balancing the risks and benefits of fish consumption (Exhibit HH-1). The MDH can take into account a broader range of factors in setting advice thresholds, such as ease of communication and understandability and consistency with other Great Lakes States. HH-WQS have inherently less flexibility because the methods have to be more broadly applicable statewide and based on standard risk assessment approaches.

The MPCA's goal of incorporating fish tissue-based algorithms and HH-WQS into the rule is to have these standards replace the reference to FCA. As described in Exhibit HH-1, Section IV. E., and recognized by the EPA, there are important differences between the two programs. While FCA is a tool for determining if HH-WQS are being met, having actual fish tissue CS_{ft} is the more appropriate approach and criterion for determining if waters are meeting HH-WQS or if they are impaired and should be listed on the CWA 303(d) list. HH-WQS will be developed for a broader suite of pollutants in fish and used for evaluation of fish tissue monitoring data. The current reliance on FCA limits the MPCA's options for assessing this data. For example, because FCA is specific to the pollutant with the most restrictive advisory it does not need to cover all bioaccumulative pollutants present in fish tissue; whereas, the use of fish tissue-based CS_{ft} (or CC_{ft}) are needed to cover a broader suite of these pollutants.

Another advantage of using CS_{ft} is to distinguish terminology associated with State programs related to pollutants in fish. In other words, while a waterbody may be listed as impaired due to a contaminant in fish, such as mercury, the public can still consider following FCA provided by the MDH, and consume fish in a way that minimizes exposure to toxic pollutants while still gaining benefits of healthy fish lipids from that waterbody. Impairment listing has a different purpose than the FCA. An impairment listing identifies waterbodies that need additional control measures to reduce pollutant loading with the ultimate goal being to reduce or eliminate any advisories on fish consumption.

E. Conclusions - Need

The MPCA is proposing to make significant revisions to the methods used to develop HH-WQS. There are many needs identified for making these amendments.

1. The HH-WQS methods for toxic pollutants were adopted in Minn. R. ch. 7050 in 1990 and Minn. R. ch. 7052 in 1998 and have remained unchanged.
2. Numerous advances in risk assessment methods have occurred.

[18] The term *waterbody* is used in this document, but is synonymous with *water body* or *body of water* as used in Minn. R. ch. 7050.

3. Method improvements have been recommended by the EPA and adopted in State rule by the MDH.
4. Critical advancements in risk assessment have centered on improving consideration and protection for infants and children. These advances include the recognition that significant toxic effects occurring during short windows of development have implications for a person's lifetime and that those toxic effects need to be accounted for in environmental standards designed for lifetime protection.
5. HH-WQS applied only as water concentrations are not as effective or germane for addressing toxic pollutants present in fish, particularly when fish consumption is the main route of exposure. The addition of algorithms specific for developing CS_{ft} and CC_{ft} applicable in fish tissue will augment the current water-based standards.

VIII. Reasonableness of the Proposed Rule Amendments as a Whole

The reasonableness portion of the SONAR provides the discussion and background on the data and approaches used to develop the proposed rule amendments. The discussion includes the data quality and technical and policy foundation for the proposed amendments.

The proposed rule revisions, updating the methods listed in Minn. R. chs. 7050 and 7052 to develop HH-WQS, are reasonable because they:

1) Meet the CWA and Minnesota statutory requirements for revising State WQS using the most current, acceptable and reliable scientific data and information for protecting the beneficial uses of Minnesota's surface waters.
2) Maintain consistency in the goals and approaches used by the MDH and EPA for protecting humans from adverse health effects stemming from exposure to toxic pollutants, including reliance on more Minnesota-specific data.
3) Reflect comprehensive and thoroughly reviewed risk assessment methods developed and promulgated with significant public input by the MDH.
4) Add protection for sensitive populations, in this case, early life-stages: developing fetuses, infants, and children.
5) Expand the applicability of pollutant data measured in fish tissue.
6) Address mixtures and environmental break-down products or degradates.

In this rulemaking the MPCA is also incorporating by reference existing federal WQS applicable in the Lake Superior Basin and specifically identifying the applicable *E. coli* numeric standards. The BEACH Act, a 2000 amendment to Section 406[19] of the Clean Water Act, (adopted in 40 CFR 131.41 on November 16, 2004) establishes standards to prevent recreational exposure and illness from pathogens in Coastal Recreation Water. The BEACH Act only applies to 20 states, including Minnesota, with defined coastal Great Lakes and marine waters and beaches. Therefore, the existing federal WQS apply and are being added to Minn. R. 7052.0100, subp. 1, item E. The amendments are needed to make Minnesota's rules reflect federal standards that are already applicable.

The MPCA proposes to adopt the federal citation by reference and to identify exactly which *E. coli* numeric federal WQS specifically apply in Lake Superior. The MPCA considers this a housekeeping amendment because it simply incorporates federal WQS that have been in effect since 2004. In addition

[19] 33 U.S.C. 1346

to incorporating the federal standards by reference, and specifically identifying the *E. coli* standards that apply to Lake Superior, the proposed amendment also provides a Minnesota-specific clarification of the federal term "recreation season". The EPA *E. coli* standards being incorporated into Minn. R. ch. 7052 address both acute and chronic exposure durations. *E. coli*, must not exceed either:

- 126 organisms per 100 milliliters (mL), as a geometric mean of not less than five samples representative of conditions during any calendar month; or
- 235 organisms per 100 mL in more than 10% of all the individual samples taken during any calendar month.

For purposes of the *E. coli* standards being proposed, the MPCA is specifying that the "recreation season" is the period from April 1 to October 31, the same applicable timeframe as the statewide *E. coli* WQS already promulgated in Minn. R. ch. 7050.

IX. Statement of Specific Reasonableness of the Proposed Amendments to the HH-WQS

A. Definitions

Minn. R. chs. 7050 and 7052 have numerous definitions related to CS and site-specific CC developed to protect human health. Definitions in Minn. R. ch. 7050 are found primarily in Minn. R. 7050.0218, subp. 3, and were adopted in 1990. The definitions in Minn. R. ch. 7052 are listed in Minn. R. 7052.0010 or incorporated by reference from 40 CFR 132, Appendices B and C. As shown in Exhibit HH-1, Appendix A1 , the definitions being proposed primarily reflect those found in the MDH's HRL rule, Minn. R. 4717.7500 through 4717.7900, with the inclusion of definitions from the EPA AWQC for human health, both GLI and 2000 Guidance (Exhibits HH-3 and HH-5). For reference information, Exhibit HH-1, Appendix A2 has a table comparing definitions across these three sources. The use of the MDH and EPA definitions is reasonable in order to reflect current risk assessment definitions and to improve consistency of the HH-WQS methods with new public health practices for environmental protection. A full technical discussion on the proposed definitions is found in Exhibit HH-1 with a listing of many definitions and their sources in Appendix A1. Supplemental support for the MDH definitions is found in their 2008/2009 HRL SONAR (Exhibit HH-6).

B. Studies and datasets supporting method development

The amendments being proposed to methods in Minn. R. chs. 7050 and 7052 applicable to human health protection in Class 2 waters are based on available and reliable scientific data and information as fully described in Exhibit HH-1. As discussed in the SONAR discussion of *Need*, much of the information used in these revised methods stem from more recent risk assessment Guidance published by the EPA since 1990. The EPA Guidance is reviewed by both internal and external experts and is subject to a rigorous peer and public review process. The CWA Section 304(a) specifically requires the EPA to develop Guidance, referred to as AWQC, for states and tribes to use as a foundation for developing WQS. The EPA's 2000 HH-AWQC and their two supporting BAF TSD are the basis for the reasonableness of the revisions being proposed to the BAF methods and improvements in RSC application being proposed (Exhibits HH-3 and HH-4).

The EPA Guidance served as an important source of scientific data for other parameters the MPCA evaluated and developed values for:

- New Incidental Water Intake Rate (IWR)
- Children's $FCR_{0<2}$ and $FCR_{2 \text{ to } <16}$ for use with the cancer potency ADAF

The EPA's 2008 *Children's Exposure Factors Handbook* and updated 2011 *Exposure Factors Handbook* provide current and recommended incidental water exposure amounts and body weights for children. The MPCA used these in development of a new IWR. The previous rate was based on general estimates of ingesting a "mouthful of water." The MPCA's review of data on children's FCR used both published studies and EPA Guidance to develop new FCR for children (Exhibit HH-8). The EPA's 2002 publication, *Estimated Per Capita Fish Consumption in the United States*, was the main source of information for comparing children and adult fish consumption rates on a body-weight basis. The age groups examined for differing rates centered on the EPA's *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (2005).

The key source of data and information used to revise the HH-WQS comes from the MDH HRL rule and supporting documents (i.e., SONAR) from their 2009 methods adoption process. The MDH methods for developing health protective drinking water standards for pollutants in groundwater or HRL were founded on numerous EPA Guidance documents and reports, published scientific literature reviews, and consultation with an independent MDH-convened Expert Panel and EPA scientists with expertise in toxicology, exposure science, and risk assessment (described fully in Exhibit HH-6). The MDH also developed its methods to meet Minnesota-specific statutory requirements, informed by considerable public input. MDH's methodology received public review and scrutiny in the pre-rulemaking process, as well as through its demonstration of *Need* and *Reasonableness* through promulgation into Minn. R. ch. 4717. The MDH HRL rule methods provide a current, State-based, and reasonable foundation for the MPCA to revise HH-WQS.

In addition, the MPCA consulted with the MDH and EPA in the development of the methods for CS and site-specific CC based on protecting human health. Exhibit HH-1 provides detailed rationale, including scientific and policy decisions, used in both adoption of the original methods and the proposed revisions for use in comparing changes made in the new methods and as background for aspects of the methods that are being retained (e.g., adult FCR).

C. Toxicological parameters and evaluation, consistency with the MDH

Exhibit HH-1, Section V. fully describes the toxicological parameters being proposed and differences from what is currently in Minn. R. chs. 7050 and 7052. Table 1 provides an overview of each parameter, Agency methodology used to develop the value (MPCA, MDH, or EPA), and background on data and information sources.

Table 1 Proposed Toxicological Parameters for Developing Human Health-based Chronic Standards

Toxicological Parameter	Abbreviation	Values and Units	Agency Methodology	Data and Information
Noncancer and NonLinear Carcinogens (NLC): Reference Doses for Four Durations	$RfD_{acute.}$ $RfD_{short\text{-}term}$ $RfD_{subchronic}$ $RfD_{chronic}$	Pollutant-specific value mg/kg-d	MDH or MPCA based on amendments	EPA IRIS, OPP, scientifically peer-reviewed data, other government or industry reports and studies (Exhibit HH-6).
Health Risk Index Endpoint	Health Endpoint	No Units	MDH or MPCA based on amendments	Based on same studies used to develop the RfD (Exhibit HH-6).
Cancer Potency Slope Factor	CSF (previously q1*)	Pollutant-specific value $(mg/kg\text{-}d)^{-1}$	MDH or MPCA based on amendments	EPA with supporting information from the National Toxicology Program (NTP) and International Agency for Research on Cancer (IARC) (Exhibit HH-6).
Adjustment Factors for Cancer Potency Slope Factors	$ADAF_{<2}$ $ADAF_{2\ to\ <16}$ $ADAF_{16\ to\ 70}$ $AF_{Lifetime}$	10 3 1 Pollutant-specific	MDH or MPCA based on amendments	ADAF established in EPA and MDH Guidance; $AF_{Lifetime}$ based on chemical-specific data used to develop CSF and other supporting studies (Exhibit HH-6).
Cancer Risk Level	CR	10^{-5} or 1 in 100,000	MPCA Minn. R. chs. 7050 and 7052	Policy level used by MDH and EPA (Exhibit HH-1).

RfD and CSF. As previously introduced in the discussion of *Need* and thoroughly discussed in Exhibit HH-1, Sections IV. and V., toxicological evaluations used for developing future HH-WQS will be consistent with MDH methods as incorporated into the revised HH-WQS. Pollutant-specific toxicological values will be completed by MDH or MPCA in consultation with the MDH. While the MDH reviews toxicological evaluations completed by the EPA's National Center for Environmental Assessment's Integrated Risk Information System (IRIS) and Office of Pesticide Programs (OPP), differences in the MDH's toxicological methods mean State-specific evaluations are needed to ensure consistency between the toxicological values (RfD, CSF, and AF) developed by the MDH and EPA for use by the MPCA in HH-WQS. Important differences include the MDH's more extensive review and development of less-than-chronic RfD and broader application of the ADAF. In addition, more current evaluations may be needed than those available from the EPA. The MDH fully describes their toxicological methodology in the HRL Rule, Minn. R. ch. 4717, and 2008/2009 SONAR; particularly see Part IV. C. Toxicity Evaluation (Dose-Response Evaluation), Part V. E. Risk Characterization, and Appendices B-J, M, and P (Exhibit HH-6). The MPCA proposes to adopt the MDH's methods for development of toxicological values. A short summary of each new proposed toxicological parameter follows.

$RfD_{duration}$. The MDH methods have more complete and extensive toxicological noncancer evaluations than the EPA's IRIS human health assessment program. Through consideration of developmental windows of higher sensitivity to adverse effects from environmental pollutants and determination of the need to quantitatively address these windows and any less-than-chronic duration effects, the MDH develops multiduration RfD. If acceptable data are available, the RfD are developed for up to four durations (Exhibit HH-6). The durations as shown in Table 1 include:

1. Acute – a period of 24 hours or less
2. Short-term – a period of more than 24 hours, up to 30 days

3. Subchronic – a period of time more than 30 days, up to approximately 10% of the human life span (approximated at 70 years for use in HH-WQS)
4. Chronic – a period of more than approximately 10% of the life span

When evaluating these durations for RfD development, the MDH methods address animal toxicity tests of comparable durations for the animal's lifespan. In most cases, the RfD for the chronic duration is the most stringent value; this fits the consideration that organisms can generally tolerate a higher exposure to a toxicant for a shorter time than that same exposure for a longer time. However, as fully discussed in *Proposed Methods: Noncancer and Linear Carcinogen Algorithms*, when the shorter duration RfD is paired with a higher, shorter duration exposure rate, the final standard for these durations can be more stringent than the chronic. This has relevance to ensuring that a final CS or CC meets the narrative standard of providing protection from a *lifetime* of exposure. MPCA has incorporated MDH methods into the amendments for developing HH-WQS.

Health Endpoint. In addition to having additional durations of toxic effects to consider, the MPCA is proposing to include the MDH's use of Health Risk Index Endpoints (Health Endpoints) into HH-WQS for evaluation of mixtures of noncarcinogens. The MDH lists Health Endpoints for each RfD unless the available study did not identify a specific adverse effect (Exhibit HH-6). Health Endpoints identify the most sensitive target organs or systems (e.g., nervous) or developmental process affected by that pollutant. These endpoints are used to group chemicals to evaluate mixtures if more than one pollutant with the same adverse effect is measured in a sample or waterbody. This mixtures approach is described in *Proposed Methods: Noncancer and Linear Carcinogen Algorithms*.

Cancer Potency Adjustment Factors. Another toxicological parameter that is being proposed is the use of $AF_{Lifetime}$ and ADAF for addressing the higher risks of early-life exposure to linear carcinogens (Exhibit HH-1, Sections IV. B. and V. B.). Linear carcinogens, as opposed to nonlinear carcinogens, either show no threshold for initiating cancer processes or for any amount of exposure there is a risk of cancer. Carcinogens with unknown modes of action are also classified as linear carcinogens. The EPA and MDH reviewed the available data and determined that, for linear carcinogens early-life exposure resulted in: 1) a higher risk of developing cancer; 2) cancer manifestation at an earlier age; and 3) higher incidence of cancer resulting from exposure in early life stages as compared to adult exposure (Exhibit HH-6). The EPA determined that for some carcinogens, data were available to develop a chemical-specific $AF_{Lifetime}$. The MDH also uses this approach. However, for many pollutants there are insufficient data to develop this factor and a default adjustment is necessary. The EPA developed the ADAF of 10, 3, and 1 for the age groups of birth to less than 2 years of age (birth to <2), 2 to less than 16 years of age (2 to <16), and 17 to 70 years of age (17-70), respectively, for application with mutagenic chemicals. The MDH broadened the application of the ADAF to include any linear carcinogen. Their review found that there is not a clear definition for a mutagenic carcinogen and higher cancer risk was also observed in chemicals with known non-mutagenic MOAs. The MDH's health protective policy led them to apply the ADAF to all linear carcinogens to ensure the HRL methods were protective for infants and children. As previously stated, the MPCA strives for consistency in the State's risk assessment methods; therefore, the MPCA is proposing to adopt the MDH's methods for ADAF application to ensure the HH-WQS are meeting its protection level goals for all age groups.

Increased protection to early life for NLC is built into the enhanced process of RfD development, which considers the full suite of available information on all adverse effects from exposure to a pollutant during developmental life stages.

GLI Methods. The MPCA's proposed revisions to the human health methods for developing Class 2 CS or site-specific CC will be replacing those currently listed in Minn. R. 7050.0218 and in Minn. R. 7052.0110 as incorporated by reference from 40 CFR 132 Appendix C based on the EPA GLI (Exhibit HH-5). 40 CFR

132 Appendix C provides detailed information on the development of the toxicological values (RfD and cancer slope factors). The MDH toxicological evaluations are either consistent with the EPA GLI methods or improve upon these methods through the use of the most current guidance from the EPA on noncancer and cancer evaluations, as well as advancements in use of less-than-chronic duration toxicity information and Minnesota-specific policies to better protect a person from a *lifetime* of exposure (Exhibits HH-1 and HH-6).

It should be noted that the GLI criteria have methods for developing two types of human health criteria for use by states as the basis for HH-WQS, either Tier I: Human Noncancer Criterion (HNC) and Human Cancer Criterion (HCC) or Tier II: Human Noncancer Value (HNV) and Human Cancer Value (HCV). Both Tiers describe minimal datasets. However, the Tier I methods require a more robust dataset and specific suite of toxicological studies then the Tier II method. The Tier II method requires a minimum of at least one acceptable 28-day short-term repeated dose study that provides a No Observed Adverse Effect Level (NOAEL), with some allowances for other studies if only a Lowest Observed Adverse Effect Level (LOAEL) is available.

The CWA 1990 amendments for protecting the Great Lakes from bioaccumulative chemicals centered on having water quality criteria available for all of the Bioaccumulative Chemicals of Concern (BCC). Therefore, application of the Tier II method was necessary to help ensure that the EPA and Great Lakes States could develop numeric human health criteria or values (40 CFR 132)(Exhibit HH-5). However, all the final GLI human health criteria previously adopted by the MPCA into Minn. R. 7050.0100 met Tier I minimum data requirements (Exhibit HH-1). Therefore, in the proposed amendments the reference to the Tier II methods for human health is being replaced by the revised methods that can address both robust and minimal datasets. In addition, reliance on a past minimal dataset, as described in 40 CFR 132, would not be appropriate for all pollutants, where more data may be needed to develop a defensible criterion or standard.

For Site-Specific CC, which are developed for pollutants lacking promulgated CS, the minimum toxicological datasets may be less robust than that used to propose promulgating a CS, but must still meet minimum federal regulations and State-methods (i.e., consistent with the MDH health-based guidance) for their designated purpose (e.g., NPDES effluent limit). With the adoption of the proposed revisions, the MPCA will continue to meet the GLI requirements in 40 CFR 132 for developing human health-based criteria when relevant for GLI pollutants as described in Minn. R. ch. 7052.

D. Exposure parameters and evaluation

The proposed amendments to the HH-WQS involve five exposure parameters, with differences in data sources and considerations (Table 2 and Exhibit HH-1, Sections IV. C. and V.).

Table 2 Proposed Exposure Parameters for Developing Human Health-based Chronic Standards

Exposure Parameter	Abbreviation	Values and Units	Agency Methodology	Data and Information
Drinking Water Intake Rates	$DWIR_{acute}$ $DWIR_{short\text{-}term}$ $DWIR_{subchronic}$ $DWIR_{chronic}$ $DWIR_{0-<2}$ $DWIR_{2\ to\ <16}$ $DWIR_{16\ to\ 70}$ $DWIR_{lifetime}$	0.289 L/kg-d 0.289 L/kg-d 0.077 L/kg-d 0.043 L/kg-d 0.137 L/kg-d 0.047 L/kg-d 0.039 L/kg-d 0.043 L/kg-d or Pollutant-specific	MDH-HRL Rule (4717) drinking water Intake Rates (IR)	CSFII 1994 to 1996, 1998 on community water intake by, consumers only as evaluated by EPA; MDH time-weighted average 95th percentile values (Exhibit HH-6).
Incidental Water Intake Rate	IWR	0.0013 L/kg-d	MPCA	EPA, MDH, and ATSDR (Exhibit HH-1).
Fish Consumption Rates	FCR_{adult} $FCR_{child\ (1\text{-}5)}$ $FCR_{0\ to\ <2}$ $FCR_{2\ to\ <16}$	0.00043 kg/kg-d (default) (0.43 g/kg-d, derived from: 30 g of fish per day/70 kg BW) 0.00086 kg/kg-d 0.00086 kg/kg-d 0.00055 kg/kg-d	MPCA	Regional fish consumption surveys and other relevant national surveys used by EPA (Exhibits HH-1 and HH-8).
Bioaccumulation Factors	BAF_{TL3} (24%) BAF_{TL4} (76%)	Pollutant- and Use Class specific value L/kg	EPA (MPCA – fish lipid and organic carbon fraction values)	40 CFR 132, Appendix B and EPA 2000 HH-AWQC and TSDs specific to BAFs (Exhibits HH-3, HH-4); Fish lipid and organic carbon fraction reviews from Minnesota data (Exhibit HH-1).
Relative Source Contribution factor	RSC	Pollutant-specific value between 0.2 and 0.8 (or use of defaults: 0.2 and 0.5 when pollutant-specific value cannot be determined)	EPA	EPA 2000 HH AWQC: RSC Exposure Decision Tree (Exhibit HH-3).

Drinking Water Intake Rate. The DWIR data and analysis behind this revised exposure parameter came from the MDH's revisions to the HRL Rule (Minn. R. 4717.7500 to 4717.7900) and is also the basis for health-based guidance. The rationale for the use of their data and values has already been fully described.

Incidental Water intake Rate. The MPCA developed a new IWR as part of the revised methods (Exhibit HH-1, Section IV. C.). IWR are used for HH-WQS to address recreation as a beneficial use. A revised rate was reasonable to address the children's age groups most relevant for a chronic duration – defined as

eight years, ages one through eight. Children are also more likely than adults to ingest water while swimming and take in more water on a per body weight basis. A new rate is also reasonable because it reflects recently available data on actual incidental water intake for children during swimming. The EPA first published recommended incidental water amounts for children in their 2008 *Children's Exposure Factors Handbook*. The latest *Exposure Factors Handbook: 2011 Edition*, includes a refined upper percentile rate for children (Exhibit HH-1). The rate of 120 mL per day is used with estimates of swimming duration (1 hour per day) and frequency (77.4 days per year) based on Minnesota site-specific risk consultations completed by the MDH and the Center for Disease Control's (CDC) Agency for Toxic Substance and Disease Registry (ATSDR). The body weight used (20.1 kg) is the average for ages one through eight.

Fish Consumption Rate. The HH-WQS have used an adult fish consumption amount of 30 g/d since first adopting these standards in 1990. With the inclusion of the adult body weight of 70 kg, the adult fish consumption rate on a per body weight basis is 0.43 g/kg-d. Using this rate as the basis for protecting fish consumers from chronic exposure to pollutants is reasonable and representative of an upper percentile rate for most freshwater, caught fish consumers given the available and reliable information (Exhibit HH-1, Section IV. C. e.).

Because of the newer risk assessment approaches to protect infants and children, the MPCA also evaluated the rationale and available data to develop proposed FCR for children. These proposed FCR_{child} will supplement the existing rate that applies for the chronic duration, developed based only on adult survey data (Exhibit HH-8). The MPCA's review concluded that available regional fish consumption survey data were not sufficient to develop a FCR representative of children using the same statistical approaches as was done for the current adult rate. However, based on weight of evidence comparison of intake ratios between adults and children and implementation of an MPCA policy objective to enhance protection of more vulnerable life stages, the MPCA is proposing a body weight base children's FCR for ages one through five that is twice the adult rate. The adult rate (FCR_{adult}) of 30 g/d for a 70 kg body weight is equal to 0.43 g/kg-d; the proposed children's $FCR_{child\ (1\text{-}5)}$ is 0.86 g/kg-d (Exhibits HH-8 and HH-1, Section IV. C. e.).

The MPCA's application of this rate in HH-WQS considers the appropriate matching of this exposure window (age one through five) to the toxicological data. For this exposure window, the most relevant application is to address the higher early-life susceptibility to linear carcinogens (Exhibit HH-1, Section V. B.). The EPA *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (2005b) describes two developmental windows where an increased risk from carcinogen exposure occurs: birth to age 2 (0 to <2) and age 2 to 16 (2 to <16). The cancer potency differences are addressed through the application of new ADAF for the first age group, the EPA recommends an $ADAF_{0<2}$ equal to 10 and for the second, $ADAF_{2\ to\ <16}$ of 3 (as a matter of convention: an ADAF of 1 is assigned to ages 16 to 70). The MPCA determined the new children's FCR was relevant for application with the ADAF windows. To fit the age groups, the MPCA is proposing two $FCR_{0<2}$ and $FCR_{2\ to\ <16}$ of 0.86 g/kg-d and 0.55 g/kg-d, respectively. No adjustment in the original rate is made for the first age group. Because the second age group extends 10 years beyond the age of 5, this rate was age-adjusted with four years assigned the 0.86 g/kg-d and 10 years assigned the adult rate of 0.43 g/kg-d and divided by 14 total years for the final age - adjusted rate of 0.55 g/kg-d. The final ADAF group of ages 16 to 70 would apply the FCR_{adult}. The FCR_{adult} will also be used when there is an $AF_{lifetime}$ or no cancer potency adjustment.

Bioaccumulation Factor. Regarding BAF methods, Minn. R. ch. 7052 currently incorporates by reference 40 CFR 132 Appendix B, originally developed as the 1995 304(a) *Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors*. The MPCA is not revising the methods currently in Minn. R. ch. 7052, which were used to develop WQS for the Lake

Superior Basin. However, the MPCA is proposing to replace all of the BAF methods in Minn. R. 7050.0218, subp. 7, with new methods based on the 2000 304(a) HH-WQC in Minn. R. 7050.0219 (Exhibit HH-3) (Exhibit HH-1, Section IV. C.). The MPCA also used the EPA's supporting TSD on bioaccumulation factors (Exhibits HH-4) to replace default values with Minnesota-specific data (Exhibit HH-1). As the 2000 HH-AWQC methods were developed based on those from the GLI, the proposed methods are almost identical, although the EPA made a few adjustments to the 2000 HH-AWQC to ensure broader applicability to waters outside the Great Lakes (Exhibit HH-3).

As stated in the CWA and EPA 304(a) AWQC, where sufficient data are available, national defaults should be replaced with local to regional data. Minnesota-specific data were used to refine national defaults in the EPA's new BAF methods. The MPCA reviewed data on fish lipid content and particulate organic carbon (POC) and dissolved organic carbon (DOC) water fractions for use in the revised BAF methods for statewide application (excludes Lake Superior Basin). Both of these reviews are detailed in Exhibit HH-1, Appendices A4 and A5. In summary, in 1990 and 1998 the MPCA developed Minnesota-specific fish lipid values of 8.5% for Lake Superior, 6% for Class 2A cold-water communities (trout waters), and 1.5% for Class 2B cool to warm-water communities. The proposed revisions to the BAF methods include a new distinction of Trophic Levels (TL) 3 and 4 fish species represented of different levels of the aquatic food chain (based on the Lake Superior methods). To establish these levels, the MPCA examined Class 2B fish species data by these TL (with BAF) and found a slight difference with TL_3 species, such as catfish and perch, on average being higher in lipid (2.0%) than TL_4 (1.5%) species, such as trout and walleye. Data on DOC from lakes and stream monitoring studies, but not POC, was sufficient to develop the proposed Minnesota-specific value of 7.5 mg/L.

Relative Source Contribution Factor. As outlined in Table 2, the exposure parameters other than DWIR either drew directly from or were supported by the EPA Guidance and survey data evaluations (i.e., *Exposure Factors Handbook*) (Exhibit HH-1, Section IV. C.). The methods for developing RSC and BAF stem primarily from EPA Guidance found in AWQC documents and GLI regulations. The RSC Exposure Decision Tree was developed as part of the 2000 304(a) *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (Exhibit HH-3). The Decision Tree refines and provides consistency for the development and application of a RSC. If there are sufficient data available to develop a chemical-specific RSC, it may be used to estimate the percentage of exposure a receptor would likely obtain from surface water compared to other sources of exposure, such as soil or air. The EPA recommends using no less than a minimum RSC of 0.2 (20% exposure from surface water) and no more than a maximum RSC of 0.8 (80% exposure from surface water). When data are not sufficient for a chemical-specific RSC, default values are used. The previous methods almost exclusively used a default RSC of 0.2. The new methods propose the use of two default values, 0.2 and 0.5 chosen based on chemical-specific properties and other sources of exposure.

E. Proposed methods: Noncancer and linear carcinogen algorithms

1. Introduction

As previously stated, there have been numerous advances in risk assessment methods since both the MPCA and MDH first adopted human health-based standards. One of the most critical aspects missing from current methods is a clear and defined consideration of changes in toxicological sensitivity and exposure throughout human life stages. These deficiencies were of most concern in the reliance on toxicological data primarily drawn from adult animal studies to address adverse effects across developmental life stage: fetal, infant, childhood, and adolescence. A related shortcoming was in the use of exposure parameters based solely on adult intake rates. The MDH's revision to the HRL methods centered on addressing these deficiencies as described in the introduction of their 2008/2009 SONAR (Exhibit HH-6):

> *The most significant changes in this revision represent a concerted effort to ensure that the process used for deriving HRLs incorporates provisions necessary to protect sensitive or highly exposed populations.*
>
> *Many of the changes resulting from this effort are based on scientific data; for example, toxicity testing indicating that development is a particularly sensitive period for a specific chemical, and data indicating that, for their body weight, infants and children drink more than do adults. Other changes may reflect societal values; data that, while not conclusive, are cause for concern based on physiological and biological reasons; or the mandate of MDH to protect the health of all Minnesotans.*

As described fully in Exhibit HH-1 and overviewed in the SONAR discussion of *Reasonableness*, the MPCA is adopting revised methods for developing human health-based CS and site-specific CC to ensure the beneficial uses of surface waters (drinking water source, fish consumption, and recreation) are protected. The revisions center on the algorithms described below that apply the latest risk assessment approaches, use the most current data, and more fully meet the protection level goals in the relevant Class 2 narrative standards in Minn. R. ch. 7050 and 7052. A key aspect of the revisions, as recognized by the MDH, is to enhance lifetime protection by ensuring health protective standards account for life stage differences in exposure and toxicity. Standards specifically address shorter (less-then chronic) durations of higher exposure rates that accompany greater windows of vulnerability to toxic effects to fully protect infants and children.

The fundamental formula for developing Class 2 HH-WQS is:

Chronic Standard (CS) or Chronic Criterion (CC) = Toxicological Value / Exposure

where, the *Toxicological Value* is either based on protection from noncancer and nonlinear carcinogenic (when observed) adverse effects using a RfD or linear carcinogenic potency expressed by a CSF, and now, early-life potency ADAF or $AF_{Lifetime}$. *Exposure* represents the intake rates for the specific beneficial uses and adjustment for other sources of exposure RSC. Specific algorithms are presented below that build off of this basic equation and address the details for application.

Because each pollutant will be applied in more than one algorithm, a short discussion is needed to define the nomenclature that will identify the different calculated CS (or site-specific CC). The CS (or CC) developed as a water concentration will be distinguished by the beneficial uses applicable for each Use Classification.

1. For Class 2A and 2Bd waters that protect drinking water sources, fish consumption, and recreation (through use of incidental water as part of drinking water rate and RSC), the acronym used is CS_{dfr} (or CC_{dfr}).
2. For Class 2B (2C and 2D) where drinking water use is not included, the beneficial uses include fish consumption and recreation (through use of incidental water rate and RSC), the acronym is CS_{fr} (or CC_{fr}).
3. When a CS is developed for a pollutant with acute, short-term, or subchronic developmental or less-than-chronic toxicity and higher early-life exposure rates, the acronym will be CS_{dev} (or CC_{dev}).
4. If more than one CS can be developed for a pollutant (e.g., for a pollutant with a chronic RfD and a less-than-chronic toxicity-based RfD or a chronic RfD and linear carcinogen), the more stringent CS (or CC) by use classification (CS_{dfr}/CS_{dev} or CS_{fr}/ CS_{dev}) will be listed as the final applicable HH-WQS [20].

Important new algorithms are being added to address development of fish tissue-based CS (or CC) to supplement the water-based CS (or CC) for chemicals defined with final BAF greater than 1,000 (Exhibit HH-1, Section IV. E.). These numeric standards, like the fish tissue-based CS for mercury, provide a more direct and meaningful value for assessing bioaccumulative pollutants that reach higher concentrations in fish than water. Fish tissue-based CS (or CC) will be referred to as CS_{ft} (or CC_{ft}). This value – the most stringent from the noncancer or cancer algorithm – is the same for all Class 2 waters, because it is based solely on fish consumption and does not differ due to different water intake rates (these rates are negligible for these pollutants) or BAFs as is the case for CS (or CC) applicable in water.

2. Noncancer and nonlinear carcinogen (NLC) algorithms (excerpt from Exhibit HH-1, Section V. B. b.)

Below are the algorithms for developing the HH-WQS or CS (or site-specific CC) for pollutants characterized for noncancer adverse effects. When the pollutant has also demonstrated cancer potential through a nonlinear or threshold MOA, the RfD is also used to set the protective dose; therefore, CS (or CC) for NLC will also be derived using the same algorithms.

The first two noncancer algorithms are always examined when developing a CS (or CC) for a pollutant. The foundation for these algorithms is the same as the 1990 noncancer algorithms, because of their consistency in the use of chronic duration RfD and intake rates. The only difference in the algorithms is the use of either the chronic DWIR or IWR to reflect the difference in use classifications between Class 2A or 2Bd and Class 2B (2C and 2D).

[20] The CS will be listed with two significant figures for consistency with the EPA's AWQC (USEPA 200b). The MPCA will round down the final value to ensure final CS is below and not higher than the calculated values.

Table 3 Revised Noncancer and NLC Algorithm for Class 2A and 2Bd Waters (DW+FC Noncancer Algorithm 1)

Beneficial Use Classification
Class 2A or 2Bd: Drinking Water source, Fish Consumption, and Recreation , CS_{dfr} (µg/L)

$$RfD_{chronic}\ (mg/kg\text{-}d)\ x \frac{RSC\ (no\ units)\ x\ 1000\ \frac{\mu g}{mg}}{\{DWIR_{chronic}\ (L/kg\text{-}d) + FCR_{adult}\ (kg/kg\text{-}d)\ [(0.24\ x\ BAF_{TL3}\ (L/kg)) + (0.76\ x\ BAF_{TL4}(L/kg))]\}}$$

$RfD_{chronic}$ And list Health Endpoints	Reference Dose (RfD) designed for chronic durations (> 10% of lifetime); comparable to 1990 RfD definition.	Pollutant-specific in mg/kg-d (sources: MPCA, MDH and EPA)
Water Exposure	Drinking Water Intake Rate (DWIR) = MDH $IR_{chronic}$ (or pollutant-specific)	0.043 L/kg-d (default)
Fish Exposure	Fish Consumption Rate (FCR): adult	0.00043 kg/kg-d (0.43 g/kg-d) (default)
	Bioaccumulation Factors (BAFs): State-BAFs and Lake Superior-BAFs proportioned by Trophic Level (TL) 4 at 76% and TL 3 at 24% & Lipid content 8.5% Lake Superior; 6% for Class 2A, and 1.5% TL4 and 2% TL3 for Class 2Bd	Pollutant-specific in L/kg (sources: MPCA and EPA)
Relative Source Contribution (RSC)	Based on EPA 2000 Exposure Decision Tree: Accounts for exposures other than ingestion of water and fish	Pollutant-specific or more often: 0.2 or 0.5 (defaults) (sources: MPCA, MDH, and EPA)

Table 4 Revised Noncancer and NLC Algorithm for Class 2B Waters (IW+FC Noncancer Algorithm 1)

Beneficial Use Classification
Class 2B: Fish Consumption and Recreation (Incidental Water exposure), CS_{fr} (µg/L)

$$RfD_{chronic}\ (mg/kg\text{-}d)\ x \frac{RSC\ (no\ units)\ x\ 1000\ \frac{\mu g}{mg}}{\{IWR\ (L/kg\text{-}d) + FCR_{adult}\ (kg/kg\text{-}d)\ [(0.24\ x\ BAF_{TL3}\ (L/kg)) + (0.76\ x\ BAF_{TL4}(L/kg))]\}}$$

$RfD_{chronic}$ And list Health Endpoints	Reference Dose (RfD) designed for chronic durations (> 10% of lifetime); comparable to 1990 RfD definition.	Pollutant-specific in Mg/kg-d (sources: MPCA, MDH and EPA)
Water Exposure	Incidental Water Intake Rate (IWR)	0.0013 L/kg-d
Fish Exposure	Fish Consumption Rate (FCR): adult	0.00043 kg/kg-d (0.43 g/kg-d) (default)
	Bioaccumulation Factors (BAFs): State-BAFs proportioned by Trophic Level (TL) 4 at 76% and TL 3 at 24% & Lipid content of 1.5% TL4 and 2% TL3 for Class 2B	Pollutant-specific in L/kg (sources: MPCA and EPA)
Relative Source Contribution (RSC)	Based on EPA 2000 Exposure Decision Tree: Accounts for exposures other than ingestion of water and fish	Pollutant-specific or more often: 0.2 or 0.5 (defaults) (sources: MPCA and EPA)

If the pollutant also has a final BAF > 1,000, the noncancer fish tissue-based CS is also calculated.

Table 5 New Fish Tissue-based Noncancer and NLC Algorithm for Class 2 Waters (Fish Tissue Noncancer Algorithm 1)

Beneficial Use Classification Class 2A, 2Bd, 2B: Fish Consumption, pollutant with a final BAF > 1,000, CS_{ft} (mg/kg) $$= \frac{RfD_{Chronic}\ (mg/kg\text{-}d)\ x\ RSC\ (no\ units)\ or - RSC\ (mg/kg\text{-}d)}{FCR_{Adult}\ (kg/kg\text{-}d)}$$		
$RfD_{chronic}$ And list Health Endpoints	Reference Dose (RfD) designed for chronic durations (> 10% of lifetime); comparable to 1990 RfD definition.	Pollutant-specific in mg/kg-d (sources: MPCA, MDH and EPA)
Fish Exposure	Fish Consumption Rate (FCR): adult	0.00043 kg/kg-d (0.43 g/kg-d) (default)
Relative Source Contribution (RSC)	Based on EPA 2000 Exposure Decision Tree: Accounts for exposures other than ingestion of fish; as with other RSC applications, can include percentage or subtraction approach. Subtraction was used for the 2008 fish tissue - based mercury CS_{ft}	Pollutant-specific or more often: 0.2 or 0.5 (defaults) (sources: MPCA and EPA)

3. Supplemental algorithm for developmental susceptibility (excerpt from Exhibit HH-1, Section V. B. c.)

Described in detail in Exhibit HH-1 (*Defining Developmental Protection,* Section IV. A.), the profile of a developmental toxicant is such that the prenatal and neonatal life stages may be uniquely susceptible to toxic insults from environmental pollutants. While developmental life stages include preconception to adulthood, the available toxicological data typically center on studying the more sensitive fetal (prenatal) and immediate neonatal developmental windows. This is the time when critical developmental changes are most pronounced, reflecting the fact that physiological processes initiated prenatally provide the essential foundation and map for a lifetime of growth, function, and maturation. The MDH's expanded review of available less-than-chronic toxicological data provides relevant RfD for these life stages. The new RfD require complementary evaluations of exposure pathways and intake rates (Exhibits HH-1 and HH-6).

For the drinking water pathway, the MDH determined that the highest and appropriate drinking water intake rate to apply with an acute or short-term RfD was the neonatal rate from birth to age 3 months ($IR_{acute/short\text{-}term}$ = 0.289 L/kg-d). This rate is based on infants fed almost exclusively formula made with a household's tap water. This is the most highly exposed life stage (as compared to pregnant or lactating women) and subpopulation of infants (Exhibit HH-6).

When considering the other exposure pathways used in HH-WQS, fish consumption and incidental water, the exposure considerations change. In the case of these two exposure routes, the life stages of higher direct exposure would be later childhood when children would start to eat solid food, including fish, or recreate in surface waters (Exhibit HH-1). In addition, women who are or plan to be pregnant are another important subpopulation (or life stage) to consider as an indirect route of prenatal exposure, particularly for highly bioaccumulative pollutants in fish. Regarding this subpopulation, the MPCA would evaluate the available data on fish consumption rates to determine if another rate besides the default

adult FCR should be applied on a pollutant-specific basis (see full discussion in Exhibit HH-1). Methylmercury is an example where the EPA developed a chronic RfD based on protecting fetal exposure by using an UF specific to maternal exposure and by applying the national adult fish consumption rate. However, the approach used for methylmercury may not be appropriate if newer data on women of child-bearing age would suggest a different FCR or for other pollutants of concern in fish tissue with different toxicological profiles. Therefore, considerations for these later life-stage exposures and developmental effects will need to be examined on a pollutant-specific basis and not part of the standard CS_{dev} (or CC_{dev}) algorithm proposed for rule.

The review for fish or recreational exposure and toxicological profiles to protect fish consumers or their children from developmental effects will consider: 1) the less-than-chronic duration toxicological profiles; 2) whether prenatal or childhood toxicity could be evaluated with, or sufficiently addressed by, toxicological values for either less-than-chronic duration or chronic duration; and 3) while, in most cases, the chronic duration is expected to be the basis for these pollutants, if a more stringent standard (or criterion) is developed for a less-than-chronic duration (also defined as a CS_{dev} or CC_{dev}), that value would be the final applicable CS or CC for that media (fish or water) and use classification (CS_{dfr} or CC_{dfr} or CS_{fr} or CC_{fr}).

In contrast, for the drinking water pathway, this exposure route has the potential to result in the highest exposure to infants during a development window of high sensitivity and has defined toxicological data relevant to this developmental window, standard algorithms are available to include in the HH-WQS methods as shown in Table 6. As described at the beginning of this section, for a CS (or CC) to provide *lifetime* protection, this standard has to be protective of shorter duration adverse effects. Therefore, if a CS_{dev} (or CC_{dev}) results in a more stringent concentration than the CS_{dfr} (or CC_{dfr}), the value will be applied as the final CS for Class 2A and 2Bd waters.

Table 6 New Drinking Water Supplemental Algorithm for Class 2A and 2Bd Waters to Address Developmental Toxicity (Dev Algorithm 1)

<table>
<tr><td colspan="3">Beneficial Use Classifications
Class 2A or 2Bd: Drinking Water source, CS_{dev} (µg/L)
$= RfD_{duration\ (acute\ to\ subchronic)}\ (mg/kg\text{-}d)\ x\ \frac{RSC\ (no\ units)}{DWIR_{duration\ (acute\ to\ subchronic)}(L/kg\text{-}d)}\ x\ 1000\ \frac{\mu g}{mg}$</td></tr>
<tr><td>$RfD_{duration(dev)}$
$RfD_{acute/short\text{-}term,\ or\ subchronic}$ And list
Health Endpoints</td><td>Reference Dose (RfD) based on less than chronic duration</td><td>Pollutant-specific in mg/kg-d
(sources: MPCA, MDH and EPA)</td></tr>
<tr><td>Water Exposure</td><td>Drinking Water Intake Rate (DWIR) =
MDH IR_{acute}
MDH $IR_{short\text{-}term}$
MDH $IR_{subchronic}$
(or pollutant-specific)</td><td>
0.289 L/kg-d (default)
0.289 L/kg-d (default)
0.077 L/kg-d (default)</td></tr>
<tr><td>Relative Source Contribution (RSC)</td><td>Based on EPA 2000 Exposure Decision Tree: Accounts for exposures other than ingestion of water (Follows MDH)</td><td>Pollutant-specific or more often: 0.2 or 0.5 (defaults)
(source: MPCA or MDH)</td></tr>
</table>

4. Linear carcinogen (C) algorithms (excerpt from Exhibit HH-1, Sections V. B. d. and e.)

The algorithms for evaluating linear carcinogens have expanded to address the use of new Adjustment Factors ($AF_{Lifetime}$ and ADAF) for application with the CSF. These AF enhance protection for higher cancer risk from early-life exposure.

Table 7 Revised Linear Cancer Algorithm for Class 2A and 2Bd Waters (DW+FC Linear Cancer Algorithm 1)

Beneficial Use Classification

Class 2A or 2Bd: Drinking Water source, Fish Consumption, and Recreation, CS_{dfr} (µg/L)

$$\frac{CR(1\ x\ 10^{-5})}{CSF(mg/kg\text{-}d)^{-1}\ x\ AF_{Lifetime}} x \frac{1000\ \frac{\mu g}{mg}}{\{DWIR_{Lifetime}(L/kg\text{-}d) + FCR_{Adult}\ (kg/kg\text{-}d)\ [(0.24\ x\ BAF_{TL3}\ (L/kg)) + (0.76\ x\ BAF_{TL4}(L/kg))]\}}$$

CSF	Cancer potency Slope Factor for linear carcinogens	Pollutant-specific in $(mg/kg\text{-}d)^{-1}$ (sources: MPCA, MDH and EPA)
$AF_{Lifetime}$	The CSF Adjustment Factor-Lifetime ($AF_{Lifetime}$) is used when data are available to examine the additional excess risk associated with pollutant if exposed in early life. The $AF_{Lifetime}$ would replace the default ADAF approach and could equal one if no additional risk is expected.	Pollutant-specific (sources: MPCA, MDH and EPA)
CR	Incremental excess Cancer Risk Level	1 in 100,000 (1×10^{-5})
Water Exposure	Drinking water Intake Rate (DWIR) = MDH $IR_{Lifetime}$ (or pollutant-specific)	0.043 L/kg-d (default)
Fish Exposure	Fish Consumption Rate (FCR) is adult rate	0.00043 kg/kg-d (0.43 g/kg-d) (default)
	Bioaccumulation Factors (BAFs): State-BAFs apportioned by Trophic Level (TL) 4 at 76% and TL 3 at 24% & Lipid content 6% for Class 2A and 1.5% TL4 and 2% TL3 for Class 2Bd	Pollutant-specific in L/kg (sources: MPCA and EPA)

Table 8 Revised Linear Cancer Algorithm for Class 2B Waters (IW+FC Linear Cancer Algorithm 1)

Beneficial Use Classification

Class 2B: Fish Consumption and Recreation (Incidental Water exposure), CS_{fr} (µg/L)

$$\frac{CR(1\ x\ 10^{-5})}{CSF(mg/kg-d)^{-1}\ x\ AF_{Lifetime}} x \frac{1000\ \frac{\mu g}{mg}}{\{IWR\ \ (L/kg-d) + FCR_{Adult}\ (kg/kg-d)\ [(0.24\ x\ BAF_{TL3}\ (L/kg)) + (0.76\ x\ BAF_{TL4}(L/kg))]\}}$$

CSF	Cancer potency Slope Factor for linear carcinogens	Pollutant-specific in $(mg/kg\text{-}d)^{-1}$ (sources: MPCA, MDH and EPA)
$AF_{Lifetime}$	The CSF Adjustment Factor-Lifetime ($AF_{Lifetime}$) is used when data are available to examine the additional excess risk associated with pollutant if exposed in early life. The $AF_{Lifetime}$ would replace the default ADAF approach and could equal one if no additional risk is expected.	Pollutant-specific (sources: MPCA, MDH and EPA)
CR	Incremental excess Cancer Risk Level	1 in 100,000 (1×10^{-5})
Water Exposure	Incidental water Intake Rate (IWR)	0.0013 L/kg-d
Fish Exposure	Fish Consumption Rate (FCR) is adult rate	0.00043 kg/kg-d (0.43 g/kg-d) (default)
	Bioaccumulation Factors (BAFs): State-BAFs proportioned by Trophic Level (TL) 4 at 76% and TL 3 at 24% & Lipid content 1.5% TL4 and 2% TL3 for Class 2B	Pollutant-specific in L/Kg (sources: EPA and MPCA)

If the pollutant also has a final BAF > 1,000, the linear cancer fish tissue-based CS is also calculated.

Table 9 New Fish Tissue-based Linear Cancer Algorithm for Class 2 Waters (Fish Tissue Linear Cancer Algorithm 1)

Beneficial Use Classification

Class 2A, 2Bd, 2B: Fish Consumption, pollutant with a final BAF > 1,000, CS_{ft} (mg/kg)

$$= \frac{CR\ (1\ x\ 10^{-5})}{CSF\ (mg/kg-d)^{-1}\ x\ AF\ _{lifetime}(no\ units)}\ x\ \frac{1}{FCR_{Adult}\ (kg/kg-d)}$$

CSF	Cancer potency Slope Factor for linear carcinogens	Pollutant-specific in $(mg/kg\text{-}d)^{-1}$ (sources: MPCA, MDH and EPA)
$AF_{Lifetime}$	The CSF Adjustment Factor-Lifetime ($AF_{Lifetime}$) is used when data are available to examine the additional excess risk associated with pollutant if exposed in early life. The $AF_{Lifetime}$ would replace the default ADAF approach and could equal one if no additional risk is expected.	Pollutant-specific (sources: MPCA, MDH and EPA)
CR	Incremental excess Cancer Risk Level	1 in 100,000 (1×10^{-5})
Fish Exposure	Fish Consumption Rate (FCR) is adult rate	0.00043 kg/kg-d (0.43 g/kg-d) (default)

The algorithms that incorporate the new ADAF have to address exposure and cancer risk specifically for the age groups defined by EPA in the *Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* as applied by the MDH (Exhibits HH-1 and HH-6). For the three age groups — birth to <2, 2 to <16, and 16 to 70 years of age — the MDH developed the appropriate drinking water IR

and the MPCA had developed appropriate FCR. For the IWR, the MPCA determined application of the single IWR was appropriately applied to all age groups. The duration in years for each age group is included in the algorithm and divided by the total *lifetime* averaging duration of 70 years.

Table 11 Revised Linear Cancer Algorithm with Age Dependent Adjustment Factor for Class 2A and 2Bd Waters (DW+FC Linear Cancer Algorithm 2)

Beneficial Use Classification

Class 2A or 2Bd: Drinking Water source, Fish Consumption, and Recreation, CS_{dfr} (µg/L)

$$= \frac{CR\,(1 \times 10^{-5}) \times 1000}{\left(\begin{array}{l}\left\{CSF \times ADAF_{<2} \times D_{<2} \times [DWIR_{<2} + FCR_{<2} \times (0.24BAF_{TL3} + 0.76BAF_{TL4})]\right\} + \\ \left\{CSF \times ADAF_{2\,to\,<16} \times D_{2to<16} \times [DWIR_{2\,to<16} + FCR_{2\,to<16} \times (0.24BAF_{TL3} + 0.76BAF_{TL4})]\right\} + \\ \left\{CSF \times ADAF_{16to70} \times D_{16to70} \times [DWIR_{16to70} + FCR_{Adult} \times (0.24BAF_{TL3} + 0.76BAF_{TL4})]\right\}\end{array}\right) /70yrs}$$

(Equation does not show units, see below)

CR	Incremental excess Cancer Risk Level	1 in 100,000 (1 x 10^{-5})
CSF	Cancer potency Slope Factor for linear carcinogens	Pollutant-specific in $(mg/kg\text{-}d)^{-1}$ (sources: MPCA, MDH and EPA)
ADAF	Age Dependent Adjusted Factor (ADAF) $ADAF_{<2}$ $ADAF_{2to<16}$ $ADAF_{16to\,70}$	 10 for birth to less than 2 years 3 for 2 to less than 16 years 1 for 16 to 70 years
D	Durations in years for ADAF	2, 14, and 54
Water Exposure	Drinking Water Intake Rate (DWIR) = MDH $IR_{<2}$ MDH $IR_{2to<16}$ MDH IR_{16+}	 0.137 L/kg-d 0.047 L/kg-d 0.039 L/kg-d
Fish Exposure	Fish Consumption Rates (FCR) $FCR_{<2}$ $FCR_{2to<16}$ FCR_{Adult}	 0.00086 kg/kg-d (0.86 g/kg-d) 0.00055 kg/kg-d (0.55 g/kg-d) 0.00043 kg/kg-d (0.43 g/kg-d)
	Bioaccumulation Factors (BAF): State-BAFs proportioned by Trophic Level (TL) 4 at 76% and TL 3 at 24% & Lipid content 6% for Class 2A, and 1.5% TL4 and 2% TL3 for Class 2Bd	Pollutant-specific in L/kg (sources: MPCA and EPA)

Table 12 Revised Linear Cancer Algorithm with Age Dependent Adjustment Factor for Class 2B Waters (IW+FC Linear Cancer Algorithm 2)

Beneficial Use Classification

Class B: Fish Consumption and Recreation (Incidental Water exposure), CS_{fr} (µg/L)

$$= \frac{CR\,(1 \times 10^{-5}) \times 1000}{\left(\begin{array}{l} \left\{ CSF \times ADAF_{<2} \times D_{<2} \times [IWR + FCR_{<2} \times (0.24BAF_{TL3} + 0.76BAF_{TL4})] \right\} + \\ \left\{ CSF \times ADAF_{2\,to\,<16} \times D_{2\,to\,<16} \times [IWR + FCR_{2\,to\,<16} \times (0.24BAF_{TL3} + 0.76BAF_{TL4})] \right\} + \\ \left\{ CSF \times ADAF_{16\,to\,70} \times D_{16\,to\,70} \times [IWR + FCR_{Adult} \times (0.24BAF_{TL3} + 0.76BAF_{TL4})] \right\} \end{array} \right) / 70yrs}$$

(Equation does not show units, see below)

CR	Incremental excess Cancer Risk Level	1 in 100,000 (1×10^{-5})
CSF	Cancer potency Slope Factor for linear carcinogens	Pollutant-specific in $(mg/kg\text{-}d)^{-1}$ (sources: MPCA, MDH and EPA)
ADAF	Age Dependent Adjusted Factor (ADAF) $ADAF_{<2}$ $ADAF_{2\ to\ <16}$ $ADAF_{16\ to\ 70}$	 10 for birth to less than 2 years 3 for 2 to less than 16 years 1 for 16 to 70 years
D	Durations in years for ADAFs	2, 14, and 54
Water Exposure	Incidental Water Intake Rate (IWR)	0.0013 L/kg-d
Fish Exposure	Fish consumption rates (FCR) $FCR_{<2}$ $FCR_{2\ to\ <16}$ FCR_{Adult}	 0.00086 kg/kg-d (0.86 g/kg-d) 0.00055 kg/kg-d (0.55 g/kg-d) 0.00043 kg/kg-d (0.43 g/kg-d)
	Bioaccumulation Factors (BAFs): State-BAFs proportioned by Trophic Level (TL) 4 at 76% and TL 3 at 24% & Lipid content 1.5% TL4 and 2% TL3 for Class 2B	Pollutant-specific in L/kg (sources: MPCA and EPA)

Table 13 New Fish Tissue-based Linear Cancer Algorithm with ADAF for Class 2 Waters (Fish Tissue Linear Cancer Algorithm 2)

Beneficial Use Classification

Class 2A, 2Bd, 2B: Fish Consumption, pollutant with a final BAF > 1,000, CS_{ft} (mg/kg)

$$= \frac{CR\ (1\ x\ 10^{-5})}{\left[\frac{(CSFx\ ADAF_{<2}\ x\ D_{0-2} x\ FCR_{<2}) + (CSFx\ ADAF_{2-16}\ x\ D_{2-16}\ x\ FCR_{2-16}) + (CSFx\ ADAF_{16-70} x\ D_{16-70}\ x\ FCR_{16-70})}{70\ years}\right]}$$

(Equation does not show units, see below)

CSF	Cancer potency Slope Factor for linear carcinogens	Pollutant-specific in $(mg/kg\text{-}d)^{-1}$ (sources: MPCA, MDH and EPA)
ADAF	Age Dependent Adjusted Factor (ADAF) $ADAF_{<2}$ $ADAF_{2\ to\ <16}$ $ADAF_{16to\ 70}$	 10 for birth to less than 2 years 3 for 2 to less than 16 years 1 for 16 to 70 years
D	Durations in years for ADAFs	2, 14, and 54
CR	Incremental excess Cancer Risk Level	1 in 100,000 (1×10^{-5})
Fish Exposure	Fish consumption rates (FCR) $FCR_{<2}$ $FCR_{2\ to\ <16}$ FCR_{Adult}	 0.00086 kg/kg-d (0.86 g/kg-d) 0.00055 kg/kg-d (0.55 g/kg-d) g-d (0.43 g/kg-d)

F. Additional human health algorithms

1. Environmental breakdown products (Environmental Degradates) (Exhibit HH-1, Section IV. B.)

Some pollutants, when introduced into the environment, undergo chemical transformation from microbial, photolysis, or other processes. Particularly for pesticides, there are known common environmental breakdown products referred to as degradates. The MDH has determined that in order to be health protective, breakdown chemicals that originate from a "parent" chemical should be assessed the same as the "parent" when toxicological data on the degradate are insufficient for a chemical-specific health based water value (Minn. R. 4717.7900). To address degradates found in water resources, the MPCA is proposing to also apply parent HH-WQS to environmental degradates when the MDH health-based guidance values are unavailable.

2. Mixtures analysis (Exhibit HH-1, Section V. B. f.)

HH-WQS methods currently include specific language on dealing with and limiting exposure to carcinogens in surface water. Minn. R. ch. 7052 also has general language for noncarcinogens. The carcinogen additive algorithm ensures that exposure to more than one carcinogen in surface waters does not exceed the cumulative incremental cancer risk level of 1 in 100,000 (Minn. R. 7050.0222, subp. 7, item D, and Minn. R. 7052.0230, subp. 2).

For linear carcinogens, the additivity algorithm is as listed in Minn. R. 7050.0222, subp. 7.D, and Minn. R. 7052.0230, subp. 2. The additivity equation applies to chemicals that are linear carcinogens and have HH-WQS calculated with a CSF. The risk index level is slightly changed for consistency with the MDH. The

index has to be equal to or less than one to meet HH-WQS. An index that exceeds one indicates the excess cancer risk level is greater than 1 in 100,000 and is in violation of the HH-WQS. The additive equation applied to mixtures of toxic pollutants with linear cancer Chronic Criteria or Standards is:

$$Cancer\ Health\ Risk\ Index = \frac{C_1}{CS_1} + \frac{C_2}{CS_2} + \cdots + \frac{C_n}{CS_n} \leq 1$$

Where:

$C_1 \ldots C_n$ are the concentrations [(as a 30-day average)][21] or fish tissue concentrations for the first through the n^{th} carcinogen.

$CS_1 \ldots CS_n$ is the Chronic Standard (or site-specific Chronic Criterion) for water or fish tissue by use classification (either CS_{dfr}/CC_{dfr} or CS_{fr}/CC_{fr} or CS_{ft}/CC_{ft}) for the first to the n^{th} carcinogen.

The revised methods include the application of the mixtures analysis to fish-tissue pollutants.

The MPCA is proposing to supplement the existing protection to surface water users by including a new approach for noncancer mixtures: an additivity analysis modeled on the MDH HRL rule. The algorithm is based on summing up the ratio of each pollutant concentration measured in the surface water or in fish tissue to their respective CS with the same *Health Endpoint*. To ensure total exposure does not exceed the threshold for noncancer effects in the target organ, system, or process (development), the sum or *Health Risk Index* has to equal one or less to meet the HH-WQS. The additive equation applied to mixtures of toxic pollutants with linear cancer Chronic Criteria or Standards is:

$$Noncancer\ Health\ Risk\ Index\ by\ Common\ Health\ Endpoint = \frac{C_1}{CS_1} + \frac{C_2}{CS_2} + \cdots + \frac{C_n}{CS_n} \leq 1$$

Where:

$C_1 \ldots C_N$ are the surface water concentrations (as a 30-day average) or fish tissue concentrations for the first through the n^{th} noncancer pollutant with the same *Health Endpoints*.

$CS_1 \ldots CS_N$ is the chronic standard (or site-specific criterion) for water or fish tissue by use classification (either CS_{dfr}/CC_{dfr} or CS_{fr}/CC_{fr} or CS_{ft}/CC_{ft}) for the first to the n^{th} noncancer pollutant.

3. Provision to Meet Chronic Standards through Substitution of Maximum Standard and Final Acute Value

For pollutants that are highly bioaccumulative or carcinogenic, the HH-WQS implemented as CS may be two or more orders of magnitude smaller than the aquatic life-toxicity based MS or FAV. To ensure the CS can be met in surface waters, Minn. R. 7050.0222, subp. 7, item G (formerly item E) includes a provision of replacement of the MS or FAV with 100 times and 200 times the CS, respectively. This item previously included a more vague statement of when this substitution may be warranted as determined by the commissioner, but that statement is being removed as the language regarding this substitution was already available and adds more specificity for application.

[21] The revised algorithm will include a reference to the concentration being a 30-day average and use new parameter abbreviations.

G. Uncertainty analysis for human health methods (excerpt from Exhibit HH-1, Section VI.)

Many factors come together to help ensure HH-WQS meet their *Protection Level Goals*. The proposed revised parameters and algorithms offer many improvements including more accurate exposure estimates and toxicological values. In addition, the application of more protection for developmental life stages will result in more meaningful *lifetime* protection from surface water pollutants. Where there are uncertainties in risk assessment approaches to address site-specific scenarios that may have different risk than used to calculate HH-WQS, the MPCA has further clarified approaches for improving human health protection on a site-specific basis.

The MPCA has taken steps to strengthen both the narrative standards and the pollutant-specific HH-WQS. The revised methods are adding approaches for addressing degradates of pollutants and mixtures of pollutants. There is uncertainty in both proposed approaches. For example, it is possible that degradates could be more or less toxic than the parent pollutant or that there could be increased toxicity as a result of synergy of mixtures (Exhibit HH-6). However, inclusion of more defined approaches for these scenarios represents an improvement over the existing methods. Exhibit HH-1, Section VI. more fully discusses uncertainty considerations in the revised methods and opportunities for minimizing and eliminating risks. For example, a related consideration for risk characterization being the need to utilize public outreach programs, specifically, the MDH FCA, to address pollutants with multimedia sources that are not fully managed by water-media standards. The MPCA also continues to follow advancements in risk assessment methods and pollutant toxicological profiles for future revisions.

H. Application of revised human health methods

1. Process for updating pollutant-specific chronic standards

Currently, Minn. R ch. 7050 contains WQS for 69 toxic substances with 36 being more restrictive for human health than aquatic life (Minn. R. 7050.0222); Minnesota R. ch. 7052 contains WQS for 29 pollutants, where for 15, human health is the basis for the most stringent CS (Minn. R. 7052.0100). With this rulemaking, the MPCA is proposing to adopt the revised methods in Minn. R. 7050.0217 to 7050.0219, with applicability also to Minn. R. ch. 7052 (except for the BAF methods). These methods provide the basis for both future promulgated CS and site-specific CC. Future rulemakings to update pollutant-specific CS will be based on the latest toxicological and supporting data available from the MDH, EPA, and other available and reliable scientific data. On a site-specific basis, a few specific scenarios related to use of the MDH Health Consultations are discussed below.

2. Application of Minnesota Department of Health consultations (Exhibit HH-1, Section V. C.)

Currently, Minn. R. ch. 7050 has one fish tissue HH-WQS for mercury; otherwise, when evaluating fish tissue data for compliance to HH-WQS, the MPCA uses the narrative language in Minn. R. 7050.0150, subp. 7, based on the MDH FCA. As discussed previously in this SONAR, as part of the proposed revisions to Minn. R. chs. 7050 and 7052, the MPCA plans to include algorithms to develop fish tissue CS_{ft} for statewide application and on a site-specific basis as CC_{ft}. The MPCA plans to continue to add fish tissue HH-WQS for pollutants with a final BAF > 1,000 in future WQS revisions, as new and updated toxicological reviews are completed by the MDH or developed based on the revised human health methods in Minn. R. chs. 7050 and 7052.

During the transition time between adopting the new fish tissue algorithms and having CS_{ft} for pollutants with BAF > 1,000 that will lead to the eventual repeal of the reference to FCA in the WQS, the MPCA may need to develop CS_{ft} or CC_{ft} for pollutants detected in fish tissue that lack FCA. In those cases, any calculated CS_{ft} or CC_{ft} would be done in consultation with the MDH using current toxicological values developed using the revised HH-WQS on a pollutant-specific basis to determine if HH-WQS are being met in fish tissue. The EPA approval is required if a Site-Specific Modified Standard would be needed (Minn. R. 7050.0220, subp. 7, or Minn. R. 7052.0270). Otherwise, use of a CC_{ft} would be accomplished through impaired waters list development or through the processes described in Minn. R. 7050.0220, subp. 7.

The MDH plays a critical role in Minnesota for supporting numerous human health risk-based programs, including responding to public requests for information on toxic chemicals. The MDH's Site Assessment and Consultation Unit develops site-specific *Health Consultations* as part of a program with the Center for Disease Control's Agency for Toxic Substances and Disease Registry (more details are available at http://www.health.state.mn.us/divs/eh/hazardous/index.html). The MPCA may determine that for particular surface water pollutants and scenarios, a more detailed site-specific review is needed to supplement the information currently available for developing HH-WQS. If a MDH *Health Consultation* determines that alternate, more stringent water concentrations are recommended to protect human health, the MPCA would proceed to develop either a Site-Specific Modified Standard requiring EPA approval or a site-specific CC as discussed in Minn. R. chs. 7050 and 7052.

3. Language for Revised Methods for HH-WQS and Site-Specific CC for Both Rules in Minn. R. 7050.0217 to 7050.0219

Minnesota Rules chs. 7050 and 7052 differ in how the definitions and methods for developing human health-based CS are cited in rule language. Minnesota Rules ch. 7052 is based on the GLI requirements that stemmed from CWA amendments and formal inclusion in 40 CFR 132, which required that states and tribes adopt the methods for WQS in rule. Minnesota Rules ch. 7052 met this requirement by incorporating by reference the human health methods in 40 CFR 132, Appendix C, with the exception of replacing GLI defaults with a Minnesota-specific fish consumption rate and fish lipid values (Exhibit HH-5). The MPCA is proposing to replace the methods currently incorporated by reference with the fully listed methods described in this SONAR and Exhibit HH-1. To limit redundancy and for ease of understanding and application, the MPCA plans to adopt the methods for Minn. R. ch. 7052 in Minn. R. 7050.0217 through Minn. R. 7050.0219. This approach is consistent with existing language in Minn. R. ch. 7052 that reference Minn. R. ch. 7050.

The decision to house the human health methods in Minn. R. ch.7050, instead of in both rules, reflects that this rule already includes the language describing the full methods, but had previously limited their application to site-specific CC. The revised methods will now be the basis in both rules (applicable statewide and in the Lake Superior Basin) for both site-specific CC and promulgated CS based on human health. The application of the promulgated methods for both CS and site-specific CC reflect past and current practice, because previously adopted statewide CS for human health used the same methods in rule as were referenced only for use in developing CC. The MPCA is also proposing to change language in Minn. R. 7050.0217 to broaden the application of those protection level goals to both rules and for both listed CS and CC. In addition, because the revised methods distinctly provide for the use of pollutant-specific data in place of default parameters, it is reasonable to use the revised methods for all human health-based numeric criteria or standards to improve consistency and transparency in how these values are developed.

I. Implementation overview

The HH-WQS in Minn. R. chs. 7050 and 7052, along with other WQS, provide the foundation for effluent limits in NPDES wastewater and stormwater permits and assessment of available pollutant-specific monitoring data in surface waters and fish that may be of concern for human health. Implementation of new or revised effluent limits based on revised pollutant-specific HH-WQS will occur as described in application of revised methods, following the adoption of future CS or development of new or updated site-specific CC. Implementation of the standards is broader than the scope of this document, but is founded in MPCA and other State agencies' programs and approaches to water resource protection. However, due to limitations in scientific understanding, available resources, and nonpoint pollutant sources, not all pollutants have control measures to achieve the WQS to meet beneficial uses in all water bodies. The MPCA assesses many pollutants with WQS and if they don't meet WQS list those water bodies as impaired and develop studies (Total Maximum Daily Load or TMDL) to determine sources and reductions needed to meet WQS. The processes of identifying and listing impaired waters and completing TMDLs are required under the CWA. The MPCA continually works with many State, federal, academic, local partners, and the public to identify and eliminate impaired water and gaps in monitoring data and control measure to ensure HH-WQSs are being met. An overview of HH-WQS implementation and limitations is provided in Exhibit HH-1, Section I. D.

J. Reasonableness conclusion

The proposed revisions to the methods to develop human health-based CS are based on extensive consideration of meeting the protection level goals (i.e., the narrative standards in Minnesota rules) and CWA and State Statute requirements for protecting the beneficial uses of Minnesota's surface waters. The proposed methods are built on the latest risk assessment methods and data as developed and implemented in EPA 304(a) AWQC and the MDH in Minn. R. ch. 4717. The revised methods include specific parameters, from exposure intake rates to Adjustment Factors, to address early life stage differences from adults and a new algorithm for *Developmental Susceptibility*. Other important additions to the HH-WQS are new algorithms to develop fish tissue-based CS. Standards directed at pollutants of concern in fish will improve the applicability of the water-based CS. The MPCA is also adopting the MDH's methods that address mixtures of pollutants in surface water and environmental degradates with limited toxicological data.

X. Regulatory Analysis

Several Minnesota statutes establish requirements that must be addressed in the SONAR.
Minn. Stat. § 14.131 requires that an Agency include a discussion on economic effect of the proposed rule amendments on the regulated community, regulatory entities and other affected parties. An Agency proposing a rule must also consider the effect of the rule on local government, and provide a discussion of how it has addressed additional specific legislative directives in the development of the rule. The following discussion addresses each of the statutory requirements of Minn. Stat. §§ 14.127, 14.128 and 14.131 to the extent that they specifically relate to the proposed amendments to the HH-WQS. The amendments to incorporate the BEACH Act requirements incorporate already applicable requirements and will not be further discussed.

A description of the classes of person 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.

As with all statewide WQS, all the citizens of Minnesota could be affected by, and benefit from, the proposed revision to the methods to develop HH-WQS. The MPCA promulgation of HH-WQS based on the most current, scientifically defensible, and State-based approaches is a necessary step to ensure protection of Minnesota's valuable water resources and fulfill the protection level goals established under the CWA and under State statutes and rules. Citizens and visitors to Minnesota engaged in the beneficial uses of surface waters (source water supply to public drinking water, fish consumption and recreation) will have assurances of the higher protection afforded by future development and application of HH-WQS based on these newer methods. Citizens rely on the MPCA to set standards and effluent limits that protect human health and the environment. The MPCA sees the revised methods as a benefit to all classes of persons.

There are no direct costs associated with the adoption of the revised human health methods. Costs will be determined as part of future rulemaking on a pollutant-specific basis as new and revised HH-WQS are developed using the amended methods. Based on the revised methods alone, it is not possible to develop a single, comprehensive statement describing whether these revised methods will result in less or more stringent CS as they are applied statewide and over time. Some parameters will tend to decrease the CS (e.g., higher DWIRs and application of cancer potency Adjustment Factors), and if newer toxicological values are less stringent than those used in the current rule, the final CS could be less stringent and not lead to costs when implemented.

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 adoption of the revised methods themselves will not result in any costs to the MPCA, other State agencies, or generally affect State revenues.

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

As described earlier, the MPCA does not expect any costs to any party with the adoption of the revised methods. In consideration of responding to this required question there are two aspects to address. First, could the MPCA achieve the desired result without amending the rules and secondly, are there less costly ways to achieve the result other than what is being proposed.

In answer to the first question, no, the MPCA cannot achieve the desired result revising the HH-WQS methods without adopting them into rules. The algorithms in the current rule are out of date and incomplete and must be amended. The application of the criteria through the use of guidance or unpromulgated documents would not have the legal authority to support the future development of WQS or site-specific CC.

The CWA requires the MPCA to promulgate numeric WQS to protect the beneficial uses of surface waters. And in the case of the GLI, the MPCA is also required to promulgate the methods used to develop the standards. The MPCA has not revised the methods for protecting human health since they were initially adopted in 1990 and 1998 for Minn. R. chs. 7050 and 7052, respectively. In order to use the more advanced and improved methods for developing human health-based WQS, the MPCA has to promulgate revised methods; in other words, there are no less costly or intrusive methods to apply these advances in risk assessment to WQS development.

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.

As previously discussed, promulgation of revised methods as part of the State rules is the only approach the MPCA considered for improving the HH-WQS.

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.

No costs are ascribed to this rule revision. Some costs may be associated with future rulemaking efforts as human health-based CS are added or updated based on the revised methods. Those costs would be discussed at the time those rules are proposed.

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.

The MPCA has presented substantial evidence as to why the proposed methods for human health protection are needed. The MPCA expects there will be costs or consequences to surface water users if WQS are not kept current and reflective of the latest scientific data and policies for protection from environmental pollutants. HH-WQS protect humans from detrimental effects. If HH-WQS are exceeded there can be a direct and indirect cost to human health and quality of life, resulting in monetary losses. Minnesotans place a high value on our water resources for drinking water, fish consumption, recreation, and support of healthy ecosystems. Maintaining protective WQS has many benefits for human health and welfare and the environment. These benefits include ensuring safe drinking water; maintaining the availability and quality of recreation activities, including lake and river fishing, swimming, boating, and nature viewing; ensuring the viability of commercial enterprises that involve water uses; and maintaining property values of land around Minnesota's waterways. A deterioration in any of these benefits has real costs and thus to the extent to which the amendments ensure the maintenance of adequate water quality, not adopting these rules may have significant costs.

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.

Federal regulations in the CWA and implemented in EPA Guidance, including CWA Section 304(a) AWQC documents, provide beneficial uses as the basis to develop WQS. The CWA gives states the authority to promulgate WQS based on EPA AWQC. However, the CWA and EPA Guidance encourage states to modify criteria based on regional, state, or local data or other scientifically defensible data. Therefore, the MPCA's development and promulgation of revised human health methods meets the federal requirement that states review and revise WQS as needed. The adoption of the revised methods into Minn. R. ch. 7050 will not cause the State rules to be either more or less stringent that the federal regulations, the differences between the federal regulations and the proposed methods simply reflect the federal intent for state-specific implementation of the CWA.

To address the revisions to the human health methods in Minn. R. ch. 7052, the MPCA needs to address this question in a slightly different context. In 1990, amendments to the CWA Section 118(c)(2), *Great Lakes Critical Programs Act,* required the EPA to publish and states to adopt methods and WQS specific to the Great Lakes. EPA worked with states and tribes to develop five AWQC documents specific to the Great Lakes, and further, adopted into 40 CFR 132, *Water Quality Guidance for the Great Lakes System.* This document provided the minimum criteria and requirements for implementation of the CWA requirements. While these AWQC, including the methods for developing human health-based CS, are in

the CFR, the same statements that encourage states and tribes to modify the national methods and criteria based on more site-specific data, were also included. The statements encouraging states and tribes to consider site-specific data include an important caveat that those methods must be consistent with (meaning "as protective as") the Guidance published in 40 CFR 132. In 1998 the MPCA met these requirements with the adoption of Minn. R. ch. 7052 for the Lake Superior Basin and the modification of two aspects of the human health methods (higher fish consumption rate and fish lipid value), resulting in Minnesota CS that were more stringent than the published GLI methods and AWQC (Minn. R. 7052.0110, subp. 4) (Exhibit HH-5).

The amendments being proposed in this rulemaking are the first revisions to those methods adopted in 1998 and again, some of the changes to the methods will differ from those published in 40 CFR 132, Appendix C. All the proposed differences stem from the State-specific risk assessment methods already adopted into Minn. R. ch. 4717. Use of state-specific data and policies is encouraged by the EPA and, as already described, is needed for consistent protection of drinking water as implemented by the MDH. The use of state-specific data and policy also reflects the latest risk assessment guidance published by the EPA. The differences between the State rules and EPA Guidance include the development of RfD for less-than-chronic durations, updated DWIR, new adjustment factors for early-life susceptibility to carcinogens ($AF_{Lifetime}$ and ADAF), children's Fish Consumption Rates ($FCR_{<2}$ and $FCR_{2\ to\ <16}$), IWR. These differences are reasonable, as fully described previously, to meet CWA requirements to update WQS and methods based on the latest science and public comments. Because the revisions are consistent with the 40 CFR 132 requirements, they are neither more nor less stringent than federal requirements, only different due to the directive that they reflect state-specific data and policies.

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

Minn. Stat. § 14.131 defines "cumulative effect" as

> *"the impact that results from incremental impact of the proposed rule in addition to the other rules, regardless of what state or federal agency has adopted the other rules. Cumulative effects can result from individually minor but collectively significant rules adopted over a period of time."*

The proposed amendments will not result in any cumulative effect in association with any other State or Federal regulations. WQS covering the spectrum of beneficial uses currently exist in State rule as required by the CWA. The CWA requirement for states to adopt WQS has existed since 1965. The proposed amendments merely refine and amend the existing standards and do not add additional regulation that could be considered to be cumulative and do not extend the impact of existing rules.

Assessment of differences between the proposed rule and federal standards, rules in bordering states and rules in states within EPA Region V.

Minn. Stat. § 14.131 together with Minn. Stat. § 116.07, subd. 2(f), requires the SONAR to include a comparison of how the rules being proposed compare to other states, specifically those in neighboring states and the EPA's Region 5. For this assessment the MPCA also provides a comparison of the WQS of Tribal WQS authorities in the State.

The proposed amendments to the HH-WQS methods have many aspects that are similar to other states and some that are unique to Minnesota. One significant difference that is a primary basis for the proposed amendments is the existence of strong human health risk assessment programs at the MDH. The MDH's improved risk assessment methods are relevant for use in HH-WQS. Therefore, incorporating State-specific considerations for protecting infants and children and other improvements in the methods, including higher intake rates, mean that when the proposed methods are applied to future

HH-WQS development, they may tend to result in more stringent, pollutant-specific HH-WQS than those in neighboring or other Region 5 states. The need for these differences is established in Part VII and the specific reasonableness is described in Part IX.

As noted below, the Great Lakes States (Region 5) and Tribes already have methods based on Great Lakes Initiative (GLI) that include many similarities to Minnesota and EPA's 2000 AWQC revised BAF methods. A few Region V states also use the EPA pollutant-specific criteria updated since 2000 (Exhibit HH-9), but do not include use of the 2000 BAF methods.

Region 5

It is difficult to compare the proposed amendments with the requirements of other states in the EPA's Region 5, because with the GLI, most states in Region 5 (including Minnesota) have two sets of human health methods; one for its Great Lakes Basin and one for the rest of the state. All states must meet requirements in the CWA for groundwater and surface water protection, but states with Great Lakes waters must also meet more specific requirements for addressing bioaccumulative and persistent pollutants in the Great Lakes. All Great Lakes states and Tribes are required to adopt the GLI methods and AWQC for bioaccumulative and persistent toxics of concern listed in 40 CFR 132 (with allowances for other scientifically defensible changes as long as they are "as protective as" those published by the EPA). The following comparison discusses the GLI methods comparison and other adopted human health methods used by Region 5 states.

The GLI methods are the basis for human health-based WQS statewide in Michigan and Wisconsin. Ohio, Illinois, and Indiana apply these methods only in their Great Lake Basin WQS and use different methods for the rest of their state (using two sets of methods to establish WQS is similar to Minnesota's current process). The proposed methods for developing HH-WQS differ from the GLI methods, except the development of BAF, which are the same as the GLI methods. Therefore, except for the development of BAF, the MPCA will establish future WQS through different methods than other Region 5 states. Minnesota's revised methods will have different algorithms and exposure parameters and differences in toxicity values are likely in the future depending on the rate at which EPA updates, and other states adopt national human health-based AWQC. Minnesota's use of current toxicological reviews completed according to the revised methods or by the MDH will mean the MPCA is using more defensible toxicological values in future HH-WQS that may differ from states using only historical EPA values.

The MPCA's proposed amendments will reflect the latest EPA Guidance on BAF and RSC methods. Use of the EPA's 2000 HH-AWQC methods statewide increases consistency with other Great Lake states that use the GLI BAF methods.

As far as other aspects of the human health methodology, Ohio is the only state to recently update their WQS rules related to methods for human health protection based on the EPA's 2000 HH-AWQC to apply to waters that are not in the Lake Erie Basin. Wisconsin uses some aspects of the EPA's 2000 methods in their WQS program for BAF development. Otherwise, their promulgated methods still reflect older 1980 methods. Of the remaining Region 5 states – Indiana, Illinois, and Michigan – none have updated any human health methods based on the EPA's 2000 HH-AWQC.

Other neighboring states

South Dakota's WQS rules incorporate EPA's updated 2006 304(a) AWQC. These EPA criteria primarily reflect the methods the EPA published in 2000, but do not use the newer BAF methods. The EPA still uses the old bioaccumulation methods that generally result in the use of less stringent Bioconcentration Factors. BCF are less accurate than BAF methods for quantifying bioaccumulation in fish, especially for highly bioaccumulative organic chemicals. Like South Dakota, WQS rules in North Dakota and Iowa reference EPA 304(a) AWQC based on the use of newer toxicological values from the EPA's IRIS (Exhibit

HH-9), but none of these states have revised their criteria or methods to reference the most current BAF methods that Minnesota is proposing.

Tribes in Minnesota (Grand Portage and Fond du Lac)

Two Tribes in Minnesota have HH-WQS applicable to waters in Lake Superior and its basin. The Grand Portage Reservation HH-WQS (2006 version), like those in Minn. R. ch. 7052, are based on GLI AWQC and incorporate by reference 40 CFR 132, Appendices B and C. Grand Portage's HH-WQS do use parameters that differ from the GLI defaults: fish consumption rate of 142.5 g/d, water ingestion rate of 2.01 L/d; and cancer risk factor of one in 1,000,000. These exceptions make the Grand Portage Reservation HH-WQS more stringent than the existing parameters in the MPCA's methodology. Except for the drinking water rate, the Grand Portage HH-WQS are more stringent than the proposed adult FCR and cancer risk level being proposed for statewide application in this rulemaking. *The Fond Du Lac Band of Lake Superior Chippewa Water Quality Standards of the Fond Du Lac Reservation* (2001 version) also incorporate the methods in 40 CFR 132, Appendices A, B, and C by reference with a few differences. The Fond Du Lac Band methods for human health protection use different fish lipid values and a higher adult fish consumption rate of 60 g/d. This higher fish consumption rate is one of the main differences between MPCA's proposed methods and the HH-WQS of the Fond Du Lac Band

An assessment of how the Agency considered and implemented the legislative policy supporting performance-based regulatory systems set forth in Minn. Stat. § 14.002

The proposed revised methods are "prescriptive" as are all numeric WQS that will be developed as a result of the methods. The methods are used on both a site-specific and statewide basis and are meant to provide the technical basis and algorithms to develop numeric standards protective of the beneficial uses associated with human health. The methods can be considered to be performance-based because they provide for flexibility, when warranted, based on toxicological or exposure data specific to a pollutant. The proposed methods stand as the most recent and robust foundation for developing numeric HH-WQS to implement narrative standards in Minn. R. chs. 7050 and 7052 to protect beneficial uses in Minnesota's water resources. The MPCA asserts that their prescriptiveness is not inconsistent with the intent of this statute.

XI. Consideration of Economic Factors

In exercising its powers, the MPCA is required by identical provisions in Minn. Stat. § 116.07, subd. 6, and Minn. Stat. § 115.43, subd. 1, to give due consideration to:

> *"...the establishment, maintenance, operation and expansion of business, commerce, trade, industry, traffic, and other economic factors and other material matters affecting the feasibility and practicability of any proposed action, including, but not limited to, the burden on a municipality of any tax which may result there from, and shall take or provide for such action as may be reasonable, feasible, and practical under the circumstances…"*

The proposed amendments will not have any economic effect on business, commerce, trade, industry, traffic or other economic factors nor will they present a burden on a municipality. The amendments will only improve the basis on which the MPCA will, through future rulemaking, update its WQS.

XII. Impacts and Notification

Impact on farming operations

Minnesota Statutes § 14.111, requires an Agency to provide a copy of the proposed rule changes to the Commissioner of Agriculture no later than 30 days prior to publication of the proposed rule in the *State Register,* if the rule has an impact on agricultural land.

The proposed amendments are not expected to impact agricultural land or farming operations, thus, the Commissioner of Agriculture will not be notified.

Impact on Chicano/Latino People

Minnesota Statutes § 3.9223, subd. 4, requires agencies to give notice to the State Council on Affairs of Chicano/Latino People for review and recommendation at least 5 days before initial publication in the State Register, if the proposed rules have its primary effect on Chicano/Latino people.

The proposed amendments are not expected to have a primary effect on Chicano/Latino people, thus, the State Council on Affairs of Chicano/Latino People will not be notified.

Notification of Commissioner of Transportation

Minnesota Statutes § 174.05, requires the MPCA to inform the Commissioner of Transportation of all rulemakings that concern transportation, and requires the Commissioner of Transportation to prepare a written review of the rules.

The proposed amendments are not expected to impact or concern transportation, thus, the Commissioner of Transportation will not be notified.

Consult with Minnesota management and budget on local government impact

As required by Minn. Stat. § 14.131, the MPCA consults with Minnesota Management and Budget (MMB) by sending MMB copies of the documents sent to the Governor's office for review and approval. The MPCA will consider the comments received from MMB and will provide a copy of the cover correspondence and any response received from MMB to the Office of Administrative Hearing (OAH) for review.

Determination if local government will be required to adopt or amend an ordinance or other regulation to comply with proposed Agency rules

Minnesota Statutes § 14.128, subd. 1, requires an Agency to determine whether a proposed rule will require a local government to adopt or amend any ordinances or other regulation in order to comply with the rule. The proposed amendments will not have any effect on local ordinances or regulation or require the adoption of corresponding local ordinances or regulations.

Determination of the cost of complying with a proposed rules in the first year after the rules takes effect will exceed $25,000 for a small business or city

Minnesota Statutes § 14.127, requires an Agency to determine if the cost of complying with proposed rules in the first year after the rules take effect will exceed $25,000 for any small business or small city.

> *An agency must determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed $25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees.*
>
> *For purposes of this section, "business" means a business entity organized for profit or as a nonprofit, and includes an individual, partnership, corporation, joint venture, association, or cooperative.*

The MPCA does not anticipate any scenario where the amendments to the HH-WQS will result in any costs to a small community or small business in the first year after adoption. As discussed previously, there will not be any direct costs to any parties as a result the adoption of the revised HH-WQS. In the

future, as WQS are developed using the revised methods, those new and revised WQS may result in costs on a pollutant-specific basis. Those costs will be evaluated in future rulemakings when such standards are proposed.

XIII. List of Authors, Witnesses and SONAR Attachments

A. Authors

1. Angela Preimesberger , Water Quality Standards Technical Coordinator, Environmental Assessment and Outcomes Division, MPCA
2. Carol Nankivel, Rule Coordinator, Resource Management and Assistance Division, MPCA

B. Witnesses

The MPCA anticipates that the following witnesses will testify in support of the proposed amendments:

1. Angela Preimesberger, Water Quality Standards Technical Coordinator, Environmental Analysis and Outcomes Division, MPCA
2. Laura Solem, Research Scientist, Environmental Analysis and Outcomes Division, MPCA
3. Mark Tomasek, Supervisor Water Standards Unit, Environmental Analysis and Outcomes Division, MPCA
4. Carol Nankivel, Rule Coordinator, Agency Rules Unit, Resource Management and Assistance Division, MPCA
5. Kathleen Izzo, Rule Coordinator, Agency Rules Unit, Resource Management and Assistance Division, MPCA
6. Jean Coleman, Attorney, MPCA

C. Exhibits

A-14 Kris Sigford (Ericka Schmidt), Minnesota Center for Environmental Advocacy, Sept. 26, 2008

A-18 State Register Request for Comments published July 28, 2008

A-19 State Register Request for Comments published March 2, 2009

HH-1 MPCA *Human Health-based Water Quality Standards Technical Support Document* (Final Draft-November 2013). 162 p. Available at http://www.pca.state.mn.us/index.php/water/water-permits-and-rules/water-rulemaking/amendments-to-the-human-health-methods-for-developing-class-2-chronic-standards.html.

HH-2a MPCA *Statement of Need and Reasonableness: In the Matter of Proposed Revisions of Minnesota Rules Chapter 7050, Relating to the Classification and Standards for Waters of the State*. December 1989

HH-2b List of Errata and Revisions to MPCA *Statement of Need and Reasonableness: In the Matter of Proposed Revisions of Minnesota Rules Chapter 7050, Relating to the Classification and Standards for Waters of the State*. December 1989

HH-3 USEPA *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*. USEPA EPA-822-B-00-004. October 2000. Available at http://www.epa.gov/waterscience/criteria/humanhealth/method/complete.pdf

HH-4 USEPA *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health*: *Technical Support Document, Volume 2: Development of National Bioaccumulation Factors*. USEPA EPA-822-R-03-030. December 2003. Available at http://www.epa.gov/waterscience/criteria/humanhealth/method/tsdvol2.pdf

HH-5 MPCA *Statement of Need and Reasonableness: Amended Rules Governing Water Quality Standards for Protection of Quality and Purity, Minn. R. 7050.0180, 7050.0185, 7050.0210, 7050.0216, 7050.0224, 7050.0460 and 7050.0470; and Proposed New Rules Governing Water Quality Standards, Standard Implementation, and Nondegradation Standards for Great Lakes Initiative Pollutants in the Lake Superior Basin, Minn. R. ch. 7052*. July 1997.

HH-6 MDH *Statement of Need and Reasonableness: In the Matter of Proposed Rules of the Minnesota Department of Health Relating to Health Risk Limits for Groundwater, Minnesota Rules, Parts 4717.7100 to 4717.7800 (to be repealed) and Parts 7810 to 7900 (to be added)* July 11, 2008.

HH-7 MPCA *Statement of Need and Reasonableness: In the Matter of the Proposed Revisions to the Rules Governing the Classification and Standards for Waters of the State, Minnesota Rules Chapter 7050*. April 27, 1993.

HH-8 MPCA *Development of Fish Consumption Rates for Children* Maschwitz, D.E. and A.L.H. Preimesberger. Environmental Bulletin, No. 12, November 2009. Available at http://www.pca.state.mn.us/index.php/about-mpca/mpca-publications/environmental-bulletin.html

HH-9 USEPA *National Recommended Water Quality Criteria: 2002; Human Health Criteria Calculation Matrix.* USEPA EPA-822-R-02-012. November 2002. Available at http://water.epa.gov/scitech/swguidance/standards/upload/2002_12_30_criteria_wqctable_hh_calc_matrix.pdf.

XIV. Conclusion

The MPCA has presented substantial evidence, information, and references to demonstrate that the revisions to the human health methods and incorporation of the BEACH Act requirements are needed and reasonable. The main points include:

- Currently applicable human health methods for developing CS or site-specific CC protective of human health uses of surface waters have not been updated since they were adopted although the MDH, EPA, and scientific literature demonstrate significant advances in risk assessment approaches relevant to these methods.
- Many of the risk assessment method improvements being proposed evolved from a better understanding of the implications for higher susceptibility to adverse effects resulting from both higher exposure and sensitivity to noncancer and cancer effects in early life. The current methods are based on adult only exposure rates and toxicology information and are not adequate to protect all life stages for all environmental pollutants. The proposed methods address these deficiencies.
- The MDH adopted critical updates to its HRL rule, Minn. R. ch. 4717, in 2009 based on newer science, policy, and legislative mandates to improve protection of Minnesota's citizens, particularly infants and children. HRL are the foundation for health protective drinking water standards. The MPCA's HH-WQS for surface waters need to reflect the MDH's approaches to maintain consistency in environmental risk assessment methods and health standards relevant to the State.
- The revised methods enhance protection for surface water users by adding new algorithms for fish tissue-based standards, a noncancer mixtures approach, and a statement on environmental breakdown products or degradates.

The MPCA expects the revised methods to improve protection for all surface water users as they are implemented through the process of developing pollutant - specific CS or through development of updated site-specific CC. After the adoption of the proposed methods, the MPCA will be working with the MDH to obtain new toxicological reviews for pollutants to ensure all beneficial uses are being addressed with the best standards.

In this SONAR, the MPCA has established the need for and the reasonableness of each of the proposed amendments to Minn. R. chs.7050 and 7052. The MPCA has provided the necessary notifications and in this SONAR documented 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.

April 22, 2014
Date

John Linc Stine, Commissioner
Minnesota Pollution Control Agency