Minnesota Department of Transportation
395 John Ireland Blvd.
Saint Paul, MN 55101

September 4, 2014

Katie Izzo
MPCA-RMAD
520 Lafayette Road North
Saint Paul, Minnesota 55155-4194

RE: Comments on the Proposed Amendment of Rules Governing Water Quality Standards (Human Health Methods and BEACH Act) Minnesota Rules, 7050.0150, 7050.0217, 7050.0218, 7050.0129, 7050.0222, 7052.0005, 7052.0010, 7052.0100, 7052.0110, 7052.0220 and 7052.0230; Revisor's ID Number 4117

Dear Ms. Izzo:

The Minnesota Department of Transportation (MnDOT) appreciates the opportunity to provide comments on the proposed modification to Minnesota Water Quality Rules. MnDOT supports efforts to protect Minnesota's water resources. We work diligently to preserve and protect water quality in a responsible and cost effective manner. MnDOT activities and facilities are subject to the Construction Storm Water (CSW) and Municipal Separate Storm Sewer Systems (MS4) National Pollutant Discharge Elimination System (NPDES) permits. As such, the implementation of water quality rules can have a profound effect on MnDOT especially with respect to these permits.

Please find attached several questions, concerns, comments and recommendations on the proposed rules. We hope that our comments will assist MPCA in continuing to identify issues and steps to take ensure that appropriate standards are applied in appropriate situations. Our goal is to work toward protecting water quality in a cost effective manner, while also providing high levels of protection for public safety. Please feel free to contact our office should you have any questions regarding our comments.

Sincerely,

Lynn Clarkowski, P.E.
Chief Environmental Officer
Office of Environmental Stewardship

Enclosure

wq-4rule4-08f

cc: Mark Schmitt, Director, MPCA Municipal Division
Jon Chiglo, MnDOT Engineering Services
Scott Peterson, MnDOT Government Affairs
Mike Barnes, MnDOT Operations
Beth Neuendorf, MnDOT Metro Water Resources

MnDOT COMMENTS ON MPCA WATER QUALITY STANDARDS FOR PROTECTION OF HUMAN HEALTH

General Considerations

The MPCA web site for these amendments states that the MPCA considers these to be "housekeeping amendments". Given the lengthy time between adoption in 1990/1998 of the HH-WQS and this update in 2014, the MPCA should include a complete table of current and revised HH-WQS for all priority pollutants or at least reference where to find them.

It appears that a cost/benefit analysis for implementing these amendments would improve transparency and add justification?

There are equations in the amendments where the chronic standard or chronic criteria include surface water ingestion and fish tissue consumption. If these methods only apply to drinking surface water where people catch fish for consumption, that should be stated clearly. It would be good to know the percentage of the Minnesota population that drink the same surface water that they eat fish from.

7050.0218 Subd. 3, AA. Food Chain Multiplier. The definition states that values to calculate FCM are "developed using EPA models". The models used by the MPCA should be specified so that model validation can be confirmed by stakeholders. A list of the models that could be used for FCM calculation should be included.

7050.0218 Subd. 3,F. Available and reliable scientific data. The means of selecting "reliable scientific data" from specific scientific literature should be fully described so that the data meet specified quality (QA/QC, peer reviewed). The process for specifying new sources of scientific data should also be fully described. A list of reliable data sources (e.g. journals, agencies producing reports) should be included so that data would be publicly available.

7050.0218 Subd. 3 RR. The MPCA states there are five uncertainty factors, of which one or more may be used as a divisor in the calculation of a Reference Dose (RfD). No equation for the RfD is given. No explanation about the value of each uncertainty factor is given and no limit on the number of factors used in one calculation is stated. Even if the relative source contribution is limited to 3000, that is over three orders of magnitude. This results in highly conservative CC or CS values. It is doubtful that current analytical chemistry methods will achieve a meaningful detection limit for some chemicals. MnDOT recommends that no CC or CS be adopted for any chemical unless the current published EPA analytical methods used by commercial laboratories achieve method detection limits less than the HH-WQS values.

7050.0218 Subp. 5, E. The MPCA states "If an approved chronic value for a commercially, recreationally, or ecologically important freshwater species is lower than the CCtox, the CCtox will be set to equal that chronic value". This statement does not consider analytical feasibility. This sentence should end with "when analytical methods and Quality Assurance permit."

7050.0219 Subd. 5, Exposure Values. MnDOT appreciates the need for precautionary adjustments to criteria when data or research studies are not available. The default RSC value is stated as 0.2 for most pollutants unless there are no data deficiencies to produce a specific value. In all 2014 Updated National Water Quality Criteria the EPA has used 0.2 for RSC values. Are there sufficient data held by the EPA, MPCA or MDH to use a RSC with confidence? The 0.2 RSC appears to be overly conservative and indicates a value that is policy driven rather than science driven. MnDOT recommends that 0.8 be used as the default RSC in all cases unless sufficient site specific data exist for a site-specific RSC.

Furthermore, multiplying RSC and UF drive the resulting WQC to extremely low concentrations where current laboratory analytical methods are insufficiently sensitive. Extremely low WQC will create situations where false positive results are more frequent causing regulatory action that is unjustified. 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 (3X) the published method detection limit.

7050.0222 Subp. F. "Chemical breakdown products or environmental degradates … must be considered when meeting the objectives for toxic pollutants". This appears to be an over extension of the Clean Water Act (CWA). The CWA is intended to address chemical discharges from primary sources and not intended to regulate all sources of risk. While knowing that chemical breakdown products are present in surface water is beneficial for chemical fate considerations, including their concentration in the total chemical concentration value may, in many cases, overstate the health risk.

From:	Holst, Linda
To:	PCA, MinnRule7050 (MPCA)
Cc:	Preimesberger, Angela (MPCA); Pfeifer, David; Poleck, Thomas; Richards, Ken
Subject:	EPA Letter on Amendments to MN"s Human Health Criteria Methods
Date:	Thursday, September 04, 2014 3:30:42 PM
Attachments:	MN HH crit_EPA ltr_1.pdf

Attached is EPA's letter regarding the proposed rule.

Linda Holst | U.S. EPA Region 5, Water Division, Water Quality Branch | 77 West Jackson Blvd., WQ-16J, Chicago, IL 60604 | Ph. (312) 886-6758 | holst.linda@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
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SEP 0 4 2014

REPLY TO THE ATTENTION OF:
WQ-16J

Katie Izzo
Minnesota Pollution Control Agency
520 Lafayette Road N
St. Paul, MN 55155-4194
[transmitted electronically: minnrule7050.pca@state.mn.us]

Dear Ms. Izzo:

Thank you for the opportunity to review Minnesota's proposed *Amendments to the Human Health-based Methods for Developing Water Quality Standards* that are currently for public review and comment. My staff have completed review of the proposed revisions to Minnesota's water quality standards at 7050.0150, 7050.0217, 7050.0218, 7050.0219, 70505.0222, 7052.0005, 7052.0010, 7052.0100, 7052.0110, 7052.0220, and 7052.0230. We have no comments or recommendations to make on the proposed revisions. We commend the Minnesota Pollution Control Agency on its effort to incorporate the most current science on human health risk assessment into Minnesota's water quality standards.

These comments are the U.S. Environmental Protection Agency's preliminary review for purposes of technical support of Minnesota's rulemaking efforts and do not constitute a final EPA action under section 303(c) of the Clean Water Act. Consistent with section 303(c) of the Clean Water Act, EPA must approve or disapprove new and revised water quality standards following adoption by the state and submittal of the adopted standards to EPA.

Sincerely,

Linda Holst

Linda Holst
Chief, Water Quality Branch

cc: Angela Preimesberger [angela.preimesberger@state.mn.us]

From:	blfrismanis@mmm.com
To:	Stine, John (MPCA); Izzo, Katie (MPCA)
Cc:	jbsweeney@mmm.com
Subject:	Comments on MPCA Proposed Permanent Rules Relating to Human Health Methods for Water Quality
Date:	Thursday, September 04, 2014 4:04:29 PM
Attachments:	ATT00001.gif Correspondence to Mr. John Linc Stine and Ms. Katie Izzo.pdf

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On behalf of Jean Sweeney, the attached letter will be coming to you via Certified Mail. For your convenience and records, the following electronic copy is provided.

Brenda L. Frismanis | Legal Administrative Assistant to Mary Cullen Yeager, Ann Anaya, Terry L. Beyl and David L. Peterson
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3M

September 4, 2014

Via Certified Mail and Electronic Mail

Mr. John Linc Stine
Commissioner
Minnesota Pollution Control Agency
520 Lafayette Road North
St. Paul, MN 55155-4194

Ms. Katie Izzo
MPCA-RMAD
520 Lafayette Road North
St. Paul, MN 55155-4194

Subject: Comments On MPCA Proposed Permanent Rules Relating to Human Health Methods for Water Quality

Dear Commissioner Stine and Ms. Izzo:

I am writing on behalf of 3M Company ("3M") regarding the Minnesota Pollution Control Agency ("MPCA") *Proposed Permanent Rules Relating to Human Health Methods for Water Quality,*[1] dated May 1, 2014. Specifically, comments are provided on the following issues presented in these proposed rules, including consistency with recent MPCA documents and the science regarding exposure and health risks, with particular focus on perfluorinated alkyl substances (PFASs):

- The preference for evaluation and listing of water as impaired based on fish tissue concentration rather than on the use of an estimated water concentration that would be protective of accumulation in fish tissue and consumption by humans (as has been calculated for PFOS in Pool 2 by MPCA),

- Scientific deficiencies and inconsistencies in the specified values and method of applying a relative source contribution (RSC) in a chronic criterion (CC) based on fish tissue concentration,

- Lack of clarity and scientific inaccuracies in definitions of certain terms,

[1] http://www.comm.media.state.mn.us/bookstore/stateregister/38_51.pdf

- Assumed additive risks for chemicals with the same general health effects that would not be additive at exposure levels for the purposes of health protection and regulation,

- Assumed increase in exposure per body weight and susceptibility of infants and young children as a precautionary policy, even when not justified by the science.

Most concerning is that proposed rule updates with inadequate scientific justification could result in new, overly-conservative fish tissue criteria and thresholds for water body impairment, potentially leading to significant economic burdens on municipalities and businesses with no actual health benefit.

Impairment of Waters Based on Fish Consumption (7050.0150 Subpart 7)

The proposed updates to this section state that the determination of impairment of waters is to be based on the site-specific fish tissue-based chronic criterion (CC_{ft}) or chronic standard (CS_{ft}). If a CS_{ft} has not been established for a chemical with other chronic standards applicable in water (i.e., based on drinking water and fish residue levels, developmental effects from drinking water, or fish residue levels only), the residue levels in fish muscle tissue must be used to evaluate impairment. Thus, the proposed update specifies that when various chronic criterion or standards are available for a water body, those based on fish tissue concentration (CC_{ft}, CS_{ft}) must be the basis of impairment determinations (7050.0150 Subpart 7.C).

MPCA's recent assessment of impairment of Pool 2 of the Mississippi River (2014 impairment listing and MPCA response to public comment) based on water concentrations of PFOS is therefore inconsistent with the updated language presented in the proposed rules.

In response to comments challenging the use of water concentrations for impairment determinations, the MPCA stated: "*The 2009 study was repeated in 2012, and found that in this same stretch of river, which is part of the fourth (most downstream) of four assessment units comprising Pool 2, the average PFOS concentration was 347 ng/g in freshwater drum and 438 ng/g in carp. Therefore, fish in this portion of the AUID continue to exceed the use-support threshold for PFOS in fish tissue, and thus this AUID does not support the established aquatic-consumption beneficial use of this water. PFOS concentrations in water collected in 2009, 2011, and 2012 from this AUID, near the 3M Cottage Grove facility, were above the site-specific water quality criterion for Pool 2 (criterion was 7 ng/L based on 2009 results and recalculated to 14 ng/L based on 2012 results). Therefore, this AUID exceeds the use-support threshold for PFOS in water. It is recommended that this AUID be listed for PFOS in the Water Column in addition to the existing listing for PFOS in Fish Tissue*[2]."

[2] http://www.pca.state.mn.us/index.php/view-document.html?gid=20955

MPCA's response indicates that the Agency is incorrectly listing the AUID based on both fish criterion and a site-specific water criterion when it should only be listing based on the fish tissue criterion.

Relative Source Contribution or RSC (7050.0218 Subpart 1 and other places)

A RSC reduces the allowable exposure to any particular pathway (e.g., drinking water, fish) because other exposures to a chemical may occur from additional exposures to the chemical in food, air, water, and consumer products. A RSC term has often been included in the derivation of EPA's drinking water standards and in the Minnesota Department of Health's (MDH) drinking water values. The State of Minnesota and EPA have typically applied a default RSC value of 0.2 (20%) to drinking water standards. The application of such a value decreases the allowable drinking water value to (20%) of that otherwise allowed by the chemical's toxicity reference dose. The State of Minnesota and EPA have derived a CC_{ft} for mercury in fish tissue using a 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.

The updated rule extends the use of a RSC to the calculation of the criteria and standards for fish tissue. Nevertheless, the updated rule language and the associated MPCA (2014b) technical support document[3] are inconsistent and ambiguous in the specified value for the RSC (20%, 50%, 80% or 0.2, 0.5, 0.8, respectively) and method of incorporation (i.e., whether a percent or subtraction method would be allowed). For example, the proposed rules state in:

- **7050.0218, Subpart 3. Paragraph SS** - ***"...percentage or apportioned amount (subtraction method)*** *of the reference dose for a pollutant allocated to surface water exposures from drinking or incidental water ingestion and fish consumption. In the absence of sufficient data to establish a pollutant- or chemical-specific RSC value, the default RSC is* ***0.2 or 0.5*** *as described in part 7050.0219, subpart 5."* [emphasis added]

- Additionally, in section **7050.0219, Subpart 5. Exposure values** - *"Drinking water intake rates are obtained from the MDH. RSC uses a default value of* ***0.2*** *for most pollutants, unless: A. there are no significant known or potential sources other than those addressed for the designated use, then* ***0.5*** *must be used; or B. sufficient exposure data are available to support an alternative pollutant-specific value between* ***0.2*** *and* ***0.8***. "[emphasis added]

No guidance is noted for the subtraction method or for acceptance of exposure data that support a value that is higher than 0.8.

[3] http://www.pca.state.mn.us/index.php/view-document.html?gid=20552

- **7050.0219, Subparts 13 and 14. Algorithms for Class 2A or 2Bd surface waters**

  A RSC factor is used in the equations to calculate surface water CC or CS for drinking water and fish consumption and recreation or for non-potable waters involving fish consumption and recreation only. The RSC is *multiplied* in the equation; no default value is stated. No guidance is noted for the subtraction method.

- **7050.0219, Subpart 15. Algorithms for Class 2 fish tissue**

The algorithm in this section allows for the *multiplication or subtraction* of a RSC, but does not specify the percentage in the case of multiplication. It also does not state the conditions under which the multiplication or subtraction approach can or should be used.

RSCs, especially at the default values, are often times overly conservative relative to protection of human health. For many chemicals, including PFOS, background exposures are well below the reference dose and thus a RSC of 20% is overly stringent. The guidance should allow chemical specific assessments of background exposure which may then be subtracted from the reference dose in determining allowable exposures. This is the method used for mercury. In general, the subtraction method is more scientifically appropriate and less subject to overly stringent reduction of the CC or CS for surface water or fish tissue concentration. For PFASs, for example, background exposures based on 2009-2010 NHANES data (CDC 2012) indicate a geometric mean serum level for PFOS, for example, of 9.3 ng/ml which is approximately equivalent to 7 to 9 x 10^{-7} mg/kg-day when converted to a steady state dose based on modeling by Loccisano et al. (2011). This dose is on the order of 100 times less than the MDH reference dose for PFOS (8 x 10^{-5} mg/kg-day). Thus, the more scientifically supportable subtraction method, based on actual exposure data would have a negligible effect on the reference dose, whereas application of the fractional method and only allowing 20, 50, or 80% of the reference dose would result in a large reduction in the calculated standard without a scientific basis nor benefit to human health.

In addition, application of a default RSC of 0.5 specifically when there are "*...no significant known or potential sources other than those addressed for the designated use*" (as stated in the proposed rules) is inconsistent with the definition and purpose of a RSC. If there are no other significant sources of exposure for a chemical (i.e., no significant background exposures), there is no need to apportion 50% of the reference dose to source exposures. Likewise, if exposures due to other sources are much less than 50% of the reference dose, allowing only 50% of the reference dose is overly stringent for calculating water quality criteria.

It is premature for MPCA to be specifying various default RSCs for fish consumption until the Minnesota Department of Health (MDH) has completed their investigation and developed guidance based on the science and actual exposure data for U.S. populations. Guidance on RSC in the State of Minnesota is in a developing phase. The MDH has been

investigating whether the EPA default RSC of 20% applied to drinking water criteria is appropriate for exposure to chemicals in water, food, consumer products, or air. Thus far, MDH has had a contractor evaluate different models, but no findings are available.[4]

Definitions (7050.0218 Subpart 3)

The proposed updates and newly added definitions are generally based on definitions published by EPA in several glossaries (e.g. IRIS, Risk Assessment) as well as a number of EPA reports. Twenty new definitions were added to the 34 definitions in the currently published Minnesota rule. Several of the currently published definitions were revised with additions and or deletions to the existing text. In a number of cases, as described below, the definitions lack clarity and/or are inaccurate:

- Available and reliable scientific data – definition presented is limited in scope and does not consider scientific data produced by non-governmental agencies. For example, responsible parties and stakeholders may collect data that is submitted for review by MPCA. If such data are collected and analyzed in accordance with standard procedures and the scientific literature, they should be considered by MPCA. The proposed new rules should include appropriate language that is inclusive of these data sources.

- Bioaccumulation factor (BAF) – the last clause indicates that BAFs are to be determined under steady-state conditions. Elsewhere in the proposed rules (e.g., beginning on line 22.3), MPCA (as well as EPA) states a preference for field data over lab data for derivation of BAFs. However, individual fish in the field are unlikely to be at steady state as they move around in the environment with variable contaminant concentrations. Steady-state is therefore not a relevant description for field data; however, when field data are unavailable, a laboratory bioconcentration factor (BCF) at steady state should be used instead. The proposed rules should be revised accordingly for enhanced clarity and to reduce this apparent inconsistency.

- Biota-sediment accumulation factor (BSAF) – the definition is consistent with how the term is defined by the EPA and in the scientific literature. BSAF is a lipid-normalized concentration of chemical in fish tissue to organic carbon normalized concentration of chemical in sediment. Cautions on use of BSAFs other than as a screening tool have been provided in primary literature since the development of BSAFs. Wong et al. (2001) state that the BSAF model could be useful under *in situ* riverine conditions as a first-level screening tool for predicting bioaccumulation; however, variability in BSAF values may impose limits on its utility. Thomas et al. (1995) found similar issues in working with BSAFs and stated that they can vary by a factor of 3. EPA's website on BSAFs cautions

[4] http://www.health.state.mn.us/divs/eh/risk/guidance/dwec/relativeproj.html, http://www.legacy.leg.mn/projects/relative-source-contribution-project-phase-ii

researchers and managers using BSAF data that for analysis one needs to understand that outliers exist and may skew the analysis when highly anomalous data are used[5]. Further caution is applicable to the use of BSAF values to describe the behavior and fate of PFAS as these compounds do not preferentially partition to lipid compartments, therefore lipid-normalized BSAF values should not be used for PFAS. The MPCA should specify exceptions to the use of BSAF values and provide alternative guidance.

- Chronic Criterion – "CC_{dfr} or CS_{dfr} represent values applied in surface water based on protecting humans from exposure to the pollutant from drinking water, eating fish, and aquatic recreation." The use of aquatic recreation is too vague a term. Adverse impacts to humans can only occur by contact with a potential toxicant and many aquatic recreational activities do not have direct or potential contact with water. This definition should be modified as "exposure to the pollutant from drinking water, eating fish, and exposure to surface water by contact or ingestion during recreational activities".

- Health risk index endpoint or health endpoint – are defined as "a **general description** [emphasis added] of toxic effects used to group chemicals for the purpose of calculating a health risk index." This definition is vague and in practice will result in chemicals being grouped because of generally similar effects, even though the chemicals act through very different mechanisms or physiological/biochemical pathways and cause effects that are not the same.

- No observable adverse effect level (NOAEL) – the revised definition is now consistent with the EPA Human Health Risk Assessment definition of a NOAEL[6] except the proposed new rules describes the NOAEL as "an exposure level" and not the highest exposure level with no effects. The EPA defines the NOAEL as the "highest exposure level at which no statistically or biologically significant increases are seen in the frequency or severity of adverse effect between the exposed population and its appropriate control population." This (highest exposure with no effects) is an important distinction because below an upper threshold for health effects all doses will have no effects. Selecting an ultra-low dose with no effects will result in overly stringent regulations at tremendous cost with no benefit. Although the definitions for both NOAEL and lowest observable adverse effect level (LOAEL) are based on EPA guidance, the words "biologically significant" are vague and subjective and need additional explanation. Perhaps this would be better stated as statistically "and" (instead of "or") biologically significant.

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[5] http://www.epa.gov/med/Prods_Pubs/bsaf.htm - US EPA website on Biota-Sediment Accumulation Factor Model

[6] http://www.epa.gov/risk_assessment/dose-response.htm

- Toxic effect – According to the definition: "*means an observable or measurable adverse biological event in an organ, tissue, or system. The designation of health endpoints does not exclude other possible observable or measurable biological events. For the purpose of grouping chemicals and creating a health risk index when multiple chemicals are present, toxic effects may be ascribed to more general health risk index endpoints or health endpoints.*" This definition, particularly the second sentence and the latter part of the third sentence beginning with "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. Scientifically, grouping of chemicals to evaluate cumulative risk, is only appropriate for those chemicals that have critical low dose effects (i.e., effects that determine the reference dose) that result by the same mechanism. Only these effects would truly be additive for the purposes of setting cleanup levels or regulatory limits; chemicals that affect the same organ or system will not have additive effects at and below their reference dose if each acts independently via different mechanisms of action. For this reason, EPA guidance (U.S. EPA 1989) recommends adding hazard quotients, then if the subsequent hazard index exceeds unity, chemicals that act by the same mechanisms on the same organ or endpoint should be considered separately. Thus, grouping should be based on the toxic effects that occur at the lowest doses via mechanisms that would be additive.

- Toxic Unit - To enhance the definition, the addition of the word "adverse" is suggested such that "causes 50 percent adverse effect or mortality"

Additivity of Risks for Mixtures (7050.0222, Subpart 7)

The new text in this section notes the grouping of chemicals that affect the same health effect endpoint and the adding of the individual non-cancer health risk quotients (i.e. site exposure for a chemical divided by its reference dose). The sum of these health risk quotients is a health risk index which is intended to not exceed 1. First, the guidance should incorporate the above comments regarding the definition of Toxic Effect. Second, for related compounds (e.g., PFAS) with many possible isomers or congeners, MPCA should consider that if non-detected concentrations of isomers are included as ½ the detection limit (a common data assessment approach; often many isomers or congeners are possible but few are detectable or even present in fish and water sampled), inclusion of a large number of compounds could result in a much lower value for CC_{fi} for the detected compounds in fish tissue. Nevertheless, typically few PFASs appear to accumulate in fish tissue and many of the non-detectable compounds in fish may not even be present at levels near the detection limit. This procedure for grouping of chemicals affects other sections such as 7052.0110 METHODOLOGIES FOR DEVELOPMENT OF TIER I AND TIER II STANDARDS AND CRITERIA, Subpart 4. For these reasons, the text presented in these proposed rules regarding additivity should be reconsidered and revised for clarity and scientific accuracy regarding non-detectable compounds.

Noncarcinogenic human health GLI [Great Lakes Initiative] pollutant additivity (7052.0230 Subpart 3)

"*The agency must determine the additive effects of non-carcinogenic human health pollutants where individual WQBELs have been established under part 7052.0200, subpart 5, and where the pollutants exhibit the same adverse effects through the same mechanisms of action as established through the use of health risk index endpoints or health endpoints according to part 7050.0222, subpart 7, item D.*"

Toxicologically, additivity of effects is valid for chemicals that affect the same target organ by the same mechanism of action; however, the update seems to equate having the same health endpoint (which is defined as a general description of toxic effect) as also acting by the same mechanism of action. However, the two are not the same. For example, one chemical may inhibit vitamin K (necessary for blood clotting factor) and thereby cause bleeding, whereas another may cause anemia. Although both affect the blood, their different modes of action would not result in additive exposure when either is below their respective reference doses. Similarly, for example, the critical effect level (i.e., the LOAEL or NOAEL on which the reference dose is based) for a chemical may be based on one type of effect, such as central nervous system (CNS) depression, and that chemical may also affect heart rhythm at much higher doses. Exposures to this chemical below the reference dose for CNS effects, however, would not be additive with another chemical for which the critical effect is on the heart, whether that effect is also arrhythmia or an effect on the heart by a completely different mode of action (e.g., increase in cardiovascular disease risk). Because regulatory limits are based on keeping all chemicals at or below their respective reference doses, effects that occur at higher levels are neither relevant nor additive. As noted above, although EPA risk assessment guidance specifies that non-cancer risks of chemicals with the same health endpoint or target organ be initially added in risk characterization, if the total hazard index exceeds unity, one then evaluates whether chemicals act by the same mechanism of action and thus might actually be additive at doses below their reference dose (U.S. EPA 1989).

Calculating BAFs (7050.0219, Subparts 8 -13)

Methods for baseline BAF: This section should caution the user to understand that all of these methods are using predictive model tools that often provide very conservative estimates of the potential bioaccumulation of pollutants of concern due to their use of normalizing parameters (ie., organic carbon, lipids) surrogate parameters (i.e., log octanol-water partition coefficients) and other factors. In addition, 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. In fact, the MPCA lists the calculation of the geometric mean of "all the normalized BAFs for each species as step 'c' in the determination of bioaccumulation factors" (MPCA 2014b). In addition, the MPCA has

previously used the geometric mean to determine PFOS BAF values for fish collected in Pool 2 (MPCA 2010) and elsewhere in Minnesota (STS 2007).

Analysis and Conclusions

3M requests that MPCA reconsider the proposed new rule changes in light of these comments. In particular, a number of the assumptions that are lacking scientific justification will multiply in the algorithms that are used to derive water quality criteria and thereby inflate the amount of overestimation of risk, thereby resulting in overly-stringent criteria. For noncarcinogenic chemicals, a number for parameters are biased toward overestimation of risk and lower calculated water quality criteria:

- Higher fish consumption rate than national EPA guidance
- Relative source contribution that defaults to 20% of the reference dose
- Additivity or lowering of acceptable thresholds for multiple chemicals with generally similar health endpoints, without guidance on how to treat non-detected chemicals, nor recognition of mode of action, specific type of effect, or possibly even dose at which such effects would occur.

In the case of PFOS, for example, the combination of more stringent assumptions in these proposed rules (i.e., RSC and other assumptions) will have potentially large consequences for impairment determinations. The impairment threshold for PFOS will apparently decrease from 200 ng/g to about 40 ng/g (assuming a RSC of 20%). However, lacking from this proposed rulemaking is guidance or clear direction about how the proposed new fish tissue based criteria will be applied. It is presumed, based on the precedent set by the adoption of a mercury fish tissue standard, that a 90^{th} percentile test in each fish species with sufficient data will be used to assess future data sets and determine impairment status. Clarity concerning future application of these proposed new standards, and related justification of positions taken, should be addressed as part of this rulemaking. Arguably, the actions being taken by the State could lead to overly conservative and implausible scenarios. More specifically, an impairment determination appears likely if only 20% of the reference dose is allocated to protect a fisherman who consumes one meal per week of filets containing the 90^{th} percentile concentration level in the worst-case species in a specific area for a lifetime. These extreme assumptions thus 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.

If you have any questions or require additional information, please do not hesitate to contact me at (651) 737-3569.

Sincerely,

Jean B. Sweeney by MEYeager

Jean B. Sweeney
Vice President, 3M Environment, Health, Safety and Sustainability Operations
Building 224-5W-03

cc: Michelle Beeman, MPCA Deputy Commissioner
Rebecca Flood, MPCA Assistant Commissioner
Shannon Lotthammer, MPCA Director Environmental Analysis and Outcomes Division
Miranda Nichols, MPCA Draft Impaired Waters List Coordinator
Dan Abelson, Metropolitan Council
Gary Hohenstein, 3M

References

Loccisano, A.E., J.L. Campbell Jr., M.E. Andersen, H.J. Clewell III. 2011. Evaluation and prediction of pharmacokinetics of PFOA and PFOS in the monkey and human using a PBPK model. Regul. Toxicol. Pharmacol. 59:157–175.

MPCA 2014a. Guidance manual for assessing the water quality of Minnesota surface water for determination of impairment: 305(b) report and 303(d) list. Minnesota Pollution Control Authority, Minneapolis, MN.

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