STATE OF MINNESOTA
MINNESOTA POLLUTION CONTROL AGENCY

Adoption of Amendments to Rules Governing the Classification and Standards for Waters of the State, *Minnesota Rules*, Chapters 7050 and 7052

ORDER ADOPTING RULES

Office of Administrative Hearings (OAH) Docket No. 68-2200-31489
Revisor's ID: 4177

WHEREAS:

1. The Minnesota Pollution Control Agency (MPCA) has the statutory authority to adopt the rules referenced above based on *Minnesota Statutes* (*Minn. Stat.*) § 115.03, subd. 1(b) and 1(c), as described in the Statement of Need and Reasonableness (SONAR) for this rulemaking.
2. The MPCA has complied with all notice and procedural requirements in *Minn. Stat.*, ch. 14; *Minnesota Rules* (*Minn. R.*), ch. 1400; and other applicable law.
3. The MPCA received three written comments on the rules. None of the comments included a request for a public hearing. As identified in the Notice of Intent to Adopt Rules Without a Hearing published in the June 16, 2014, *State Register*, if 25 or more parties submit valid written requests for a public hearing on the rules, hearings will be held following the procedures in *Minn. Stat.* §§ 14.131 to 14.20. The MPCA did not hold a public hearing on the proposed rules because it received fewer than 25 requests. The MPCA received no requests to be notified of submission of the rules to the OAH.
4. The MPCA submitted the rules to the OAH for review and approval on January 14, 2015. The submitted rules included changes to the published rules. These changes were based on written comments received by MPCA and are listed in items 9 through 12, below. After reviewing the published rules with the changes based on written comments, Administrative Law Judge (ALJ) Jeanne M. Cochran approved the rules in a letter dated January 23, 2015.
5. The ALJ approval included a Memorandum recommending revisions for clarity and readability. The MPCA has made changes A and B from the ALJ's Memorandum, listed below as items 7 and 8, respectively.
6. The following changes to the proposed rules are not substantially different from the proposed rules as published in the June 16, 2014, *State Register*, based on the criteria set forth in *Minn. Stat.* § 14.05, subd. 2.

Change to Part 7050.0150, subp. 7, item B

7. ALJ Cochran commented in her review that the proposed language refers to the abbreviations CS_{ft}, CS_{dfr}, CS_{dev}, and CS_{fr}; of these, CS_{ft} is defined in subp. 7, item A, of *Minn. R.* 7050.0150, but the other three (CS_{dfr}, CS_{dev}, and CS_{fr}) are only defined in later provisions of the rules. To add clarity and ensure the reader is easily able to find the meaning of these three abbreviations, ALJ Cochran recommended that *Minn. R.* part 7050.0150, subp. 7, item B, be revised to include cross-references to the definitions of CS_{dfr}, CS_{dev}, and CS_{fr}. The MPCA agrees that this revision improves the rule's clarity and has made the recommended change.

   In response to this comment, part 7050.0150, subp. 7, item B, of the proposed rule language has been amended to read:
   B. If CS_{ft} has not been established for a pollutant with chronic standards (CS) applicable in water

(CS_{dfr}, CS_{dev}, or CS_{fr} as defined in parts 7050.0218, subp. 3(Q), and 7050.0219, subp.13(B)), the residue levels in fish muscle tissue established by the Minnesota Department of Health must be used to identify surface waters supporting fish for which the Minnesota Department of Health recommends a reduced frequency of fish consumption for the protection of public health.

Change to Part 7050.0218, subp. 3, item Q

8. ALJ Cochran commented that Appendix A-1 of the SONAR for this rulemaking described CC and CS as the "highest water concentration or fish tissue concentration of a toxicant or effluent to which organisms: aquatic life, humans or wildlife, can be exposed over a long-term duration without causing chronic toxicity." The ALJ therefore considers the phrase "or other organisms" to be unnecessary in subp. 3, item Q, of part 7050.0218 and believes it could cause confusion. To be consistent with the intent expressed in the SONAR, MPCA agrees with the ALJ's recommendation that this phrase be deleted in the rule text.

   In response to this comment, part 7050.0218, subp. 3, item Q, of the proposed rule language has been amended to read:
   Q. "Chronic criterion" or "CC" and "chronic standard" or "CS" mean the highest water concentration or fish tissue concentration of a toxicant or effluent to which aquatic life, humans, or wildlife~~, or other organisms~~ can be exposed indefinitely without causing chronic toxicity.

Change to Part 7050.0218, subp. 3, item OO

9. The 3M Company (3M) commented that the proposed revised definition of "no observable adverse effect level" (NOAEL) differs from the EPA's NOAEL definition by describing the NOAEL as "an exposure level" rather than "the highest exposure level with no effects." 3M considered this distinction important and suggested that the rule language be revised to, "statistically ~~or~~ and biologically significant." Although the NOAEL is generally known and accepted in the field of risk assessment to represent the highest dose at which there is no observable adverse effect, the MPCA agrees that inclusion of the word "highest" does increase clarity in the definition and is therefore adding "the highest" into its definition. However, the MPCA is not changing the "or" to "and" in its definition of NOAEL, because both measures are independently relevant for identifying a NOAEL. This is consistent with NOAEL definitions used by the Minnesota Department of Health (MDH) and the U.S. Environmental Protection Agency (EPA) (see Exhibit HH-1, page 136).

   In response to this comment, part 7050.0218, subp. 3, item OO of the proposed rule language has been amended to read:
   OO. "No observable adverse effect level" or "NOAEL" means ~~an~~ the highest exposure level at which there is no statistically or biologically significant increase in the frequency or severity of adverse effects between the exposed population and its appropriate control group.

Change to Part 7050.0218, subp 3, item RR

10. The Minnesota Department of Transportation (MnDOT) commented that the proposed rule language does not state a limit on the number of uncertainty factors that may be used in the calculation of a reference dose (RfD). The MPCA unintentionally omitted a limit to the divisors that account for uncertainty in the proposed RfD definition. To correct this omission and to advance consistency with MDH's Health Risk Limits (HRL) rule, the MPCA is adding a sentence to the RfD definition to match the MDH's HRL rule definition of an RfD that limits the product of the divisors to 3,000, as stated in *Minn. R.* 4717.7820, subp. 21.

In response to this comment, part 7050.0218, subp. 3, item RR, of the proposed rule language has been amended to read:

RR. "Reference dose" or "RfD" means an estimate of a dose for a given duration to the human population, including susceptible subgroups such as infants, that is likely to be without an appreciable risk of adverse effects during a lifetime. It is derived from a suitable dose level at which there are few or no statistically or biologically significant increases in the frequency or severity of an adverse effect between the dosed population and its associated control group. The RfD includes one or more divisors, applied to the suitable dose level, accounting for:

(1) uncertainty in extrapolating from mammalian laboratory animal data to humans;

(2) variation in toxicological sensitivity among individuals in the human population;

(3) uncertainty in extrapolating from effects observed in a short-term study to effects of long-term exposure;

(4) uncertainty in using a study in which health effects were found at all doses tested; and

(5) uncertainty associated with deficiencies in the available data.

The product of the divisors is not to exceed 3,000 in an RfD used for a chronic standard. The RfD is expressed in units of daily dose as milligrams of chemical per kilogram of body weight-day or mg/kg-day.

Change to Part 7050.0219, subp. 13

11. MPCA staff noted in internal review that the supplemental algorithm equation needed a conversion factor so that the chronic criterion or chronic standard is measured in µg/L. This correction makes the equation consistent with other algorithms in the rule.

Part 7050.0219, subp. 13 of the proposed rule language has been amended to read:

B. Supplemental algorithm for developmental susceptibility for noncarcinogenic or NLC chemicals applicable to surface waters designated Class 2A or 2Bd to calculate: CC_{dev} or CS_{dev} =

$$\frac{RfD_{duration\ (acute,\ short\text{-}term,\ or\ subchronic)}(mg/kg\text{-}d) \times RSC\ (no\ units)\ \underline{x\ 1000\ \mu g/mg}}{DWIR_{duration(acute,\ short\text{-}term,\ or\ subchronic)}\ (L/kg\text{-}d)}$$

Change to Part 7050.0222, subp 7, items D–E

12. From the narrative language of the proposed rule and discussion in the SONAR and supporting document Exhibit HH-1, it is clear that both chronic criterion (CC) and chronic standard (CS) are to be considered and factored into risk index calculations when mixtures of pollutants are found in water or fish samples. However, the equations as placed on public notice only illustrated the use of "CS" for chronic standard in the representative equations. Informal discussions between MPCA and EPA highlighted that including "CC" in both the narrative and the mixture equations would provide additional clarity on the use of site-specific chronic criterion as a factor in calculating a health risk index. The MPCA is adding "CC" for the purposes of clarity and internal consistency.

Part 7050.0222, subp. 7, items D and E, of the proposed rule language have been amended to read:

D. Concentrations of noncarcinogenic or nonlinear carcinogenic (NLC) chemicals in water or fish tissue from point or nonpoint sources, singly or in mixtures, must be below levels expected to produce known adverse effects. This is accomplished through the application of an additive noncancer health risk index using common health risk index endpoints or health endpoints. Mixtures

of chemicals with listed CS or site-specific CC are evaluated using the following approach:

Chemicals must be grouped according to medium (water or fish) and each health endpoint. Chemicals for which no health endpoint is specified are not grouped. Chemicals that are also linear carcinogens must be grouped as described under item E. Using the following equation, a noncancer health risk index must be determined for each group of two or more chemicals that have a common health endpoint listed in this part. To meet the protection objectives in part 7050.0217, the noncancer health risk index must not exceed a value of one.

$$\text{Noncancer health risk index by common health endpoint} = \frac{C_1}{CS_1 \text{ or } CC_1} + \frac{C_2}{CS_2 \text{ or } CC_2} + \ldots + \frac{C_n}{CS_n \text{ or } CC_n} \leq 1$$

where: C_n is the concentration of the first to the n^{th} chemical by common health endpoint and medium

CS_1 ... CS_n is the drinking water plus fish consumption and recreation chronic standard (CS_{dfr} or CS_{dev}), fish consumption and recreation chronic standard (CS_{fr}), or fish tissue chronic standard (CS_{ft}) for the first to nth chemical by common health endpoint

CC_1 ... CC_n is the drinking water plus fish consumption and recreation chronic criterion (CC_{dfr} or CC_{dev}), fish consumption and recreation chronic criterion (CC_{fr}), or fish tissue chronic criterion (CC_{ft}) for the first to n^{th} chemical by common health endpoint

E. Concentrations of carcinogenic chemicals from point or nonpoint sources, singly or in mixtures, must not exceed an incremental or additional excess risk level of one in 100,000 (10^{-5}) in surface waters or fish tissue. Carcinogenic chemicals will be considered additive in their effect according to the following equation unless an alternative model is supported by available scientific evidence. The additive equation applies to chemicals that have a human health-based chronic standard (CS) or site-specific chronic criterion (CC) calculated with a cancer potency slope factor. To meet the protection objectives in part 7050.0217, the cancer health risk index must not exceed a value of one.

$$\text{Cancer health risk index} = \frac{C_1}{CS_1 \text{ or } CC_1} + \frac{C_2}{CS_2 \text{ or } CC_2} + \ldots + \frac{C_n}{CS_n \text{ or } CC_n} \leq 1$$

where: C_1 .... C_n is the concentration of the first to the n^{th} carcinogen in water or fish tissue

CS_1 ... CS_n is the drinking water plus fish consumption and recreation chronic standard (CS_{dfr}), fish consumption and recreation chronic standard (CS_{fr}), or fish tissue chronic standard (CS_{ft}) for the first to n^{th} carcinogenic chemical

CC_1 .... CC_n is the drinking water plus fish consumption and recreation chronic criterion (CC_{dfr}) fish consumption and recreation chronic criterion (CC_{fr}), or fish tissue chronic criterion (CC_{ft}) for the first to n^{th} carcinogenic chemical

13. The rules are needed and reasonable.

IT IS ORDERED that the above captioned rules, in the form set out in the *State Register* on June 16, 2014, with modifications as indicated in the Revisor's file number AR4177, dated January 27, 2015, are hereby adopted.

Commissioner John Linc Stine
Chair, Citizens' Board
Minnesota Pollution Control Agency

2/18/2015
Date