Response to comments received during the public comment period on the Notice to Adopt Rules Without a Hearing for revisions to the rules governing the Classification and Standards for Waters of the State, *Minnesota Rules*, Chapters 7050 and 7052 (Revisor's ID #4177)

The Minnesota Pollution Control Agency (MPCA) placed the Notice of Intent to Adopt Rules Without a Hearing on public notice in the *State Register* on June 16, 2014, with a comment period running through September 4, 2014. The MPCA received three comment letters on the proposed rules during this comment period. Comments fell into two areas: general comments about the overall rule, and comments about specific rule parts and rule language. The MPCA's rationale for changes it will make to the proposed rules as a result of the comments received on specific rule parts is provided in the Order Adopting Rules. The MPCA's response to the general comments and its response to comments on specific rule parts where no change is proposed are provided in this Response to Comments document.

A. List of interested parties

The following is a list of interested parties who submitted written comments to the MPCA on this rule amendment during the public notice comment period from June 16, 2014, through September 4, 2014.

1. Letter from the U.S. Environmental Protection Agency (EPA), received via email on September 4, 2014
2. Letter from the Minnesota Department of Transportation (MnDOT), received via email on September 4, 2014
3. Letter from 3M Company (3M), received via email on September 4, 2014

B. General comments

1. The EPA had no recommendations regarding the proposed revisions.

Comment: The EPA made no specific comments or recommendations on the proposed revisions to the methods for developing human health–based water quality standards (HH-WQS) but commended the MPCA on its efforts to incorporate the most current science on human health risk assessment into Minnesota's water quality standards.

Response: None.

2. The MPCA should include more information in the rule language.

Comment: MnDOT commented that the proposed rule language should include a complete table of current and revised water quality standards for all priority pollutants; a cost/benefit analysis for implementing these amendments; and clarification regarding whether the equations in the amendments only apply to surface water used for drinking where people also catch fish for consumption.

Response: These revisions did not involve updating pollutant-specific standards, only the methods for developing them. The MPCA addressed required determinations and information, including costs and affected parties, in chapters 10 and 11 of the Statement of Need and Reasonableness (SONAR).

Water quality standards for protecting human health differ by use classification. The SONAR and rule language fully describe the uses (drinking water intake, fish consumption, and recreational activities) addressed for each use classification: Class 2A, 2Bd, and 2B (also applicable for Classes 2C and 2D). All surface waters, unless designated Class 7, support primary contact recreation and consumption of fish. Class 2A and 2Bd waters also protect for drinking water use (Domestic Consumption). The algorithms in the SONAR and rule language identifying the use classifications and relevant algorithms for

developing chronic standards or criteria are found in SONAR ch. 2A and 9E, and *Minnesota Rules* (*Minn. R.*) ch. 7050.0217 to 7050.0219 (revised language) and ch. 7050.0221 and 7050.0222 (existing language).

The equations are not applicable solely to a specific use, because when setting standards protective of human health, multiple exposure parameters are commonly considered. Because many pollutants in fish are commonly found across water bodies—mercury, for example, is detected in almost all freshwater fish—the basic foundation for ensuring protection from adverse health effects to the majority of surface water users requires acknowledging and accounting for these multiple exposures; therefore, the HH-WQS include exposure parameters for drinking water use, fish consumption, and recreational activities. This approach is also a long-standing foundation for the EPA Office of Water's National Ambient Water Quality Criteria and water quality standards methods for the reasons described in Exhibit HH-3, ch. 4.1.

3. The proposed rule language lacks scientific justification and will result in overly stringent criteria.

Comment: 3M stated that several of the assumptions the MPCA made in the rule are lacking in scientific justification, which will affect the algorithms used to derive water-quality criteria, resulting in an overestimation of risk and overly stringent criteria. The risk parameters 3M believes to be overestimated include (1) higher fish consumption rate than national EPA guidance; (2) relative source contribution (RSC) that defaults to 20% of the reference dose (RfD); and (3) additivity or lowering of acceptable thresholds for multiple chemicals with generally similar health endpoints, without guidance on how to treat nondetected chemicals nor recognition of mode of action, specific type of effect, or dose at which such effects would occur. 3M specifically remarked, "These extreme assumptions… have the potential to result in unnecessarily stringent water quality limits that will in turn cause a significant financial burden to municipal water treatment facilities, and other stakeholders, without actual health benefits."

Response: The MPCA response to comments on specific rule parts (below) addresses issues and questions raised by the commenter on RSC and mixtures procedures using health risk index endpoints. The fish consumption rate of 30 g/d with 70 kg body weight is in *Minn. R.* ch. 7050 and is not being revised. Regarding future development of fish tissue site-specific criteria or water quality standards, the full details and data used to develop values for specific pollutants will be available for public review and comment when each is proposed by the MPCA.

Per *Minnesota Statutes* (*Minn. Stat.*) ch. 115 and the Clean Water Act, one of the purposes of water quality standards is to be protective of human health; some conservatism in methods to address data limitations is therefore warranted in ensuring that outcome as fully described in the EPA's 2000 *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (Exhibit HH-3). In addition, as described further in the following responses on specific rule parts, when sufficient available and reliable scientific data are available, the goal is to reduce conservatism by using chemical-specific data in lieu of default values and to develop the most accurate HH-WQS.

The commenter also made an unclear statement regarding impacts to municipal **water** treatment facilities. HH-WQS are not applicable to municipally treated drinking water, but are implemented at wastewater facilities. The MPCA evaluated costs related to adoption of these revised methods, as noted on page 51 of the SONAR, and determined that there were no direct costs identified for wastewater facilities. Costs and benefits 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.

C. Comments on specific rule parts

4. 7050.0150, subp. 7

Comment 1: 3M commented that MPCA's assessment of impairment of Pool 2 of the Mississippi River (in the 2014 impairment listing and the MPCA response to public comment, available at

http://www.pca.state.mn.us/index.php/view-document.html?gid=20955) based on water concentrations of perfluorooctane sulfonate (PFOS) is inconsistent with the proposed rule revision, which specifies that fish-tissue concentration criteria or standards must be the basis of impairment determinations when various chronic criteria or standards are available.

Comment 2: 3M commented that MPCA incorrectly lists the assessment unit identification number (AUID) based on both fish-tissue and site-specific water criteria and that the MPCA should only be listing the AUID based on the fish-tissue criterion.

Response to both comments: The MPCA determined the impairment listings in the draft 2014 Impaired Waters List based on the existing rule language in *Minn. R.* ch. 7050. Existing rule language supports the identification of impaired waters using both site-specific criteria developed under *Minn. R.* ch. 7050.0218 and the Minnesota Department of Health's (MDH's) limitations on fish consumption described in the narrative standard in *Minn. R.* ch. 7050.0150, subp. 7. The MPCA will base its development of future impaired waters lists on any amended water quality standards.

5. 7050.0218, subp. 3F

Comment 1: 3M commented that the definition of "available and reliable scientific data" is limited in scope and fails to consider data from nongovernment agencies and that the proposed rule should include appropriate language to include these additional sources.

Comment 2: MnDOT commented that the MPCA should describe (1) the means of selecting "reliable scientific data" from specific literature in order for the data to meet specified peer-reviewed standards of quality assurance/quality control, and (2) the process for specifying new sources of data. MnDOT also said that MPCA should include a list of reliable data sources to make the data publicly available.

Response to both comments: "Available and reliable scientific data" means information derived from scientific literature, including published literature in peer reviewed scientific journals, EPA ambient water quality criteria documents, and other reports or documents published by the EPA or other governmental agencies. The proposed definition only adds the term "reliable" to the existing definition for clarification and consistency with other definitions in *Minn. R.* ch. 7050. The definition does not exclude use of scientific studies from private industries or companies. The MPCA considers all available and reliable scientific data for developing methods and pollutant-specific water quality standards and criteria. The definition as proposed allows for use of this type of scientific data.

This term has its basis in the MPCA's determination that the scientific data being used to develop water quality standards or criteria has a measure of consistency or repeatability, repeatability being the hallmark of the scientific method. The use of any scientific data for development of the water quality standards methods (as is the case in this specific rulemaking) or pollutant-specific standards or site-specific criteria is subject to public comment on the data used, as well as consideration of additional scientific data or information. All information used to support rulemaking, including adoption of future pollutant-specific water quality standards or development of site-specific criteria, is publicly available. The definition as revised sets the foundation for evaluating that data, but is ultimately determined by the data in question and its proposed use.

6. 7050.0218, subp. 3G

Comment: 3M commented that the last clause in the definition of "bioaccumulation factor" (BAF), which indicates that BAFs are to be determined under steady-state conditions, appears to be inconsistent with wording elsewhere in the rule that states a preference for field data over lab data, and that the proposed rules should be revised to clarify that a lab bioconcentration factor at steady state should be used when field data are unavailable.

Response: The rule language, SONAR, and supporting Exhibits HH-1 (particularly ch. 4C.g) and HH-3 all clearly state that field study data on bioaccumulation are preferred over any other data used to develop a BAF. The existing definition states: "Bioaccumulation Factor or 'BAF' means the concentration of a pollutant in one or more tissues of an aquatic organism, exposed from any source of the pollutant but primarily from the water column, diet, and bottom sediments, divided by the average concentration in the solution in which the organism had been living, under steady state conditions." According to EPA guidance, approximating a steady state condition is the goal when conducting BAF field studies. As such, use of the term steady state is a relevant descriptor for field data. Full details of the EPA discussion on BAF development are found in Exhibits HH-3 ch. 5 and HH-4.

7. 7050.0218, subp. 3Q

Comment: 3M commented that the use of "aquatic recreation" in the definition of "chronic criterion" is too vague and should be changed to "exposure to surface water by contact or ingestion during recreational activities."

Response: Existing rule language that is not being revised through this rulemaking (*Minn. R.* ch. 7050.0140, subp. 3) describes the beneficial uses protected with Class 2 water quality standards, which states "aquatic life and recreation." It is reasonable to be consistent with this language. This paragraph describes the uses protected as required under the Clean Water Act and *Minn. Stat.* ch. 115, including aquatic life and recreation.

8. 7050.0218, subp. 3AA

Comment: MnDOT commented that the MPCA should specify the EPA models used to calculate food chain multiplier (FCM) so stakeholders can confirm model validation. MPCA should also include a list of models that could be used.

Response: The definition of FCM in the proposed rule language states that only EPA models would be used. The EPA as administrator of the Clean Water Act is required to provide scientifically-based methods and models for states and tribes to use to develop water quality standards. These types of supporting material undergo peer review and public comment. For example, the EPA developed a robust FCM model as part of the Great Lakes Initiative criteria in 1995 that is still used by Great Lake States. The values from that model are incorporated by reference in *Minn. R.* ch. 7052. In addition, for MPCA to use a newer model-based FCM, it would be done under the processes described for rulemaking or implementation of site-specific criteria and would thus be subject to public comment on a pollutant-specific basis when any site-specific criteria are being established. There is also a preference for field or laboratory FCM data that have the potential to be more reliable than modeled values.

9. 7050.0218, subp. 3XX

Comment: 3M commented that "adverse" should be added to the following text from the "toxic unit" definition: "causes 50 percent <u>adverse</u> effect or mortality."

Response: This item relates to the methods to develop aquatic-life based water quality criteria and is outside the scope of this rulemaking.

10. 7050.0218, subps. 1 and 3, and 7050.0219, subps. 5 and 13–15

Comment 1: 3M commented that the proposed rule language is inconsistent with the MPCA 2014b technical support document and ambiguous in the specified value for the RSC and method of incorporation. Specific areas of inconsistency cited by 3M include *Minn. R.* ch. 7050.0218 subp. 3SS and ch. 7050.0219 subp. 5, which 3M says note no guidance for the subtraction method or for acceptance of exposure data that support a value higher than 0.8; *Minn. R.* ch. 7050.0219 subps. 13 and 14, which 3M says multiplies the RSC factor used in the equations but states no default value and provides no

guidance for the subtraction method; and *Minn. R.* ch. 7050.0219 subp. 15, regarding which 3M states that the algorithm allows for multiplication or subtraction of an RSC but does not specify the percentage for multiplication, nor does it state the conditions under which each approach can/should be used.

Comment 2: 3M commented that an RSC reduces the allowable exposure to any particular pathway because other exposures to a chemical can occur through other food, air, water and consumer-product exposures. The derivation of EPA's and MDH's drinking-water standards has often included an RSC term, typically with a default RSC value of 0.2 (20%). 3M specifically stated, "The application of such a value decreases the allowable drinking water value to 20% of that otherwise allowed by the chemical's toxicity RfD. The State of MN and EPA have derived a [site-specific fish tissue–based chronic criterion (CC_{ft})] for mercury in fish tissue using an RSC term (since 2008 for MPCA). However, the RSC term applied in the determination of the mercury CC_{ft} is subtracted from allowable exposure rather than multiplied as a percent. The subtraction method used for mercury more accurately accounts for actual background exposure."

Response to comments 1 & 2: *Minn. R.* ch. 7050.0218, subp. 3, states, "Definitions. For the purposes of parts 7050.0217 to 7050.0227, the following terms have the meaning given them." Therefore, the RSC definition in *Minn. R.* ch. 7050.0218, subp. 3SS applies to that term in the portions of *Minn. R.* ch. 7050.0219 listed by the commenter, where the RSC is further described or applied in algorithms. The definition of the RSC specifically allows for both the percentage and apportioned amount (subtraction method). Regarding the use of an RSC percentage or apportioned amount, the maximum or upper value allowed for any pollutant is 0.8. This limit is based on the EPA Exposure Decision Tree and policies to ensure water quality criteria (and standards) are protective values as fully described in Exhibit HH-3, ch. 4.2. This upper value or ceiling is relevant to the subtraction method as a pollutant-specific intake value in mg/kg-d from sources other than those included in the algorithms applied as an RSC cannot be greater than 80% or 0.8 of the RfD.

For example, in the case of the EPA 2001 methylmercury ambient water quality criteria, the RSC was developed in mg/kg-d and subtracted from the RfD; however, multiplying the RfD by the comparable percentage of this apportioned amount (in this case, it was 27% of the RfD) would have resulted in the same fish tissue-criterion. Although the definition of the RSC in *Minn. R.* ch. 7050.0218, subp. 3SS allows for the use of the subtraction method in any of the human health–based algorithms regardless of whether the RSC is only showed as being multiplied with the RfD in specific algorithms, in fact the more relevant consideration to the points raised by the commenter is that the methods allow for use of pollutant-specific data in RSC development, and that is clearly a requirement in RSC development as stated in the rule language and SONAR. In addition, EPA policies on RSC development go beyond the issues of percentage and subtraction methods to evaluate the appropriate approach and values. More supporting information on this topic is found in Exhibit HH-1 and HH-3, ch. 4.

Comment 3: 3M commented that RSCs, especially default values, are often overly conservative relative to protection of human health; that background exposure data should be used to evaluate the use of RSC; and that chemical-specific assessments are preferred.

Comment 4: MnDOT commented that the 0.2 RSC is overly conservative and indicates a policy- rather than science-driven value. MnDOT recommends that 0.8 be used as the default unless site-specific data suffice to justify a site-specific RSC.

Response to comments 3 & 4: The MPCA is proposing to adopt the EPA method of ascribing an RSC, termed the Exposure Decision Tree. The policy and scientific basis for this method is fully described in Exhibit HH-3, ch. 4.2. The use of the RSC defaults as stated in EPA's Exposure Decision Tree (Exhibit HH-3) were developed based on reasonable assumptions of what is known in general about exposure to pollutants from fish consumption and drinking water in order to address data limitations when sufficient and reliable chemical-specific data are not available for defining the relevant population exposure estimates. The Exposure Decision Tree allows for use and development of different RSC values. The

MDH also adopted this method into their Health Risk Limit (HRL) rule. The public will have the opportunity to comment on development of pollutant-specific water quality standards or site-specific criteria and the applicable RSC. The data and rationale behind RSC development are fully described in Exhibit HH-3.

Comment 5: 3M commented that applying a default RSC of 0.5 when there are no significant known or potential sources other than those addressed for the designated use is inconsistent with the definition and purpose of an RSC. Also, if exposures through other sources are much less than 50% of the RfD, 3M maintains that allowing only 50% of the RfD is overly stringent for calculating water quality criteria.

Response: The MPCA is basing the RSC method on EPA's Exposure Decision Tree, which was also the basis for the MDH to adopt RSC of either 0.2 or 0.5 in the HRL rule. The policy and scientific basis for this method is fully described in Exhibit HH-3, ch. 4.2, including the requirement that water quality criteria (and standards) be protective, and that if adequate data to calculate a pollutant-specific RSC is unavailable, a conservative RSC of 0.5 is warranted to meet the protection level goals.

Comment 6: MnDOT commented that multiplying RSC and uncertainty factors (UF) drive the resulting water quality criteria (WQC) to extremely low concentrations where current laboratory analytical methods are insufficiently sensitive, which will cause more frequent false-positive results and thus lead to unjustified regulatory action. MnDOT specifically stated, "Revised WQC values should be listed with current EPA-published analytical methods and their published detection limits to show revised WQC are achievable. Where proposed WQC are less than analytical detection limits, the WQC should be three times the published method detection limit." This comment classed the RfD with UF and RSC as being based on similar considerations and thus adding in too much conservatism or stringency in the concentrations used as the basis for pollutant-specific water quality standards.

Response: The limits on UF and RSC follow the MDH and EPA requirements or guidance. As previously described, water quality standards are based on protecting a beneficial use, in this case human health, and do not take into account analytical detection limits. Issues of available analytical detection limits are outside the scope of this rulemaking.

Comment 7: 3M stated that MDH investigation is ongoing to determine whether the EPA default RSC of 20% applied to drinking-water criteria is appropriate for exposure to chemicals in air, water, food, or consumer products. An MDH contractor has evaluated several models but not yet made findings available. Therefore, 3M considers the timing premature for MPCA to specify various default RSCs for fish consumption until the MDH has completed its investigation, including the contracted study, and developed guidance "based on the science and actual exposure data for U.S. populations."

Response: The MPCA is not proposing any pollutant-specific RSC in this rulemaking. Any future use of the revised methods to develop pollutant- or site-specific criteria or water quality standards would at that time offer the opportunity for public review and comment on the data used.

11. 7050.0218, subp. 3, and 7052.0230, subp. 3

Comment 1: 3M commented that the definition of "health risk index endpoint" or "health endpoint" as "a general description of toxic effects…" is overly vague and does not account for different mechanisms or physiological/biochemical pathways that lead to different effects.

Response: The definition for health risk index endpoint is identical to the term and definition in the MDH HRL rule in *Minn. R.* ch. 4717.7820, subp. 12. The MDH first adopted this approach for mixtures analyses in 2009 and has adopted and published many chemicals with defined health risk index endpoints since then. The MPCA described in the SONAR and Exhibit HH-1 the need to maintain consistency with MDH risk assessment methods, including toxicological values and health risk index endpoints.

Comment 2: 3M commented that the definition of "toxic effect"—particularly the parts about the designation of health endpoints and how to ascribe toxic effects—is unclear and appears to promote the broad grouping of risks of different chemicals based on general similarity in health effects, but no specificity in type or mechanism of effect or dose at which it occurs. 3M recommends that grouping be based on the toxic effects that occur at the lowest doses via mechanisms that would be additive.

Comment 3: 3M commented that the proposed rule language appears to falsely equate chemicals having the same health endpoint with acting by the same mechanism of action. If the total hazard index exceeds unity, the chemicals should be evaluated for whether they act by the same mechanism of action and thus might actually be additive at doses below their RfD.

Response to comments 2 & 3: One of the main goals of the revisions to the human health methods used to develop water quality standards was to increase consistency with the MDH HRL rule methods, *Minn. R.* ch. 4717.7500 to 4717.7900. As fully described in the SONAR, the MDH is the lead agency for risk assessment methods. The MDH conducted extensive reviews, public comment periods, and expert panel consultation to develop the methods adopted in their HRL rule. The MDH methods for identifying health risk index endpoints are clearly described in Exhibit HH-6. The MDH methods have accounted for the issues raised by this commenter in their health risk index endpoint process. As with the definition of health risk index endpoint, the definition of toxic effect is identical to the MDH term and definition in *Minn. R.* ch. 4717.7820, subp. 24.

12. 7050.0218, subp. 5E

Comment: MnDOT commented that MPCA's rule language for Toxicity-based criteria—which states, "If an approved chronic value for a commercially, recreationally, or ecologically important freshwater species…"—does not consider analytical feasibility and should include a phrase at the end stating, "when analytical methods and Quality Assurance permit."

Response: The only amendment being proposed in *Minn. R.* ch. 7050.0218, subp. 5E, is to more clearly label the acronym "CC" as being aquatic toxicity-based, so "CC_{tox}." The comment raised is out of scope for this rulemaking.

13. 7050.0219, subps. 8–13

Comment: 3M commented that the section on methods for baseline BAF should caution the user to understand that all of these methods use predictive model tools that often provide very conservative estimates of the potential bioaccumulation of pollutants of concern because of their use of normalizing parameters, surrogate parameters, and other factors. 3M specifically stated, "More specific to the PFOS issues in Pool 2, the methods do not provide direction for the use of arithmetic and geometric averages in the determination of site-specific BAF values. Geometric means are more statistically appropriate for log-normal data such as for BAF values and have been MPCA's stated preference in other guidance."

Response: The foundation of developing a BAF is to obtain an average value; the BAF is not designed to be overly conservative. Additional details about the strengths and limitations of the BAF methods are described in Exhibit HH-3 and HH-4. Again, future application of the proposed methods and data used to develop pollutant-specific BAF for water quality standards or site-specific criteria would be open for public comment.

14. 7050.0219, subp. 9Q

Comment: 3M commented that the variability in biota-sediment accumulation factor (BSAF) values may impose limits on the BSAF model's utility, and lipid-normalized BSAF values should not be used for perfluorinated alkyl substances (PFAS). MPCA's definition of BSAF should specify exceptions to the use of BSAF values and provide alternative guidance.

Response: The methods for developing bioaccumulation factors (BAF) in the proposed rule language, *Minn. R.* ch. 7050.0219, subp. 9, describe the relevant procedures available for use based on chemical categorization and other physiochemical properties. The six procedures are not relevant for all chemicals. For example, the BSAF procedure is not relevant to ionic, inorganic, or organometallic chemicals. Some PFAS are characterized as ionic in surface water. A BAF would not be developed using the BSAF procedure for any chemical characterized as ionic. Additional details about the strengths and limitations of the BAF methods are described in Exhibit HH-3 and HH-4. Again, future application of the proposed methods and data used to develop pollutant-specific BAF for water quality standards or site-specific criteria would be open for public comment.

15. 7050.0222, subp. 7

Comment: 3M commented that the proposed new rule language in this section should incorporate the related 3M comments regarding the "toxic effect" definition. In addition, MPCA should consider that for related compounds (e.g., PFAS) with many possible isomers or congeners, if nondetected concentrations of isomers are included as 1/2 the detection limit, inclusion of a large number of compounds could result in a much lower value for CC_{ft} for the detected compounds in fish tissue.

Response: The determination of concentrations ascribed to fish tissue monitoring data when reported as less than a reporting limit or detection limit would be addressed as part of the implementation of specific criteria for impaired waters or permitting purposes and is not part of this rule. Those processes include a discussion of how monitoring data was handled and provides the opportunity for public comment.

16. 7050.0222, subp. 7F

Comment: MnDOT considered some of the proposed language to be an overextension of the Clean Water Act, which is intended to address chemical discharges from primary sources, not to regulate all sources of risk. While awareness of the chemical breakdown products present in surface water is helpful for chemical fate considerations, "including their concentration in the total chemical concentration value may, in many cases, overstate the health risk."

Response: The Clean Water Act requires states with delegated authority to develop water quality standards and to adopt them for any pollutant with the potential to affect a beneficial use. In this case, any pollutant, regardless of it being characterized as a parent chemical or degradate, is subject to application of water quality standards or site-specific criteria. The MPCA added language in *Minn. R.* ch. 7050.0222, subp. F, to clarify the need to use parent chemical health-based guidance, if available, in order to address the situation where reliable scientific data are insufficient to develop a water quality standard or criterion for defined breakdown products of the parent pollutant. This approach is consistent with the MDH HRL rule, *Minn. R.* ch. 4717.7500 to 4717.7900.