Section Break

Comments related to changes in draft rule language

1. Comment on PFAS drinking water standards
   January 31, 2020
   National Wildlife Federation
   213 W. Liberty Street, Suite 200
   Ann Arbor, MI 48104

2. Comments proposed PFAS rule
   January 29, 2020
   City of Ann Arbor, Water Treatment Services
   919 Sunset Road
   Ann Arbor, MI 48103

Section Break

Smith, Ian (EGLE)

From: Oday Salim <[redacted]@nwf.org>
Sent: Friday, January 31, 2020 8:27 AM
To: EGLE-PFAS-RuleMaking
Subject: Comment by National Wildlife Federation on proposed drinking water rules for PFAS
Attachments: Comment by NWF on Michigan SDWA PFAS rules 20200131.pdf

Please see the attached comment. Thank you.

Oday Salim

Staff Attorney
National Wildlife Federation, Great Lakes Regional Center
213 West Liberty Street, Suite 200, Ann Arbor, MI 48104
[redacted]@nwf.org • [redacted] o • [redacted] c

Clinical Assistant Professor of Law & Director
Environmental Law & Sustainability Clinic, University of Michigan Law School
701 South State Street, Jeffries Hall 3018, Ann Arbor, MI 48109-3091
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Uniting all Americans to ensure wildlife thrive in a rapidly changing world

National Wildlife Federation
Great Lakes Regional Center
213 W. Liberty Street, Suite 200 • Ann Arbor, MI 48104-1398 • [redacted]

January 31, 2020

Sent by email to EGLE-PFAS-RuleMaking@Michigan.gov

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, MI 48909-8311

Re: Comment on draft Safe Drinking Water Act rules to address PFAS

Dear Ms. Ruch and whomever else it may concern:

The National Wildlife Federation applauds the decision by the State of Michigan to address the serious and widespread problem of contamination of our public water by per- and polyfluoroalkyl substances or PFASs. Millions of people in Michigan are counting on the state to protect their drinking water from toxic PFAS. The draft rules are a strong step in the right direction, and by strengthening these clean water protections, Michigan can set a standard that other states can follow to protect the health of people and wildlife.

In our 2019 report, *The Science and Policy of PFASs in the Great Lakes Region: A Roadmap for Federal, State, and Local Action*[1], we recommended that, instead of waiting for the current U.S. Environmental Protection Agency to set standards, states should act as soon as possible to protect public health. Michigan is already a leader in investigating PFAS. Michigan must also be a leader in establishing standards to regulate PFAS to protect public health and environment. PFASs are toxic. They can bioaccumulate. They persist in the environment. They are seemingly ubiquitous: wherever researchers

[1] https://www.nwf.org/Educational-Resources/Reports/2019/09-09-19-PFAS-Great-Lakes

look for PFASs, they find them. Their toxicity is often expressed in parts per *trillion*. They can negatively impact fetal development, liver, thyroid, kidneys, and cholesterol levels. In Michigan, PFASs have been detected in groundwater, surface water, and public drinking water, as well as in fish, wildlife, and people.

To address the serious threat PFAS pose, the Michigan Department of Environment, Great Lakes, and Energy (EGLE) has proposed Safe Drinking Water Act rules that address seven kinds of PFASs: hexafluoropropylene oxide dimer acid (HFPO-DA), perfluorobutane sulfonic acid (PFBS), perfluorohexane sulfonic acid (PFHxS), perfluorohexanoic acid (PFHxA), perfluorononanoic acid (PFNA), perfluorooctane sulfonic acid (PFOS), and perfluorooctanoic acid (PFOA). Overall, the rules are well crafted and will help to manage the risk of PFAS contamination of public water. In addition, we appreciate the explanatory documents (e.g., Overview of Michigan's Screening Values and MCLs) that accompanied the draft rules. One terminology recommendation for those documents – where there is a reference to "laws" (e.g. Understanding Risk: What's Behind the Numbers), we recommend these cases be changed to "laws and rules", given that more typically, the formal backstop for acceptable contaminant levels will be in the form of a rule rather than a law.

We offer the following comments on the draft rules:

- EGLE must stay vigilant and be prepared to address additional PFASs if necessary. To that end, either in this rulemaking or some other act, EGLE should periodically require certain public water systems to analyze whether other PFASs are present in finished water at concerning levels. This is particularly true for short-chain PFASs that some technologies (e.g. granular activated carbon systems) may not be able to treat.
- EGLE must stay vigilant concerning acceptable drinking water levels for the contaminants addressed in these rules, as new science develops. The agency should have a formal commitment to periodically review (e.g., every 2-3 years) the new scientific literature to determine if a reassessment of MCLs is warranted for any PFASs already addressed, as well as for any PFASs not addressed by the extant rules, as noted above.

- In terms of Rule 717d(9), no water supplier should sample for PFASs any less than four consecutive quarters before EGLE determines that monitoring can be reduced from quarterly to semiannually or annually.
- In terms of Rule 708 (on Certification for PFAS analysis), note that the Chemical Abstract Services (CAS) Registry Number for two compounds are in error:
    - For Perfluorobutane sulfonic acid, the CAS number should be 375-73-5.
    - For Perfluorohexane sulfonic acid, the CAS number should be 355-46-4.
- Concerning the MCL levels themselves for all regulated contaminants in Rule 405 (Table 1), we have a few recommendations:
    - Concerning the PFAS chemicals in particular, for the Health effects language in the right column of the table, EGLE should ensure the proper balance between brevity and comprehensive consideration of potential health effects of concern. In the draft language, it appears only examples of health effects are provided. For example, for PFOA, the language focuses on development impacts to infants exposed *in utero*, and other effects (e.g. pre-eclampsia and pregnancy-induced hypertension in women exposed to higher PFOA levels in the C8 Health Study) are not mentioned (Summarized in the Agency for Toxic Substances and Disease Registry, Agency for Toxic Substances and Disease Registry (ATSDR), Toxicological Profile for Perfluoroalkyls — Draft for Public Comment. June 2018.).
    - Concerning the MCL for perfluorohexanoic acid (PFHxA), we realize the recommended MCL is consistent with the health-based drinking water value derived by the Michigan Science Advisory Workgroup (Dewitt, J., Cox, C., and Savitz, D., 2019. Health-Based Drinking Water Value Recommendations for PFAS in Michigan. Michigan Science Advisory Workgroup.) We also note this value is orders of magnitude higher than the lowest value derived for the other evaluated PFASs in that effort, which may partly reflect assumptions on toxicokinetics. A recent paper exploring an internal dose approach to toxicity found that PFHxA may be of greater concern than assumed based on toxicokinetics (e.g. generally more rapid removal from the body) (Gomis, M. I.,

Vestergren, R., Borg, D., Cousins, I. T. 2018. Comparing the toxic potency in vivo of long-chain perfluoroalkyl acids and fluorinated alternatives. *Environ. Int.* **113**: 1-9.). Thus, EGLE should revisit assessments of toxicity of PFHxA as part of reviewing existing and new science on PFAS toxicity in the next few years.

- One general point on the table is there is reference to "CCR" concerning units, but the term is not defined in the Key at the start of the table. A definition should be provided in that Key.

- Three additional general points on development of MCLs that should be borne in mind are the following:
  - There is increasing research on the need to consider more subtle effects of PFASs in management decisions. For example, a recent review paper noted that drinking water levels for PFOA and PFOS set to protect against immunotoxicity in children would be < 1.0 ng/l for both chemicals (Grandjean, P. 2018. Delayed discovery, dissemination, and decisions on intervention in environmental health: a case study on immunotoxicity of perfluorinated alkylate substances. *Environ. Health,* **17**: 6.)
  - Likelihood of multiple PFAS exposures in people. The possibility of exposure to multiple PFASs is made on several occasions in the report by the Michigan Science Advisory Workgroup on PFAS drinking water values (Dewitt et al. 2019). Given the paucity of information on potential interactive effects of PFASs in the human body (e.g. Wang, Z.; DeWitt, J. C.; Higgins, C. P.; Cousins, I. T., A never-ending story of per- and polyfluoralkyl substances (PFASs)? *Environ. Sci. Technol.* 2017, 51 (5), 2508-2518), it is important for EGLE to be taking a precautionary approach in development of drinking water criteria that considers the implications of exposure to multiple PFASs, including in reassessing criteria in the future.
  - Likelihood of other, non-drinking water exposures to PFAS. While there are challenges in limited data, assessments have shown that other sources of PFASs (e.g. food) can be important in human exposures, with a recent assessment of the European Food Safety Authority finding

significant contributions of food-based PFASs for multiple age groups, including toddlers and adults (EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Knutsen HK, Alexander J, Barreg_ard L, Bignami M, Br€uschweiler B, Ceccatelli S, Cottrill B, Dinovi M, Edler L, Grasl-Kraupp B, Hogstrand C, Hoogenboom LR, Nebbia CS, Oswald IP, Petersen A, Rose M, Roudot A-C, Vleminckx C, Vollmer G, Wallace H, Bodin L, Cravedi J-P, Halldorsson TI, Haug LS, Johansson N, van Loveren H, Gergelova P, Mackay K, Levorato S, van Manen M and Schwerdtle T, 2018. Scientific Opinion on the risk to human health related to the presence of perfluorooctane sulfonic acid and perfluorooctanoic acid in food. *EFSA Journal* 2018;16(12):5194, 284 pp. https://doi.org/10.2903/j.efsa.2018.5194). Addressing this phenomenon can be done using the relative source contribution (RSC) approach, and we note that in the assessment done by the Michigan Science Advisory Workgroup, RSC values for three PFASs were set at 50 percent (Dewitt et al. 2019), while more conservative values may be warranted for multiple PFASs.

- Concerning helping inform subsequent changes to PFAS MCLs, EGLE should carry out and support research and monitoring on relevant issues, including initiatives such as the new federally-funded west Michigan PFAS health effects study involving the state and ATSDR (ATSDR, Multi-site Health Study – PFAS Cooperative Agreement, available from https://www.atsdr.cdc.gov/pfas/Multi-Site-Health-Study.html.)

Of course, public water systems will have to invest in compliance. To do so they will pass the cost to ratepayers. Many water systems serve vulnerable communities who will be especially impacted by any rate increase. While we believe public drinking water standards for PFAS are necessary, the legislature and EGLE must simultaneously do everything they can to ensure that water systems serving vulnerable communities can bear any new costs in ways that allow for affordable rates. The legislature must increase funding available to water systems that serve vulnerable

communities. EGLE must prioritize vulnerable communities when allocating in the Drinking Water State Revolving Fund program.

We appreciate the opportunity to comment. Please contact us if there are questions.

Sincerely,

Mike Shriberg, Ph.D.
Regional Executive Director

Michael Murray, Ph.D.
Staff Scientist

Oday Salim
Staff Attorney

Smith, Ian (EGLE)

From: Philip, Kris (EGLE)
Sent: Wednesday, January 29, 2020 5:06 PM
To: EGLE-PFAS-RuleMaking
Subject: FW: Comments proposed PFAS rule

Forwarding…

From: Steglitz, Brian <[redacted].org>
Sent: Wednesday, January 29, 2020 4:26 PM
To: Ruch, Suzann (EGLE) <RuchS@michigan.gov>; Philip, Kris (EGLE) <PHILIPK@michigan.gov>
Cc: Brian Steglitz [redacted].org>
Subject: Comments proposed PFAS rule

The City of Ann Arbor would like to amend its previously submitted comments with the following addition:

It has come to my attention that the CASRN numbers for two of the proposed PFAS to be regulated may be incorrect. The city requests that EGLE review the CASRN numbers for each of the seven PFAS proposed for regulation to ensure the CASRNs are correct in the final rule. I believe that the ones in error are PFBS and PFHxS.

Thank you again for the opportunity to comment.

Brian Steglitz, P.E. | **Manager, Water Treatment Services** | [redacted].org | **City of Ann Arbor**
919 Sunset Rd. | Ann Arbor, MI 48103 | [redacted]

Think Green! Please don't print this e-mail unless absolutely necessary.

Section Break

Non-form letter comments

Section Break

Smith, Ian (EGLE)

From: Susan & Ken [redacted]@gmail.com>
Sent: Friday, January 31, 2020 9:11 PM
To: EGLE-PFAS-RuleMaking
Subject: Comment on proposed drinking water PFAS standards

I am a resident of Michigan whose well water has been directly affected by PFAS contamination. After spending the last several months learning about these chemicals and their effects as well as working directly with the Flint water crisis, I have a new found appreciation of the importance of our water resources and how important it is to protect them. I fully support the proposed more stringent PFAS standards. As we continue to learn more about these chemicals and contamination impacts, I feel we need to have flexibility in the future to adjust the standards and recommend a mandatory review be built into the new standards so that they are reviewed every 2-3 years so as to keep up with current information and technology. The health of our citizens, particularly our youth, is critical for the future of Michigan. We cannot afford to not do the utmost in protecting them from this silent danger and I hope you support passing new rules that will increase protection of Michigan residents from PFAS contamination.

Thank you,

Susan Thiel
[redacted]
Grayling, MI 49738

Sent from Mail for Windows 10

Smith, Ian (EGLE)

From: Rex Vaughn [redacted].com>
Sent: Wednesday, January 8, 2020 12:38 PM
To: EGLE-PFAS-RuleMaking
Subject: Administrative Rules for Supplying Water to the Public - Rule Set 2019-35 EG

Please accept my comments below concerning the proposed rule changes that provide provisions to reduce exposure to several per- and polyfluoroalkyl substances (PFAS) in drinking water. I am concerned that the proposed changes fall short of adequately protecting the public unless the following changes are incorporated into the final rules:

- **Take a class-based approach to regulate PFAS in drinking water.** Considering health-based values for the seven individual PFAS chemicals separately does not take into effect how these chemicals interact with each other to cause health impacts.

- **Ensure that the health-based value used to set the PFAS-class drinking water standard protects those most vulnerable to harm.** Children, pregnant women, the elderly, and people suffering from chronic illness are more vulnerable to PFAS health impacts. Fetuses and infants have greater exposure to PFAS via maternal transfer in utero and contaminated breast milk or infant formula, and they are more sensitive to the exposure.

- **Use the most recent science to set a health-based value PFAS-class drinking water standard.** New research shows a relationship between exposure to PFHxS and impaired reproduction issues at 18 parts per trillion (ppt). The health-based value proposed by Michigan for PFHxS is 2.5 times higher or 51 ppt. Given the rapid pace at which new information on the effects of PFAS chemicals on human health at low doses is emerging, Michigan's rules should strive to reflect the very best science in the development of health-based values for PFAS. In addition, Michigan's rules should build in a process for updating the standard as new science emerges.

Kindest Regards,

Rex Vaughn
[redacted]
Flint, MI 48532
PH: [redacted]
Email: [redacted].com

Smith, Ian (EGLE)

From: Corina Donati [redacted]@mail.gvsu.edu>
Sent: Friday, January 31, 2020 2:05 PM
To: EGLE-PFAS-RuleMaking

As a concerned Michigan resident of our Great Lakes state protecting our water quality is of monumental importance to me as it affects all quality of life. I'm asking the department to follow California's regulations to limit PFOA to 5.1ppt and PFAS to 6.5ppt. These are the lowest levels at which these contaminates can be reliably detected.

Thank you for considering my comments and protecting our Pure Michigan!

Corie Donati

Sent from my iPhone

Smith, Ian (EGLE)

From: Armas Soorus <[redacted]@gmail.com>
Sent: Wednesday, January 8, 2020 10:08 AM
To: EGLE-PFAS-RuleMaking
Subject: New Rules for PFAS

I am writing to support the implementation of rules for PFAS in drinking water water that are carefully crafted to protect the consumers of drinking water in Michigan. The suggestions below by Freshwater Future are what I consider a minimum. In Michigan our natural resources are often exploited to the point my rights as a citizen to clean water are subjugated to rights of an entity for financial profit.

As a citizen of Michigan I consider it my right to expect clean water flows past my house in the Little Manistee River and that my well water is not polluted with ANY chemicals.

- **Take a class-based approach to regulate PFAS in drinking water.** Considering health-based values for the seven individual PFAS chemicals separately does not take into affect how these chemicals interact with each other to cause health impacts.
- **Ensure that the health-based value used to set the PFAS-class drinking water standard protects those most vulnerable to harm.** Children, pregnant women, the elderly, and people suffering from chronic illness are more vulnerable to PFAS health impacts. Fetuses and infants have greater exposure to PFAS via maternal transfer in utero and contaminated breast milk or infant formula, and they are more sensitive to the exposure.
- **Use the most recent science to set a health-based value PFAS-class drinking water standard.** New research shows a relationship between exposure to PFHxS and impaired reproduction issues at 18 parts per trillion (ppt). The health-based value proposed by Michigan for PFHxS is 2.5 times higher or 51 ppt. Given the rapid pace at which new information on the effects of PFAS chemicals on human health at low doses is emerging, Michigan's rules should strive to reflect the very best science in the development of health-based values for PFAS. In addition, Michigan's rules should build in a process for updating the standard as new science emerges.

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Penelope Minhinnick-Burns [redacted]@everyactioncustom.com>
Sent: Wednesday, January 8, 2020 8:32 PM
To: EGLE-PFAS-RuleMaking
Subject: Michigan standards for PFAS in drinking water

Dear Drinking Water and Environmental Health Division Suzann Ruch,

I live in Cascade Township on Tanglewood Drive, in the area affected by the GFIA PFAS plume. My home's EGLE well water testing did not detect PFAS. My family has health issues that could be caused by the presence of PFAS in our home well water after we moved here in 1988.

I support the current proposed PFAS drinking water limits. I am looking forward to seeing the "total PFAS" limits that would trigger action even if no single PFAS compound exceeds state limits.

Please address the significant number of homes like mine that have wells.

Michigan must look at science to set standards. Please consider all current science available to set Michigan standards. I hope Michigan can take steps to diminish or delete the lame duck session's actions to limit the science that can be considered in setting and enforcing standards.

I am glad to see that the Wolverine settlement is being used as a model, but I urge Michigan to encourage as much public participation as possible in the investigation and mitigation process to ensure the needs of every different public site are addressed.

I agree with the many people who urged Michigan to include all the PFAS chemicals in one or more classes.

I encourage Michigan to study the cumulative effects of PFAS, and act to create and implement rules to set and enforce safe standards.

I hope Michigan can look to other states that are beginning to limit PFAS, and build from their progress.

Please impress upon the EERCs make it clear to the EERCs that only the two constituents will become cleanup standards; not all 7 MCLs would become cleanup standards. Because EERC could veto any progress you have made, mollify them to get the current rules passed.

Sincerely,
Penelope Minhinnick-Burns
[redacted] Grand Rapids, MI 49546-7256 [redacted]@comcast.net

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of krista lilley <[redacted]@everyactioncustom.com>
Sent: Friday, January 10, 2020 8:54 AM
To: EGLE-PFAS-RuleMaking
Subject: Protect our residents, enforce the standards, raise the bar

Dear Drinking Water and Environmental Health Division Suzann Ruch,

It's time for Action now. Now that we know about the PFAS contamination, it's time to move quickly.
This is not time for bureaucracy and partisan gamesmanship, this affects everyone in our community. Please work quickly to pass the recommended standards and enforce them because we know it will take time to actually address these. There is no excuse for waiting, and if it's true that WWW is still using this in product being shipped to other countries, they need to be held accountable.
Thank you.

Sincerely,
krista lilley
[redacted] Kentwood, MI 49508-7018 [redacted]@yahoo.com

Smith, Ian (EGLE)

From: Claudette Ashley <[redacted]@yahoo.com>
Sent: Wednesday, January 8, 2020 6:58 PM
To: EGLE-PFAS-RuleMaking
Subject: Michigan needs the strongest possible MCL for PFAS

Dear PFAS Rulemaking,

We are in the midst of a public health crisis. PFAS chemicals, which have been linked to serious health concerns including reproductive problems and cancer, are in the drinking water of over 1 million Michigan residents. I urge you to protect Michiganders by setting the strongest possible drinking water standards for PFAS. Please consider the following when finalizing the PFAS MCL:

Take a class-based approach to regulating PFAS in drinking water: Considering health based values (HBVs) for seven individual PFAS chemicals is not protective against the likelihood of additive or synergistic effects from exposure to multiple PFAS chemicals. Water testing has confirmed that when drinking water is contaminated with PFAS, people are nearly always ingesting multiple chemicals.

Ensure drinking water standards for PFAS protect those most vulnerable to harm: PFAS chemicals are more toxic during pregnancy, early life, and for people who are elderly or already suffering from other chronic illness. We must set standards that are protective of our most vulnerable populations.

Take into account the most recent science when setting HBVs: Recent studies show a relationship between exposure to PFHxS and impaired reproduction. Given the rapid pace at which new information on the effects of PFAS chemicals on human health is emerging, we should strive to reflect the very best science in our assessment of water safety.

Thank you for your attention to these comments.

Sincerely,
Claudette Ashley
[redacted]
Waterford, MI 48329

Smith, Ian (EGLE)

From: [redacted]@parchment.org
Sent: Friday, January 10, 2020 10:52 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Rule Making

To Whom It May Concern:
Having lived through a crisis, I think it is important to let the science determine safe PFAS levels for drinking water in Michigan. While we all agree that zero detect would be ideal, what is a reasonable level given the industrial nature in much of our State.
I am concerned that we are rushing to conclusions for political expediency and would suggest that we keep the levels at the current EPA's standards of of 70 ppt. if or until the science concludes otherwise via exposure assessments and health studies.
Thank you for the opportunity to comments and feel free to contact me with any questions.
Robert D. Britigan III
Mayor, City of Parchment

Smith, Ian (EGLE)

From: Dacia T. Meng <[redacted]@bdlaw.com>
Sent: Friday, January 31, 2020 6:23 PM
To: EGLE-PFAS-RuleMaking
Subject: 3M Comments on Pending Rule Set Number 2019-35 EG Regarding Enforceable Drinking Water Standards for Certain PFAS
Attachments: 2020-01-31 3M Comments on Michigan Proposed MCLs.PDF

Please find attached comments from 3M on Pending Rule Set Number 2019-35 EG Regarding Enforceable Drinking Water Standards for Certain PFAS.

Thank you,
Dacia

Dacia T. Meng
Associate

1350 I Street, NW, Suite 700 ~ Washington, DC 20005 ~ bdlaw.com
O [redacted] ~ M [redacted] ~ [redacted]@bdlaw.com

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Mobile: [redacted]
Fax: [redacted]
Email: [redacted]@mmm.com

January 31, 2020

Ms. Suzann Ruch
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
PO Box 30817
Lansing, Michigan 48909-8311

3M Comments on Pending Rule Set Number 2019-35 EG Regarding Enforceable Drinking Water Standards for Certain PFAS

Dear Ms. Ruch:

3M is pleased to submit comments to the Drinking Water and Environmental Health Division of the Michigan Department of Environment, Great Lakes, and Energy (EGLE) regarding pending rule set number 2019-35 EG ("Proposed Rule"), which proposes establishing enforceable drinking water standards for certain per- and polyfluoroalkyl substances (PFAS). The rushed regulatory process has resulted in a Proposed Rule that is scientifically flawed and relies on speculative and unquantified benefits in an attempt to demonstrate it is necessary to protect human health. 3M's comments and concerns regarding the Proposed Rule are explained below and in the Attachment to this letter.

I. The proposed MCLs are scientifically flawed

The Michigan Science Advisory Workgroup (Workgroup) was given only eleven weeks to develop recommended health-based drinking water values for PFAS. In its June 2019 report titled "Health-Based Drinking Water Value Recommendations for PFAS in Michigan" (Workgroup Report), the Workgroup acknowledged that this compressed timeframe necessarily limited the scope of its technical review and analysis to "existing and proposed national and state-derived PFAS assessments to inform its decision-making process as opposed to conducting a full systematic review of the available scientific literature on PFAS." In doing so, the Workgroup replicated many of the flaws in other national and state PFAS assessments. According to the regulatory impact statement and cost-benefit analysis (RIS), the Proposed Rules rely heavily on the Workgroup's recommendations and other flawed reports, meaning that the Proposed Rules incorporate the same scientific flaws and are not based on sound and objective scientific reasoning.

A detailed explanation of the technical flaws and errors in the Workgroup Report, including in the data underlying the Workgroup Report, is appended to these comments as Attachment A. The detailed technical analysis in Attachment A may be summarized as follows:

a. <u>PFOA</u>

There are many technical uncertainties associated with the current PFOA Health-Based Value (HBV) derivations. The two studies selected by Michigan Science Advisory Workgroup lacked fundamental scientific rigor (*e.g.*, a single dose study without any dose-response; small sample size with only 6 pregnant dams; no details on the reproductive nor the developmental hallmarks; litter bias; non-standard testing methods; no internal serum PFOA dosimetry data) The single dose study design made it impossible to establish a realistic no observed adverse effect level (NOAEL) and/or lowest observed adverse effect level (LOAEL) for the data reported, and the corresponding data should not be used in any meaningful risk assessment for humans.

b. PFHxA and PFBS

The Workgroup should be consistent and use the same methodology when deriving the human equivalent dose for PFHxA and PFBS given they have similar serum elimination half-lives (in the range of a few hours in rodents, a few days in monkeys, and approximately one month in humans). In addition, the elimination half-life of each species for both PFBS and PFHxA approaches direct proportionality with body weight. It is therefore scientifically unjustified for the Workgroup to use allometric scaling adjustment for PFHxA but use serum TK adjustment for PFBS in its calculation for water guidance values for these compounds. In our detailed comments provided below, 3M has shown that, similar to PFHxA, the elimination half-life in each species for PFBS also approach direct proportionality with body weight in regression analysis. Therefore, the Workgroup should have used either allometric scaling or serum TK adjustment for both compounds.

c. PFOS

Michigan should not accept the NOAEL as the point of departure (POD) for the PFAS MCL based on analyses by New Jersey's Drinking Water Quality Institute (NJDWQI). In their analysis, NJDWQI made a serious technical error in its benchmark dose (BMD) modeling by using the standard error of the mean (SEM) from the Dong et al. (2009) study, rather than the required standard deviation. This error led the NJDWQI to reject the BMD modeling approach and instead accepted a much less accurate NOAEL. The NOAEL was 674 ng/mL to be used as the POD for calculation of the PFOS MCL. If NJDWQI's BMD modeling error is corrected by using the standard deviation (rather than SEM), a serum BMD can be properly calculated and used as the POD for the PFOS MCL. Correcting NJDWQI's error results in a PFOS $BMDL_{1SD}$ of 3,400 ng/mL, which is 5 times higher than the current POD (674 ng/mL). 3M pointed out this mistake to the New Jersey Department of Environmental Protection in 3M's public comments (submitted to this agency in May 2019). Michigan should acknowledge this error by NJDWQI and accept a $BMDL_{1SD}$ of 3,400 ng/mL as the POD. In so doing, the Michigan PFOS HBV of 16 ng/L should be multiplied by a factor of 5 to yield a drinking water guidance value for PFOS of 80 ng/L (16 ng/L x 5 = 80 ng/L).

d. PFHxS and PFBS:

The serum T4 measurement alone does not fully represent the overall thyroid function. Thyroid histology and/or serum TSH (the primary diagnostic indicator for serum thyroid hormone status) should be included in any determination of thyroid status in laboratory studies when feasible. The available rodent studies do not lead to a conclusion that the collective data supports a hazard for a thyroid effect with either PFHxS or PFBS.

e. PFBS

The developmental outcomes reported from the non-GLP short-term gestation exposure in mice (Feng et al. 2017) exposed to PFBS were vastly different than those reported from the full GLP two-generation study in rats by Lieder et al. (2009). The discrepancies from the short-term study need to be carefully evaluated prior to any meaningful risk assessment for humans.

II. The Proposed Rule is Not Necessary and Suitable to Achieve its Purpose

a. The benefits identified in the RIS and Cost-Benefit Analysis are speculative and unquantified

The RIS fails to provide "[a]n estimate of the primary and direct benefits of the rule" as required by MCL 24.245(3)(x). The RIS provides no quantitative estimate of the benefits of the rule. Instead, the RIS states "there is likely a significant benefit to the reduction (in) exposure to PFAS chemicals given recent findings of the health effects." The RIS does not substantiate that these "health effects" are established as cause-and-effect relationships. The referenced "health effects" are actually reported only as associations. In fact, the purported health effects have been inconsistently reported in the literature to such an extent that both the ATSDR (see page 637 of "Toxicological Profile for Perfluoroalkyls: Draft for Public Comment" by ATSDR (2018)) and the Michigan PFAS Science Advisory Panel (see page 10 of "Scientific Evidence and Recommendations for Managing PFAS Contamination in Michigan" by the Michigan PFAS Science Advisory Panel (2018)) have explicitly concluded that cause-and-effect relationships have not been established for any of the associations reported. Therefore, to assume there will be a significant benefit in reduced health cost due to the reduction of PFAS exposure is highly speculative when such cause-and-effect relationships have themselves not been established.

The speculative nature of the analysis is plain from the RIS's conclusion that a "significant" benefit is "likely." The Administrative Rules Division (ARD) should provide analysis and supporting evidence to show *how likely* any particular benefit is to occur with and without the proposed rule, as well as a more specific measure of the benefit that will result.

b. The RIS and Cost-Benefit Analysis does not relate any purported benefits to the specific MCLs proposed

Even assuming the missing causal relationship, the RIS and Cost-Benefit Analysis entirely fail to evaluate the benefits to be obtained by setting an MCL at the proposed levels as opposed to 5, 50, or 500 ppt higher or lower. Without evaluating the incremental benefits of setting an MCL at one level versus another, there is no way to evaluate whether the specific rules proposed are necessary and suitable to protect human health. This is particularly true in light of

the Workgroup's acknowledgment that "the nature of this process is inherently subject to uncertainty and other equally qualified experts presented with the same scientific data the Workgroup drew upon might well make somewhat different conclusions."

As described in detail in Attachment A, the proposed rules are based on flawed and unsound science. In the RIS, EGLE acknowledges that "[m]ore study on the health benefits and impacts of PFAS exposure reduction and the economic benefit is required before a serious estimate [of the costs and benefits] can be made." EGLE must engage in precisely that "serious estimate" before it can reasonably reach any conclusion about whether the proposed rule is necessary and suitable to achieve its purpose in proportion to the burden it places on individuals.

c. <u>The RIS and Cost-Benefit Analysis should include all costs associated with the proposed MCLs and should ensure those costs are outweighed by any benefits of the proposed MCLs</u>

It is critical that any benefit EGLE purports to find must outweigh the costs of the proposed MCLs. Those costs have not fully accounted for the financial impact the rule will have on public water systems, their customers, and other businesses and groups in Michigan. The analysis should appropriately account for the rule's ongoing operation and maintenance costs for water systems, in addition to the costs for retrofitting, treatment and pretreatment, sampling, and disposing of waste arising from those activities. EGLE should update its cost-benefit analysis to consider all such costs and should ensure that any purported benefits of the proposed MCLs would outweigh those costs. At present, given the limited information on the benefits of the proposed MCLs, the costs are not proportionate to the benefits, let alone outweigh them.

3M appreciates the opportunity to provide comments on the proposed rule. Thank you for your consideration.

Regards,

Oyebode A. Taiwo, MD, MPH

ATTACHMENT A

3M DETAILED TECHNICAL COMMENTS

I. TOXICOLOGY

a. PFOA

For PFOA, the Michigan Science Advisory Workgroup (Workgroup) deferred to the provisional assessment by ATSDR for the critical study selection, which were Onishchenko et al. (2011) and Koskela et al. (2016), its companion study. The critical effects chosen were neurobehavioral activities and skeletal alteration in offspring in mice. These critical effects were not supported by the available animal data (described in detail below) and 3M respectfully disagrees with the resulting PFOA drinking water health-based value (HBV) recommended by Workgroup. There are major technical concerns associated with these two published studies with respect to their use in any human risk assessment. They include:

1. A single dose experiment cannot address (any) dose-response relationship.

Albeit published five years apart, these two publications actually originated from one single study. From the same pregnant dams treated with a single dietary PFOA dose during gestation, the pups evaluated by Onishchenko et al. (2011) were litter-mates of the pups evaluated by Koskela et al. (2016). As such, it was really one study and the corresponding outcomes (from both studies) should be consolidated when discussed. In essence, there was only one PFOA dose group used in these two studies and it is impossible to interpret the experimental data reported by these authors in terms of any dose-response. Others, including Minnesota Department of Health, echoed the same opinion in their public comments to ATSDR (MDH 2018). Considering the inherent variations in biological responses in any animal study, the nature of a single-dose study simply does not allow any specific evaluation of any dose-and-effect responses or biological plausibility inference.

2. An uncertainty factor of 10 (LOAEL-to-NOAEL extrapolation) was not scientifically justified.

Given that there was only one PFOA dose group used, the study design did not follow the fundamental practice of toxicology testing such as evaluation of a dose-response relationship. Given the lack of any dose-response, it is scientifically impossible to establish a realistic NOAEL and/or LOAEL for the data reported. Therefore, an uncertainty factor of 10 was not scientifically justified. This opinion was also echoed by the Minnesota Department of Health.

In addition to the flawed experimental designs, there are major technical concerns associated with these two studies which preclude meaningful scientific interpretation of the results. These include limited sample size, lack of reproduction and developmental outcome information, pup litter selection bias, questionable dietary preparation, inadequate timing for behavior assessments, non-standard behavior assessment procedures, and absence of background data for bone morphology and bone density (see Appendix I, 3M's comments to ATSDR, for further details). Overall, the studies by Onishchenko et al. (2011) and Koskela et al. (2016) lack the

scientific rigor to properly address the selected developmental endpoints and they should not be used for any human risk assessment.

b. PFHxA human equivalent dose (HED) calculation

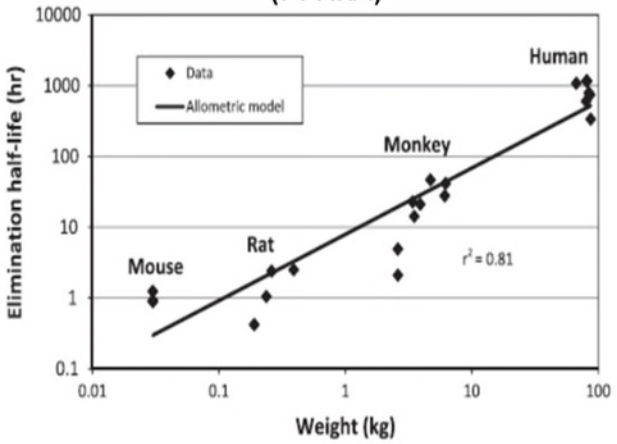
In recommending the drinking water limit for PFHxA, the Workgroup used body weight allometric scaling adjustment (between animal and human) as the basis for deriving an HED. For other PFAS evaluated by the Workgroup (e.g., PFNA, PFOA, PFOS, PFHxS, and PFBS), the differences in serum elimination half-lives (between animal and human) were used to derive the HED. The Michigan Science Advisory Workgroup reviewed the available serum half-life data presented in Russell et al. (2013) and concluded that, unlike the other PFAS, allometric scaling could be supported in deriving an HED. Therefore, the Workgroup calculated an HED of PFHxA equal to the POD (90.4 mg/kg-d) divided by an allometric scaling factor of 3.65 [$=(80kg/0.45kg)^{1/4}$]. This yields an HED of 24.8 mg/kg-d. This HED was then used to derive a water guidance value for PFHxA of 400,000 ng/L.

Russell et al. (2013) suggested that chemical elimination half-lives are usually poorly correlated with body weight, in part due to different volumes of distribution in various species. However, in their analysis for PFHxA, they showed a reasonable statistical model fit in their regression analysis with the experimental data ($r^2 = 0.81$) and therefore concluded that the elimination half-life in each species for PFHxA approached direct proportionality with body weight (Figure A). It is worth noting that while Russell et al. suggested the absence of species-specific transporters in the kidney appeared to drive the rapid elimination of PFHxA; this information is only limited to a few transporters that had been studied.

3M attempted to replicate the data presented by Russell et al. (Figure B) and also obtained a model fit ($r^2 = 0.91$). The slopes for the log (body weight) between these two analyses (Figure A and Figure B) were very similar (0.93 vs. 1.02, respectfully). Only the intercepts differed (9.5 vs. 0.78 for Russell et al. and 3M analysis, respectively). The intercept value of 9.5 reported by Russell et al. is not consistent with the y-axis as reported in Figure A, which was taken directly from Russell et al. (2013). This discrepancy could be a simple typographical error or a graphical error.

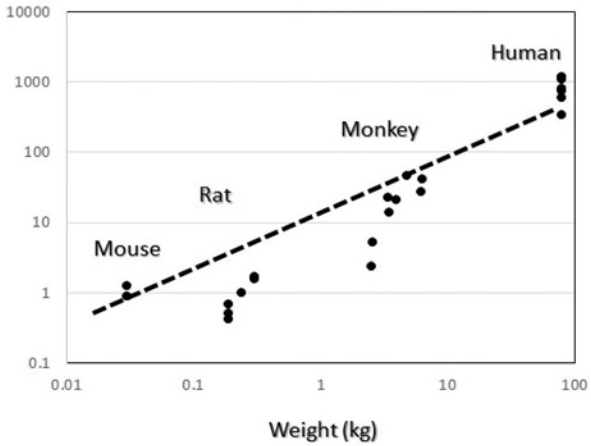
Given that the Workgroup opted to use an allometric scaling approach to calculate the HED for PFHxA (based on findings from Russell et al.), 3M is puzzled why a similar allometric scaling approach was not used for PFBS to calculate its HED. Specifically, the elimination half-lives for both PFHxA and PFBS are relatively similar (in the range of a few hours in rodents, a few days in monkeys, and approximately one month in humans). Therefore, the Workgroup should be consistent with its methodological approach as it applies to PFBS (see below for more detailed discussion).

Figure A
Russell et al. 2013[1]
(PFHxA)



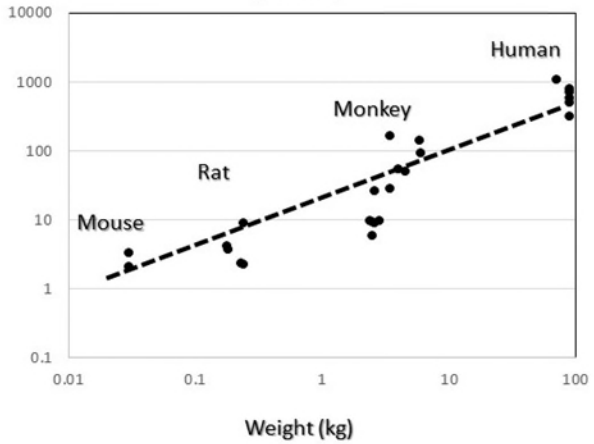
log(half-life) = log(9.54) + 0.93log(weight)
r² = 0.81

Figure B
3M analysis
(PFHxA)[2]



log(half-life) = log(0.79) + 1.02log(weight)
r² = 0.91

Figure C
3M analysis
(PFBS)[3]



log(half-life) = log(1.24) + 0.78log(weight)
r² = 0.89

1. This is Figure 2 from Russell et al. (2013)
2. 3M's analysis of the study data reported by the original authors (see below); these studies were cited by Russell et al. (2013)
   - Chengelis et al. 2009 Reproduct Toxicol 27 400-406
   - Russell et al. 2013 Chemosphere 93 2419-2425
   - Noker, P.E., 2001. A pharmacokinetic study of potassium perfluorohexanoate in the Cynomolgus monkey. Southern Research Institute.

2. Olsen et al. 2009 Toxicology 256 65-74; Rumpler et al. 2016 The Toxicologist 150, abstract 3439, pg 572

c. PFOS toxicology

For PFOS, the Workgroup deferred to the provisional assessment by New Jersey Department of Environmental Protection (NJDEP) for the critical study selection, which was Dong et al. (2009). NJDEP based its decision on a technical evaluation by its New Jersey Drinking Water Quality Institute (NJDWQI). The critical effect selected was immune suppression on the basis of decreased plaque forming cell response. These critical effects were not supported by the available animal data (described in detail below) and 3M respectfully disagrees with the resulting PFOS drinking water health-based value (HBV) recommended by Workgroup. There are major technical concerns associated with the study by Dong et al. (2009) which preclude the results from being meaningful in any human risk assessment. They include:

1. <u>There is a serious technical error with DWQI's benchmark dose (BMD) modeling for PFOS with Dong et al. (2009) data.</u>

BMD modeling is advocated by the USEPA as the preferred approach for identification of a dose-response when there are sufficient data to support it and NJDWQI explicitly stated that "if a benchmark dose can be developed, it is **preferred** for use as the POD."

When evaluating the Dong et al. (2009) data, NJDWQI reported that it was unsuccessful in its attempts to compute a BMD or BMDL based on the PFOS-included plaque forming cell response (PFCR). As a result, it subsequently used the serum NOAEL of 674 ng/mL from the study as the POD for its MCL derivation (see NJDWQI 2018, which was also published as Pachowski et al. 2019). 3M's review of NJDWQI's BMD modeling discovered a major technical error in NJDWQI's BMD modeling, in which standard error was used as the input for BMD modeling rather than the required standard deviation. If corrected to the standard deviation, an acceptable serum PFOS BMDL can be derived; specifically, a $BMDL_{1SD}$ will be 3,400 ng/mL, which is five times higher than the serum NOAEL (674 ng/mL) (see Appendix II, 3M's comments to NJDEP, for further details). Correspondingly, if the Dong et al. (2009) study is to be used, and the correct BMD modeling is used with the standard deviation, then the PFOS HBV should be raised by a factor of five to 80 ng/L (16 ng/L x 5 = 80 ng/L).

2. <u>Evidence of immune suppression was not supported by Dong et al. (2009) data.</u>

From a fundamental immunology perspective, there were several important technical aspects that Dong et al. (2009) failed to address, and the study also lacked overall scientific validity to support the conclusion that PFOS causes immune suppression. Specifically:

- It is well-known that body weight plays a critical role in studying immune response and any factors that can influence body weight will likely indirectly affect immune responses. Although Dong et al. claimed that body weight was not affected in the first two lower dose groups (0.5 and 5 mg/kg TAD), based on simple ANOVA and Dunnett's t tests, there appeared to be a difference in mean body weight change between the control group (mean body weight change = 3.10 ± 0.13 g) and the NOAEL dose group at 0.5 mg/kg/day (mean body weight change = 2.58 ± 0.15 g). With a 1-sided test, the final body weights in the 0.5 mg/kg/day dose group were significantly lower than the control group at $\alpha = 0.10$ ($0.05 < p < 0.10$). With a 2-sided test, it was statistically significantly different at α

= 0.20 ($0.15 < p < 0.20$). Therefore, Dong et al. (2009) data may have been confounded by decreased body weight effect which hindered the overall interpretation.

- The standard clinical marker for antibody titers to vaccination is secondary IgG antibody isotype, not primary IgM. Dong et al. reported the PFOS dose-dependent reductions in sheep red blood cell (SRBC)-induced IgM plaque forming cell assay *in vitro*; they did not evaluate IgG or other potential antibody responses that can develop, including IgG or IgE. In addition, the use of the SRBC-induced antibody response to measure antigen-induced antibody response is very crude and non-specific to T cell activation. There are better T cell-dependent antigens available for use in the immunology research (i.e., ovalbumin) and Dong et al. did not acknowledge such fact.
- Furthermore, the study by Dong et al. (2009) did not take the time-based progression of IgM → IgG antibody class switching into consideration. The normal progression of antibody development involves the IgM production by B cells first as primary immune response. The B cells will subsequently proliferate and become activated when further challenged by antigen, ultimately leading to antibody class switching to produce IgG, which is the clinical measurement for the assessment of antibody titer.
- Dong et al. did not appropriately evaluate the memory response in their study. They only challenged the animals with SRBC (antigen) once, which was insufficient to determine a memory response.
- While Dong et al. claimed that the antibody response was reduced based on IgM PFCR data, the IgM PFCR activity was only evaluated in spleen cells. The authors should have also looked at thymus and serum for IgM levels to illustrate that the responses are consistent in other primary immune organs. By way of similar scientific rationale, Dong et al. should have looked at IgG in addition to IgM, as well as evaluated IgG levels in thymus and serum.
- While the immune cell populations were reported by Dong et al. in spleen and thymus, they did not look at these cell populations in another key immune organ: bone marrow. Similarly, while NK cell activity was reported for the spleen, it was not done for the thymus. These were major technical omissions.
- With regards to NK cell activity, the LDH assay used by Dong et al. is not a typical assay used to assess NK cell activity. The LDH measurement is associated with cell membrane integrity and it is a non-specific assay. The LDH values reported by Dong et al. should not be used *in lieu* of NK cell activity data. The standard method for NK cell activity is flow cytometry, which Dong et al. did not perform; therefore the conclusions that NK cell activity is changed cannot be reliably drawn from this study.
- Dong et al. reported a negative effect of PFOS and the splenic lymphocyte proliferation as a way of demonstrating that the immune cells were not "proliferating" upon challenge. However, two major technical flaws associated with the study design limit a scientific support for this conclusion:
- Dong et al. reported Concanavalin A (ConA)-mediated responses as antigen specific T cell receptor-based proliferation *in vitro*. However, ConA stimulates T cells via a different set of pathways than through the T cell receptor. The more appropriate method

would have been using anti-CCD3/CD28 antibodies to mimic antigen specific cell stimulation *in vitro*.

- The second concern is the use of the MTT assay to determine T cell proliferation *in vitro*. The MTT assay determines metabolic activity, not cell numbers. It is simply an indicator of cells' mitochondrial respiration state and is not a reflection any proliferative response(s). The standard assay for cell proliferation would be BrDU assay or PCNA staining, neither of which was used by Dong et al. and the readers were misinformed.
- Dong et al. should have looked at/report blood lymphocyte counts, which are part of the standard CBC panel parameters.
- Dong et al. did not provide any histological evidence for thymus, spleen, or bone marrow.
- Dong et al. only evaluated male mice; they should have also examined female mice to rule out any gender-specific difference in the immune response.

Collectively, the study by Dong et al. did not provide any robust or compelling scientific evidence to support the claim that PFOS is associated with immune suppression in mice. As discussed in detail above, Dong et al. (2009) misinformed the readers in their data presentation with incomplete antibody isotyping and partial assessments in some, but not all, primary immune organs. Using a crude (non-specific) antigen SRBC, they only challenged the mice once without any follow up for a second challenge to elicit permanent antibody response (to antigens and/or vaccines). They did not use the correct methods to evaluate cell proliferation and NK cell activity responses and improperly reported their data.

d. PFHxS toxicology

For PFHxS, the Workgroup selected the NTP 28-day repeated oral dose study in rats as the critical study. The critical effect selected was decreased serum free thyroxine (T4) levels. As described in detail below, this thyroid endpoint was not fully evaluated with the available accompanying data and 3M respectfully disagrees with the resulting PFHxS drinking water health-based value (HBV) recommended by Michigan Science Advisory Workgroup.

1. Serum free T4 alone does not fully represent the overall thyroid function.

The NTP 28-day rat study reported decreased total T4, total T3, and free T4 in serum at the end of 28 days dosing with PFHxS, however, these three endpoints alone did not provide adequate (clinical) evidence to suggest that thyroid was being affected. Specifically, thyroid histology should be included in any determination of thyroid status in rodents when terminal sacrifice is part of the study protocol because "in the rodent, thyroid gland histopathology is a more sensitive indicator of thyroid status than T3 or T4 serum hormone values." (Jahnke et al. 2004). In addition, if thyroid histology is not available, serum TSH should be used as the primary diagnostic indicator for serum thyroid hormone status (Oppenheimer et al. 1995).

2. Thyroid histology and serum TSH were normal in the NTP 28-day study.

The Workgroup does not explicitly recognize that thyroid histology is considered the "gold standard" for determining thyroid status, nor did it recognize that serum TSH is the primary diagnostic indicator for serum thyroid hormone status. In the NTP 28-day study, thyroid histology and serum TSH were normal. This observation is important because these studies showed a lack of dose-response in either thyroid histology and/or serum TSH with PFHxS treatment, which further suggest that thyroid was not being affected.

3. The Michigan Science Advisory Workgroup failed to recognize the critical negative bias measurement issue associated with high serum PFHxS levels.

The Workgroup did not sufficiently recognize the sensitivity of the assays used to measure serum thyroid hormones to the presence of compounds that can interfere and compete with thyroxine for protein bindings. In such situations, this interference can negatively bias the free T4 results when conventional analog methods are used. This is in fact the case with PFHxS and other PFAS such as perfluorobutanoate and perfluorooctane sulfonate (Chang et al. 2007; Weiss et al. 2009; Butenhoff et al. 2012a). Therefore, the workaround is to measure free T4 by *equilibrium dialysis*-based methods. This was not done in the NTP 28-day study, which was acknowledged by NTP in its report for this technical omission.

Therefore, given that there were normal TSH levels (primary diagnostic indicator for thyroid hormone status) and normal thyroid histology in these same rats (where decreased serum total T4, total T3, and free T4 were reported as measured by analog method only), collectively, these data strongly suggested that overall thyroid hormone status in these rats was normal. Based on the criteria for overall evidence to support a hazard based on animal data, these data do not lead to a conclusion that the collective thyroid data supports a hazard for a thyroid effect.

e. PFBS toxicology

For PFBS, the Workgroup deferred to the provisional toxicity assessment by USEPA for the critical study selection, which was a mouse developmental study by Feng et al. (2017). The critical effect selected was decreased serum total thyroxine (T4) levels in newborn mice. As described in detail below, this thyroid endpoint was not fully evaluated with the available accompanying data and 3M respectfully disagrees with the resulting PFBS drinking water health-based value (HBV) recommended by Workgroup. 3M's key technical comments include:

1. Serum total T4 levels primarily are the biologically inactive T4 and it does not represent the overall thyroid function.

In this gestation exposure study in mice with PFBS, Feng et al. (2017) reported decreased total T4, decreased total T3 (triiodothyronine), and normal TSH in serum at birth for female pups. However, decreased total T4 and T3 alone did not provide adequate (clinical) evidence to

suggest that thyroid was being affected. Serum total T4 and total T3 measurements are measurements of largely (> 99.5%) inactive thyroid hormones and they alone do not represent functional aspects of the thyroid (Oppenheimer et al. 1995). As stated earlier, thyroid histology should be included in any determination of thyroid status in rodents when terminal sacrifice is part of the study protocol because "in the rodent, thyroid gland histopathology is a more sensitive indicator of thyroid status than T3 or T4 serum hormone values" (Jahnke et al. 2004). In addition, if thyroid histology is not available, serum TSH should be used as the primary diagnostic indicator for serum thyroid hormone status (Oppenheimer et al. 1995).

2. Serum TSH is normal.

Workgroup does not explicitly recognize that the serum TSH is the primary diagnostic indicator for serum thyroid hormone status. Again, in the study by Feng et al. (2017), total T4 and total T3 alone did not provide adequate (clinical) evidence to suggest that thyroid was being affected, especially when TSH, the primary diagnostic indicator for thyroid hormone status was normal.

3. Feng et al. (2017) did not provide adequate information to allow a full interpretation of thyroid status.

Albeit terminal necropsies were performed in this study, it was unclear why there were no thyroid histology reported for either dams or offspring. In addition, on the thyroid-related parameters, there were no TRH mRNA or serum FT4 measured in offspring even though it was done for dams.

4. The observations from Feng et al. (2017) study need to be validated.

There was a total of eight individual serum hormones measured and reported by Feng et al. (2017) based on the blood samples collected from the newborn mice; and each of the hormones was measured using the commercial ELISA kits obtained from USCN Life Science Inc., as described in the paper. According to the manufacturer's information (see https://www.cloud-clone.us), each ELISA kit requires 50 uL of serum sample volume. Given that a newborn mouse pup is quite small in size (approximately 1 gram), it is not clear how Feng et al. was able to measure all the hormones with such a limited blood volume. To better understand this, 3M consulted with Charles River Laboratories who concluded that, if they were to repeat the Feng et al. study, at least 75 dams per dose group would have been needed to achieve the blood sample volume required for the specified hormone measurements. Feng et al. only had 30 dams per dose group.

5. The discrepancies between mouse and rat developmental data need to be addressed.

The developmental endpoints from the short-term gestation exposure study in mice by Feng et al. (2017) were vastly different than the outcomes from the full 2-generation study in rats

by Lieder et al. (2009). These differences need to be properly assessed before a scientific conclusion can be made. Key observations included:

- Effects reported by Feng et al. lacked dose-responses; the effects from 200 mg/kg-d were usually similar in magnitude to 500 mg/kg-d.
- The study design and PFBS dosing regimen by Lieder et al. (2-generation in rats) was more rigorous than Feng et al. (gestational only in mice) in terms of treatment duration, doses, as well as direct treatments to developing fetuses and pups during sensitive life stages, see Table 4 below for comparison.

			Lieder et al. 2009	Feng et al. 2017
Species			Sprague Dawley rats	ICR mice
Test guideline			OECD 416 / OPPTS 870.3800 (2-gen)	None
GLP			Yes	No
Daily K^+PFBS treatments (direct gavage)	Daily doses		30, 100, 300, 1000	50, 200, 500
	P-generation	Pre-mating, males	Yes, 70 days	No
		Pre-mating, females	Yes, 70 days	No
		Gestation, dams	Yes	Yes
		Lactation, dams	Yes	No
	F1-generation pups (before mating)	Weaning and on	Yes, ≥ 70 days	No

- It was not clear why Feng et al. did not include male offspring in their evaluation.
- The female mouse offspring in the Feng et al. study were not directly dosed with K^+PFBS, however, the reported myriad of adverse developmental outcomes occurred in these female mouse pups (e.g., reduced body weight and changes in reproductive organ morphology). In contrast, female rat offspring (from Lieder et al. 2009) were not only exposed to PFBS during gestation and lactation, they were also directly dosed with PFBS (at higher dose levels than the Feng et al. study) after weaning and into their adulthood. There were no developmental effects noted in the female rat pups in Lieder et al. study.
- Regarding the alterations in ovary and uterus-related data, as reported by Feng et al., there were several technical details not provided by the study authors which precluded a meaningful interpretation of the data. They include:
    - Evaluation was reported for female pups at PND 60 only, not on PND 30 and not for dams (who were directly dosed with PFBS).
    - "Impaired" development reported by Feng et al. was based on decreased surface area (on microscopic slides) and limited morphological measurements. Surface area can be also attributed from different sectioning location (of the tissue). Feng et al. did not address how this was controlled among different animals. In addition, Feng et al. only provided relative organ-to-body weight data. There

were no absolute organ weight data for the readers to interpret. Organ-to-brain weight data were not presented either.

- Feng et al. did not take body weight into consideration when interpreting estrous cycle data which is unfortunate because they are related (Bermejo-Alvarez et al. 2012).
- In Feng et al. (2017), albeit there were changes in female reproductive organ morphology, functional aspects of reproduction appeared not to be affected according to study authors (i.e., maternal body weight, maternal body weight-gain, and various pregnancy outcomes).

6. The Michigan Science Advisory Workgroup should use $BMD_{0.4SD}$, not $BMDL_{20}$, to determine POD if T4 is continued to be used as the critical endpoint.

In EPA's draft assessment for PFBS, a benchmark response (BMR) of 20% relative deviation (i.e., dose that results in a 20% reduction of mean T4) was used to derive a $BMDL_{20}$ value. 3M respectfully disagrees with the selection of T4 as well as a $BMDL_{20}$ value based on the assumption of a continuous dataset, which, in itself was inconsistent with EPA's past practices with many other compounds.

A better alternative analysis for consideration requires a different dose-response model and a definition of the BMR using standard deviation (SD). This is fully explained by 3M and Mr. Bruce Allen who is a biostatistician and consultant to both EPA and 3M. 3M's entire written comments to EPA, which included Mr. Allen's detailed explanation as an appendix, are attached in this report (see Appendix III). According to Mr. Allen, the POD estimate would yield a $BMDL_{0.4SD}$ value of 8.3 mg/kg-d, which is approximately two-fold higher than the current POD (4.2 mg/kg-d). Correspondingly, the PFBS HBV should be raised by a factor of two to 840 ng/L (420 ng/L x 2 = 840 ng/L). We strongly recommend to the state of Michigan to thoroughly understand the reasoning behind Mr. Allen's recommendation.

7. The Workgroup should be consistent in its methodology

The Michigan Science Advisory Workgroup should be consistent in its methodology when HED for PFBS as it did with PFHxA given the elimination half-lives for both PFHxA and PFBS are relative similar (in the range of a few hours in rodents, a few days in monkeys, and approximately one month in humans). Specifically, based on the data reported by Russell et al., the Workgroup should acknowledge the following important points:

- Both PFBS and PFHxA have comparable elimination kinetics across different species.
- Biomonitoring of PFHxA has not been routinely included in the CDC National Health and Nutrition Examination Survey (NHANES) due to the low potential for detecting significant PFHxA concentrations in human blood (Calafat, A., personal communication with Russell et al. 2013). Simlarly, PFBS has also not been detected in the general

population according to NHANES since 2007/2008 and onward through 2013/2014, such that NHANES chose not to even measure PFBS in its 2015/2016 cycle.

- Based on the methodology by Russell et al., there is also a weight-normalized blood elimination seen for PFBS. 3M constructed a regression model for the available PFBS elimination kinetic data among difference species (mouse, rat, monkey, and humans). The PFBS regression model (see Figure C on page 5) had a good fit ($r^2 = 0.89$) and the slope for the log (body weight) was similar to that reported by Russell et al. Similar to PFHxA, the elimination half-life in each species for PFBS approach direct proportionality with body weight in this regression analysis.

Based on these two points above and using the same line of reasoning recognized by the Michigan Science Advisory Workgroup that supported the allometric scaling adjustment for PFHxA, the same approach should then also be used for PFBS. Doing so, an allometric scaling factor of 7.2 for PFBS can be calculated between human and mouse [= 80 kg / 0.03 kg)$^{1/4}$]. Using this allometric scaling adjustment of 7.2 instead of a serum TK adjustment of 316 results in a 44-fold difference (=316 / 7.2). This 44-fold difference, if applied, would result in a water guidance value for PFBS that would be approximately 18,000 ng/L.

II. Epidemiology:

Health effects listed by ARD in **statement 31** include lowering a woman's chance of getting pregnant, increase in pregnancy induced hypertension, increase chance of thyroid disease, increase in cholesterol levels, changes in immune responses, and increase in kidney and testicular cancers. Besides the Workgroup's conclusion that cause-and-effect relationships have not been established for any of the associations listed, the Workgroup also acknowledged that "the Panel also notes some of the concerns call into question whether the assessment of PFAS being causality related to certain disease in humans is accurate given the potential for reverse causality" (see page 31 of this Panel report). Such concerns about reverse causality include a lower chance to get pregnant. As highlighted in their systematic review of the reproductive epidemiology literature regarding perfluoroalkyls, Bach et al. (2015) reported that of the 8 epidemiologic studies related to time to pregnancy and PFAS exposure, only one study found an association when restricted to nulliparous women; 4 studies reported an association with parous women such that Bach et al. concluded the association was not causal but likely the result of reverse causation and unmeasured confounding related to prior pregnancies and childbirths. In its 2018 draft Toxicological Profile, ATSDR failed to discuss methodological issues that have been repeatedly discussed in the published epidemiology literature surrounding the metric of time-to-pregnancy and the amount of interpregnancy time for re-accumulation of PFOA or PFOS. Other conditions that have been considered related to reverse causality or confounding include thyroid disease (see recent publication by Dzierlenga et al. 2019), chronic kidney disease (Watkins et al. 2013; Dhingra et al. 2017), lower birthweight (Verner et al. 2015; Steenland et al. 2018), early onset menopause (Ruark et al. 2017; Dhingra et al. 2017), and delayed puberty (Wu et al. 2015).

Finally, 3M is only aware of one report that has attempted to estimate the socioeconomic analysis of health impacts linked to exposure to PFAS (Nordic Council of Ministers, 2019). This report was based on numerous misguided assumptions. As a prime example, this report assumed the economic cost related to kidney cancer with occupational exposure to PFOA in all European Economy Area (EEA) countries is between 12.7 and 41.4 million Euros. This was calculated assuming an occupational population estimated between 84,000 and 273,000 (a 3X difference in itself). This report then selectively considered only the mortality study results from one occupational cohort study whose workers used PFOA as a processing aid in the production of tetrafluoroethylene (TFE). TFE is a known rat renal carcinogen (Steenland and Woskie 2012) and is considered a "probable" human carcinogen by IARC (2017). This Nordic Council of Ministers report chose not to include the lack of kidney cancer mortality or incidence risk that was reported from a different PFOA manufacturing plant which had a near absence of TFE exposure (Raleigh et al. 2014). These two occupational cohorts, residing in West Virginia and Minnesota, respectively, were comparable in size. The Minnesota cohort actually manufactured the PFOA for use at the West Virginia TFE production facility. In addition, the economic analysis also chose not to cite Consonni et al. (2013) who studied a multi-plant cohort engaged in TFE production, including the West Virginia plant. Consonni et al. arrived at the conclusion that they could not "disentangle" the exposures between PFOA and TFE because the former is used as a processing aid in TFE production. Also, not mentioned in the Nordic Council of Ministers report, were the lack of findings of increased incidence of renal neoplasms in three lifetime bioassays of Sprague Dawley rats (Butenhoff et al. 2012b; Biegel et al. 2001; NTP 2019). Despite these lack of findings in other studies related to PFOA and kidney cancer, this economic analysis report relied solely on only a single point estimate from Steenland and Woskie (2012). Unfortunately, the Michigan PFAS Science Advisory Panel chose also not to cite the contrary kidney cancer evidence reported by the other epidemiology and toxicology studies. These other studies were referenced in the IARC 2017 report which resulted in the "possible" hazard classification i.e., limited epidemiology and toxicology data, issued by the IARC workshop on PFOA.

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Appendix I:
3M's written comments to ATSDR on its draft toxicology profiles for perfluoroalkyls, August 2018

(NOTE: these comments were excerpted for only PFOA toxicology)

Detailed Comments on PFOA MRL

ATSDR position (page A-16)

MRL Summary: A provisional intermediate-duration oral MRL of $3x10^{-6}$ mg/kg/day was derived for PFOA based on altered activity at 5–8 weeks of age and skeletal alterations at 13 and 17 months of age in the offspring of mice fed a diet containing PFOA on GD 1 through GD 21 (Koskela et al. 2016; Onishchenko et al. 2011). The MRL is based on an HED LOAEL of 0.000821 mg/kg/day and a total uncertainty factor of 300 (10 for use of a LOAEL, 3 for extrapolation from animals to humans with dosimetric adjustments, and 10 for human variability).

Selection of the Critical Effect: Intermediate-duration oral studies of PFOA in animals indicate that the liver, immune system, reproductive system, and the developing organism are the primary targets of toxicity because adverse outcomes were observed at lower doses than other effects and have been consistently observed across studies.

3M Conclusion

A. Studies by Onishchenko et al. (2011) and Koskela et al. (2016) should not be used to derive the PFOA MRL
B. The critical effects cited by ATSDR for the PFOA MRL derivation (altered activity and skeletal alterations in offspring in mice) were not supported by the available animal data, and they contradicted ATSDR's own evaluation of epidemiological data
C. PFOA does not affect the reproductive system in laboratory animals
D. The developmental effects reported in laboratory animals for PFOA were primarily mediated by maternal effects
E. Liver findings in rodents are not relevant for human risk assessment
F. Immune findings in rodents are not consistent; they lack concordance with epidemiological observation data
G. A study with one single dose group is not adequate in estimating point-of-departure
H. Serum PFOA concentrations in pups should be considered for POD instead of dams because critical effects chosen by ATSDR were based on (developing) pups
I. HED cannot be reliably estimated in the absence of serum concentration data
J. HED for PFOA will be higher when considering faster half-life
K. Wambaugh benchmark dose model used by ATSDR was not optimized
L. Uncertainty factors by ATSDR were conservative and not supported by scientific data
    1. Incorrect use of "10" for a LOAEL.
    2. Use of "3" for animal-to-human, in addition to large dosimetric TK adjustment, is conservative because humans are less sensitive than rodents with exposure to PFOA

ATSDR's overall interpretation on both toxicology and epidemiology data are inconsistent with the most current knowledge. Its application of uncertainty factors is not scientifically justified

and the proposed PFOA MRL is not supported by the scientific data. The PFOA MRL derived for the human-health risk assessment is therefore inappropriate and not justified by an adequate scientific foundation.

3M Comments (Details):

A. Studies by Onishchenko et al. (2011) and Koskela et al. (2016) should not be used to derive PFOA MRL. The toxicology database for PFOA is quite comprehensive. Many of these studies included detailed information on the reproductive and developmental toxicity with these compounds across different PFOA dose levels as well as valuable insights on the role of maternal effects and its attribution to the developmental outcomes in laboratory animals. Comprehensive review on the potential developmental toxicity of PFOA in laboratory animals was reported in 2004 (Kennedy et al. 2004; Lau et al. 2004) and updated subsequently (Abbott 2015; Andersen et al. 2008; Lau 2012; Lau et al. 2007). Despite the wealth of data available, ATSDR chose mouse developmental studies reported by Onishchenko et al. (2011) and Koskela et al. (2016) as reference studies for its derivation of PFOA MRL (based on altered activity and skeletal alterations seen in offspring in mice).

   ATSDR's assessments on these studies (and the corresponding reported critical effects) failed to make clear to the public that the proposed MRL did not reflect the absence of an association between PFOA exposure and musculoskeletal outcomes or neurological outcomes in humans (cf. pages 141 – 145; pages 293-296). Furthermore, there are major technical concerns associated with these studies that preclude the results (from these studies) to be meaningful in any human risk assessment. They include:

   3. They are the same study. Albeit published five years apart, these two publications actually originated from one single study. From the same pregnant dams treated with dietary PFOA during gestation, the pups evaluated by Onishchenko et al. (2011) were litter-mates of the pups evaluated by Koskela et al. (2016). As such, it was really one study (in essence) and the corresponding outcomes (from both studies) should be consolidated when discussed.

   4. A single dose experiment cannot address (any) dose-response relationship. There was only one PFOA dose group used in these two studies and as such, it is impossible to interpret the experimental data reported by these authors in terms of any dose-response. Considering the inherent variations in biological responses in any animal study, the nature of a single-dose study simply does not allow any specific evaluation of any dose-and-effect responses or biological plausibility inference.

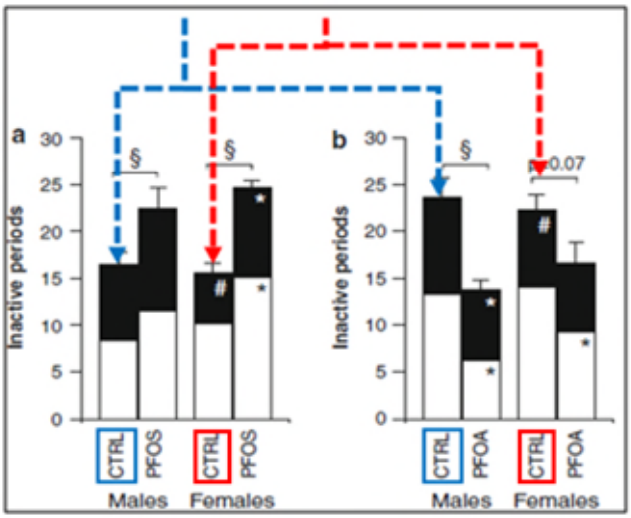
      Using a study that evaluated a single PFOA dose group was in absolute contradiction of what ATSDR stated in its MRL approach. On page A-6 of the draft profile, ATSDR explicitly stated that one of the MRL approach was to "*Identify laboratory animal studies that have evaluated dose-response relationship for toxicity targets identified in epidemiology studies*".

Hence for PFOA, not only did ATSDR not identify musculoskeletal or neurological outcomes as sensitive endpoints in humans; it did not select a laboratory animal study that appropriately addressed or evaluated dose-response relationship.

5. The study design was flawed and insufficient to support a NOAEL or LOAEL. Again, given that there was only PFOA dose group used, the study design did not follow the fundamental practice of toxicology testing such as evaluation of a dose-response relationship. Hence, given the lack of any dose-response, it is scientifically impossible to establish a realistic NOAEL and/or LOAEL for the data reported.

6. Limited sample size. There were only 6 dams that received PFOA diet to produce the pup cohort, and there was a total of 10 dams that received control diet; however, the control animals spanned from two (separate) blocks of individual experiments. The sample size for the study was quite small and given that only a single PFOA dose group was used, it is impossible to properly address biological plausibility (if any) and background variability.

   For example, regardless of sex, Onishchenko et al. (2011) reported a statistically significant difference between control and PFOA pups for the number of inactive periods (Figure 3b). However, on the accompanying graph (Figure 3a), they also reported a statistically significant difference between control and female pups from PFOS dose group for the number of inactive periods. Without looking at the treatment groups and just comparing the sex-matched control responses alone between Figure 3a and Figure 3b (see illustration below), it became very apparent the large variations exist even in the sex-matched control animals. This large variation (on the background control alone) most likely attributed to the statistical significance when compared to the treatment groups (either PFOS or PFOA).



Another similar example is on the body weight. The absence of statistical power to address inherent biological variations due to the limited study design did not allow for a valid comparison of biological responses between control and treatment. While Koskela et al. (2016) reported an increase in the body weight in the female pups from PFOA-treated group with statistical significance at 13 months and 17 months; however, the difference was already present at birth (as stated by the authors) hence the reported difference may well have reflected normal variation which cannot be adequately demonstrated as there were insufficient animals and litters.

7. Lack of reproduction (pregnancy) outcome information. Given the study design included the gestation and lactation periods, it was perplexing that very little information on the pregnancy or lactation outcomes were discussed by the authors (*e.g.,* gestation length, number of implantation, litter size, sex ratio, or lactation performance). All these are critical in evaluating the quality of the study.

8. Lack of litter outcome information. Given the study design included the developmental phase of pups, it was also perplexing as to why the authors did not disclose any detailed litter outcomes from dams received PFOA treatment (*e.g.,* survival, birth weight, anogenital distance, nipple retention, onset of number of implantation, gestation length, litter size, sex ratio, onset of sexual maturation…etc.) All these are critical in evaluating the quality of the study.

9. Questionable pup selection bias / litter bias. It was unclear as to how the pups were selected for the evaluations. To rule out litter-related effects, it is a standard practice for pups from the same litter to be evaluated as one single unit (rather than individual pups) in the assessment of reproductive and developmental outcomes in laboratory animals (OECD 2007, 2016). Given that there were only 6 dams that received PFOA treatment, therefore, the maximum number of pups from PFOA dose group should be 6 (*i.e.*, one pup per litter). Depending on the endpoints, the authors reported the data based on 6 – 10 pups, which would indicate that the pup selection was confounded by litter effect; and subsequently, the study findings were also confounded by litter effects.

10. Questionable dietary preparation. In the studies by Onishchenko et al. and Koskela et al., pregnant dams were administered with dietary PFOA throughout gestation for a total of 21 daily doses (as described by Koskela et al. 2016). According to the study authors, PFOA was dissolved in 95% ethanol first and then applied on food pellet. The pellets were kept on the bench for 2 hours (presumably at room temperature) to allow for ethanol evaporation prior to feeding them to the animals.

    This was a very crude method of preparing a dietary formulation – there were no information on the final PFOA concentration achieved in the diet and there was no information on the homogeneity distribution of PFOA in the diet. All these parameters were essential in contributing to a good dietary study and none of the information was available or explained by the study authors.

11. Possible residual ethanol present in the dietary PFOA chow. In addition to the crude dietary preparation method, the study authors assumed that the 95% ethanol used to dissolve PFOA would have been completely evaporated within 2 hours after sitting on the bench (presumably at room temperature), however, there were no supporting data to prove this. It is well-known that pure ethanol does evaporate faster than water on the basis of higher vapor pressure, lower boiling point, and less hydrogen bonds (Innocenzi et al. 2008). When ethanol is mixed with water, more hydrogen bonds are created; and when ethanol-in-water mixture is further mixed with PFOA as well as applied onto the surface of food chow (such as this study), the additional intramolecular forces (between ethanol and water, ethanol-in-water and PFOA, and, ethanol-in-water and PFOA and food chow ingredients) would have reduced the overall volatility of ethanol. The authors should have obtained a quantitative measurement of the PFOA/chow mixture to demonstrate the absence of ethanol after 2-hour evaporation.

    This verification step was critical for this study because the authors evaluated and reported neurobehavior endpoints as findings. Albeit the control animals also received food chow diet that had been applied with 95% ethanol followed by evaporation, however, the intramolecular force between ethanol, water and food chow (i.e., control food chow) would be different than the intramolecular force between ethanol, water, PFOA, and food chow (i.e., PFOA food chow). Given that ethanol is well-known for its effects on the central nervous system (Boschen and Klintsova 2017; Harrison et al. 2017) and 95% ethanol was used in the study, any ethanol that had not evaporated and remained on the food chow could have confounded the study results, especially on the neurobehavior parameters.

12. There were no serum PFOA data reported in these studies. ATSDR has determined that, rather than relying on external dose, serum PFOA concentration (internal dosimetry) is the appropriate exposure matrix when determining a point-of-departure (POD) for the MRL derivation with PFOA (*cf.* page A-16 and Table A-7 on page A-24 of the draft profile). Neither Onishchenko et al. (2011) or Koskela et al. (2016) reported any information on the serum PFOA concentrations; and this was a major deficiency of the study. Even though ATSDR "estimated" the time-weighted-average serum PFOA concentration based on its PBPK model, the absence of serum PFOA data preluded the verification of the ATSDR PBPK model, in addition to the other unknowns associated with the study (*i.e.*, no dose-response and no dose verification).

    It is also worth noting that the study authors had the technical capability to perform PFOA analysis because Onishchenko et al. (2011) reported PFOA concentrations in a subset of pup brain and liver samples.

13. Timing of behavior assessments in pups were not appropriate. In the study data reported by Onishchenko et al. (2011), numerous neurobehavior endpoints were evaluated by the study authors. Given that the study was done under non-GLP protocols and by a university research lab(s), most of the timings and behavior assessment procedures (as described by the study authors) did not appear to follow the conventional recommendations and methodology. As a result, it is difficult to determine the quality of

the data that had been reported. For instance, compared to the OECD 426 test guideline (TG) for developmental neurotoxicity study (OECD 2007), these authors did not follow standardized timeline recommended to FOB evaluations for the developing pups. The table below is a side-by-side comparison between the OECD 426 TG recommendation timeline vs. what Onishchenko et al. did. It was apparent that Onishchenko et al. had missed critical windows for the assessments on many key parameters (i.e., no behavior assessments were done prior to weaning) and there were no specific references or rationales to explain or justify their study design.

	OECD 426 TG Recommendation for developmental neurotoxicity study	Study by Onishchenko et al. 2011
Dosage	Control + 3 dose levels	Control + 1 dose level
Animal number	20 litters / group	6 litters / group
Detailed clinical observation	20 pups /sex (1 / sex/ litter)	6 – 10 pups / sex
Brain weight PND 11-22	10 pups / sex (1 / litter)	No data reported
Brain weight PND 70	10 pups / sex (1 / litter)	No data reported
Neuropathology PND 11-22	10 pups / sex (1 / litter)	No data reported
Neuropathology PND 70	10 pups / sex (1 / litter)	No data reported
Sexual maturation	20 pups /sex (1 / sex/ litter)	No data reported
Behavioral ontogeny (e.g., righting and reflex)	2X prior to weaning at PND 21	No data reported
Motor activity	1-3X prior to weaning at PND 21; 1X during PND 60-70	None prior to weaning; 1X during PND 35 – 56;
Motor and sensory function	1X during PND 23-27; 1X during PND 60-70	None prior to weaning; 1X during PND 90 - 120
Learning and memory (~ PND 23-27 and 60-70)	1X during PND 23-27; 1X during PND 60-70	None prior to weaning; 1X during PND 35 – 56;

14. Non-standard behavior assessment procedures used in pups. Among the behavior endpoints evaluated by Onishchenko et al., given that the study was done under non-GLP by university research lab(s) and it did appear that the tests were done on a single day without further repeat(s) later, it raised the question as to the overall reliability and reproducibility of the instruments and the corresponding data generated.

    For instance, to measure and record circadian activity in the home cage, the TrafficCage™ used by Onishchenko et al. is shown in the picture below (obtained from manufacturer's website). Compared to the conventional 3-D photo beam boxes where movements were recorded in vertical, horizontal, and lateral directions, the TrafficCage™ system lacks the ability to measure any vertical movements. In addition, the TrafficCage™ system has several "dead spots" without any sensors. The validity of the instrument and the corresponding results generated (circadian activity) are questionable.

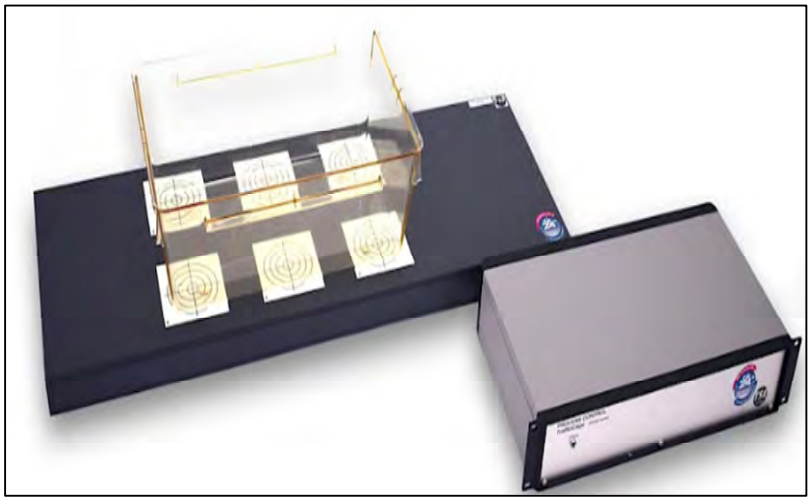


Illustration of TrafficCage™

(Source: https://www.tse-systems.com/product-details/phenoworld/trafficage?open=3806#trafficage-3806)

15. No information on background data for bone morphology and bone density. Koskela et al. (2016) reported that female offspring from PFOA-treated dams had increased femoral periosteal area and decreased mineral density of tibias, hence ATSDR concluded that "skeletal alterations in offspring" was a critical effect with PFOA exposure in mice.

    Bone morphology is a collective description on the shapes (geometry) of the bones, such as long bones (*e.g.,* femur and tibia), short bones (*e.g.*, bones of the feet and hands), or flat bones (*e.g.*, calvaria or breast bones). There are many factors contributing to the morphological sizes of the bones. The morphology of bone is not a "fixed" static structure, rather, it is a composite structure that will continue to evolve like other organs in the body. While the components of the bones are maintained in a balanced manner, there are also inherent biological variability within each component that needs to be taken into account when determining the overall homeostatic status of the bones (Boskey and Coleman 2010; Jepsen 2009).

    It is well-known that age and body weight are two factors in establishing the size, mass, and strength of the bones (Iwaniec and Turner 2016). In the data reported by Koskela et al., there was a pre-existing difference in body weight in female pups at birth where higher body weight was consistently observed in these female pups from PFOA-treated groups; and that difference reached statistical significance at 13 months and 17 months (*vide supra*). Therefore, it should not be a surprise that increased bone sizes in offspring with higher body weight (*e.g.*, offspring from PFOA-treated dams) had increased

periosteal and medullary areas in both femurs and tibias. On the other hand, given the small sample size of the animals used in this study, the inherent background variation cannot be ruled out. For example, compared to control, the study authors also reported a decrease in mineral density in tibias in offspring born from PFOA-treated dams. The extent of decrease was very minor (only 2.5%) and it was only observed in tibias, not in femurs. Because the study authors did not have any additional information on the background data with regards to these parameters, this minor difference may be well within the normal biological variations (again, especially with such small sample size).

16. Mechanical determinants of bone functions were not affected in pups from PFOA-treated dams. Based on study data reported by Koskela et al. (2016), ATSDR concluded that there were skeletal alterations in offspring from PFOA-treated dams and deemed it to be a critical health effect. However, in the same cohort of pups, Onishchenko et al. (2011) reported motor and sensory function assessments (muscle grip strength and rotarod test) and found no differences in the outcomes between control and PFOA-treated groups. Given that muscle force is a strong determinant of bone integrity, the slight morphological difference noted by ATSDR possibly reflected the normal background variations in this strain of mice and not likely due to PFOA.

17. Lack of supporting evidence on the effect of PFOA and bone development. If PFOA exposure does have a direct (causal) effect on the bone development, then one would expect such effect to be even more pronounced under longer (repeated) dose conditions. This was not the case, as long-term toxicology studies in rodents and non-human primates have not identified bone as a target tissue with exposure to PFOA (Biegel et al. 2001; Butenhoff et al. 2002; Butenhoff et al. 2012b).

18. Other technical comments about the study data by Koskela et al. (2016).

    - In addition to the likely litter-bias that has been discussed earlier, it is unclear why Koskela et al. only included female offspring in their evaluation but not male offspring.

    - PFOA has a high affinity to binding with serum albumins and given that bone marrow is the hemopoietic origin of blood, one should not be surprised to find trace level of PFOA in the bone. Albeit Koskela et al. claimed that bone marrow had been flushed out and only the hard bones were powdered and analyzed for PFOA content, it is important to recognize that the bone consists of "live" mesenchymal cells with lots of protein components (chondrocytes, osteoblasts, and osteocytes), not just marrow (Boskey and Coleman 2010; Iwaniec and Turner 2016; Jepsen 2009).

    - The study authors only evaluated long bone morphology but not others. If bone is indeed a target tissue with exposures to PFOA, other bones (in addition to femur and tibia) also need to be included in the evaluation.

- It is well-known that there are large inter-species differences in bone composition, density, quality, as well as genetic variability within the same species (Aerssens et al. 1998). Again, if bone is indeed a target tissue with exposures to PFOA, such cause-and-effect needs to be demonstrated in a dose-response fashion within the same animal model as well as other species.

- Other factors that can affect bone morphology and density should also be comprehensively evaluated before drawing a conclusion. For example, endocrine effects such as estrogen and IGF-1, essential nutrient status such as calcium and vitamin D3.

- The use of imaging devices in the assessment of bone morphology is not a new concept, and CT images have been used in both clinical settings as well as research settings. However, similar to the comments provided above on the behavior assessments provided above, Koskela et al. should have demonstrated that the validity of the micro-CT scanning technique used in their facility as well as their competency in using the instrument. Given the fact that a very small magnitude of surface area was being reported as a "statistically significant" change (in the range of 0.2 – 0.3 mm^2), it is important to validate the sources of these measurements. For example, was the instrument calibrated? Were the operator(s) trained in using the equipment? Were the acquired images analyzed by qualified radiologists who are trained in doing image interpretation?

- For any imaging-based scanning, it is absolutely critical that the object (or subject) remained steady for the duration of the scanning acquisition. Any movement during the scanning process will deviate the result. The study authors described that the bone was "*wrapped in a PBS-moistened tissue paper and inserted into a plastic tube, with the proximal end pointing upwards. The container was then placed into the chamber of the microCT device*". The description did not address attempts to prevent any movement of the bone (inside the plastic tube) during the scanning process. Given the asymmetrical shape of femurs and tibias, it is important to immobilize the bone inside the tube and any slight shift will artificially affect the image data during scanning.

Overall, the studies by Onishchenko et al. (2011) and Koskela et al. (2016) lacked scientific rigors to properly address the selected developmental endpoints and they should not be used for any human risk assessment.

B. <u>The critical effects cited by ATSDR for PFOA MRL derivation (altered activity and skeletal alterations in offspring in mice) were not supported by available animal data and contradicted ATSDR's own evaluation of epidemiological data.</u> There is insufficient evidence for an association between PFOA exposure and musculoskeletal outcomes or neurological outcomes in humans (cf. pages 141 – 145; pages 293-296). ATSDR should offer a plausible explanation as to why it believes these effects are relevant to human risk assessment.

C. PFOA does not affect the reproductive system in laboratory animals. It is incorrect for ATSDR to conclude that the reproductive system is one of the primary targets of toxicity with exposure to PFOA (cf. page A-16).

On the contrary, PFOA did not affect the functional aspects of male or female reproduction in laboratory animals. These included estrous cycles, sperm parameters, mating index, fertility index, and reproductive organ morphology. A number of studies on the reproductive and developmental effects of PFOA in laboratory animals have been published (Abbott et al. 2007; Albrecht et al. 2013; Butenhoff et al. 2004; Gortner 1981, 1982; Lau et al. 2006; Staples et al. 1984; Yahia et al. 2010). Many of these studies included detailed information on the reproductive and developmental toxicity with these compounds across different PFOA dose levels as well as valuable insights on the role of maternal effects and its attribution to the developmental outcomes in laboratory animals.

The potential of PFOA to influence reproductive performance has been evaluated in mice, rats, and rabbits. Gestational exposure to ammonium PFOA did not affect the number of uterine implantation sites in various strains of mice such as CD-1, Sv129, PPARα knockout, and humanized PPARα (Abbott et al. 2007; Albrecht et al. 2013; Lau et al. 2006; White et al. 2007). At inhalation dose up to 25 mg/m^3/day of ammonium PFOA or oral doses up to 100 mg/kg/day given during gestation to rats did not affect mating, pregnancy, and implantation (Staples et al. 1984). Oral administration of ammonium PFOA up to 150 mg/kg/day in rats or 50 mg/kg/day in rabbits during GD 6 – 15 (period of organogenesis) also caused reduced body-weight gain, however, they did not affect the ovaries or the reproductive contents of the dams (Gortner 1981, 1982). In a two-generation reproduction/developmental study in rats (Butenhoff et al. 2004), the reproductive outcome was not affected with daily oral ammonium PFOA administrations up to 30 mg/kg/day (the highest dose used in the study). There were no effects on the mating or fertility indices in either male or female rats. Male rats had normal sperm parameters (count, motility, morphology) and female rats had regular estrous cycling with normal gestation lengths, and microscopic examination did not reveal any abnormalities in sex organs. Furthermore, effects of PFOA on reproductive organ morphologies in male non-human primates were evaluated from a six-month oral study and results indicated no abnormalities (Butenhoff et al. 2002).

D. The developmental effects reported in laboratory animals for PFOA were primarily mediated by maternal effects. While ATSDR concluded that developing organisms are primary targets of toxicity with exposure to PFOA (cf. page A-16), there are strong experimental evidences demonstrating that developmental effects associated with PFOA exposures in offspring are observed only where there were significant effects in the maternal animals. Because neither Onishchenko et al. (2011) nor Koskela et al. (2016) reported detailed maternal-related endpoints with regards to reproduction, no maternal influence discussion is possible. However, observations involving maternal effects in the outcome of the developmental toxicity, as seen in the disruption of maternal homeostasis, include the following examples:

Using the mouse developmental study data reported by Lau et al. (2006), which was the critical study chosen by U.S. EPA Office of Water for the derivation of the Lifetime Water

Health Advisory for PFOA issued in 2016, there were statistically significant ($p \leq 0.05$), dose-related increases in maternal liver weight observed at doses 1 mg/kg/day ammonium PFOA or higher (the corresponding serum PFOA concentration was 21,900 ng/mL at the end of gestation). Various developmental effects were reported (*e.g.,* decreased postnatal survival, decreased body weight at birth and body-weight gain thereafter, and delays in eye openings) and they were only for litters from dams receiving 3 mg/kg/day or higher. Maternal responses clearly were present at doses that affected the fetus/neonate. In addition, because the influence of body weight on sexual maturation is well-described in the literature, it is not surprising that Lau et al. noted altered pubertal maturations in the offspring.

The developmental toxicity of ammonium PFOA has also been studied in rats (Butenhoff et al. 2004; Gortner 1981; Staples et al. 1984) and rabbits (Gortner 1982). In these studies, no increase in malformations relative to controls was observed at oral doses up 150 mg/kg/day in rats and 50 mg/kg/day in rabbits, as well as inhalation concentrations up to 25 mg/m^3/day (6 hours/day). In the studies by Gortner and by Staples et al., any effects on fetal or pup body weight were present at dose levels equivalent to or higher than those causing effects such as body weight in the maternal animals. In a two-generation reproduction and developmental study in rats (Butenhoff et al. 2004), F1-generation pups from the highest dose group (30 mg/kg) had decreased birth weight and reduced viability that were in apparent relationship to the corresponding reduced body weight at birth and weaning. These latter effects are similar to those observed in mice by others (Abbott et al. 2007; Lau et al. 2006; Yahia et al. 2010). Even though similar to the observation by Lau et al. (2006) in that sexual maturation were slightly delayed (at the highest dose group only), there was no significant difference in F1 pups when days to sexual maturation was adjusted by (reduced) body weight.

Based on data from the large scale 2-generation reproductive and developmental studies (which are considered as the most comprehensive test by various agencies for evaluating endocrine functions), PFOA clearly did not alter the reproductive functions as the reproductive performances in both males and females were normal (*vide supra*). In addition, there is sufficient evidence in experimental animals (mammals) to suggest that rodents may not be the best model in evaluating the reproductive-related outcomes for human risk assessment. PFOA is a known activator for xenosensor nuclear receptors such as PPARα, constitutive androstane receptor (CAR), and pregnane X receptor (PXR) (Corton et al. 2014; Elcombe et al. 2010; Elcombe et al. 2014; Klaunig et al. 2003; Klaunig et al. 2012). It is well documented that PFOA causes hepatomegaly in rodents as a result of PPARα activation with some contribution from CAR and PXR. It is well-known that human liver is less responsive to the pleiotrophic effects of activation of PPARα or CAR (Gonzalez and Shah 2008; Klaunig et al. 2003; Klaunig et al. 2012; Lake 2009; Ross et al. 2010). Thus, with respect to PPARα and CAR-mediated effects in the liver and related metabolism, the human response is either attenuated or absent as compared to that of the rodents.

Mechanistic studies have demonstrated that many of the observed effects upon PFOA exposure, including those observed in developing mice, can be explained, in part, by the activation of PPARα. Many of the developmental effects were either absent or attenuated

when PFOA was administrated to PPARα knockout mouse. The influence of PPARα on the fetal developmental effects of PFOA in the Sv/129 mouse strain (wild-type vs. PPARα knockout) was investigated by Abbott et al. (2007) and Albrecht et al. (2013). While it is not possible to rule out completely the contribution of other modes of action(s), many of the developmental effects with PFOA described above were attenuated and/or improved with PPARα knockout mice such as post-natal survival and body weight effects. Given that rodents are more responsive and susceptible than humans to PPARα-mediated biological effects (*vide supra*) and PPARα may not play a critical role in normal development (Braissant et al. 1996; Lee et al. 1995), it calls into question the relevance of nuclear receptor-mediated effects in rodents and their biological significance to humans. Therefore, the developmental effects reported in the laboratory animals for PFOA were primarily mediated by maternal effects and based on the recent mode of action data, rodents may not be the most appropriate species for the hazard assessment of PFOA on developmental toxicity in humans.

E. Liver findings in rodents are not relevant for human risk assessment. While it is commonly acknowledged that liver is a primary target organ with exposure to PFOA, it is important to recognize that the liver effects observed in laboratory animals were adaptive in nature and there was no conclusive evidence to support that liver findings observed in laboratory animals with exposure to PFOA are relevant for human risk assessment. Given the known knowledge on the nuclear receptor activation and species relevance discussed earlier (*vide supra*), liver findings cited by ATSDR should not be deemed relevant for human risk assessment. For instance, in the study by Butenhoff et al. (2004), increased liver weights were reported in male rats of both the P and F1 generations at all dose levels.

The corresponding increases in liver weight in laboratory animals with exposure to perfluoroalkyls reflected the adaptive nature of liver, which is a natural phenomenon due to cytochrome P450 enzyme inductions in the liver. Given that PFOA is a known activator for several xenosensor nuclear receptors (as discussed above), microscopic changes in the liver of some PFOA-treated male rats such as hepatocellular hypertrophy and focal to multifocal necrosis were consistent with activation of these receptors and as discussed earlier, it is well-known that human liver is less responsive than rodents to the pleiotrophic effects of activation of these receptors (Gonzalez and Shah 2008; Klaunig et al. 2003; Klaunig et al. 2012; Lake 2009; Ross et al. 2010). Thus, with respect to PPARα and CAR-mediated effects in the liver and related metabolism, the human response is either attenuated or absent as compared to that of the rodents. Another federal agency, USEPA (in its assessments of PFOA in 2009 and again in 2016), as well as other international regulatory authorities such as European Chemical Agency Risk Assessment Committee (2015), European Food and Safety Authority (2018), and Australian Expert Health Panel (2018) also considered the liver weight findings in laboratory animal studies with PFOA (or other perfluoroalkyls) to be irrelevant for human risk assessments.

It should be noted that, acetylsalicylic acid (commonly known as aspirin) and alcohol can also elicit increased liver weight in laboratory animals similar to the observations reported with perfluoroalkyls in rodents (EMEA 1999b).

F. Mammary gland development findings in mice are inconsistent: Despite that the availability of several studies that have investigated the potential effects of PFOA on the developing mammary glands in mice as a consequence of exposure during either the *in utero* or postnatal/peripubertal (Albrecht et al. 2013, Tucker et al. 2014, White et al. 2007, White et al. 2009, White et al. 2011, Yang et al. 2009, Zhao et al. 2010), ATSDR is correct that this endpoint *cannot be consistently* described and quantified in mouse models. Given that 1) to date, there is no standardized method or guideline of evaluating rodent mammary gland; and 2) there is a lack of concordance among all the available data on mammary gland development in mice as well as an absence of such findings in human epidemiological studies calls for question on the biological significance of this phenotype and its relevance to human health. This conclusion is consistent with the assessments from another federal agency, USEPA (in its assessments of PFOA in 2009 and again in 2016), as well as other international regulatory authorities such as European Chemical Agency Risk Assessment Committee (ECHA 2015), European Food and Safety Authority (EFSA 2018), and Australian PFAS Expert Health Panel (2018).

It should be noted that there are three epidemiologic studies that have examined the potential association between maternal PFAS exposure and shorter duration of breastfeeding or greater risk of stopping breastfeeding (Fei et al. 2010b; Romano et al. 2016; Timmermann et al. 2016). Fei et al (2010) measured PFOA and PFOS concentrations of 1400 women during early pregnancy. Self-reported data on the duration of breastfeeding (any and exclusive) were collected around 6 and 18 months after birth. While the study reported significant associations between PFOA concentrations and shorter duration of breastfeeding (before 3 and 6 months) among multiparous women, no significant associations were observed among primiparous women. The authors note that multiparous women who breastfed during prior pregnancies or breastfed longer may have had lower serum PFOA levels through excretion via breast milk. Consequently, reverse causation could not be excluded. The second study (Romana et al. 2016), observed a significant association between PFOA exposure and ending "any" breastfeeding by 3 and 6 months; however, no association was observed between PFOA exposure and ending "exclusive" breastfeeding by 3 and 6 months. More importantly, when stratified by parity, associations between PFOA and ending "any" breastfeeding at 3 and 6 months were largely attenuated for nulliparous women. Like Fei et al (2010), the significant associations observed among multiparous women were likely attributed to reverse causation. The third study (Timmerman et al. 2016), examined the potential association between PFOA exposure and duration of breastfeeding (both total and exclusive) among 1092 Faroese women with general population PFOA levels (median = 2.40 ng/mL). The authors reported that a doubling of maternal serum PFOA was significantly associated with a reduction in exclusive breastfeeding of 0.5 months. This association was observed among both primiparous and multiparous women (excluding the role of reverse causation). One important limitation of this study, worth noting, is that self-reported breastfeeding duration was collected 5 years after birth and was likely prone to misclassification error.

Finally, it is important to recognize that reduced breastfeeding duration in humans is not equivalent to "delayed mammary gland development" in rodents. In humans, numerous factors can influence breastfeeding duration other than diminished milk production (e.g., lack of prenatal education, inadequate lactation support from healthcare providers after delivery, medications incompatible with breastfeeding, lack of spousal/family support, short maternity leave, sore nipples/breasts, infant intolerance to breast milk, and individual choice). These factors were not considered in the epidemiology studies, and may have influenced the observed associations.

G. Immune findings in rodents are not consistent; and they lack concordance with epidemiological observation data. With exposure to PFOA, ATSDR also concluded that immunotoxicity is a primary target of toxicity based on decreased antigen-specific antibody responses in mice reported by DeWitt et al. (DeWitt et al. 2008; DeWitt et al. 2016) where PFOA suppressed T cell-dependent IgM antibody response (TDAR) but not the secondary IgG response. While ATSDR concluded that such findings were consistent with human epidemiology studies with regards to vaccine responses (see epidemiology discussion below), it is important to recognize that the humoral immune response to vaccinations, as measured in the human epidemiology studies, is mainly a secondary IgG memory response.

While suppression of the IgM response by PFOA was demonstrated in several studies where administered doses also induced signs of overt toxicity (i.e., reductions in body and lymphoid organ weight), the levels of IgG were not suppressed (either unchanged or enhanced). It is difficult to interpret why the primary IgM response was suppressed in mice by PFOA and yet the secondary IgG response was either not affected or enhanced. Collectively, human and animal bodies of evidence for antibody response are divergent. Mouse studies showed suppression of the IgM response with no impairment of the secondary antigen specific IgG response, which is in contrast to the epidemiological associations which suggested suppression by PFOA of IgG-mediated antibody titers to vaccinations in some studies for certain vaccines. Therefore, the weight of evidence and the lack of concordance between animal and human epidemiological data do not support the claim that PFOA induces immunotoxicity or caused decreased antibody response to certain vaccines. Finally, as noted above, the fact that the epidemiological data does not reveal a consistent association between exposure and response across all vaccines is further evidence that the animal and human data are not consistent.

Contrary to what ATSDR stated "the potential immunotoxicity of PFOA has not been investigated in chronic-duration studies" (*cf.* page A-30), it should be noted that the primary immune organs were evaluated microscopically in rats after 2 years of dietary treatment containing ammonium PFOA (Butenhoff et al. 2012c). In this study, representative primary immune organs were collected (mesenteric lymph node, spinal cord, bone marrow, and spleen) and evaluated microscopically by a board-certified veterinary pathologist at the end of a 2-year period. There were no neoplastic or non-neoplastic lesions observed in these immune organs. This is important because it demonstrated the absence of a direct effect on primary immune organs with chronic PFOA exposures in the rats. In addition, PFOA-treated

rats had similar or higher percent survival compared to controls, which is contrary to chronic immunosuppression-mediated toxicity such as cyclosporin (a known immunosuppressant) that ultimately resulted in increased mortality in rats (Ryffel and Mihatsch 1986).

H. A study with one dose group is not adequate in estimating point-of-departure. ATSDR selected two mouse studies with developmental endpoints (Onishchenko et al 2011 and Koskela et al 2016) for the point-of-departure (POD) to derive the MRL value for PFOA (endpoints were altered activity and skeletal alterations in offspring of C57Bl/6 mice). These studies tested only a control group and one dose of 0.3 mg/kg, which was chosen as the LOAEL. As only one dose was tested, a dose-relationship cannot be evaluated. Selection of studies with no information on dose-response for effects is not acceptable to establish a point-of-departure. ATSDR should follow its own guidance (as stated in pages A-6).

I. Serum PFOA concentrations in pups should be considered for POD instead of dams because critical effects chosen by ATSDR were based on (developing) pups. The studies chosen by ATSDR examined developmental endpoints that were measured in offspring, which are used as the basis for the MRL. In order to estimate steady-state plasma concentrations of PFOA, ATSDR used the Wambaugh model for PFOA that is parameterized for adult animals and cannot be used to predict concentrations in fetuses or pups. This model also does not account for life stage differences in physiology or pharmacokinetics, and can potentially over-predict as well as under-predict the area-under-the-curve (AUC). In addition, AUC and steady-state concentration are probably different in the offspring than in the dam. Overall internal exposure (as estimated by calculation of the AUC) may change with growth, and there could be a period of peak exposure. Use of the Wambaugh model (and thus use of the maternal plasma concentration as a surrogate for the offspring) introduces uncertainty in the MRL derivation as the offspring plasma concentration may be different that than of the maternal animals. Use of a physiologically-based model that incorporates fetal and pup compartments would provide an estimate of fetal and pup internal exposure (rather than use of the maternal concentration as a surrogate), which would reduce the uncertainty in the MRL value.

J. HED cannot be reliably estimated in the absence of serum concentration data. As discussed above, studies by Onishchenko et al. (2011) and Koskela et al. (2016) did not have any analytical verification on either the dietary PFOA level or the resulting serum PFOA concentrations in the mice. With the questionable reliability of the study design as well as the data gathered, there were a great number of inherent uncertainties associated with attempting to predict the mean serum concentrations using modeling approach.

Appendix II:
3M's written comments to New Jersey Department of Environmental Protection (NJDEP) on its proposed PFOS MCL, May 2019

(NOTE: these comments were excerpted for only PFOS BMD modeling)

3M's DETAIL COMMENTS ON THE PROPOSED PFOS MCL

There is a Serious Technical Error with DWQI's BMD Modeling for PFOS with Dong et al. (2009) data:

The DWQI states that "The first step in dose-response analysis is identification of a Point of Departure (POD), which is the dose within or close to the dose range used in the study from which extrapolation begins." DWQI also recognized that "if a Benchmark Dose can be developed, it is **preferred** for use as the POD." Additionally, DWQI recognized that "Benchmark dose modeling is identified by the USEPA as **the preferred** approach for dose-response modeling when the available data are sufficient to support it."

DWQI reported that it was unsuccessful in its attempts to compute a BMD or BMDL based on the PFOS-included plaque forming cell response (PFCR) reported by Dong et al. (2009). As a result, it subsequently used the serum NOAEL of 674 ng/mL from the study as the POD for its MCL derivation.

3M's review of DWQI's BMD modeling discovered a major technical error in DWQI's BMD modeling (see details below). If corrected, an acceptable serum PFOS BMDL can be derived; specifically, a $BMDL_{1SD}$ of 3,400 ng/mL.

As NJDEP has recognized, a BMD and/or BMDL is the recommended and "preferred" approach for deriving a POD value. Accordingly, NJDEP should adopt the serum $BMDL_{1SD}$ and revise its POD value for PFOS. Because the serum $BMDL_{1SD}$ (3,400 ng/mL) is five times higher than the serum NOAEL (674 ng/mL), the PFOS MCL should be raised by a factor of five to 0.065 µg/L (0.013 µg/L x 5 = 0.065 µg/L).

a. <u>DWQI erroneously used standard error and not the required standard deviation in its BMD modeling.</u>

Doses, number of animals, mean responses, and standard deviation are required to model summarized continuous response data using USEPA's Benchmark Dose Software (BMDS). According to DWQI's BMD modeling results for Dong et. al. (2009) PFCR data (*cf*. pages 236, 891 – 972, Appendix A - Health-Based Maximum Contaminant Level Support Document Perfluorooctane Sulfonate (PFOS)), the values in the standard deviation column are instead the standard error of mean values (SEM) provided by the study authors. This was a major modeling mistake by the DWQI. DWQI should have converted standard error to standard deviation by multiplying the standard error values by $\sqrt{N}$ ($\sqrt{10} \approx 3.16$). Therefore, its conclusion that the BMD modeling of the Dong et al. (2009) data did not give an acceptable fit to the data was based on faulty information.

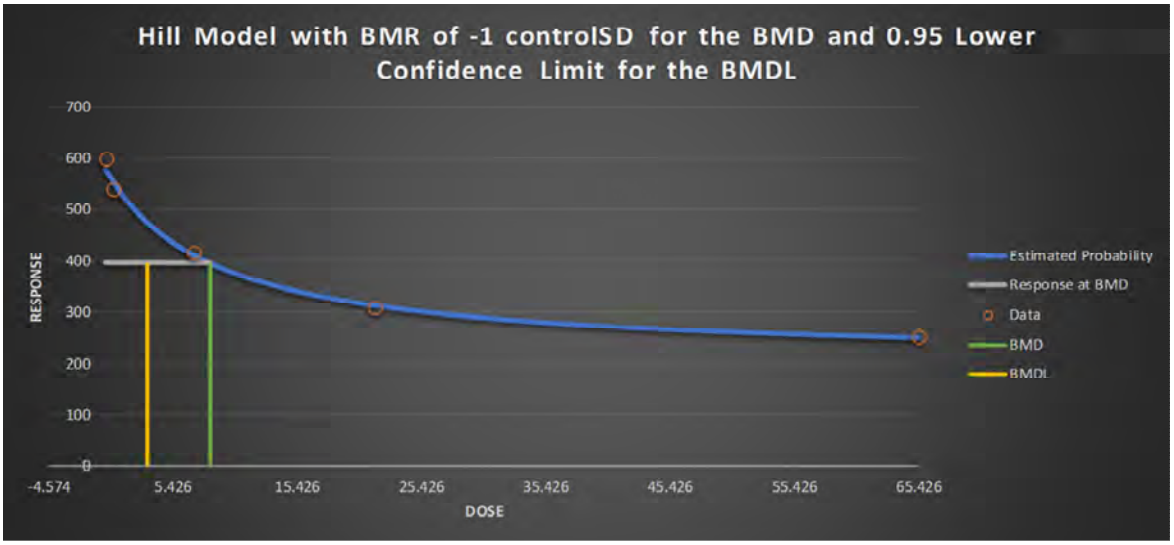
b. <u>$BMDL_{1SD}$ 3,400 ng/mL should be the POD for Dong et al. (2009) PFCR data</u>

The "correct" standard deviation can be derived by taking SEM x $\sqrt{10}$. With this corrected value, the dataset from Dong et. al. (2009) was modeled using USEPA Benchmark Dose Software (BMDS) version 3.1., a lowest $BMDL_{1SD}$ (3,400 ng/mL serum PFOS) and lowest AIC and was deemed to be the "best" fit for the dataset. Specifically, the serum PFOS concentration vs. PFCR response dataset (minus the high dose group) was modeled using Exponential, Hill, Linear, Polynomial, and Power models, both with and without parameter

restrictions. All models were run using 3 user-defined options sets which assumed 1.) responses are normally distributed and variance is constant across dose groups; 2.) responses are log-normally distributed and variance is constant across dose groups; and 3.) responses are normally distributed and variance is non-constant (i.e. varies as a power function of the mean response. For all model runs, the benchmark response (BMR) was set to one control standard deviation and a BMDL equal to the 95% lower confidence limit on the BMD was calculated. Model viability was assessed on the basis of goodness-of-fit P-value, AIC, and visual inspection of graphs in accordance with BMDS technical guidance. The restricted Hill model assuming normally-distributed responses and non-constant variance had the lowest BMDL (3,400 ng/L serum PFOS) and lowest AIC and was deemed to be the "best" fit for the dataset (see Table 3).

Table 3: Benchmark Dose analysis (V3.1) for a 1 control standard deviation change in plaque forming cell response from PFOS administration in mice (Dong et al. 2009) – excluding highest dose group

Model	Serum PFOS (µg/mL)			Test 4 P-Value	AIC	BMDS Recommendation	
	BMD	BMDL	BMDU			Viable?	Notes
Exponential 4 (NCV)	10.03	5.10	24.02	0.74	626.74	Viable - Alternate	
Exponential 5 (NCV)	9.98	5.09	24.02	0.74	626.74	Viable - Alternate	
Hill (NCV)	***8.43***	***3.40***	***25.59***	***0.78***	***626.65***	***Viable - Recommended***	***Lowest AIC***



c. DWQI's rationale for concluding that the Dong et al. (2009) PFCR data is not amenable to benchmark dose modeling was incorrect.

DWQI performed benchmark dose modeling after excluding the high dose group which yielded 4 models with acceptable fits to the dataset:

- Restricted Hill Model, constant variance
- Restricted Hill Model, non-constant variance

- Unrestricted Hill Model, constant variance
- Restricted Hill Model, non-constant variance

The models that assumed constant variance were rejected because the constant variance test failed (Test 2 P-value was < 0.05), and we agree that the BMDLs calculated for these models should be used with caution. However, the version of BMDS that DWQI used (ver. 2.6.0.1) was unable to calculate BMDLs for non-constant variance Hill models. This software-based limitation has since been resolved in the more recent release of BMDS version 3.1. In fact, when we repeated DWQI's analysis (dropping the top dose and incorrectly entering standard error into the standard deviation column) using the most up-to-date version of the software, there were 3 viable models with calculated BMDLs obtained under the assumption of non-constant variance: Restricted Exponential 4, Restricted Exponential 5, and Restricted Hill.

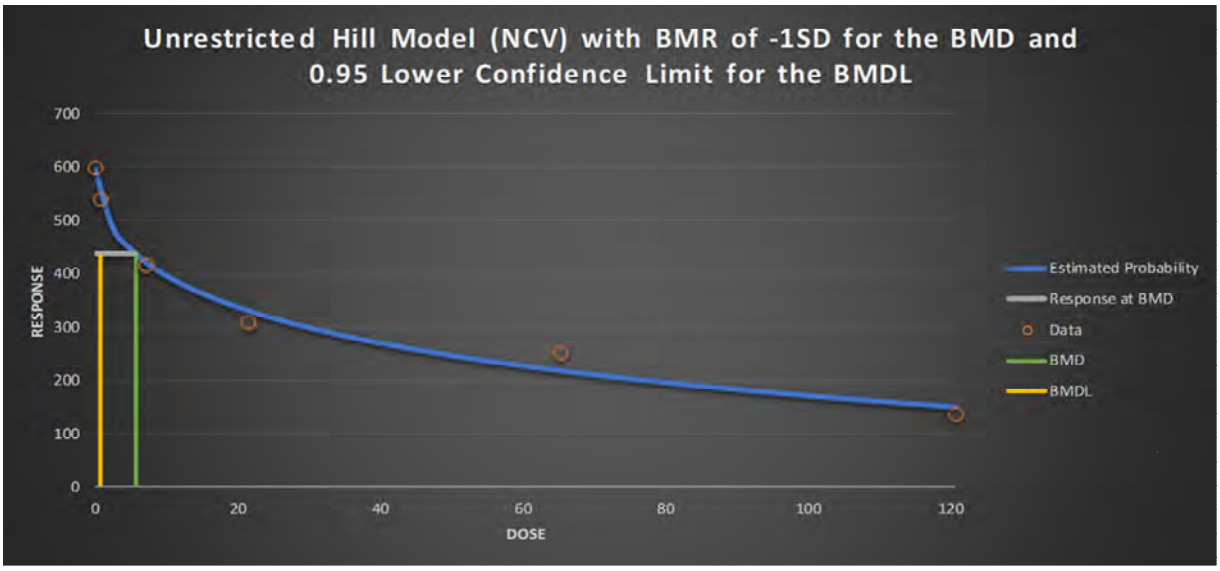
d. It should be noted that even if the highest dose group is included in the BMD modeling with the more recent release of BMDS version 3.1, there are no viable models that can be attained with the full dataset.
The complete dataset would yield 3 potential models for BMDL consideration (Table 4):

- Unrestricted Hill Model, non-constant variance
- Unrestricted Polynomial, Degree 4 Model, non-constant variance
- Unrestricted Polynomial Degree 3 Model, non-constant variance

Table 4: Benchmark Dose analysis for a 1 control standard deviation change in plaque forming cell response from PFOS in mice (Dong et al. 2009) – all dataset

Model	Restriction	Serum PFOS (µg/mL)			Test 4 P-Value	AIC	BMDS Recommendation	
		BMD	BMDL	BMDU			Viable?	Notes
Hill (NCV)	Unrestricted	5.6892	0.8301	22.0466	0.3025	736.7911	Viable - Recommended	Lowest BMDL WARNING: BMD/BMDL ratio > 5
Polynomial Degree 4 (NCV)	Unrestricted	11.9140	3.7914	13.3917	0.1881	738.8790	Viable - Alternate	Note: multiphasic curves
Polynomial Degree 3 (NCV)	Unrestricted	11.2946	7.8669	18.5970	0.4703	736.6554	Viable - Alternate	Note: multiphasic curves

However, in the unrestricted Hill Model, the ratio between BMD:BMDL > 5 reflects large uncertainty associated with the "true" shape of the dose-response curve in the low-dose region and caution should be used when selecting BMDLs from such models (Haber et. al., 2018).



The other 2 viable models (Poly 4 and Poly 3) have multiphasic curves with multiple inflection points which indicated non-monotonicity.

Taken together, these results suggest that all 3 unrestricted models should be excluded from consideration with BMDL selection which would mean no viable models were attained with the full dataset.

Appendix III:
3M's written comments to USEPA on its draft toxicity value for PFBS, January 2019

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Docket HQ- OW-2018-0614
US Environmental Protection Agency
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Re: Request for Public Review and Comment: Draft Human Health Toxicity Assessment for Perfluorobutane Sulfonic Acid (PFBS) and Related Compound Potassium Perfluorobutane Sulfonate; Docket ID No. EPA-HQ-OW-2018-0614

To Whom It May Concern:

The 3M Company (3M) appreciates this opportunity to provide comments to the U.S. Environmental Protection Agency (EPA) regarding its Draft Human Health Toxicity Assessment for Perfluorobutane Sulfonic Acid (PFBS) and Related Compound Potassium Perfluorobutane Sulfonate. As a science-based company, 3M encourages EPA to use the best available science when assessing PFBS and other chemicals. As our comments reflect, 3M has substantial experience and expertise regarding PFBS, informed in part by the fact that 3M scientists are authors or contributors to many of the studies referenced by the EPA.

The following offers 3M's thoughts responsive to EPA's request for comments regarding PFBS. Please let us know if you have any questions.

Regards,

Oyebode A. Taiwo, MD, MPH

Executive Summary

The 3M Company (3M) appreciates the opportunity to review and comment on EPA's Draft Human Health Toxicity Values for Perfluorobutane Sulfonic Acid and Related Compound Potassium Perfluorobutane Sulfonate (Draft PFBS Document). As authors or a sponsor of many of the human epidemiology and toxicology studies discussed in the Draft PFBS Document, we offer these detailed comments to assist with EPA's effort.

3M Summary Comment No. 1 - PFBS Exposure to the General Population is Minimal

Ever since 2007-2008 including the 2013-2014 biomonitoring cycle, CDC National Health and Nutrition Examination Survey (NHANES) has determined that the 95th-percentile is at the limit of detection (0.1 ng/mL) for Perfluorobutane sulfonate (PFBS). This has led CDC NHANES to not include the measurement of PFBS in its latest biomonitoring cycle (2015 – 2016). The Draft PFBS Document cites the CDC NHANES findings through 2014, but omits the CDC NHANES decision not to include the measurement of PFBS in its latest biomonitoring cycle. This decision by CDC NHANES strongly suggests that the US general population has minimal exposure to PFBS based on CDC NHANES analytical methods. Therefore, EPA should have included this important point about the lack of human exposure based on NHANES data in the Draft PFBS Document.

3M Summary Comment No. 2 - The Data Does Not Support a PFBS Thyroid Effects Hazard

3M disagrees with EPA's conclusion that "evidence in animals for thyroid effects *supports a hazard."* Given the available data that have been evaluated, there is sufficient uncertainty to conclude that PFBS cannot be categorized as "supports a hazard" for thyroid effects.

Thyroid histology should be included in any determination of thyroid status in rodents when terminal sacrifice is part of the study protocol because "in the rodent, thyroid gland histopathology is a more sensitive indicator of thyroid status than T3 or T4 serum hormone values." (see NTP-sponsored Thyroid Toxicant Workshop on chemical-induced thyroid dysfunction in experimental animals and its relevance to humans on reproductive and developmental effects: Jahnke et al. 2004, Environ Health Perspect 112 363-368). The Draft PFBS Document does not explicitly recognize that thyroid histology is considered the "gold standard" for determining thyroid status; nor did it recognize that serum TSH is the primary diagnostic indicator for serum thyroid hormone status (Oppenheimer et al 1995 Mol Endo Bas Conc Clin Corr 249-268). Three of the five thyroid studies cited by the Draft PFBS Document assessed and reported thyroid histology. Thyroid histology was normal in each of these studies when performed. Two of the five thyroid studies cited by the Draft PFBS Document assessed and reported serum TSH values. Serum TSH values were normal without dose-response in each of these studies when performed.

The Draft PFBS Document also does not sufficiently recognize the sensitivity of the assays used to measure serum thyroid hormones to the presence of compounds that can interfere and compete with thyroxine for protein bindings. In such situations, this interference can negatively bias the free T4 results when conventional analog methods are used. This is in fact the case with PFBS and other PFAS such as perfluorobutanoate and perfluorooctane sulfonate

(Chang et al. 2007 Toxicology 234 21-33; Weiss et al. 2009 Toxicol Sci 109 206-216; Butenhoff et al. 2012 Reprod Toxicol 33 513-530). Therefore, the workaround is to measure free T4 by *equilibrium dialysis*-based methods. This was not done in the thyroid assessment studies relied upon by the Draft PFBS Document, nor did any of the peer reviewers or EPA mentioned this very important issue with PFBS. Furthermore, total T4 is an assay that represents primarily biologically inactive T4. Thus, the total T4 and the analog free T4 do not provide sufficient or definite answers as to thyroid effects. Because of the resulting questionable confidence in the analog assays, thyroid histology should be used as the gold standard to determine whether there was a thyroid effect. The thyroid histology was normal as reported in the NTP study, as well as in both 28-day (3M 2001) and 90-day studies (Lieder et al. 2009a). Although terminal sacrifices were done, no thyroid histology was reported by Feng et al. (2017).

Based on the criteria for overall evidence integration judgments to support a hazard based on animal data (Table 3, page 16 of the EPA Draft PFBS Document), the summarized information (see below, Table 1 and Table 2) from these five studies does not lead to a conclusion that the collective thyroid data "supports a hazard" for a thyroid effect.

Table 1

			3M 2001	**Lieder et al. 2009a; York 2003**	**Lieder et al. 2009b; York 2003**	**Feng et al. 2017**	**NTP, 2011; 2018**
			28-day	90-day	2-generation	Developmental screening	28-day
Thyroid weight			Normal	Not performed	Not performed	Not reported	Normal
Thyroid histology			Normal	Normal	Not performed	Not reported	Normal
Serum thyroid hormones	Biologically active	TSH	Not performed	Not performed	Not performed	Normal for F1 pups on PND1	Normal
		Free T4 by equilibrium dialysis (gold standard)	Not performed	Not performed	Not performed	Not performed	Not reported[a]
		Free T4 by analog	Not performed	Not performed	Not performed	Not performed	Reported (decreased with dose-response)
	Biologically inactive	Total T4 by analog	Not performed	Not performed	Not performed	Reported (decreased, but questionable dose-response)	Reported (decreased with dose-response)
Evidence of compromised thyroid morphology and compensatory feedback response (between TSH and free T4 by equilibrium dialysis)			No	No	No	No	No

[a] Highly unlikely done given analytical complexity

Table 2	
EPA's criteria for "supports a hazard" (Table 3 on Page 16 of the EPA Draft PFBS Document)	**3M's response**
The evidence for effects is consistent or largely consistent in at least one high- or medium-confidence experiment.[a] Although notable uncertainties across studies might remain, any inconsistent evidence or remaining uncertainties are insufficient to discount the cause for concern from the positive experiments. In the strongest scenarios, the set of experiments provide evidence supporting a causal association across independent laboratories or species. In other scenarios, including evidence for an effect in a single study, the experiment(s) demonstrate additional support for causality such as coherent effects across multiple related endpoints; an unusual magnitude of effect, rarity, age at onset, or severity; a strong dose-response relationship; and/or consistent observations across exposure scenarios (e.g., route, timing, or duration), sexes, or animal strains.	There was no evidence of compromised thyroid morphology and compensatory feedback response (measurement of TSH in conjunction with measurement of free T4 by equilibrium dialysis). It is a scientific weakness to offer any interpretation of the results from these studies given the known negative bias associated with PFAS in analog free T4 measurements. Thus, the lack of measurements of free T4 by equilibrium dialysis by these studies is more than just "notable uncertainties across (the) studies… insufficient to discount the cause for concern from the positive experiments" as so stated in the EPA Draft PFBS Document (see left). The gold standard for measuring thyroid effects is histological evaluation of the thyroid gland. Thyroid histology was normal when all such evaluations were reported. The above summarized information from these five studies does not lead to a conclusion that the collective thyroid data "supports a hazard" for thyroid effects.

3M Summary Comment No. 3 - Concerns with EPA's Model Selection for Thyroid Effects

In addition to 3M's concern that the five thyroid studies evaluated by EPA do not "support a hazard" for a thyroid effect, there are technical concerns with EPA's model selection process for thyroid effect. EPA considered model selection based on model fit (e.g., AIC) and model prediction (e.g., $BMDL_{20}$). 3M retained an independent modeling expert (Bruce Allen) to review EPA's model selection process for thyroid effect. Mr. Allen concluded that EPA should not have used model prediction as a measure for the evaluation of the model fit (see Mr. Allen's report attached in Appendix A). As Mr. Allen wrote in his comments, "The predictions are what get selected, not the basis for that selection process."

Provided below are four important findings from Mr. Allen's review on EPA's model selection process.

Finding 1 – EPA's Model Selection Approach was Inappropriate: On page F-4 the EPA wrote, "Among all models providing adequate fit, the BMDL from the model with the lowest Akaike's information criterion (AIC) was selected as a potential POD when BMDL values were sufficiently close (within threefold)." Mr. Allen clearly demonstrated (see page 2 of Appendix A) the error of this logic in that a model prediction (an estimate of BMD or BMDL) "has no bearing on how well the model(s) fit the data . . . Predictions are what get selected;

they are not the basis for that selection process." Of the models considered by EPA (see Table F-2, page F5, Draft PFBS Document), the EPA selected the Exp-M4. This is not the best fitted model from an AIC perspective. Nonetheless, EPA selected it because the BMDL response was 3-fold lower. According to Mr. Allen, using a prediction as a selection measure of model fit "makes no sense." He indicated that instead, the Exp-M2 model would be the better fitting model because of the lower AIC value. He further stated that the EPA would be better served by using a weighted average of the BMDLs from each model with weights for that average equal to exp(-AIC).

Finding 2 - The BMD_{1SD} Results Should Have Been Used to Determine Points of Departure (POD) Based on the T4 endpoint: Regardless of the model choice (see Finding 1), the EPA used a BMR of 20% relative deviation (i.e., dose that results in a 20% reduction of mean T4) to derive a $BMDL_{20}$ value. The selection of a $BMDL_{20}$ value using continuous data is inconsistent with EPA's past practices with many other compounds. More importantly, it is especially inconsistent with the use of a POD based on a $BMDL_{10}$ from the dichotomous data modeled by EPA from the Lieder et al. study related to papillary tubular/ductal epithelium hyperplasia in female rats. The latter POD is based on an extra risk of 10%. The former is based on the magnitude of mean T4 change. Thus, according to Mr. Allen (see pages 3-4, Appendix A) the EPA should calculate the change in the mean T4 that will give the target 10% extra risk of low T4 in terms of the standard deviation (1.1*SD) if 1% of the unexposed population has a low T4 as was assumed by EPA in this particular analysis (see Crump et al. 1995, Risk Analysis 15:79-89). The BMD_{1SD} model better reflects this for continuous data by incorporating a conservative rounding down from 1.1SD to 1SD. Taking into account Findings 1 and 2, Mr. Allen suggests the EPA should have considered the POD (23.4 mg/kg-d) for a $BMDL_{1SD}$ from the Exp-M2 model (ignoring any model-averaging process).

Finding 3 - EPA Presents Only Weak Support for a $BMDL_{20}$ as a Biologically Based Benchmark Response Level. The EPA assessment relied primarily on 3 studies in support of the $BMDL_{20}$ estimates based on their written material (see page 55-56, Draft PFBS Document): a) a study with a 25% decrease in maternal T4 during second trimester; b) thyroid insufficiency in women below the 10^{th} percentile; and c) decreases in mean T4 of 10 – 17 percent that have elicited neurodevelopmental toxicity in rats. Using these examples, Mr. Allen concludes it is not possible to make consistent probabilistic statements without taking SD into consideration. Merely only examining relative deviations from the mean is not sufficient.

Finding 4 – A Better Alternative Analysis is Available: Mr. Allen suggested a better alternative analysis for EPA's consideration that involved a different dose-response model and a definition of the BMR using a SD approach. This involved the biological point discussed in Finding 3 (thyroid insufficiency in pregnant women defined as having T4 levels

below the 10th percentile for the study population). Assuming this background rate and specifying the BMD to be the dose that gives a 10% extra risk above the background (consistent with the analysis of a dichotomous endpoint), Crump (Risk Analysis 1995;15:79-89) indicated that the SD multiplier for the BMR should be approximately 0.4 (if the mean T4 changes by 0.4*SD, then the extra risk associated with that change will be 10%). Mr. Allen showed the results of different $BMD_{0.4SD}$ models in Appendix A. The Exp-M2 model provided the best model fit (AIC = -5.34, page 10 of Appendix A) for POD estimation. It had a $BMDL_{0.4SD}$ value of 8.3 mg/kg-d (page 11 in Appendix A). Using the same 10% extra risk above the background, Mr. Allen showed the Exp-M4 model had a higher AIC (-3.85) indicating not as good model fit with a $BMDL_{0.4SD}$ of 2.58 mg/kg/d (pages 10 – 11 in Appendix A). Although this prediction is more than 3-fold lower than that predicted with Mr. Allen's Exp-M2 model, again, as discussed in Finding 1, BMDL predictions should not be used as a basis for assessing model fit nor for performing model selection. (Note: The $BMDL_{0.4SD}$ value under Exp-M2 model is approximately twice the $BMDL_{20}$ value.)

3M Summary Comment No. 4 – If the Best Fit Model Proposed by Mr. Allen is Used, the Candidate Chronic RfD Based on Thyroid Effects Would be Higher Than That Proposed by EPA

As noted above, Mr. Allen evaluated the results of different $BMD_{0.4SD}$ models (Appendix A, pp. 8-11) and concluded that the Exp-M2 model provided the best model fit (AIC = -5.34) for POD estimation. It resulted in a $BMDL_{0.4SD}$ value of 8.3 mg/kg-d. Using this value as the POD for RfD calculation instead of 4.2 mg/kg-d used by EPA, while retaining the existing composite uncertainty factor (UFC) of 300 for the thyroid effect used by EPA, results in a candidate chronic RfD for PFBS of 0.03 mg/kg-d instead of the candidate chronic RfD of 0.01 mg/kg-day proposed by EPA.

Candidate Chronic RfD for K^+PFBS (Thyroid) = $BMDL_{0.4SD}$ (HED) ÷ UFC
= 8.3 mg/kg-day ÷ 300
= 0.028 mg/kg-day
= 3×10^{-2} mg/kg-day

3M Summary Comment No. 5 – Uncertainty Factors Used by EPA for Kidney Effects-based RfD Should be Reduced

The evidence of renal hyperplasia (based on the study by Lieder et al.) could support EPA's definition of a hazard, however, the EPA Draft PFBS Document is <u>incorrect</u> in its assessment of UF_S allocations. The Feng et al. (2017) study was deemed to be a developmental study by the Draft PFBS Document given that it was a gestation exposure study. The combined UF_D (10) x UF_S (1) allocated to the study by Feng et al. is 10, including the absence of chronic study exposure duration as part of the UF_D allocation.

Unlike the study by Feng et al., Lieder et al. (2009b) was a 2-generation study with direct K^+PFBS dosing regiments that spanned from pre-mating, mating, gestation, lactation, and post-weaning. It is scientifically unclear why the Lieder et al. study (2009b) was not considered a developmental study by the EPA. The combined UF_D (3) x UF_S (10) allocated to the study by

Lieder et al. is 30. The UF_S of 10 is "applied to account for less than chronic-duration exposure because the POD comes from a subchronic duration study."

EPA has allocated an additional factor of 3 for the study by Lieder et al. (2009b) that lacks support. At the very maximum, the combined UF_D x UF_S value should be 10 (or lower) for the Lieder et al. study; which should be the same as the combined UF_D x UF_S value of 10 used for the Feng et al. study.

3M Summary Comment No. 6 – 3M agrees with EPA Use of the Dichotomous-Hill Model

3M agrees with EPA that the Dichotomous-Hill model meets the criteria of the best-fit model for papillary tubular/ductal hyperplasia in P0 female rats. For this model, the $BMDL_{10}$ was 11.4888 mg/kg-day. This is also the expert opinion verbally expressed to 3M by Mr. Allen.

3M Summary Comment No. 7 – The Candidate Chronic RfD for PFBS Should be 0.04 mg/kg-d

Taking together 3M Summary Comments 6 and 7, using existing BMD_{10} value of 11.488 mg/kg-d and proposed composite UF of 300 for the renal hyperplasia, the proposed candidate chronic RfD for PFBS would then equal the following:

Candidate Chronic RfD for K^+PFBS (Kidney) = $BMDL_{10}$ (HED) ÷ UFC
= 11.5 mg/kg-day ÷ 300
= 0.038 mg/kg-day
= 4×10^{-2} mg/kg-day

This results in a candidate chronic RfD for PFBS of 0.04 mg/kg-d instead of the candidate chronic RfD of 0.01 mg/kg-day proposed by EPA.

3M Summary Comment No. 8 – EPA needs to inform the public why EPA selected the 2-generation study in rats (Lieder et al. 2009b) as the critical study rather than the 90-day study in rats (Lieder et al. 2009a) that the peer reviewers were charged to assess as to whether it (Lieder et al. 2009a) is scientifically justified and defensible to be the critical study.

By reviewing EPA's Response to Peer Review Comments on the Draft Human Toxicity Value for PFBS, it became apparent that EPA asked the peer reviewers to assess whether the 90-day study in rats by Lieder et al. (2009a) was scientifically justified and defensible to be the critical study. All the reviewers agreed with EPA's choice of using the 90-day study in rats by Lieder et al. (2009a) as one of the critical studies.

Yet in the current Draft PFBS Document, it selected the 2-generation study in rats (Lieder et al. 2009b) as the critical study rather than the 90-day study in rats (Lieder et al. 2009a) that the peer reviewers were charged to assess. Therefore, there is a discordance and ultimately a lack of explanation between the publicly released Draft PFBS Document and the draft document that was given to the peer reviewers. EPA needs to explain its rationale for making the switch between the two studies (Lieder et al., 2009a; 2009b) because the EPA peer review panel never provided their professional opinion on Lieder et al. 2009b and the uncertainty factors allocated for this particular study.

Detailed Comments

<u>Page ix of the EPA Draft PFBS Document:</u> "Of the examined outcomes, only asthma, serum cholesterol, and high-density lipoprotein levels were found to exhibit a statistically significant positive association with PFBS exposure."

<u>3M comments:</u>

This statement is inaccurate. No epidemiology study has reported a significant association between high-density lipoprotein (HDL) levels and PFBS exposure. The single "low-confidence" study (Zeng et al., 2015) cited by the EPA, reported a non-significant increase in HDL cholesterol (β = 5.78, 95% CI: -2.09-13.65) mg/dL increase per unit increase in PFBS. As such, the EPA should remove "high-density lipoprotein" from their statement.

Further, the EPA's statement could be misinterpreted that an association exists between these health outcomes and PFBS exposure in humans. The EPA clearly states in the Draft PFBS Document that the evidence in humans is "equivocal" for asthma (page 46; Table 7, page 53) and for lipid or lipoprotein homeostasis (Table 7, page 52). The EPA further states that "the association between asthma and PFBS exposure was observed in a single study with concern regarding the potential for residual confounding" (page 53) and that the association between total cholesterol and PFBS exposure was observed in a "low-confidence" cross-sectional study with "concern for potential reverse causality" (page 52). Accordingly, the EPA should clearly communicate that the overall evidence for an association between PFBS exposure and these health outcomes is equivocal in humans.

<u>Page x of the EPA Draft PFBS Document</u>: "The available rat and mouse studies support identification of thyroid, developmental, and kidney endpoints as potential health effects following repeated exposures in utero and/or during adulthood."

<u>3M comments:</u>

The EPA should revise this statement to be more specific for the following reasons:

- The available rat studies by 3M (28-day, 90-day, and 2-generation) did not identify thyroid as potential health effects with exposure to K^+PFBS (identified as 3M, 2001; Lieder et al. 2009a; Lieder et al. 2009b in the EPA Draft PFBS Document).
- The NTP 28-day rat study (identified as NTP 2018 in the EPA Draft PFBS Document) reported decreased total T4, total T3, and free T4 in serum at the end of 28 days dosing, however, these three endpoints <u>alone</u> did not provide adequate (clinical) evidence to suggest that thyroid was being affected (see 3M Summary Comment No. 2 above). Given that there were normal TSH levels (primary diagnostic indicator for thyroid hormone status) and normal thyroid histology in these same rats (where decreased serum total T4, total T3, and free T4 were reported as measured by analog method only), this suggested that overall

thyroid hormone status in these rats was normal. The following studies support this position:

  - PFBS at higher concentrations, similar to its eight-carbon congener PFOS, is likely capable of displacing T4 from binding proteins (Chang et al. 2007 Toxicology 234 21-33; Weiss et al. 2009 Toxicol Sci 109 206-216).
  - With increased hepatic hypertrophy reported in the rats from the NTP study (due to activation of peroxisome proliferation, reported by NTP as increased acetyl CoA activities), it also suggested that there was enhanced hepatic metabolism, which is commonly observed in rodents upon peroxisome proliferation (Corton et al. 2014 Crit Rev Toxicol 44 1-49). As a result, the increased hepatic metabolism would result in enhanced excretion of displaced thyroid hormones, which likely explain why there were alterations in total T4 and total T3.
  - Total T4 and total T3 measurements are measurements of largely (> 99.5%) inactive thyroid hormones and they alone do not represent functional aspects of the thyroid (Oppenheimer et al 1995 Mol Endo Bas Conc Clin Corr 249-268).
  - Although not specified, it is likely that NTP used an analog assay to measure free T4 and that binding displacement (by PFBS) likely contributed to a negative bias in the measurement (of free T4). The bias is commonly observed with compounds that can compete with thyroxine for protein binding and it can be avoided when an equilibrium dialysis-based free T4 method is used (Ekins 1983 Lancet 322 402-403).

- Like the NTP 28-day study, the mouse developmental study (identified as Feng et al. 2017 in the EPA Draft PFBS Document) reported decreased total T4, decreased total T3, and normal TSH in serum at birth for female pups. Again, total T4 and total T3 <u>alone</u> did not provide adequate (clinical) evidence to suggest that thyroid was being affected, especially when TSH, the primary diagnostic indicator for thyroid hormone status was normal. Feng et al. did not provide the following information to allow a full interpretation of thyroid status:
  - Albeit the pups were necropsied, no thyroid histology was reported.
  - There were no TRH mRNA or serum FT4 measured in offspring (these were done for dams).
- Study by Feng et al. (2017) did not identify kidney effects as potential health effect with exposure to K^+PFBS.

<u>Page 3 of the EPA Draft PFBS Document:</u> "PFBS has been reported in serum of humans in the general population. In American Red Cross samples collected in 2015, 8.4% had a quantifiable serum PFBS concentration; the majority of samples were below the lower limit of quantitation (.2 nanograms per milliliter [ng/mL]) (Olsen et al., 2017). The National Health and Nutrition Examination Survey (NHANES) 2013-2014 data reported the 95th percentile for PFBS at or below the level of detection (0.1 ng/mL)."

3M Comments:

Regarding the measurement of PFBS in American Red Cross adult blood donors (Olsen et al. 2017) and the National Health and Nutrition Examination Survey (NHANES), not only was PFBS not reported above the level of detection in the CDC NHANES 2013-2014 sampling analysis, the CDC NHANES has recently released preliminary data for their 2015-2016 environmental biomonitoring assessment that indicates they chose not to even analyze for PFBS in 2015-2016. See https://wwwn.cdc.gov/Nchs/Nhanes/2015-2016/PFAS_I.htm

Although CDC NHANES does not explicitly state this in the above website that they did not analyze for PFBS in 2015-2016, it is clear from reading this website that only the following PFASs (and their LLOD) were analyzed based on the 2015-2016 NHANES codebook. This table is copied from the above website. There is no mention of PFBS in the table below.

Table 3

(from https://wwwn.cdc.gov/Nchs/Nhanes/2015-2016/PFAS_I.htm)

The lower limit of detection (LLOD, in ng/mL) for each PFAS:

Variable Name	SAS Label	LLOD
LBXPFDE	Perfluorodecanoic acid (PFDeA) (ng/mL)	0.10
LBXPFHS	Perfluorohexane sulfonic acid (PFHxS) (ng/mL)	0.10
LBXMPAH	2-(N-methylperfluoroctanesulfonamido)acetic acid (Me-PFOSA-AcOH) (ng/mL)	0.10
LBXPFNA	Perfluorononanoic acid (PFNA) (ng/mL)	0.10
LBXPFUA	Perfluoroundecanoic acid (PFUA) (ng/mL)	0.10
LBXPFDO	Perfluorododecanoic acid (PFDoA) (ng/mL)	0.10
LBXNFOA	n-perfluorooctanoic acid (n-PFOA) (ng/mL)	0.10
LBXBFOA	Branch perfluorooctanoic acid isomers (Sb-PFOA) (ng/mL)	0.10
LBXNFOS	n-perfluorooctane sulfonic acid (n-PFOS) (ng/mL)	0.10
LBXMFOS	Perfluoromethylheptane sulfonic acid isomers (Sm-PFOS) (ng/mL)	0.10

Page 7, section 1.3.5.2 of the EPA Draft PFBS Document: "For rats receiving an oral dose, terminal serum K+PFBS elimination half-lives were significantly different ($p \leq 0.05$) for males (t1/2 = 4.68 ± 0.43 hours) versus females (t1/2 = 7.42 ± 0.79 hours). Thus, the half-life

estimates of Olsen et al. (2009) (4–7.5 hours) are roughly twice those estimated by Chengelis et al. (2009) based on urine data (2.4 and 3.1 hours)"

3M comments:

- $T_{1/2}$ values cited in the EPA Draft PFBS Document for Olsen et al. (2009) rat data were based on oral gavage dosing; while $T_{1/2}$ values cited in the Draft PFBS Document for Chengelis et al. (2009) rat data were based on IV dosing.
- For comparison purpose, Olsen et al. (2009) also derived a terminal half-life for rats after IV dosing, and they were 4.51 ± 2.22 and 3.96 ± 0.21 hours, respectively, in male and female rats.
- The difference could also be due to the fact that a non-compartmental model was used to calculate the kinetic parameters in Chengelis et al (2009) while a two-compartment model was used in Olsen et al. (2009).

Page 7, section 1.3.5.3 of the EPA Draft PFBS Document: "The study of Chengelis et al. (2009) indicated that, under conditions of equivalent exposure, the areas under the serum concentration-time curves (AUCs) were lower and the elimination half-lives were shorter for PFHxA than those for PFBS in both S-D rats and cynomolgus macaques. In the monkeys, for instance, PFHxA was cleared more rapidly and resulted in a lower AUC value (approximately an order of magnitude lower) with a shorter terminal half-life (2.4–5.3 hours, data not shown in the study) than PFBS at an equivalent dose (i.v. dose at 10 mg/kg)."

3M comments:

PFHxA is a 6-carbon perfluoroalkyl carboxylate. PFBS is a 4-carbon perfluoroalkyl sulfonate. Accordingly, the relevance of this statement to PFBS is unclear.

Page 26, section 4.1.2 of the EPA Draft PFBS Document: "Statistically significant dose-dependent decreases in total T3, total T4, and free T4 were also reported after exposure in male and female rats to K^+PFBS for 28 days at all doses tested (≥ 62.6 mg/kg-day) (NTP, 2018, 2011)."

3M comments:

- Again, it is important to recognize that total T3 and total T4 measured in the blood represent mostly the biologically inactive fractions of thyroid hormones (Oppenheimer et al 1995 Mol Endo Bas Conc Clin Corr 249-268) and they alone do not represent the functional aspect of the thyroid.
- As explained in detail above with increased liver hypertrophy in conjunction with thyroid hormone displacement, PFBS likely can compete with T4 for protein binding in serum (similar to its congener, PFOS, as reported in Chang et al. 2007 Toxicology 234 21-33; Weiss

et al. 2009 Toxicol Sci 109 206-216). Therefore, decreased total T4 and T3 likely reflected increased liver-mediated metabolism of the thyroid hormones that had been displaced.

- Furthermore, because of the binding competition, when measuring for free T4 (the biologically active fraction of T4) in the presence of high PFBS concentration, equilibrium dialysis-based measurement for free T4 is required. If conventional analog assays were used instead of equilibrium dialysis, most likely the case with NTP data (2018; 2011), it would result in an artificially lowered value (negative bias) for free T4 due to binding interference. It behooves EPA to clarify with NTP whether an analog or an equilibrium dialysis method was used to measure free T4.
- Most importantly, when examining the thyroid-related parameters, the gold standard is thyroid histology (which is obviously more challenging to do so in humans) and serum TSH (Jahnke et al. 2004, Environ Health Perspect 112 363-368). It should be emphasized that NTP reported normal thyroid histology and TSH levels.

Page 26, section 4.1.2 of the EPA Draft PFBS Document: "Thyroid gland weight, thyroid histopathology, and TSH levels were not changed after 28 days of PFBS exposure in male or female rats at up to 1,000 mg/kg-day (NTP, 2018, 2011)."

3M comments:

This is a very important observation, indicating that the overall thyroid hormone balance was being maintained with the NTP study, as reflected by normal TSH (primary diagnostic indicator for thyroid hormone status) and normal thyroid histopathology.

Pages 27 – 28, section 4.2.2.1 of the EPA Draft PFBS Document: "Adult (PND 60) F1 females gestationally exposed to PFBS at doses greater than 200 mg/kg-day, however, exhibited fewer primordial follicles, primary follicles, secondary follicles, early antral follicles, antral follicles, and preovulatory follicles, as well as fewer corpora lutea compared to control (Feng et al., 2017). Importantly, no effects on the health (e.g., weight gain) of the exposed dams were observed at any dose (Feng et al., 2017). Lieder et al. (2009b) evaluated ovarian follicles in F1 females after they were mated and their pups had been weaned (i.e., lactation day [LD] 22), and observed no effects compared to controls at 1,000 mg/kg-day; however, the data were not reported."

3M comments:

The observations reported by Feng et al. (2017) were very different than those reported by Lieder et al. (2009b). Technical observations included:

- Effects reported by Feng et al. lacked dose-responses; the effects from 200 mg/kg-d were usually similar in magnitude to 500 mg/kg-d.
- The study design and PFBS dosing regimen by Lieder et al. (2-generation in rats) was more rigorous than Feng et al. (gestational only in mice) in terms of treatment duration, doses, as

well as direct treatments to developing fetuses and pups during sensitive life stages, see Table 4 below for comparison.

Table 4

			Lieder et al. 2009b	Feng et al. 2017
Species			Sprague Dawley rats	ICR mice
Test guideline			OECD 416 / OPPTS 870.3800 (2-gen)	None
GLP			Yes	No
Daily K^+PFBS treatments (direct gavage)	Daily doses		30, 100, 300, 1000	50, 200, 500
	P-generation	Pre-mating, males	Yes, 70 days	No
		Pre-mating, females	Yes, 70 days	No
		Gestation, dams	Yes	Yes
		Lactation, dams	Yes	No
	F1-generation pups (before mating)	Weaning and on	Yes, ≥ 70 days	No

- It was not clear why Feng et al. did not include male offspring in their evaluation.
- The female mouse offspring in the Feng et al. study were not directly dosed with K^+PFBS, however, the reported myriad of adverse developmental outcomes occurred in these female mouse pups (e.g., reduced body weight and changes in reproductive organ morphology). In contrast, female rat offspring (from Lieder et al. 2009b) were not only exposed to PFBS during gestation and lactation, they were also directly dosed with PFBS (at higher dose levels than the Feng et al. study) after weaning and into their adulthood. There were no developmental effects noted in the female rat pups in Lieder et al. study.
- Regarding the alterations in ovary and uterus-related data, as reported by Feng et al:
    - Evaluation was reported for female pups at PND 60 only, not on PND 30; and not for dams (who were directly dosed with PFBS).
    - "Impaired" development reported by Feng et al. was based on decreased surface area (on microscopic slides) and limited morphological measurements. Surface area can be also attributed from different sectioning location (of the tissue). Feng et al. did not address how this was controlled among different animals. In addition, Feng et al. only provided relative organ-to-body weight data - there were no absolute organ weight data for the readers to interpret. Organ-to-brain weight data were not presented either.
    - Feng et al. did not take body weight into consideration when interpreting estrous cycle data which is unfortunate because they are related (Bermejo-Alvarez et al. 2012, Hum Reprod 27 3513-3522).

Overall, applying the criteria for evidence of integration and hazard characterization, as specified in the EPA Draft PFBS Document Section 2.3.6, there was a lack of concordance among the datasets reported by Lieder et al. (2009b) and Feng et al. (2017).

Page 28, section 4.2.2.3 of the EPA Draft PFBS Document: "The hormonal effects observed in the NTP (2018) and Feng et al. (2017) studies might be associated with adverse reproductive effects reported in these studies."

3M comments:

- NTP study (2018) did not evaluate reproductive effects directly. It was a 28-day repeated dose study where a statistically significant increased trend in testosterone was observed in females ($p \leq 0.05$), but not in males. In pairwise analyses, the increase in testosterone was not statistically significant for any individual dose group when compared to control (cf. page 28 of EPA Draft PFBS Document).
- In Feng et al. (2017), albeit there were changes in female reproductive organ morphology, functional aspects of reproduction appeared not to be affected according to study authors (i.e., maternal body weight, maternal body weight-gain, and various pregnancy outcomes).

Page 30, section 4.4 Renal Effects: The EPA states that Qin et al. (2016) was a "medium-confidence study."

3M comments:

The EPA's statement is incorrect. The overall confidence of this study was rated as deficient/low confidence in the EPA's evaluation of epidemiology studies (Figure 5, page 23).

Page 34, section 4.5.2 of the EPA Draft PFBS Document: "In general, serum biomarkers associated with altered liver function or injury, including alanine aminotransferase (ALT) and aspartate aminotransferase (AST), were not significantly changed in male and female S-D rats across multiple oral gavage studies of varying exposure durations up to 90 days, at K+PFBS doses up to 1,000 mg/kg-day (Lieder et al., 2009a; 3M, 2001, 2000d). NTP (2018) and NTP (2011), however, reported increased serum ALT and AST in male (500 mg/kg-day only) and female (≥ 250 mg/kg-day for ALT; ≥ 500 mg/kg-day for AST) rats exposed to K+PFBS for 28 days."

3M comments:

There were apparent changes in serum liver enzymes in the NTP study that were not seen in the 90-day study by Lieder et al. (2009). Even more striking is that there was a large percentage of deaths that occurred in the NTP 28-day study. Mortality was not observed in the 28-day study by 3M (3M, 2001) with comparable doses (see Table 5 below).

Table 5					
Parameters		**3M Study**		**NTP Study**	
Doses evaluated (mg/kg/d)		100, 300, 900		62.5, 125, 250, 500, and 1000	
Dosing method		Oral gavage		Oral gavage	
Survival at the highest dose	Time	Study Day 22	Study Day 28	Study Day 22	Study Day 28
	Males	100% (15/15)	100% (15/15)	30% (3/10)	0% (0/10)
	Females	100% (15/15)	100% (15/15)	50% (5/10)	20% (2/10)

The 3M study (2001) had no mortality at the end of 28 days at the top dose of 900 mg/kg/d (3M 2001). In the 90-day study by 3M (Lieder et al. 2009), there was no mortality at 600 mg/kg/d. In the 2-generation study by 3M (Lieder et al. 2009b), where male rats were treated for at least 10 weeks (70 days) for two generations, there was no mortality at 1000 mg/kg/d. Hence it is perplexing what contributed to the mortality (at much shorter duration) in the NTP study, which adds difficulties and uncertainties in assessing the corresponding data, such as AST and ALT with the NTP study.

Page 34, section 4.6.2 of the EPA Draft PFBS Document: "PFBS studies have not particularly focused on perturbations in lipids or lipoproteins as a potential health outcome, as studies have typically focused only on measures of serum cholesterol and triglyceride as part of a broader panel of clinical chemistry measures in high- or medium-confidence rat studies of 10, 28, and 90 days (see Figure E-11) (3M (2000d)]; 3M (2001)]; and Lieder et al. (2009a)], respectively)."

3M comments:

This is not correct. PFBS has been carefully evaluated, mechanistically, for its effect in lipid metabolism by Bijland et al. (2011) using a humanized ApoE*3.Leiden.CETP transgenic mouse model which expresses human-like lipoprotein profile. Unlike longer-chain perfluoroalkyl sulfonates (PFHxS and PFOS) that markedly reduced plasma triglycerides, non-HDL-cholesterol, and HDL-cholesterol, PFBS modestly reduced plasma triglycerides only. Unlike PFHxS and PFOS, PFBS did not affect lipid metabolism-related gene expressions in the liver.

Page 35, section 4.4 Other Effects of the EPA Draft PFBS Document: The EPA states that one medium-confidence study was reported in five publications (Qin et al., 2017; Zhou et al., 2017b; Zhou et al., 2017a; Zhu et al., 2016; Dong et al., 2013b).

3M comments:

The EPA states that one medium-confidence study was reported in five publications (Qin et al., 2017; Zhou et al., 2017b; Zhou et al., 2017a; Zhu et al., 2016; Dong et al., 2013b), but does not reference the study of medium-confidence (Dong et al., 2013a). Further, the EPA did not include these 5 publications in their evaluation of epidemiology studies nor did they provide an explanation why the studies were excluded.

Page 43, Section 5.3 of the EPA Draft PFBS Document:

- See previous comments (vide supra)

Page 45, Section 5.5 of the EPA Draft PFBS Document:

- See previous comments (vide supra)

Page 53, Table 7 on asthma of the EPA Draft PFBS Document: The EPA refers to a "Medium-confidence case-control study (Zhou et al., 2016; Zhu et al., 2016; Dong et al., 2013b).

3M comments:

Given that the EPA did not include these individual studies in their evaluation of epidemiology studies, only the study by Dong et al (2013) should be referenced.

Page 55 (Section 6.1.1.) and pages F-4 to F-16 of the EPA Draft PFBS Document:

- See expert opinion by Mr. Bruce Allen (Appendix A)

Page 55, section 6.1.1. of the EPA Draft PFBS Document: "The EPA considered the 2014 *Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation* in determining interspecies and intraspecies UFs (UFAs and UFHs, respectively) (U.S. EPA, 2014c). Using the decision process described in Figure 2 of that guidance (U.S. EPA, 2014c), the EPA concluded that data are inadequate to support derivation of data-derived extrapolation factors. Specifically, given the lack of available models and data to address external dose and clearance in humans with any certainty or the magnitude of difference in half-life across species as a function of dose or time, the default approach of the use of $BW^{3/4}$ scaling to obtain a HED is considered appropriate in this case."

3M Comments:

3M agrees.

Pages 65 – 67, Section 6.1.2 of the EPA Draft PFBS Document: In the derivation of candidate chronic RfDs, specifically, on the UF allocations for UF_D and UF_S (Tables 14 and 15 of the EPA Draft PFBS Document), Table 6 below is reproduced, in part, to illustrate the allocation of UF_D and UF_S assigned to each study.

3M Comments:

Table 6		
	Feng et al. 2017 (Table 14)	**Lieder et al. 2009b (Table 15)**
	Thyroid effects	Kidney effects
UF_D	A **UF_D of 10** is applied to account for database deficiencies. The oral exposure database contains multiple short-term and subchronic-duration toxicity studies of laboratory animals (NTP, 2018; Bijland et al., 2011; NTP, 2011; Lieder et al., 2009a; 3M, 2001, 2000d), a two-generation reproductive toxicity study in rats (Lieder et al., 2009b), and multiple developmental toxicity studies in mice and rats (Feng et al., 2017; York, 2002). However, as thyroid hormone is known to be critical during developmental life stages, particularly for neurodevelopment, the database is limited by the lack of developmental neurotoxicity studies. **Further, due to the lack of chronic duration studies, there is additional uncertainty regarding how longer-term exposures might impact hazard identification and dose-response assessment for PFBS via the oral route (e.g., potentially more sensitive effects).** Lastly, as immunotoxicity is an effect of increasing concern across several members of the larger PFAS family, the lack of studies evaluating this outcome following PFBS exposure is a limitation in the database.	A **UF_D of 3** is applied due to database deficiencies. The oral exposure database contains multiple short-term and subchronic-duration toxicity studies of laboratory animals (NTP, 2018; Bijland et al., 2011; NTP, 2011; 3M, 2010; Lieder et al., 2009a; 3M, 2001, 2000d), a two-generation reproductive toxicity study in rats (Lieder et al., 2009b), and multiple developmental toxicity studies in mice and rats (Feng et al., 2017; York, 2002).However, the observation of decreased thyroid hormone is known to be a crucial element during developmental life stages, particularly for neurodevelopment, and the database is limited by the lack of developmental neurotoxicity studies. In addition, as immunotoxicity is an effect of increasing concern across several members of the larger PFAS family, the lack of studies evaluating this outcome following PFBS exposure is a limitation in the database.
UF_S	A **UF_S of 1** is applied because the POD comes from a developmental study of mice. The developmental period is recognized as a susceptible life stage in which exposure during certain time windows (e.g., gestational) is more relevant to the induction of developmental effects than lifetime exposure (U.S. EPA, 1991b). The additional concern over potential hazards following longer-term (chronic) exposures is accounted for under the UF_D above.	A **UF_S of 10** is applied to account for less than chronic-duration exposure because the POD comes from a subchronic duration study.

Based on the table shown above:

- For each study, the combined (UF_D x UF_S) is 10 for the Feng et al. study and 30 for the Lieder et al. study.
- When comparing the UF_D allocations, both studies were subjected to similar dataset deficiencies (i.e., developmental neurotoxicity and immunotoxicity data). However, the EPA Draft PFBS Document inferred a lack of chronic exposure duration with the Feng et al. study

hence an overall higher UF_D value of 10 was assigned (see bold underlined text shown in the table above).

- When comparing the UF_S allocations, according to the EPA Draft PFBS Document, Feng et al. has an UF_S allocation of 1 because it was a developmental study and additional uncertainty for it not being a chronic study had been adjusted with higher UF_D. The EPA Draft PFBS Document inferred a lack of chronic exposure duration with Lieder et al. study and an overall UF_S value of 10 was assigned to Lieder et al. study.
- The EPA Draft PFBS Document is <u>incorrect</u> in its assessment of UF_S allocations without valid scientific justifications. Feng et al. (2017) study was deemed to be a developmental study by the EPA Draft PFBS Document given that it was a gestation exposure study (direct K^+PFBS dosing was administered during gestation only to time-pregnant dams without additional dosing afterward). Unlike the study by Feng et al., Lieder et al. (2009b) was a 2-generation study with direct K^+PFBS dosing regiments that spanned from pre-mating, mating, gestation, lactation, and post-weaning. It not only had the gestation exposure period, the rigorous dosing schedules from Lieder et al. study (before and after gestation) unequivocally covered more life stages for pups than those reported by Feng et al. It is perplexing why Lieder et al. (2009b) was not considered as a developmental study. In addition, Feng et al. only carried one generation, Lieder et al. produced two generations with the same rigorous dosing schedules. Again, from all aspects of study design and robustness, a full-scale 2-generation study such as the one reported by Lieder et al. (2009b) is far more comprehensive in terms of evaluation during susceptible life stage when compared to the gestation-only study such as the one reported by Feng et al. (2017). A previously shown table (Table 4) is provided here again for illustration.

Table 4

			Lieder et al. 2009b	Feng et al. 2017
Species			Sprague Dawley rats	ICR mice
Test guideline			OECD 416 / OPPTS 870.3800 (2-gen)	None
GLP			Yes	No
Daily K^+PFBS treatments (direct gavage)	Daily doses		30, 100, 300, 1000	50, 200, 500
	P-generation	Pre-mating, males	Yes, 70 days	No
		Pre-mating, females	Yes, 70 days	No
		Gestation, dams	Yes	Yes
		Lactation, dams	Yes	No
	F1-generation pups (before mating)	Weaning and on	Yes, ≥ 70 days	No

Clearly EPA has inappropriately allocated an additional factor of 3 for the study by Lieder et al. (2009b) without sufficient justification. For all these scientific facts articulated herein, the current combined UF_D x UF_S value of 30 for Lieder et al. study should be re-assigned. At the very maximum, the combined UF_D x UF_S value should be the same as the combined UF_D x UF_S value of 10 or lower for the Lieder et al. study.

<u>Page 67, mathematical calculation of the EPA Draft PFBS Document</u>: EPA provided the following calculation for the Candidate Chronic RfD for kidney effects.

Candidate Chronic RfD for K^+PFBS (Kidney) = BMDL10 (HED) ÷ UFC

= 11.5 mg/kg-day ÷ 1,000
= 0.12 mg/kg-day
= 1×10^{-2} mg/kg-day

<u>3M Comments:</u>

There is a typo on the third line. It should be 0.0115 mg/kg-day, not 0.12 mg/kg-day

<u>Page F-17, Appendix F of the EPA Draft PFBS Document:</u> EPA selected the Dichotomous-Hill model for the model that best fit the papillary tubular/ductal epithelium hyperplasia in F0 female rats.

<u>3M Comments:</u>

We agree with EPA's selection of the Dichotomous-Hill model for the model that best fit the papillary tubular/ductal epithelium hyperplasia in F0 female rats, as shown in Table F-3 of the EPA Draft PFBS Document. This resulted in a $BMDL_{10}$ (HED) (mg/kg-day) of 11.4888.

Appendix A

Comments Related to BMD Analysis of PFBS

January 18, 2019

Introduction

I am an independent consultant and have been a practitioner in the field of risk assessment for 35 years. My emphasis has been on dose-response modeling, including benchmark-dose and statistical analysis. During that time I have contributed to the advancement of the science of risk assessment and have performed or responded to assessments of many chemicals suspected of posing problems for human health. Moreover, I have consulted with EPA regarding its BMDS program development, the software used by EPA for the analysis of perfluorobutane sulfonic acid (PFBS).

I was asked by 3M to independently review EPA's Draft Human Health Toxicity Values for Perfluorobutane Sulfonic Acid and Related Compound Potassium Perfluorobutane Sulfonate (EPA-823-R-18-307); hereafter referred to as the "EPA assessment." Specifically, I was asked to provide insight concerning EPA's benchmark dose modeling in its identification of points of departure (PODs) for PFBS, one based on kidney hyperplasia observed in Sprague Dawley rats and the other based on a decrease in total T4 levels in female ICR (CD-1) mice offspring at birth (postnatal day 1). I have been compensated by 3M for this review.

One specific item, posed by EPA to its selected peer-reviewers, was related to the modeling approaches used, with specific reference to the selection of benchmark response levels used to identify each POD. For decreased total T4 in female mice offspring, specifically, when considering species- and/or lifestage-specific differences in thyroid economy (e.g., differential reserve capacities for thyroid hormone in infants compared to adults and mice compared to humans), the reviewers were asked to comment on how EPA addressed these factors in the choice of a biologically based benchmark response level (i.e., level of change that characterizes the lower limit of biological significance compared with normal background responses, which EPA identified as a $BMDL_{20}$).

This document provides additional comments related to those concerns. Specifically, it addresses the choice of model and of a $BMDL_{20}$ for the T4 endpoint referenced above. In the following sections, we address the following issues:

- Concerns about choice of BMD model
- Lack of history for use of a $BMDL_{20}$ for POD derivation
- Decreased consistency associated with the use of a $BMDL_{20}$
- Lack of rationale for selection of $BMDL_{20}$ as a biologically based benchmark response level

Choice of BMD Model

For purposes of the discussion provided herein, values from Table F-2 (p. F-5) in EPA's draft toxicity assessment, reproduced in part, are summarized in the Table below:

Table: Modeling results for total T4 in PND 1 female offspring (litter n) exposed GDs 1–20

Model	Global p-value	AIC	$BMDL_{20}$ (HED) (mg/kg-d)
Linear	0.558	-4.72314	20.2211
Exp M2	0.7627	-5.34819	12.5215
Exp M4	0.8421	-3.85031	4.22705

Note: Other models not shown because they had no p-value for global fit (Hill and Exp M5) or because they devolved into one of the simpler forms shown here (i.e., polynomial and power models were identical to the simpler linear form; Exp M3 was identical to the simpler Exp M2).

For the sake of argument, we consider here the EPA's selected BMR (20% reduction in mean T4). We will argue later that this is a poor choice in itself, but the observations that follow in this section apply whatever the choice of BMR, and so our example calculations will focus on that BMR. EPA rationalizes the choice of the Exponential M4 model on the grounds that the BMDL estimates derived across the models differ by more than a factor of 3. Had it not been for that magnitude of difference, then the best fitting model (as judged by having the smallest AIC) would be the standard EPA basis for the choice of model and therefore of the BMDL.

It is not hard to demonstrate the logical inconsistency associated with the EPA model selection procedure. Suppose a "lazy modeler" had run just the Exponential model suite (as some in Europe are advocating). In that case, the Exp M2 model would still be the best fitting (based on AIC), but the difference in BMDL estimates is less than a factor of 3 (it equals 2.96), and so application of the EPA selection criteria would have resulted in the choice of Exp M2 and a BMDL of 12.5.

Now suppose that a "good modeler" adds to that analysis by being more thorough in considering model shapes; she adds to the set of models the Linear model (and the power and polynomial models, which devolve to the simpler Linear form). That addition results in another model that fits the data adequately and would be considered for selection (see table above). Moreover that model predicts a BMDL *greater* than either of the previous BMDL estimates. However, EPA's procedure would dictate that the selected BMDL would now be 4.23, even though the additional modeling results suggest that 12.5 might itself be too low.

That makes no sense. It leads to decisions that can never be changed in the direction of increasing a POD as more information is obtained and more modeling is completed. That is so because, if modeling results are added that predict higher BMDLs (which *should* tend to move the weight of evidence toward higher BMDL values), the paradoxical effect is that the lowest BMDL is more likely to be selected under this procedure.

The gist of the problem is that model *predictions* of a certain quantity (e.g., of a BMD or BMDL) have no bearing on how well the models fit the data. Clearly, we expect different models to predict different BMDs (otherwise we would not bother to run more than one model), but the ordering of those models with respect to BMD values is not inherently correlated with model fit and the associated model selection (or model averaging) process. The predictions are what gets selected, not the basis for that

selection process.

So, clearly, in this case a value of 12.5 would be selected as coming from the best fitting model. The Linear model, with a BMDL of 20.2, would be judged superior to Exp M4. Yet, the worst model (from an AIC perspective, which is a typical metric for model selection) is the one that EPA used to define the POD. A crude modeling averaging technique would suggest an even higher value could be used, 13.8 mg/kg-d.[1]

Choice of BMR

Irrespective of the model choice considerations discussed above, we are also concerned about the other choice EPA made when defining the POD, i.e., the use of a BMR of 20% relative deviation (20% reduction in mean T4) to derive what are labeled the $BMDL_{20}$ values. The comments in the following subsections indicate reasons why the $BMDL_{20}$ is not appropriate.

No History of Use

To our knowledge, no other EPA assessment has used a 20% relative deviation as the BMR.[2] It is not a BMR that is mentioned in EPA guidance. Its use here appears to be idiosyncratic except insofar as that choice can be supported as a biologically or toxicologically based decision. Comments related to that criterion are given in the "Biological Basis" subsection below.

Lacks Consistency

One of the main goals when the BMD approach was developed was to reduce the inconsistencies associated with the method prevailing at that time (called the LOAEL/NOAEL approach) (Crump, 1984).

An associated goal is to be consistent across compounds and endpoints. Only in that manner can we hope to derive RfDs (for example) that adequately reflect the relative risks across those compounds and endpoints. Such consistency allows us to believe that the costs associated with risk reduction can be rationally allocated and that higher risks are addressed more urgently than lower risks.

As mentioned above, the use of $BMDL_{20}$ is inconsistent with what has been done in other cases, for other compounds. Moreover, even internally to this PFBS assessment, the use of $BMDL_{20}$ makes it less consistent with the analysis of the other PFBS-induced effect modeled by EPA: papillary tubular/ductal epithelium hyperplasia in P0 female rats. The latter is a dichotomous effect, for which BMRs are typically defined in terms of extra risk. A $BMDL_{10}$ for a dichotomous effect, for example, is the BMDL associated with an increase in risk of 10%. This is different from the T4-associated $BMDL_{20}$, which is based on the magnitude of mean T4 change, not on a change in risk. Thus there is an inconsistency in terms of the metric for defining the POD.

But there is an approach for BMD analysis of continuous endpoints that is consistent with the risk metric used with dichotomous endpoints. It is the approach that expresses BMRs in terms of standard deviation (SD) "units" (Crump, 1995). Some results for this approach were presented in the EPA assessment, but they were not used to define the POD.

[1] A weighted average of the BMDLs from each model, with weights for that average equal to exp(-AIC). More sophisticated model averaging techniques are available from EPA-sponsored software; they have been evaluated favorably internally by EPA and by external peer-reviewers.

[2] We have not done a systematic search of the IRIS database with respect to selected BMR metrics.

Specifically, what Crump (1995) showed is the following, using the PFBS assessment of T4 and hyperplasia as the example.

- Suppose that it is possible to specify
    - the cut-point between "normal" and "low" T4 levels ***or***
    - the proportion of the (unexposed, control) population that would be considered low with respect to T4.
- Suppose you want to estimate the dose (BMD) that increases the extra risk of T4 abnormality by 10%. That is, you want to use the same metric you used for the kidney hyperplasia endpoint in this assessment.
- Then, you can calculate the change in the mean T4 that will give the target 10% extra risk of low T4, ***if*** you express that change in terms of the standard deviation, x*SD.

As an example, Crump (1995) showed that if you assume that 1% of the unexposed test population has low T4, then a reduction of the mean T4 by (1.1*SD), increases the risk of low T4 by 10%.[3] EPA has partially captured this relationship in their default choice in BMDS of the BMD_{1SD} for continuous endpoint analysis, incorporating a conservative rounding down from 1.1SD to 1SD.

It is our conclusion that, in the absence of additional information, the BMD_{1SD} results should have been used to determine PODs based on the T4 endpoint. This conclusion is on top of the conclusion above that model choice was not handled appropriately. Together they suggest that a T4-associated POD should have been based on a value of 23.4 (HED) mg/kg-d, the $BMDL_{1SD}$ from the Exp M2 model (see Table F-2, p. F-5 of the EPA assessment) if a model-selection (as opposed to a model-averaging) process is enacted.

Weak Support for $BMDL_{20}$ as a Biologically Based Benchmark Response Level

The EPA assessment ultimately relies on biologically based arguments in support of the $BMDL_{20}$ estimates. We consider the following lines of support offered for the choice of a 20% relative decrease as being biologically relevant (see pp. 55-56 of the EPA assessment):

a. "With regard to what level of decrease in thyroid hormone is sufficient for anatomical and/or functional alterations, particularly in neurodevelopment in developing fetuses or newborns, several studies have identified a fairly stable range across humans and experimental rodents. Neurodevelopmental and cognitive deficits have been observed in children who experienced a 25% decrease in maternal T4 during the second trimester in utero (Haddow et al., 1999)."
b. "In other studies, mild-to-moderate thyroid insufficiency in pregnant women was defined as having serum T4 levels below the 10th percentile for the study population, which was associated with a 15%–30% decrease relative to the corresponding median (Finken et al., 2013; Julvez et al., 2013; Román et al., 2013; Henrichs et al., 2010)."
c. "Similarly, decreases in mean maternal T4 levels of ~10%–17% during pregnancy and lactation have been found to elicit neurodevelopmental toxicity in rat offspring (Gilbert et al., 2016; Gilbert, 2011). As the lower end of the range of T4 changes associated with untoward developmental health outcomes (e.g., 10%) commonly falls within normal experiment-to-experiment variation in control values, a BMR of 20% RD from control mean was determined to

[3] All of these calculations make the same assumptions about endpoint distribution that are made by EPA in its BMDS runs (Appendix F), i.e., that T4 is normally distributed and that the variance is constant across dose groups.

be a minimally biologically significant degree of change when performing BMD modeling on thyroid hormone alterations in pregnant females and associated offspring."

a. 25% decrease in maternal T4 during second trimester

It should be immediately recognized that the 25% decrease cited is from a very specific scenario, confined to the second trimester. More importantly, the 25% decrease is compared to levels that pertained in each individual in the first trimester. They do not reference a change in mean levels. In fact, there is no way to determine what a mean change would be; all we can gather from this statement is that among those with the requisite 25% decrease, there were some cognitive deficits. We do not know how many deficits (what was the rate of response) even among those individuals. Nor do we know the proportion of individuals who had such decreases and therefore we have no basis for imputing a change in the mean T4.

Conclusion: this evidence provides no support for selecting a mean change of 20% as the BMR.

b. Thyroid insufficiency in women below the 10th percentile

This observation is tied to the determination that the 10th percentile is 15-30% below the population mean. Let us examine what those two observations entail.

Under the assumption of normally distributed T4 in the population (the same assumption used for the BMD modeling), the 10th percentile point would be at

$$\mu - 1.28*\sigma$$

where μ and σ are the mean and standard deviation of the T4 distribution, respectively. For the sake of this illustration, let us suppose that that was 20% less than the mean (equal to the relative deviation EPA has chosen to use for their T4 BMR, and within the range of 15-30% cited in their support). Therefore

$$\mu - 1.28*\sigma = 0.8*\mu$$

yielding the relationship

$$\sigma = (0.2/1.28)*\mu = 0.16*\mu.$$

Note that there is no more "simplification" that can be done here – we cannot solve for σ without knowing μ. Moreover, consider our contention that the BMR ought to be expressed in terms of SD units. This expression illustrates why that is the case: linking a population percentile for thyroid insufficiency (essentially a statement that 10% of women had T4 that was too low) to a change in mean T4 requires estimates of the SD for it to be translatable to extra risk.

But there is something more troublesome about this line of support for a 20% relative-deviation BMR. EPA's suggestion that that change be set as the BMR level is equivalent to specifying that the dose that decreases the T4 mean down to the 10th percentile of controls (the imputed cut-point for low T4) be the BMD. But if that is the mean T4 at the BMD, then by definition of the mean of a normal distribution, the probability of low T4 at the BMD is 50%. That is 44% extra risk. We contend that is the wrong level for any BMD, and (returning to an earlier point) is certainly inconsistent with other BMD analyses.

c. Decreases in mean T4 of 10-17% have elicited neurodevelopmental toxicity in rats

Once again we must note that, in the absence of information about the SD, there is no tie-in between the cited range of decrease and the change in proportion of rats who had adversely low T4.

But let us examine this statement using actual values from Feng et al. (2017). The control group mean T4 was 1.44 and the standard deviation in that group was 0.33. So how unlikely is it to see T4 values 10% to 17% below the mean? The following table shows that it is not at all unlikely to see such observations, nor indeed to see T4 values as much as 30% below the mean:

Percent below mean	T4 Value	Likelihood of observation below that value
10	1.296	0.331
17	1.1952	0.229
20	1.152	0.191
30	1.008	0.095

There is almost a 10% chance that an observation will be more than 30% lower than the mean in any random sample of control animals. There is nothing special about 20% decrease in that respect. With 19% of the observations in controls being expected to be less than 20% of the mean value, it is not as if picking a 20% relative deviation BMR defines a "critical range" that is numerically improbable even in the absence of exposure.

If anything, these calculations suggest that, if one desired to use relative deviation as the basis for BMR definition, then at least a 30% relative deviation is required to define a range of abnormal T4, i.e., the level below the mean predicted to have a low background rate (about 10% in this case). Importantly, however, note that this is not to say that the BMR should be set to 30% relative deviation; that would fall prey to the same issue addressed in point b above, i.e., that the probability of low T4 would go from about 10% to 50%. Here, as in the other cases discussed above, it is not possible to make consistent probabilistic statements without taking SD into consideration; merely examining relative deviations from the mean is not sufficient. The choice by EPA to use 20% relative deviation is shown here to have no support in that regard.

Suggested Alternative Analysis

Given the discussion above, we have a suggested alternative approach to the BMD analysis of the T4 endpoint. It incorporates the two major suggestions inherent in the above sections:

- Selection of a different dose-response model
- Definition of the BMR using a SD approach

If the default value of 1SD as the BMR was retained (as in EPA's reported-but-not-used analysis), then the POD for the T4 endpoint would be 23.4 (HED) mg/kg-d, as mentioned previously, just on the basis of model selection.

However, there is one piece of information mentioned by EPA that might be relevant to the choice of the BMR level, and that would suggest a non-default choice for the BMR. That is the observation provided in the EPA assessment that "thyroid insufficiency in pregnant women was defined as having serum T4 levels below the 10th percentile for the study population." We follow through with that additional input in the analysis below, using it to defend a choice of a 10% background rate of thyroid insufficiency. We recognize that there are some (perhaps major) assumptions associated with that

choice, including that that observation in humans is relevant to determining a background rate in the experimental animals. It is also an open question whether it is appropriate to use a response that has such a high background rate of abnormality. By that we mean that as the background rate of a purported "abnormality" increases, there is less chance that the "abnormality" under consideration (T4) bears any relation to adverse health outcomes.[4]

Nevertheless, by assuming a background rate of 10% and specifying the BMD to be the dose that gives 10% extra risk over and above that background (to be consistent with the analysis of the dichotomous endpoint), the methodology described in Crump (1995) dictates that the SD multiplier for the BMR should be approximately 0.4. I.e., if the mean T4 changes by 0.4*SD, then the extra risk associated with that change will be 10%.

We have run that version of the analysis using BMDS (results shown in the appendix for the Exponential models). It is still the case that the Exp M2 model fits the data best and is the single best model to select for POD estimation; that is not impacted by the choice of BMR. In that case, the $BMDL_{.4SD}$ is 8.3 (HED) mg/kg-d. Even with the more stringent conditions imposed by the choice of a higher background than the default background (10% as opposed to 1%), the resulting POD (8.3 (HED) mg/kg-d) is about twice the value of 4.2 (HED) mg/kg-d that EPA used to derive an RfD.

If we were going to conduct a full re-analysis, we would also recommend running the other continuous models from BMDS and averaging the results across models, with weights based on AIC values. A higher value of the POD would result from that approach, as it would factor in the Linear model, which happens to have both a greater BMD value and greater weight than the Exp M4 model. Until such model averaging is incorporated, we support a POD of 8.3 (HED) mg/kg-d for the T4 endpoint.

References

Crump, K. S. (1984). A new method for determining allowable daily intakes. *Toxicological Sciences*, *4*(5), 854-871.

Crump, K. S. (1995). Calculation of benchmark doses from continuous data. *Risk Analysis*, *15*(1), 79-89.

Bruce C. Allen
Independent Consultant
Chapel Hill, NC

[4] Consider the limiting case where the rate of purported "abnormalities" approaches 100% in controls: clearly, in that case the presence of the "abnormality" cannot be associated with the presence of adverse health endpoints (disease, lack of development, or death) since all or nearly all of the subjects had the "abnormality."

Appendix: Output from Alternative BMDS Run

```
================================================================
        Exponential Model. (Version: 1.11;  Date: 03/14/2017)
        Input Data File:
C:/Users/Bruce/Documents/BMDS/BMDS2704/Data/exp_Dax_Setting.(d)
        Gnuplot Plotting File:
                                              Thu Dec 20 10:32:13 2018
 ================================================================

 BMDS Model Run
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~

   The form of the response function by Model:
      Model 2:     Y[dose] = a * exp{sign * b * dose}
      Model 3:     Y[dose] = a * exp{sign * (b * dose)^d}
      Model 4:     Y[dose] = a * [c-(c-1) * exp{-b * dose}]
      Model 5:     Y[dose] = a * [c-(c-1) * exp{-(b * dose)^d}]

    Note: Y[dose] is the median response for exposure = dose;
          sign = +1 for increasing trend in data;
          sign = -1 for decreasing trend.

      Model 2 is nested within Models 3 and 4.
      Model 3 is nested within Model 5.
      Model 4 is nested within Model 5.


   Dependent variable = Mean
   Independent variable = Dose
   Data are assumed to be distributed: normally
   Variance Model: exp(lnalpha +rho *ln(Y[dose]))
   rho is set to 0.
   A constant variance model is fit.

   Total number of dose groups = 4
   Total number of records with missing values = 0
   Maximum number of iterations = 500
   Relative Function Convergence has been set to: 1e-008
   Parameter Convergence has been set to: 1e-008

   MLE solution provided: Exact


                              Initial Parameter Values

     Variable          Model 2             Model 3             Model 4          Model 5
     --------          -------             -------             -------          -------
     lnalpha          -1.29725            -1.29725            -1.29725        -1.29725
         rho                 0 *                 0 *                 0 *             0 *
           a          0.794588            0.945214               1.512           1.512
           b        0.00971785          9.5412e-005           0.0428586       0.0428586
           c                 0 *                 0 *          0.434618        0.434618
           d                 1 *                 2                 1 *               1

     * Indicates that this parameter has been specified


                              Parameter Estimates by Model

     Variable          Model 2             Model 3             Model 4          Model 5
     --------          -------             -------             -------          -------
```

lnalpha	-1.2837	-1.2837	-1.29626	-1.29725
rho	0 *	0 *	0 *	0 *
a	1.40224	1.40224	1.4541	1.44
b	0.0107117	0.0107118	0.0316353	0.0365363
c	--	--	0.416958	0.463035
d	--	1	--	1.24424

-- Indicates that this parameter does not appear in model
* Indicates that this parameter has been specified

Std. Err. Estimates by Model

Variable	Model 2	Model 3	Model 4	Model 5
lnalpha	0.0619412	0.0619412	0.0611684	0.0611078
rho	NA	NA	NA	NA
a	0.125025	0.127487	0.148456	0.165312
b	0.00345921	0.00367245	0.0322218	0.0287449
c	NA	NA	0.222523	0.208043
d	NA	NA	NA	1.32125

NA - Indicates that this parameter was specified (by the user or because of the model form) or has hit a bound implied by some inequality constraint and thus has no standard error.

Table of Stats From Input Data

Dose	N	Obs Mean	Obs Std Dev
0	10	1.44	0.329
7.5	10	1.3	0.657
29.9	10	0.92	0.493
75	10	0.69	0.657

Estimated Values of Interest

Model	Dose	Est Mean	Est Std	Scaled Residual
2	0	1.402	0.5263	0.2269
	7.5	1.294	0.5263	0.03612
	29.9	1.018	0.5263	-0.5885
	75	0.6279	0.5263	0.3729
3	0	1.402	0.5263	0.2269
	7.5	1.294	0.5263	0.03611
	29.9	1.018	0.5263	-0.5885
	75	0.6279	0.5263	0.3729
4	0	1.454	0.523	-0.08525
	7.5	1.275	0.523	0.151
	29.9	0.9355	0.523	-0.09388
	75	0.6853	0.523	0.02816
5	0	1.44	0.5228	-4.122e-007
	7.5	1.3	0.5228	4.546e-007
	29.9	0.92	0.5228	3.575e-007
	75	0.69	0.5228	2.451e-007

Other models for which likelihoods are calculated:

```
  Model A1:        Yij = Mu(i) + e(ij)
           Var{e(ij)} = Sigma^2

  Model A2:        Yij = Mu(i) + e(ij)
           Var{e(ij)} = Sigma(i)^2

  Model A3:        Yij = Mu(i) + e(ij)
           Var{e(ij)} = exp(lalpha + log(mean(i)) * rho)

  Model  R:        Yij = Mu + e(i)
           Var{e(ij)} = Sigma^2
```

Likelihoods of Interest

Model	Log(likelihood)	DF	AIC
A1	5.944999	5	-1.889998
A2	8.698072	8	-1.396144
A3	5.944999	5	-1.889998
R	0.3138778	2	3.372244
2	5.674097	3	-5.348194
3	5.674097	3	-5.348194
4	5.925156	4	-3.850311
5	5.944999	5	-1.889998

Additive constant for all log-likelihoods = -36.76. This constant added to the above values gives the log-likelihood including the term that does not depend on the model parameters.

Explanation of Tests

Test 1: Does response and/or variances differ among Dose levels? (A2 vs. R)
Test 2: Are Variances Homogeneous? (A2 vs. A1)
Test 3: Are variances adequately modeled? (A2 vs. A3)
Test 4: Does Model 2 fit the data? (A3 vs. 2)

Test 5a: Does Model 3 fit the data? (A3 vs 3)
Test 5b: Is Model 3 better than Model 2? (3 vs. 2)

Test 6a: Does Model 4 fit the data? (A3 vs 4)
Test 6b: Is Model 4 better than Model 2? (4 vs. 2)

Test 7a: Does Model 5 fit the data? (A3 vs 5)
Test 7b: Is Model 5 better than Model 3? (5 vs. 3)
Test 7c: Is Model 5 better than Model 4? (5 vs. 4)

Tests of Interest

Test	-2*log(Likelihood Ratio)	D. F.	p-value
Test 1	16.77	6	0.01017
Test 2	5.506	3	0.1383
Test 3	5.506	3	0.1383
Test 4	0.5418	2	0.7627
Test 5a	0.5418	2	0.7627
Test 5b	-1.733e-010	0	N/A
Test 6a	0.03969	1	0.8421
Test 6b	0.5021	1	0.4786
Test 7a	5.649e-013	0	N/A

Test 7b	0.5418	2	0.7627
Test 7c	0.03969	1	0.8421

The p-value for Test 1 is less than .05. There appears to be a difference between response and/or variances among the dose levels, it seems appropriate to model the data.

The p-value for Test 2 is greater than .1. A homogeneous variance model appears to be appropriate here.

The p-value for Test 3 is greater than .1. The modeled variance appears to be appropriate here.

The p-value for Test 4 is greater than .1. Model 2 seems to adequately describe the data.

The p-value for Test 5a is greater than .1. Model 3 seems to adequately describe the data.

Degrees of freedom for Test 5b are less than or equal to 0. The Chi-Square test for fit is not valid.

The p-value for Test 6a is greater than .1. Model 4 seems to adequately describe the data.

The p-value for Test 6b is greater than .05. Model 4 does not seem to fit the data better than Model 2.

Degrees of freedom for Test 7a are less than or equal to 0. The Chi-Square test for fit is not valid.

The p-value for Test 7b is greater than .05. Model 5 does not seem to fit the data better than Model 3.

The p-value for Test 7c is greater than .05. Model 5 does not seem to fit the data better than Model 4.

Benchmark Dose Computations:

Specified Effect = 0.400000

Risk Type = Estimated standard deviations from control

Confidence Level = 0.950000

BMD and BMDL by Model

Model	BMD	BMDL	BMDU
2	15.187	8.27351	37.4221
3	15.187	8.27351	44.9118
4	8.95774	2.58601	33.3712
5	10.8243	2.61069	39.7607

Smith, Ian (EGLE)

From: 003 McIntosh [redacted]@gmail.com>
Sent: Friday, January 31, 2020 4:49 PM
To: EGLE-PFAS-RuleMaking
Subject: Comments on proposed MCL's for PFAS in drinking water

Dear Ms. Ruch

I sent these comments previously through the LCV using their comment form.

However, just in case there is a glitch, I am sending them to you via this e-mail address as well.

Thank you,

Lynn McIntosh

Dear Ms. Ruch Jan 31,2020

I appreciate that the Sate of MI is one of the few states trying to set stricter standards for the amount of PFAS chemicals in our drinking water. In the absence of the EPA setting federal standards it is imperative that we move to adopt our own state standards. For this reason, I urge the State to move forward on setting these standards as soon as possible.

However, and this is a major "however," after reading the writings of Linda Birnbaum, PhD, former director of the National Toxicology Program, scientific and public health expert with vast experience, and also reading scientific literature re: Massachusetts's research model for setting standards for PFAS chemicals as a class, there is a strong likelihood that MI's proposed new standards are already outdated. In fact, in 2018, Massachusetts had adopted an MCL of 70 ppt for a sum of five PFAS chemicals. Within a year, during which the public asked their state to scientifically review again the standards, Massachusetts is in a review process that is proposing 20 ppt for a class of six PFAS chemicals.

This speaks volumes.

The fact that Vermont has set their level to 20 ppt for a sum of 5 PFAS chemicals only underscores the reality that Michigan is not being strict enough.

I am aware that Michigan used a model used by Minnesota. There were good reasons for doing so, but back to my "however." Was equal time given in looking at some of the east coast states' models and their reasons for addressing the additive and synergistic effect of PFAS chemicals as a class?

I remain unconvinced that the model Michigan chose is protective enough.

Three final points:

1. Will an annual review process be included with these standards, given the quickly changing and growing science? This seems imperative.
2. Michigan needs to address community well systems serving 1300 people or less, for example, trailer parks, campgrounds, etc. The current proposed standards will not protect these people.
3. A side issue yet interwoven with this: 25% of Michigan's citizens has private wells. The need for protections for these people cannot be ignored.

Thank you very much for having 3 public hearings so that Michigan citizens could speak with you face to face and voice their concerns. This is a great step and very much appreciated.

Lynn McIntosh

[redacted]

Rockford, MI 49341

Smith, Ian (EGLE)

From: Murray, Stephanie J. <[redacted]@varnumlaw.com>
Sent: Monday, January 27, 2020 2:16 PM
To: EGLE-PFAS-RuleMaking
Cc: Zimmerman, Matthew D.; Konwinski, Kyle P.
Subject: Comment Letter
Attachments: Comment Letter.PDF

Categories: Blue Category

Ms. Ruch:

Please see attached comment letter. A hard copy will be sent by regular mail.

Thank you.

Stephanie J. Murray
Assistant to Bill Rohn, Peter Smit, and Kyle Konwinski
Direct: [redacted]

VARNUM ATTORNEYS AT LAW

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Bridgewater Place | Post Office Box 352
Grand Rapids, Michigan 49501-0352
Telephone [redacted] | Fax [redacted] | www.varnumlaw.com

Matthew D. Zimmerman

Direct: [redacted]
[redacted]@varnumlaw.com

January 27, 2020

Via E-mail & First-Class Mail

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
P.O. Box 30817
Lansing, MI 48909-8311

Dear Ms. Ruch:

I am writing to submit comments on behalf of a client with substantial manufacturing operations in the State of Michigan (the "Manufacturer") pertaining to the Michigan Department of Environment, Great Lakes, and Energy's ("EGLE") proposed PFAS[1]-related amendments and additions to the Michigan Administrative Code. The Manufacturer's comments are articulated below.

Introduction and Background

The Manufacturer currently employs nearly 500 employees in Michigan and impacts the state's economy in the billions of dollars. The Manufacturer also has operations around the United States and internationally. The Manufacturer's interest in the proposed regulatory changes and additions is unrelated to any interest that perpetuates the use of PFAS or delays the cleanup of PFAS, but instead solely relates to the Manufacturer's interest as a non-transient, non-community ("Non-Transient") water supplier in the state of Michigan. At this time, the Manufacturer wishes to remain anonymous because of the obvious risks of commenting publicly in opposition to proposed rules that purport to protect human health. Nonetheless, I write on behalf of the Manufacturer to articulate its strong opposition to the proposed changes and additions set out at R 325.10107, R 325.10116, R 325.10308b, R 325.10313, R 325.10401a, R 325.10405, R 325.12701, R 325.10604g, R 325.10717d, R 325.12708, and R 325.12710 (collectively, the "Proposed PFAS Rules").

Comments in Opposition to Proposed PFAS Rules

1. States' piecemeal efforts to address PFAS concerns are premature and misplaced.

The Manufacturer does not dispute that PFAS contamination in ground and surface water supplies across the globe needs to be addressed on a broad scale. However, Michigan's (and other states') piecemeal attempts at regulating PFAS in drinking water are premature and misguided in light of unclear data on the effects of low-level PFAS exposure on human health.

[1] As "PFAS" has been proposed to be defined in R 325.10107.

PFAS exposure at high levels may have an impact on human health, but data on the impact of PFAS on human health at low exposure levels is anything but clear according to several sources. *See, e.g.*, U.S. Center for Disease Control, *Per- and Polyfluorinated Substances Factsheet*, https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html (accessed 1/8/20) (stating that health effects of low levels of PFAS exposure are "uncertain."); *Human Exposure to per- and polyfluoroalkyl substances (PFAS) through drinking water: A review of the recent scientific literature*, Environmental Research 177 at 2 (August 11, 2019) ("Based on the available data, at least for the most well studied compounds (PFOS and PFOA), we concluded that the potential human health risks should not be of concern for non-occupationally exposed individuals."). Indeed, the uncertainty of the effects of PFAS exposure on humans from drinking water is evidenced by the gross disparity in promulgated and proposed drinking water Maximum Contaminant Levels ("MCLs") and advisories in the U.S. and abroad. *See, e.g.*, Environmental Research 177 at 7 ("[S]even states have developed their own water guideline levels for PFOA and/or PFOS ranging from 13 to 1000 ng/l;" "the UK Health Protection Agency in agreement with the Drinking Water Inspectorate for England and Wales advises that the maximum acceptable concentration of PFOS in drinking water is 300 ng/l, and that the maximum acceptable level of PFOA in drinking water is 10,000 ng/l"). Moreover, while the available data purports to assist regulators in setting MCLs that consider *lifetime exposure*, those MCLs largely ignore the fact that the production of many PFAS compounds is already banned in a number of countries and "consequently, it would be logical to expect less exposure to PFAS in the next few years." *Id.*

In light of the uncertainty, the U.S. Environmental Protection Agency ("EPA") has taken a stepwise approach to promulgating PFAS-related drinking water standards. For example, to address concerns about the potential—but still very uncertain—impacts of PFAS on human health from drinking water, the EPA has issued Health Advisories for PFOA and PFAS for drinking water at 70 parts per trillion, and is in the process of developing an MCL for both PFOA and PFAS. *See* https://www.epa.gov/newsreleases/aggressively-addressing-pfas-epa (accessed 1/8/20). The EPA's Health Advisory already includes a cautionary buffer to ensure protection of the public health. Furthermore, the EPA's issuance of a Health Advisory in the interim, while it develops an MCL, represents a measured approach to setting nationwide drinking water standards that will allow the agency to consider the latest science and make sound decisions based on real data. Several states are waiting for the EPA to take further action before setting their own standards or adopting the EPA's. Michigan should do the same.

In addition to engaging in rulemaking with incomplete data, EGLE's Proposed PFAS Rules will also improperly burden parties which—by and large—have no connection with creating the contaminated conditions that EGLE is attempting to address. To the extent that water supplies in Michigan are contaminated with PFAS, EGLE should not first address that contamination by putting the burden on water suppliers to test their water and then require them to install expensive treatment technologies if the results do not meet the State's arbitrary standards.

Regulators (in Michigan and elsewhere) should instead temper their haste while comprehensive toxicological data is developed and focus attention on the cleanup of

contaminated ground and surface water by targeting the entities that are responsible for this public health crisis in the first place. Indeed, the Attorney General has announced her intention to seek compensation from the manufacturers of PFAS, which should be the first step in resolving this public health crisis.

2. *Non-Transient water suppliers will be unduly burdened by the Proposed PFAS Rules.*

PFAS testing is expensive and—assuming the Proposed PFAS Rules are promulgated as written—Non-Transient water suppliers will be shouldered with additional expensive annual or quarterly testing requirements. *See, e.g.*, https://www.michigan.gov/pfasresponse/ ("Testing costs vary from laboratory to laboratory and may typically range from approximately $300 to $600 per sample."). Many suppliers will also be required to install expensive treatment technology (along with any capital expenditures to accommodate that equipment) or find an alternative supply source. The on-going monitoring and treatment costs for such systems are incredibly expensive as well. These options will be out of reach for some Non-Transient suppliers. Accordingly, the Proposed PFAS Rules will almost certainly cause the State of Michigan to lose business—either through closure or to competing states that have less short-sighted policy development.

It is plainly inequitable to place these substantial burdens on Non-Transient water suppliers. Non-Transient water suppliers are already burdened by substantial testing and compliance obligations in Michigan. Non-Transient water suppliers do not have access to the same grant opportunities, user fees, and tax roll support that public water utilities enjoy. *See, e.g.*, *Noncommunity Water Suppliers Face SDWA Challenges*, On Tap, National Drinking Water Clearinghouse, http://www.nesc.wvu.edu/pdf/DW/publications/ontap/newsletter/OTNs94.pdf (accessed 1/9/2020). Accordingly, subjecting Non-Transient water suppliers to EGLE's Proposed PFAS Rules will unduly burden such suppliers while ignoring the underlying historical causes of PFAS contamination in Michigan.

3. *The Proposed PFAS Rules should not require duplicative and unnecessary testing for Non-Transient suppliers using commingled supplies when the source of PFAS is already being monitored and addressed by water utilities.*

The Proposed PFAS Rules create ambiguity for Non-Transient water suppliers that may also draw water from a public water system. For example, if a Non-Transient water supplier draws water from both a public water supply and from groundwater well(s), the draft rules appear to require the Non-Transient supplier to test the combined water from its wells and the water coming from the public water supply. Even if the groundwater obtained by the Non-Transient supplier has no detectable PFAS, the sampled water may have a detection of PFAS caused by the commingled public water supply. Under one reading of the Proposed PFAS Rules, and depending on the level of detection, the Non-Transient supplier may be required to quarterly test its commingled water and perhaps take even more substantial action if the detection is above the MCL. However, the public water system would already be required at that point to address the PFAS in its water by quarterly testing and the potential installation of additional treatment

technology. In this scenario, the Non-Transient supplier's quarterly testing and other actions required by the Proposed PFAS Rules would be duplicative and unnecessary.

EGLE should thus revise the Proposed PFAS Rules to create an express exception for commingled supplies when the sole contributor of PFAS in a commingled supply is already being monitored and addressed. If PFAS is detected in the combined water, the supplier should then be given the option to demonstrate the source of PFAS in its combined water supply by testing each combined supply separately. In the example above, the supplier could test both its groundwater well(s) and the community water supply to demonstrate that the only detectable PFAS is originating from the community water supply. If the supplier tests each supply separately and the only detections come from a water supply already being monitored and addressed under the Proposed PFAS Rules, then the supplier should not have to take any further action. Such an exception would eliminate duplicative, expensive, and burdensome testing requirements.

Conclusion

As stated above, the Manufacturer strongly opposes the Proposed PFAS Rules as drafted. The Proposed PFAS Rules will have a chilling effect on Michigan's economy and are not based on sound science or logical rulemaking principles. Michigan should take interim steps—like the EPA has done—and adopt the equivalent of a health advisory for PFAS in drinking water while going after the sources of contamination rather than end users. Such interim steps will allow the science on PFAS exposure to catch up with the rulemaking process, which will in turn allow EGLE to make informed decisions based on real data.

Sincerely yours,

VARNUM

Matthew D. Zimmerman

MDZ/sm

15901777_1.docx

Smith, Ian (EGLE)

From: [redacted]@ghd.com
Sent: Friday, January 31, 2020 4:51 PM
To: EGLE-PFAS-RuleMaking
Cc: [redacted]@ghd.com
Subject: Comments on Rule Set #2019-35 EG – PFAS Amendment to Supplying Water to the Public Rule
Attachments: EGLE PFAS MCL Comments Letter 1-31-2020.pdf

Suzann,
Attached please find GHD's comments to Review of Rule Set #2019-35 EG – PFAS Amendment to *Supplying Water to the Public* Rule. Thank you for the opportunity to be part of the state's solution to what has been identified as a challenging and complex problem.
Thanks
Beth

Beth Landale, PE PEng | A GHD Principal

GHD
Proudly employee owned
T: [redacted] | D: [redacted] | M: [redacted] | E: [redacted]@ghd.com
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Connect

January 31, 2020 Reference No. 11149638

EGLE – Drinking Water and Environmental Health Division
Attention: Suzann Ruch
PO Box 30817
Lansing, MI 48909-8311
EGLE-PFAS-RuleMaking@Michigan.gov

Dear Ms. Ruch:

Re: Review of Rule Set #2019-35 EG – PFAS Amendment to *Supplying Water to the Public* Rule

As part of the proposed amendments to Michigan (MI) Department of Environment, Great Lakes and Energy (EGLE) Rule Set 2019-35 EG Supplying Water to the Public, EGLE has proposed maximum contaminant level (MCLs) for seven per and poly-fluorinated substances (PFAS). There are no MCLs for PFAS established by the USEPA at this time, although health advisories have been calculated for several of them. However, on January 10, 2018, the residential and nonresidential drinking water criterion of 0.07 µg/L (70 parts per trillion [ppt]) for the combined concentrations of perfluorooctanoic acid (PFOA) [CAS # 335-67-1] and perfluorooctanesulfonic acid (PFOS) [CAS # 1763-23-1] took effect in Michigan as an element of the Natural Resources and Environmental Protection Act 451 of 1994 Part 201 (Section 324.20120). This criterion is a “cleanup” criterion that is protective of drinking water exposures, which means the criterion established by MI should be a protective level in groundwater used as drinking water. This rule set proposes to create Michigan’s first MCLs that are not adopted from the USEPA. The proposed rule set was issued for public comment in November 2019 and the public comment period ends January 31, 2020.

We agree the safety of public drinking water supplies in Michigan is paramount, as is public confidence in drinking water safety. We believe the state can protect the public health and its economic competitiveness while avoiding setting overly restrictive water quality criteria, especially since it is one of the few states with already enforceable groundwater criteria designed to be protective of drinking water exposure for PFOA and PFOS (in Part 201). We welcome the opportunity to be part of the state’s solution to what has been identified as a challenging and complex problem.

This comment package prepared by GHD addresses several areas of the proposed rule and the associated regulatory impact statement and cost benefit analysis (RIS). GHD believes that the development and implementation of statewide MCLs is premature based on the information proposed in the proposed rules, especially given that Michigan already has enforceable criteria for certain PFAS in established rules. Other options to protect public health, such as implementing risk-based cleanup from known or reasonably suspected releases at specific sites where PFAS was used/managed/disposed. An option like this will address many of the elevated PFAS contaminated locations without imposing widespread sampling and analysis costs, as well as potential water treatment costs, to achieve unnecessarily conservative values.

GHD
26850 Haggerty Road Farmington Hills Michigan 48331 USA
T [redacted] F [redacted] W www.ghd.com

In broad summary we have the following threshold level comments:

- Treatment Selection and Cost Benefit Analysis do not meet minimum requirements.
- Health-based values are not transparently documented.
- Novel and inconsistent exposure assumptions.
- The data provided by EGLE do not establish a clear and convincing needs to adopt an MCL beyond the criteria already in place under Part 201.

1. Treatment selection & cost benefit analysis do not meet minimum requirements

Preparing a robust and defensible assessment of the compliance costs of the proposed rule is a threshold element when establishing an MCL and it does not appear that MI has met the minimum requirements. If the state proceeds with the promulgation of the proposed MCL without meeting this requirement, it will impose additional legal costs upon the public during legal challenges. Examples of similar recent and ongoing legal challenges include the 2017 ruling over a hexavalent chromium MCL in California and a current injunction over the proposal PFAS MCL in New Hampshire.

In California, the hexavalent chromium MCL was legally withdrawn based on the State Board's failure to consider and determine that compliance with the new drinking water standard would be economically feasible. This determination was made after the state had prepared a cost analysis that was significantly more robust than the one prepared by MI for its proposed PFAS MCLs. In New Hampshire, the proposed PFAS MCL, which are similar to those proposed by MI, are currently in limbo while a higher court considers the ruling to require a more thorough cost-benefit analysis before implementation of the proposed MCL. Both of these examples illustrate how the lack of a thorough cost analysis will almost surely result in an additional and unnecessary cost burden to the public that can be completely avoided through the completion of a robust cost analysis.

The following illustrate some specific examples where the current cost analysis is lacking. These examples do not encompass the entire universe of limitations in the current cost analysis, but serve as obvious examples of limitations in the existing evaluation.

1.1 Cost of treatment using GAC, including on short chain PFAS

The RIS states the recommended treatment was based on a June 2015 New Jersey Drinking Water Quality Institute report titled Recommendation on Perfluorinated Compound Treatment Options for Drinking Water. The New Jersey Report recommended the use of GAC for the treatment of three specific long-chain perfluorinated compounds (PFCs); PFOA, PFOS and PFNA. The Report also indicates that GAC is less effective on shorter chain PFCs and that should be a consideration if the intent is to remove both long and short-chain PFCs.

The proposed rules from MI include MCLs for 7 PFAS and not only the three included in the New Jersey Report. The PFAS MCLs proposed by MI include both long and short chain PFAS. However, MI has

prepared its cost analysis assuming GAC is an effective treatment technology for long and short chain PFAS.

The ITRC Remediation Technologies and Methods for PFAS Worksheet discusses the effectiveness of liquid treatment of PFAS by GAC. This document describes that the short chain PFAS has larger GAC usage rates and quicker breakthrough times. From the limited information provided by MI, it is unclear whether the increased cost of treating short chain PFAS using GAC was appropriately calculated. If it was, then those computations should be expressly shown as part of the cost analysis. If it was not, then additional sources should be provided to justify why MI believes that treating short chain PFAS using GAC would not result in increased costs, as stated by New Jersey and ITRC.

1.2 Installation Costs

The RIS (Comment 13) uses a January 2019 report from the State of New Hampshire (NH) to identify a one-time treatment installation cost. EGLE used the high-end estimate from this source as a conservative estimate on a per gallon per day basis for the one-time installation cost for treatment of the PFAS compounds. While using the high-end estimate is a conservative approach, there are at least two significant issues with this approach:

- The NH report estimates that the total cost of treatment may range from $1.8M to $5.2M. The United States Census Bureau estimates the 2018 population of New Hampshire at 1.4 million people.

  The same 2018 Census Bureau estimate for the population of Michigan is approximately 10 million people. Assuming the 7-fold increase in population, it could be estimated that Michigan's cost of treatment may range from $12.6M to $36M, assuming that MI and NH residents use comparable volumes of water per capita. The upper end of this range is significantly higher than the $11M for the costs of treatment installation included in the RIS.

- The New Hampshire report (Section 1.2) states the proposed NH values of 38 ppt for PFOA and 70 ppt for PFOS/PFOA combined do not require the additional expenditure of funds because they are already accounted for by current treatment systems and current USEPA advisory levels. It is unclear how this statement this biases the NH cost estimates. It is also unstated how MI accounted for this, presumably low, bias in its cost analysis.

- Comment 14 (extension of comment 13) in the RIS states that the City of Plainfield is installing GAC treatment at an estimated cost of $15M in response to contamination that is not currently in excess of the proposed MCLs. If this system alone is costing $15M, then the $11M estimate included in the RIS for addressing treatment at other large community systems and smaller non-community systems across the state of Michigan that are currently known to required PFAS treatment is insufficient and a significantly larger funding amount will be necessary.

From the examples provided above, it appears that the costs to implement these proposed MCLs have been underestimated and that the public will bear a significantly higher financial burden that proposed by

MI. Prior to continuing with these proposed MCLs, a more thorough and transparent cost analysis must be conducted to present a more realistic picture of the financial implications of the proposed rules.

1.3 Operation, Monitoring and Maintenance Costs

As discussed above, the effectiveness of PFAS treatment by GAC varies based on many factors, one being chain length of PFAS. This is because short chain PFAS has larger GAC usage rates and quicker breakthrough times.

- The RIS states that the NH study was used to estimate the annual operation and maintenance costs. While using the high-end annual estimate is a conservative approach, this does not account for the specific PFAS that will need to be treated based on the MI proposed MCL relative to those proposed in NH that only focuses on four longer chain PFAS: PFOS, PFNA, PFOA and PFHxS.
- In RIS Comment 13 and 28, an “estimated cost of treatment of $46 per gallon” is cited for smaller, non-community systems. This is an extraordinarily high cost estimate. At this price water will be 20 times as expensive as gasoline. This statement also implies that smaller systems will be more costly to install on a per capita basis, but it would be similarly expected that these smaller systems would be more expensive to operate, as the economy of scale savings that would typically be observed in larger systems will not be available to smaller systems. The RIS discusses a consistent application of $0.35 per gallon rate for operation, monitoring and maintenance across large and small systems. Applying the same operation cost of $0.35 per gallon to the smaller systems ($7,000 per RIS) is unrealistically low.
- The costs associated with annual compliance sampling should also be included in the costs for operating and maintaining of the systems. Using the example of a small system as discussed in Comment 28, the annual operating costs are predicted in the RIS to be $7,000. If quarterly sampling is included, that cost increases 34% to $9,400 annually ($7,000 +4x$600).

From the examples provided above, it appears that the costs for implementation, operation, monitoring, and maintenance associated with these proposed MCLs have been underestimated and that the public will bear a significantly higher financial burden that proposed by MI. Prior to continuing with these proposed MCLs, a more thorough and transparent cost analysis must be conducted to present a more realistic picture of the financial implications of the proposed rules.

2. Health-based values are not transparently documented

The rationale behind MI’s selection of its toxicity endpoints, which were in-turn used to calculate the proposed MCLs, are not thoroughly documented and in some instances the justification and documentation appear hasty. For MCLs, which once promulgated will be challenging to alter to either make more or less stringent based on the available scientific information, a clear and methodical approach must be used and transparently presented to provide the public with an understanding of the elements considered or eliminated from the evaluation. The following are specific examples where the current documentation is inadequate:

- The drinking water health-based values and underlying toxicity criteria developed for PFOA and PFOS by EGLE (8 and 16 ppt, respectively, per the EGLE 2019 “Health-Based Drinking Water Value Recommendations for PFAS in Michigan” document) are based on animal studies and toxicity endpoints that the USEPA did not find sufficiently convincing to use as the basis of their Health Advisory guidance for PFOA and PFOS (70 ppt for each chemical or together) in drinking water. MI must provide transparent and defensible documentation of why its approach is more appropriate for the protection of drinking water.

- While the USEPA’s similar documents are clear in their presentation and discussion of the numerous toxicology and exposure assessment parameters, the EGLE document summarizes the same information in a condensed table for all PFAS. The summary table ultimately concludes by stating “Numeric health-based values derived and justified using the above information”. This approach to summarize the work performed by MI is not transparent as it is not possible to confirm and review how the EGLE numbers were actually calculated, since the complete equations are not shown.

- The Health-Based Drinking Water Value Recommendations for PFAS in Michigan document does not discuss whether significant external peer review was part of the process or whether the three authors subjectively agreed upon the values. A peer review committee tasked with considering whether the toxicity endpoints the EGLE toxicologists chose are truly “adverse” vs just a temporary observation (e.g., delayed ossification) that has no long term impacts is a necessary element to ensure transparency and defensibility in the proposed MCLs.

In addition, it is noteworthy how quickly the MI 2019 Drinking Water Recommendations document was prepared in three months (April 19 – June 27, 2019, pg 3). Whereas USEPA’s similar exercise for only PFOA spanned eight years (2009-2016). It is uncommon for sound and agreed upon science to be formulated in a matter of months. Therefore, MI should cease with its “rush to MCL” strategy and establish a more deliberative and prudent, sound science approach be taken that includes broader public engagement and peer review.

3. Novel and inconsistent exposure assumptions

MI has developed exposure scenarios, including associated uncertainty factors, and applied apparently inconsistent input assumptions when calculating the proposed MCLs that it believes are necessary to be protective. However, these proposed approaches appears subjective and even ignore the actual toxicological endpoint. The following summarizes some of the issues identified:

- MI selected receptors and exposure factors that are inconsistent with the default approaches and inputs used by MI and the USEPA in the generic evaluation of drinking water exposures. While chemical-specific approaches are sometimes necessary, MI has not transparently documented it approach in making these decisions or the chemical-specific information that it identified that

necessitated a deviation from the established generic process. MI should fully document its process and any proposed deviations from generic approaches to provide complete transparency.

One example of a unique receptor is found in MI's use of the breast-fed infant exposure as the target population. This decision required creation of receptor-specific factors, assumptions, and uncertainty factors where the basis for these values is only briefly documented. This example is most concerning because the critical effect occurs for in-utero exposure and not in the postnatal pups. Utilizing the correct toxicological endpoint would have eliminated the need to create a receptor and assumed exposure factors.

- MI has used various relative source contributions (RSCs) for the different PFAS chemicals. The process MI used to establish these RSCs is unknown and should be clearly and thoroughly documented. As part of this documentation, MI should also describe in detail how its selected RSCs account for the fact that certain PFAS chemicals are no longer produced or distributed in the US.

4. The data provided by EGLE do not establish a clear and convincing needs to adopt an MCL beyond the criteria already in place under Part 201

A prerequisite for deriving MCLs per (RIS, item 4, page 2"A statement of specific facts that establish the clear and convincing need to adopt the more stringent rules …" is necessary. EGLE has not demonstrated that there is a clear and convincing need to adopt PFAS standards more stringent than the MI Part 201 criterion/USEPA health advisory levels.

To the contrary, EGLE's website suggests that PFAS contamination in groundwater and surface water above the MI Part 201 criterion/USEPA Health Advisory level is not prevalent in the areas sampled/tested. A review of the 279 entries in the Quarterly Monitoring database showed that there were minimal exceedances of the MI Part 201 criterion/USEPA Health Advisory level of 70 ppt for PFOA and PFOS (https://www.michigan.gov/pfasresponse/0,9038,7-365-95571_95577_95587_95620-508857--,00.html).

Additionally, the Phase II (2019) database of 899 samples for PFAS also showed few samples where concentrations exceeded the MI Part 201 criterion/USEPA Health Advisory level for PFOA and PFOS (https://www.michigan.gov/pfasresponse/0,9038,7-365-95571_95577_95587_95620-508855--,00.html).

Collectively these two sources include almost 1,200 samples with a minimal number of samples exceeding the MI Part 201 criterion/USEPA Health Advisory level. With only limited data exceeding the enforceable MI Part 201 standards, these data do not on their own provide clear and convincing evidence that would justify promulgation of a much lower statewide MCL when MI is one of the few states that already have enforceable groundwater standards designed to be protective of drinking water exposures.

The RIS states that a "significant exposure was discovered in the city of Parchment" and that "this sampling also identified a number of drinking water systems with levels of PFAS contaminants that could cause adverse health effects if not addressed". However, this discovery does not appear to be shown in

the statewide sampling initiative for Michigan public water supplies database (referenced above). If significant contamination in Parchment is being cited as a reason to support statewide MCLs, those data must be presented in the EGLE statewide database. Because nearly all of the 1,200 samples in the database are below the MI Part 201 criterion/USEPA Health Advisory level, it is unclear how Michigan is justifying the need for the lower proposed MCLs.

5. Summary

In summary, GHD believes that EGLE should at a minimum address the above identified deficiencies in the proposed MCLs before proceeding further with the establishing MCLs. While MI continues to move through a thoughtful process, it should continue to protect public health, such as implementing risk-based cleanup from known or reasonably suspected releases at specific sites where PFAS was used/managed/disposed, using its existing enforceable drinking water cleanup criteria for PFOA and PFOS in Part 201. Given that the State water sampling database demonstrates that a state-wide problem does not exist relative to the current drinking water criteria, it seems unnecessary and in appropriate to compel all water supply systems to add PFAS to their treatment and sampling programs at this time. Additionally, reasonable Michigan-specific costs to achieve the proposed MCLs and the cost-benefit evaluation should be completed in a thoughtful and thorough manner to avoid unnecessary legal costs that other states have incurred/are incurring as they have attempted to propose MCLs without a sufficiently robust cost analysis.

Sincerely,

GHD

Beth Landale, PE
Principal

Francis C. Ramacciotti
Associate/Sr. Risk Assessor

BL/bl/1

Smith, Ian (EGLE)

From: Rambosk, Kevin <Kevin.Rambosk@mail.house.gov>
Sent: Thursday, January 30, 2020 2:38 PM
To: EGLE-PFAS-RuleMaking
Cc: Jesaitis, Katie
Subject: Dingell Comment Letter EGLE PFAS MCL Rule
Attachments: 200130_EGLE_PFAS MCL Rule_Dingell.pdf

(ATTN: Suzann Ruch)

Good afternoon—

Please see the attached comment letter from Congresswoman Debbie Dingell regarding EGLE's Rule on a PFAS MCL for drinking water.

Thanks and please confirm receipt.

Best,

Kevin

_____

Kevin J. Rambosk
Legislative Director
Office of Congresswoman Debbie Dingell (MI-12)
116 Cannon HOB
Washington D.C. 20515
[redacted]

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January 30, 2020

Liesl Eichler Clark
Director
Michigan Department of Environment, Great Lakes, and Energy
P.O. Box 30817
Lansing, MI 48909

Dear Director Clark:

This letter is to provide comments in support of the Michigan Department of Environment, Great Lakes, and Energy's (EGLE) proposed rule to establish drinking water protections and efforts to reduce exposure to seven per- and polyfluoroalkyl substances (PFAS). We are working on this issue at the federal level but also need states to act.

In early January, the House of Representatives passed H.R. 535, the PFAS Action Act, bipartisan legislation that would comprehensively addresses PFAS contamination in Michigan and across the country. It is anchored by a version of my original legislation that, after working with stakeholders and my colleagues on Energy and Commerce, now focuses on PFOA and PFOS. These two chemicals are the most hazardous of the class and it is time these chemicals are properly designated as hazardous substances under the U.S Environmental Protection Agency's (EPA) Superfund program. Doing this will accelerate the clean-up process at military facilities and in communities all across this country. This would be a significant first step while we allow the EPA to study the remaining compounds—which needs to start now.

Additionally, this bill would require EPA to set maximum contaminant levels for PFOA and PFOS in our drinking water—one of the most important efforts we can take to ensure all American's drinking water is clean. It will also require the development of new science before we bring new PFAS chemical into commerce, gives consumers new tool to avoid PFAS in household products, and will better protect our communities and workers, especially our firefighters.

This bill is a beginning, but this won't help communities or people unless it's passed by the Senate and signed into law by the President. We all must work together to protect human health and our environment. Further inaction only means more people continue to be poisoned and contamination spreads further.

Let's be very clear, PFAS is an urgent public health and environmental threat. And the number of contamination sites nationwide is growing at an alarming rate, including our military bases. PFAS chemicals are everywhere—it's in our non-stick cookware, food containers, carpets,

accumulates in your body, and toxic. They are man-made and known as "forever chemical" designed to stand the test of time. They do not breakdown in the environment and they do not breakdown in the human body or wildlife. Exposure to PFAS—even at low levels—poses significant health risks.

In a recent review, CDC identified a number of health effects associated with PFAS exposure, including cancer, liver damage, decreased fertility, and increased risk of asthma and thyroid disease. Experts believe 99 percent of Americans have some level of PFAS in their blood—and most don't even know.

Michigan has been hit hard. It is ground zero for where PFAS has been identified. We have 74 sites, only because Michigan is testing for it. We learned from the Flint water crisis. According to the Environmental Working Group, PFAS has been detected in the drinking water of more than 1,400 communities, across 49 states, including near 300 military installations. And those drinking water systems serve around 19 million people. Most of these sites are not being cleaned up. And the number of sites is expected to grow across the country as more states test for PFAS.

In my district, PFAS is in our water, including the Huron River where PFAS foam is washing ashore and we can't eat the fish. At a recent townhall, a man stood up and told me, 'I eat the fish. I live on it. When will the fish be safe again?'—I fear not in his lifetime.

But the most troubling thing I have learned through all of this is that the manufacturing companies knew about the harms of PFAS—and even tracked it in the blood of employees—while the EPA has completely abandoned its responsibility to act swiftly and comprehensively.

This year, Governor Whitmer and Attorney General Nessel joined together to lead a lawsuit against the manufactures that produced and failed to clean up PFAS chemicals. I thank them for their leadership and for the important proposed rule being considered.

Meanwhile, our military is arguing that they do not have to clean up PFAS contamination because the Superfund law does not require them to do so. Here is the reality. We are not cleaning up PFAS contamination. We don't even have a protective drinking water standard—not even for the two most notorious compounds, PFOA and PFOS. All we have is a health advisory guideline, that even Republican Governor Snyder's appointed PFAS task force said isn't stringent enough.

Every time EPA has testified before the Energy and Commerce Committee they make promises, and nothing has happened. Until the Senate and the President take action to enact the PFAS Action Act we will need states all across this country, like Michigan, stepping up and taking bold measures to protect human health and the environment from PFAS chemicals. Again, I commend Michigan for acting and support the proposed rule the state of Michigan is considering that will establishing drinking water standards, sampling requirements, public notification requirements, and laboratory certification criteria. Further inaction means more people will continue to be poisoned.

We all—federal, state, local, and private industry—must ultimately work together to address PFAS contamination.

Sincerely,

Debbie Dingell
Member of Congress

Smith, Ian (EGLE)

From: Heather D. Dziedzic <[redacted]@cmsenergy.com>
Sent: Friday, January 31, 2020 12:43 PM
To: EGLE-PFAS-RuleMaking
Subject: Consumers Energy Comments: 2019-35-EG PFAS
Attachments: ConsumersEnergy_PFAS_Comments-signed.pdf

On behalf of Consumers Energy Company, I am submitting the attached written comments to Rule Set 2019-35-EG, addressing per- and polyfluoroalkyl substances (PFAS) in drinking water.

We appreciate the opportunity to comment on the draft rules, and welcome any further dialogue or clarification you may require.

Sincerely,

Heather D Dziedzic
Consumers Energy, Senior Environmental Analyst Lead
Environmental Regulations & Strategy, Land & Water Management
1945 W. Parnall Rd, P22-326, Jackson, MI 49201
Office: [redacted] Cell: [redacted]

January 31, 2020

Department of Environment, Great Lakes, and Energy
Drinking Water and Environmental Health Division
Attn: Suzann Ruch
PO Box 30817
Lansing, MI 48909-8311

RE: Public Comment Deadline – Supplying Water to the Public Rules – Rule Set 2019-35-EG

Dear Sir or Madam,

Consumers Energy Company (Consumers) appreciates the opportunity to comment on the Department of Environment, Great Lakes, and Energy's (EGLE) proposed changes to administrative rules, addressing per- and polyfluoroalkyl substances (PFAS) in drinking water. (Rule Set 2019-35 EG).

Statement of Interest

Consumers is one of Michigan's largest combined gas and electric utilities, serving over 6 million of Michigan's 10 million residents. Consumers owns and operates four Type II nontransient noncommunity water supplies that serve electric generation sites and other support facilities. Thus, Consumers is affected by the proposed rule changes, and subsequent regulatory requirements.
Consumers has reviewed the proposed changes and offers the following comments.

Comments

R325.10604g MCLs for per- and polyfluoroalkyl substances

325.10604(g)(1): Hexafluoropropylene oxide dimer acid (HFPO-DA) was not tested during the 2018/2019 State of Michigan Statewide PFAS Survey (Survey). Therefore, water supplies that participated the Survey do not have analysis data required to determine initial sampling frequency described at 325.10717d(6).

R325.10717d Collection and analysis of samples for per- and polyfluoroalkyl substances

Consumers Energy
1945 W. Parnall Rd
Jackson, MI 49201

325.10717d(1): This subsection requires "Each supplier shall monitor at the time designated by the department." Due to labor, funding, and lab availability, suppliers should be given the flexibility to determine appropriate sampling schedules, so long as sampling meets the frequency dictated by the Rule.

325.10717d(3): This subsection requires that groundwater suppliers sample "every entry point to the distribution system that is representative of each well *after treatment* [emphasis added]." For some groundwater supplies, this sampling point is not feasible. For some supplies, including two operated by Consumers, multiple groundwater wells feed into a common treatment system. Therefore, a sample can either "be representative of each well" or be taken "after treatment" but not both, without modifying the system. It is recommended that the language be modified to reflect a sampling point that is representative of the post-treatment conditions as shown below:

(3) "A groundwater supplier shall take at least 1 sample at every entry point to the distribution system that is representative of *the supply* after treatment, also known as sampling point. Each sample must be taken at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant."

325.10717d(5): This subsection prescribes sampling locations for systems with "more than 1 source." It is unclear how certain groundwater systems may be interpreted, using the current definition of "source" from the rule. As currently defined at 325.10108 a "source" is "the point of origin of raw water or means treated water that is purchased or obtained by a public water supply, by a water hauler, or by a person who provides bottled water." For groundwater supplies, with multiple wells, this definition should be clarified to address the following question: If multiple wells draw from the same groundwater aquifer, are they defined as a single source or more than 1? The corollary being "If groundwater wells draw from distinct aquifers, is the supply considered to be multi-source?" In order to be consistent with 10717d(3), EGLE should consider multi-well systems, from a single aquifer, as a uniform groundwater source, with sampling points determined by 10717d(3).

325.10717d(9): This subsection addresses sampling frequency for supplies whose initial test results are below the reporting limit (RL). The rule states "the department *may* [emphasis added] allow the water supply to monitor annually." This subsection fails to clearly define what the default sampling is for systems below the RL. Given that the rule considers results below the reporting limit to be zero (325.12708(c)), supplies should be allowed to discontinue regular sampling, unless otherwise requested by EGLE. At a minimum, if regular sampling was intended, annual sampling should be the default, or EGLE should add language that more clearly defines when annual

sampling will be permitted. As the rule stands, supplies are unable to clearly predict or plan sampling frequency for compliant, low-risk systems.

325.10717d(10) and (11): This subsection prescribes ongoing sampling frequency for systems above the reporting limit (that is, not included in 101717d(9)) and those exceeding the MCL at 10604g. In each case, supplies are required to initiate quarterly sampling, despite the significant difference between the RL and MCL. For example, a system may have a result above the 2ng/L RL for Perfluorohexanoic acid (PFHxA), but could be orders of magnitude below the MCL of 400,000 ng/l. In such a situation, the subsequent sampling frequency is identical to an MCL exceedance. This approach requires potentially costly quarterly sampling for low-risk supplies, that is, those closer to the RL than the MCL. The rule should be amended to reduce the sampling frequency for these systems. For example, EGLE should consider a similar approach to 10717d(6)(a-b), which recognizes the relative proximity to an MCL as a reasonable measure of risk. A reasonable alternative would be to require sampling two times per year for systems above the RL, but less than 50% of the MCL, while retaining quarterly sampling for systems exceeding an MCL and those above the 50% threshold.

325.10717d(11): This subsection states "If not fewer than 4 quarterly samples show that the supply is in compliance." As written, it is not clear whether these samples must be consecutive.

325.10717d(13): This subsection states "The department may increase the required monitoring to detect variations within the system." Increased sampling frequency should be limited to no more than one additional sampling event, beyond a supplier's current sampling schedule. Due to sampling complexity, cost, and lab availability, reasonable limits are necessary.

Consumers Energy appreciates the opportunity to comment on this rulemaking and the consideration of the enclosed comments. We welcome the opportunity for further dialog should you have questions or desire further clarification. I can be contacted at 517-788-1285, or heather.dziedzic@cmsenergy.com.

Sincerely,

Heather Dziedzic
Consumers Energy
Environmental Regulations & Strategy
Supervisor of Land & Water Management
1945 W. Parnall Rd, P22-326
Jackson, MI 49201

Smith, Ian (EGLE)

From: Janice Tompkins <[redacted]@aol.com>
Sent: Friday, January 31, 2020 11:15 AM
To: EGLE-PFAS-RuleMaking
Subject: Comments on PFAS Standards
Attachments: PFAS Standard Legislation comments Jan 30, 2020.docx

thank you for the opportunity to make comments

Janice Tompkins
[redacted]@aol.com

January 30, 2020

Dear Drinking Water and Environmental Health Division,

Subject: PFAS Standard Legislation

It has been proven time and time again that industries do not self-regulate, that profits overrides community health interests every time. They need to be held accountable with strong standards.

The 18-30 year olds believe in protecting the environment. Safe Air, Water, and Land are critical to them in deciding where to professionally locate. If we want a healthy economy in Michigan we need a healthy environment to draw or keep the top quality people for our businesses, local governments, institutions, and communities.

The tourist industry is major component of Michigan's economy. We need safe water (surface water, groundwater, and drinking water), air, and land to have a strong tourist industry. We need strong standards to ensure we protect these natural resources that will ensure tourists will still want to come to Michigan.

PFAS contamination impacts the drinking water of more than 1.9 million Michiganders and we can't delay on protecting the health benefits of our communities. This added to the Flint Water Crisis and Michigan is getting a reputation of NOT BEING A SAFE PLACE to work or play. THEREFORE, MICHIGAN NEEDS TO BE A LEADER IN THE COUNTRY IN SETTING STRONG RESEARCH BASE STANDARDS THAT PROTECT OUR WATER, WETLANDS, AIR, AND LAND.

Given Michigan is a leader in PFAS contamination, Michigan should show the nation that we are setting the country's toughest standards for PFAS chemicals in our waters. Michigan's PFAS standards should take into account the best available research and studies, like those done in New Hampshire to ensure the limits are protective of public health. Michigan should ensure the standards are protective of our most vulnerable citizens, our developing infants and children. Recent science shows that PFAS chemicals should be evaluated as a class of individual chemicals. Their additive effect can make them more toxic. The State should set a combined total limit for all the toxic contamination instead of smaller limits for each chemical. EWG (Environmental Working Group) and Dr. Linda Bimbaum believe that the safe level for PFAS be no higher than 1ppt. Massachusetts lowered their MCL from 70ppt for the sum of 5 PFAS chemicals to 20ppt for the sum of 6 PFAS chemicals. The draft legislation does not address private wells, and campgrounds. This needs to be addressed to if we want people to believe this is safe place to live and visit.

I don't want people when they think of Michigan to think it consists of corrupt businesses, a failed state government, polluted drinking water and groundwater, and contaminated land. I don't want to live in state that doesn't feel safe and has a state legislature that fails to protect its citizens. Please act swiftly with strong PFAS standards based on the best scientific research. Thank you for this opportunity to comment.

Sincerely,

Janice L. Tompkins

Smith, Ian (EGLE)

From: Jennifer McKay <[redacted]@watershedcouncil.org>
Sent: Friday, January 31, 2020 4:10 PM
To: EGLE-PFAS-RuleMaking
Subject: Comments Administrative Rules for Supplying Water to the Public Rule Set 2019-35 EG
Attachments: TOMWC Comments on EGLE Rule Set 2019-35 EG.PDF

Please accept the attached comments regarding the Department of Environment, Great Lakes and Energy Drinking Water and Environmental Health Division Administrative Rules for Supplying Water to the Public Rule Set 2019-35 EG on behalf of Tip of the Mitt Watershed Council.

Thank you.

Jennifer McKay
Policy Director
Tip of the Mitt Watershed Council
[redacted]@watershedcouncil.org
www.watershedcouncil.org

January 31, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311

RE: Department of Environment, Great Lakes and Energy Drinking Water and Environmental Health Division Administrative Rules for Supplying Water to the Public Rule Set 2019-35 EG

Dear Ms. Ruch:

Tip of the Mitt Watershed Council, on behalf of its Board and 2,300 members, would like to comment on the Department of Environment, Great Lakes and Energy Drinking Water and Environmental Health Division Administrative Rules for Supplying Water to the Public Rule Set 2019-35 EG. The proposed rules would provide provisions to reduce exposure to seven per- and polyfluoroalkyl substances (PFAS) in drinking water throughout Michigan.

Tip of the Mitt Watershed Council is a nonprofit organization, based in Northern Michigan, whose purpose is to protect, restore, and enhance water resources, including our Great Lakes, inland lakes, rivers, wetlands, groundwater, and drinking water. We base all our programs on sound science and policy analysis, and have garnered respect for our work from local, state, and federal agencies, businesses, fellow environmental organizations, and citizens.

The Watershed Council strongly supports the Michigan Department of Environment, Great Lakes, and Energy's (EGLE) efforts to establish a rule to create a maximum contaminant level (MCL) for PFAS. We appreciate that EGLE is making progress toward setting drinking water standards, which is a vital step to protect the public health of Michigan's citizens. In the absence of adequate federal safeguards, Michigan must act to protect drinking water, reduce risks to the public, and remediate contaminated drinking water sources. Clear and mounting evidence demonstrates the link between low dose-exposures to these chemicals and serious human health risks, including cancer and adverse immunological, developmental and reproductive effects.

However, there is room for improvement in the scope and protectiveness of the proposed MCL. We encourage EGLE to make Michigan's PFAS drinking water standards more comprehensive and protective of public health. We recommend the following improvements be incorporated into the final rule.

Implement a Class-Based MCL

While there may be limited toxicity information for PFAS outside the more-studied contaminants proposed for the MCL, a growing body of scientific research indicates that the class collectively poses similar threats to human health and the environment. There is emerging consensus that adverse health impacts are linked to other PFAS, and further that their effects are additive. As a result, a MCL for only seven PFAS will not sufficiently protect against the risks from the PFAS class of chemicals.

Therefore, we recommend a PFAS class-based MCL. The PFAS class of chemicals is characterized by extreme persistence, high mobility, and is associated with a multitude of different types of toxicity at very low levels of exposure. In addition, regulating the class is the only way to avert the cycle of regrettable substitution in which one, well-studied chemical is replaced with a similar but poorly studied alternative. Ultimately, EGLE should have a goal of a MCL of zero for the entire PFAS class.

In the interim, we recommend MCLs at least be developed for other PFAS contaminants detected in the State's drinking water. In particular, the Michigan Science Advisory Workgroup recommended in their report, "Health-Based Drinking Water Value Recommendation for PFAS in Michigan," setting a screening level of 6 ng/L for all other long-chain PFAS included on the USEPA Method 537.1 analyte list for which the Workgroup did not develop an individual health-based value. Those long-chain PFAS include: NEtFOSAA (CASRN: 2991-50-6); NMeFOSAA (CASRN: 2355-31-9); PFDA (CASRN: 335- 76-2); PFDoA (CASRN: 307-55-1); PFTA (CASRN: 376-06-7); PFTrDA (CASRN: 72629-94-8); and PFUnA (CASRN: 2058-94-8). Given the chemistry of these PFAS, it is likely that they cause the similar adverse health effects as the long-chain PFAS proposed for regulation. The Department needs to be proactive and protective of public health and implement MCLS for these PFAS compounds, as well as all PFAS detected in Michigan's drinking water. The State should not wait until the adverse health effects have been proven and Michigan's citizens have been harmed to implement regulations requiring monitoring, public notification, and best available treatment technology.

Develop a Total PFAS MCL to Account for Additive and Synergistic Effects

PFAS commonly co-occur in drinking water and may have additive health effects. When multiple substances are present, the potential risk must be evaluated from the combined exposure. Evaluating a mixture of chemicals, based solely on individual health based values may not provide

an adequate margin of safety. Our concern is amplified by the potential additive and synergistic effects of the seven PFAS not only with one another, but with the thousands of other PFAS in the environment. As a result, we recommend developing a Total PFAS MCL to account for the high potential for additive effects, as well as the limited data on these effects.

Revisit Standards to Account for New and Emerging Science

Drinking water standards across the country generally go down, as we are currently seeing, informed by new scientific findings on PFAS health effects. We urge the State to commit to revisiting these standards by a date certain, preferably within two years, to ensure Michigan's standards incorporate the best available scientific data. Without this review, the drinking water standards will become out of date as new and emerging science is rapidly being developed on PFAS. This could leave Michigan citizens exposed to unsafe levels of PFAS. A date certain to revisit the PFAS drinking water standards should be incorporated into the rule as a requirement for EGLE to ensure it occurs to provide protection of drinking water for all Michiganders.

Increase Violation for Failure to Monitor

Currently, the rules list the failure to monitor as a tier 3 violation. Tier 3 violations have been found to have significant issues with public notice and late reporting, as noted in the U.S. Environmental Protection Agency audit of EGLE's Drinking Water Division associated with the Flint water crisis. As a result, tier 3 violations can lead to significant delays and a lack of vital public health information, posing considerable risk to the health of Michigan's citizens. Therefore, we recommend that the failure to monitor for PFAS be increased to a tier 2 violation. This will ensure effective and consistent monitoring and better protection of public health in the event that there is a failure to conduct the required monitoring.

Other Recommendations

Lastly, we urge the State to concurrently establish cleanup criteria for groundwater used as a drinking water source under Part 201, Environmental Remediation of the Michigan Natural Resources and Environmental Protection Act, Act 451, as amended. Michigan has already taken a proactive approach to regulate PFAS contaminants in groundwater for PFOA and PFOS, but this needs to be done for the other five PFAS that will soon have a drinking water standard. Part 201 Administrative Rules provisions [R 299.6(9) et al] allow the department to determine that a substance not listed in the generic cleanup criteria tables is a hazardous substance using best available information about toxicological and physical-chemical properties of the substance, and to use that information to develop a generic criteria. The toxicological and physical-chemical information used to develop the drinking water standards is justification to establish cleanup criteria for groundwater used as a drinking water source.

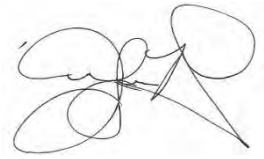
Similarly, a groundwater/surface water interface (GSI) clean-up criteria under Part 201 should be established to address groundwater discharges into surface water that is used for drinking water. These actions will provide the State with the legal tools necessary to address PFAS contamination and protect Michigan's environment and its citizen's health.

Conclusion

We commend the Whitmer Administration and EGLE for taking expeditious steps towards regulating certain chemicals within the PFAS family to protect human health. The Watershed Council strongly supports quick action to adopt the strongest possible drinking water standards for PFAS in Michigan. We urge the Administration and EGLE to to make certain we are as aggressive as possible in combatting these forever chemicals that are harmful to our environment and the health, safety and well-being of Michigan's residents. Therefore, we urge you to move forward with implementation of the Administrative Rules for Supplying Water to the Public Rule Set 2019-35 EG, incorporating the recommendations provided above.

Thank you again for the opportunity to comment and for your consideration of these comments. If you should have any questions, or would like to discuss our comments further, please contact Jennifer McKay, policy director at Tip of the Mitt Watershed Council at jenniferm@watershedcouncil.org or (231) 347-118.

Sincerely,



Jennifer McKay
Policy Director

Smith, Ian (EGLE)

From: Kelly Thayer [redacted]@flowforwater.org>
Sent: Friday, January 31, 2020 3:54 PM
To: EGLE-PFAS-RuleMaking
Cc: Dave Dempsey; Jim Olson; Liz Kirkwood
Subject: Attention: Suzann Ruch - FLOW Comments on Proposed Safe Drinking Water Act Rule Setting MCLs for 7 PFAS Compounds in Public Drinking Water
Attachments: FLOW-PFAS formal public comment letter to EGLE-Submitted 1-31-2020.pdf

January 31, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311
egle-pfas-rulemaking@michigan.gov

VIA ELECTRONIC SUBMISSION

FLOW (FOR LOVE OF WATER) COMMENTS ON THE PROPOSED SAFE DRINKING WATER ACT RULE SETTING MAXIMUM CONTAMINANT LEVELS (MCLS) FOR SEVEN PFAS COMPOUNDS IN PUBLIC DRINKING WATER

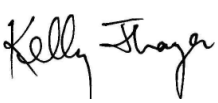
Dear Ms. Ruch:

Attached please find formal public comments from FLOW expressing support for the proposed Safe Drinking Water Act rule setting maximum
contaminant levels (MCLs) for seven PFAS compounds in public drinking water, Ruleset 2019-35 EG, R 325.10101 R 325.12820. These rules will provide critical public health protection from multiple compounds found to be widespread in Michigan public drinking water supplies.

It is imperative for Michigan to promulgate the proposed rules as soon as practicable. Testing continues to turn up new sites of PFAS contamination in Michigan, many of them exposing citizens to substantial health risks. Federal rules are likely years away and may not provide the level of protection that the people of
Michigan want and need for public health and the environment. We applaud Governor Whitmer and the Michigan Department of Environment, Great Lakes and Energy (EGLE) for your initiative to address the problem head-on.

And we also urge improvements to the rules as detailed in our attachment.

Sincerely,



Kelly Thayer
Deputy Director
FLOW (For Love Of Water)

153½ East Front St., Suite 203C

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Visit us online: www.FLOWforWater.org - Like us on Facebook and Twitter

FLOW
FOR LOVE OF WATER

Protecting the Common Waters of the Great Lakes Basin
Through Public Trust Solutions

January 31, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311
egle-pfas-rulemaking@michigan.gov

VIA ELECTRONIC SUBMISSION

FLOW (FOR LOVE OF WATER) COMMENTS ON THE PROPOSED SAFE DRINKING WATER ACT RULE SETTING MAXIMUM CONTAMINANT LEVELS (MCLS) FOR SEVEN PFAS COMPOUNDS IN PUBLIC DRINKING WATER

Dear Ms. Ruch:

We are writing to express support for the proposed Safe Drinking Water Act rule setting maximum contaminant levels (MCLs) for seven PFAS compounds in public drinking water, Ruleset 2019-35 EG, R 325.10101 R 325.12820. These rules will provide critical public health protection from multiple compounds found to be widespread in Michigan public drinking water supplies.

It is imperative for Michigan to promulgate the proposed rules as soon as practicable. Testing continues to turn up new sites of PFAS contamination in Michigan, many of them exposing citizens to substantial health risks. Federal rules are likely years away and may not provide the level of protection that the people of Michigan want and need for public health and the environment. We applaud Governor Whitmer and the Michigan Department of Environment, Great Lakes and Energy (EGLE) for your initiative to address the problem head-on.

We are particularly pleased with the science-based process used to develop the rule and the fact that it generally takes into account emerging research findings, resulting in proposed limits more protective of human health than those in place or proposed by some other states. However, New Hampshire performed new analysis of research conducted in 2018 to set an MCL for PFHxS of 18 ppt on research that shows a relationship between PFHxS exposure and impaired reproduction. The HBV recommended in Michigan for PFHxS is 2.5 times higher, or 51 ppt. Given the rapid pace at which new toxicological information on the low dose effects of PFAS chemicals on human health is emerging, Michigan should strive to reflect the very best science in its assessment of water safety.

We also urge the following improvements to the rules:

- **A total PFAS MCL.** We urge a treatment-based water standard for drinking water systems with detectable PFAS. A focus on treatments that are effective for broad numbers of PFAS chemicals will

have significant co-benefits of reducing the bulk of unclassified PFAS chemicals, which include precursors to PFOS, PFOA and other PFAS chemicals with individual health-based values.

- **Class-based regulation.** The proposed values for individual PFAS chemicals are not protective against the likelihood of additive effects from multiple PFAS. Michigan water testing confirms that when water is contaminated with PFAS, people are nearly always ingesting multiple chemicals. PFAS chemicals, including newer generation PFBS and GenX, share many of the same toxicity endpoints, including harm to the liver, thyroid, and kidney. The state should set group values, at minimum for all the carboxylic acids (PFOA, PFNA, PFHxA, Genx) and a separate combined HBV for all the sulfonic acids (PFOS, PFHxS, PFBS) on their list.

  In addition to setting numeric standards for individual compounds of PFAS, the state should set a cumulative limit. A cumulative limit would create a level of protection for residents exposed to multiple PFAS chemicals at a time.

- **Require a health review in two years.** The state is moving forward with setting drinking water standards for seven PFAS compounds. While a step in the right direction, that approach leaves thousands of PFAS compounds unregulated. The science on the risk and toxicity of PFAS chemicals is rapidly developing; standards set today could quickly become out of date as new research on toxicity comes in. To ensure Michigan remains ahead of the curve and maintains science-based standards that are protective of public health, the state should conduct a health review two years after the PFAS drinking water standards go into effect. This requirement should be written into the PFAS drinking water rules.

- **Conduct at least three years of quarterly sampling.** We do not know enough about how PFAS moves in the environment or if there are seasonal changes to discharges of PFAS to be able to set reduced sampling frequencies. The current rule requires some quarterly sampling, but also allows water plants to reduce in some cases to sampling every six months or only once a year. At a minimum, given the unknowns, all water systems should test quarterly for three years. That will give the state a solid baseline of knowledge to know when PFAS may or may not spike and which supplies are most at risk of exposure. From there the state can better establish a reduced sampling frequency process.

- **Protect fetuses, infants and children.** Fetuses and infants have greater exposure to PFAS than adults, and are also more sensitive to the effects of these contaminants. Almost all fetuses and infants will have some degree of exposure, including exposure as fetuses during pregnancy through placental transfer. For infants, exposure may be further elevated due to ingestion of contaminated breastmilk (a result of the mothers' ingestion of contaminated water and other sources) or infant formula prepared with contaminated drinking water.
  Levels of PFOA and PFOS in breast milk are much higher than what is typically found in drinking water, as PFOA and PFOS bioaccumulate in the body and are then transferred into the breast milk. Moreover, since infants consume approximately five times more water per body weight than adults, their exposure is likely higher than adults regardless of whether they are breastfed or are fed infant formula prepared with PFAS- contaminated drinking water. Infant blood serum levels of PFAS are often the highest of any age group in studies that compare people in multiple stages of life.

  Compounding the issue of increased exposure, fetuses, infants, and children are also more vulnerable

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TRAVERSE CITY, MI 49684
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to exposure-related health effects than adults. The young may be more sensitive to the effects of PFAS due to their immature, developing biological systems (such as the immune system), and rapid body growth during development. For example, exposure to PFAS before birth and/or in early childhood may result in decreased birthweight, decreased immune responses, and hormonal effects later in life.

The National Academy of Sciences (NAS) has recommended the use of an additional uncertainty factor of 10 to ensure protection of fetuses, infants and children who often are not sufficiently protected from toxic chemicals such as pesticides by the traditional intraspecies (human variability) uncertainty factor. Congress adopted this requirement in the Food Quality Protection Act for pesticides in foods. Considering the many health effects linked to PFAS that affect this vulnerable population and the substantial data gaps on exposure and toxicity of these compounds in complex mixtures, we recommend the use of this uncertainty factor when deriving health-protective benchmarks for PFAS.

These proposed rules are a critical bulwark in the defense of our families, fish and wildlife from the risk of exposure to PFAS. They are strongly supported by cutting-edge science. We urge their adoption with the improvements noted above.

Sincerely,

Kelly Thayer
Deputy Director
FLOW (For Love Of Water)
153½ East Front St., Suite 203C
Traverse City, MI 49684
[redacted]@flowforwater.org
[redacted]

Smith, Ian (EGLE)

From: Daniel Brown <[redacted]@HRWC.ORG>
Sent: Tuesday, January 28, 2020 3:35 PM
To: EGLE-PFAS-RuleMaking
Subject: HRWC public comments regarding proposed MCLs for PFAS compounds
Attachments: Comments to EGLE on PFAS MCLs 2020-01-14.pdf

Categories: Blue Category

Dear Ms. Ruch,

Attached, please find the Huron River Watershed Council's public comments regarding the proposed Maximum Contaminant Levels (MCLs) for 7 PFAS compounds.

Thank you to you and your colleagues at EGLE and other state agencies for your work on the issue.

Daniel A. Brown
Watershed Planner
Huron River Watershed Council | Huron River Water Trail
[redacted] | 1100 N Main, Suite 210, Ann Arbor, MI 48104

1/14/2020

Huron River Watershed Council

EGLE, DWEHD, Attention: Suzann Ruch
P.O. Box 30817, Lansing, MI 48909-8311

To Whom it May Concern,

The Huron River Watershed Council has been involved in efforts to address PFAS contamination in the Huron River watershed since the summer of 2018. During that time, we have gained practical knowledge of how changes in policy regarding PFAS may affect cleanup criteria and how the guidelines may be interpreted at the community level.

HRWC appreciates the substantial monitoring and communication effort that MPART and EGLE are continuing to lead. The pace of action to address PFAS contamination is encouraging, and HRWC is committed to helping MPART and other state entities protect Michigan residents from these toxic chemicals. We believe the proposed rules and process for establishing Maximum Contaminant Levels for 7 PFAS compounds should be carried forward without further delay. They are a vast improvement from the absence of meaningful protection Michigan residents currently have.

That said, based on discussions during the EGLE listening sessions, and based on discussions with other legal and scientific experts, HRWC has several concerns regarding the Health-based values to be used in the EGLE process for establishing Maximum Contaminant Levels for 7 PFAS compounds.

1. The Health-based values from MPART are an improvement from EPA guidelines, but new information coming from New Hampshire and North Carolina suggests that **some of the proposed Michigan MCLs are still way too high for specific chemicals.** (GenX, PFBS, PFHxS, PFHxA)
2. The health-based values don't include a total PFAS contamination level similar to the cumulative level that EPA recommends. **EGLE needs to put a combined MCL in place for total PFAS.**
3. **PFAS should be regulated as a class of chemicals.** There are over 5000 of them and placing regulations on some may simply make polluters use other PFAS compounds. Class regulations, or regulations on subclasses, would avoid the use of regrettable substitutes.
4. **MCLs for PFAS should be based on scientific evidence to protect human health and the environment.** They should not be relaxed based on economic, commercial or industrial concerns.

Beyond these concerns regarding the MCL's specifically, HRWC believes the most complete and cost-effective solutions available for addressing PFAS is through comprehensive watershed strategies in which sources of PFAS are addressed proactively and in collaboration with communities that use affected drinking water. It is far cheaper to taxpayers to remove these chemicals from groundwater and surface water at the source, and it is far more protective of human health.

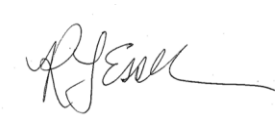
In the Huron River watershed, we unfortunately have experienced precisely this dimension of PFAS contamination. Ann Arbor draws 85% of its drinking water from the Huron River, which is contaminated

by sources upriver and a major source in Wixom. Ann Arbor is effectively treating for PFOS and PFOA, but at great cost to residents even though most of the contamination originated from a private company outside of the city.

HRWC believes collaborative solutions can be found among communities and private sources of contamination that benefit all parties and reduce overall treatment costs. In such cases, state leadership would be valuable for working across municipal boundaries. This would be a capacity in which EGLE and MPART could reaffirm their commitment to environmental protection.

We look forward to new ideas and leadership from EGLE as Maximum Contaminant Levels for PFAS chemicals are established in the near future.

Sincerely,



Rebecca Esselman
Executive Director
Huron River Watershed Council

Smith, Ian (EGLE)

From: Risotto, Steve <[redacted]@americanchemistry.com>
Sent: Friday, January 31, 2020 5:05 PM
To: EGLE-PFAS-RuleMaking
Subject: ACC comments on the MCL Proposal for PFAS
Attachments: ACC-CPTD comment on EGLE PFAS MCL proposal.pdf

The comments of the Chemical Products and Technology Division of the American Chemistry Council on EGLE's MCL proposal for PFAS are attached.

Steve

Stephen P. Risotto
[redacted]@americanchemistry.com
[redacted] (voice)
[redacted] (mobile)

January 31, 2020

Mr. Eric J. Oswald
Director
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
525 West Allegan Street
P.O. Box 30473
Lansing, MI 48909-7973

Re: Rule Set 2019-35 EG – PFAS Amendment to *Supplying Water to the Public* Rule

Dear Mr. Oswald:

The Chemical Products and Technology Division of the American Chemistry Council (ACC/CPTD) submits the following comments on the proposed maximum contaminant levels (MCLs) for seven per- and polyfluoroalkyl substances (PFAS). ACC represents a number of companies with an interest in the use of the best scientific information to develop standards for PFAS such as the MCLs under consideration by the Department of Environment, Great Lakes, and Energy (EGLE).

ACC/CPTD commends the Department for the transparent process it has used to develop the draft standards. We remain concerned about the accelerated timetable for this rulemaking process, but we are encouraged by EGLE's efforts to hear from stakeholders. The rush to develop the MCL proposal is reflected in the inadequacy of the Regulatory Impact Statement (RIS) that EGLE has filed for the rulemaking. Our comments address several contradictory and/or incomplete statements in the RIS about the impact of the proposal on small water utilities and the failure to discuss viable regulatory alternatives to the current proposal. We also provide comments on the analysis of the available data by the scientific advisory workgroup (SAWG) convened by the Department, which are the basis of the proposed MCLs.

Impact of Proposal on Small Water Systems and Residents

As noted in the RIS, EGLE has identified 22 water systems that will be impacted by the MCL proposal after a comprehensive state-wide sampling program.[1] EGLE indicates that these

[1] The Michigan PFAS Action response Team web site currently lists 76 sites. It is not clear whether the 22 sites identified in the RIS are included in the list of 76 and if there are an additional sites that may be impacted by the proposal. (https://www.michigan.gov/pfasresponse/0,9038,7-365-86511_95645---,00.html).

22 systems treat a total of 0.93 million gallons of water per day – an average of about 42,000 gallons/day per system. Yet, the Department asserts in its response to item 16 that "most of the contamination found to date occurs in larger systems." In fact, the system with the highest level of contamination identified by EGLE's sampling serves only about 3,000 residents in the city of Parchment and surrounding townships.[2]

In addressing the impact on small business elsewhere in the RIS, EGLE suggests that the impact on small private water supplies "should be minimized due to the low amount of water treated." While it is not clear which water supplies the Department considers small, the impact on these systems is determined by their *ability to afford* the required changes – not the *amount* of water they treat. In fact, the cost of treatment systems likely will be disproportionately higher for smaller systems with less access to capital and less ability to pass the costs onto to their customers.

In addition to the uncertainty regarding the estimate of 22 affected water supplies, the EGLE website indicates that Department conducted quarterly monitoring at drinking water supplies where PFAS levels were reported to be 10 parts per trillion (ppt) or greater. [3] This sampling, conducted for 12 months, was intended to help determine if there are seasonal changes in PFAS levels and to help prioritize and direct next steps. It is unclear if, or how, the EGLE quarterly monitoring data were incorporated into the impact statement. A significantly different conclusion might be reached if these quarterly data were taken into account. A robust cost-benefit analysis might even assess whether an alternative MCL would be more effective given the distribution of exceedances of median, average, and maximum treated drinking water.

EGLE's estimates for the cost of installation and maintenance of granulated activated carbon (GAC) treatment systems, moreover, are based on information developed by the state of New Hampshire. Yet, New Hampshire estimated the costs to treat drinking water only for four PFAS that are more readily removed from water[4] – and did not consider treatment of the more recalcitrant short-chain PFAS included in EGLE's proposal.[5] In the GAC installation example cited in the RIS, Plainfield Township reportedly installed an additional type of GAC

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[2] Based on the number of customers, the Parchment water system falls into one of the smallest categories of community supply providers under the state's Safe Drinking Water Act (1976 PA 399).

[3] https://www.michigan.gov/pfasresponse/0,9038,7-365-95571_95577_95587_95620-508857--,00.html

[4] The substances are perfluorooctanoic acid (PFOA), perfluorooctane sulfonate (PFOS), perfluorohexanesulfonic acid (PFHxS), and perfluorononanoic acid (PFNA).

[5] Short-chain PFAS included in the proposal are perfluorohexanoic acid (PFHxA), perfluorobutanesulfonic acid (PFBS) and hexafluoropropylene oxide dimer acid (HFPO-DA)

system designed to more effectively remove all types of PFAS.[6] In addition to the added cost of installation, these systems likely will require more frequent maintenance.

Since these capital and maintenance costs will ultimately be passed onto the customers (i.e., ratepayers) of the water systems, it is imperative that EGLE evaluate how these costs would impact the households served by the systems. In addressing the costs for individual households, EPA's National Drinking Water Advisory Council (NDWAC) recommends that a given drinking water standard be considered affordable if the annual cost per customer to meet the standard does not exceed 1.0% of the median household income for the median system in each drinking water system size category.[7] Without estimating the increased cost to households served by the affected water systems, EGLE cannot determine whether the proposed MCLs will or will not cause economic harm.[8]

Consideration of Regulatory Alternatives

In the RIS, EGLE suggests that there are "no reasonable alternatives" to the proposed MCLs that would achieve the same or similar goals and suggests that the MCLs were set by "an expert panel that considered the latest scientific data available." The expert panel's conclusions were not subject to outside review, however, despite the fact that the proposed standards are the first of their kind for three of the seven PFAS (PFBS, PFHxA, HFPO-DA). As discussed later in these comments, moreover, the panel's conclusions are not consistent with those reached by the US Environmental Protection Agency (EPA) for three of the four substances that have been evaluated by EPA or with evaluations conducted by other regulatory authorities (*e.g.*, Health Canada). In the case of PFNA, PFHxS, and PFHxA, EPA has yet to make evaluations available. As EGLE notes, EPA has only developed lifetime Health Advisories (LHAs) for PFOA and PFOS under the federal Safe Drinking Water Act.

One obvious regulatory alternative that EGLE does not appear to have considered is to establish MCLs for PFOA and PFOS equal to EPA's LHA of 70 ppt and to continue monitoring levels of the other five PFAS while EPA develops guidance on these substances. Based on the statewide PFAS sampling, only 2 water systems had PFAS above EPA's LHAs and targeted treatment in those areas is already in place. This would ensure that Michigan residents served by public water systems are not exposed to levels of PFOA and PFOS that EPA has concluded may present a health concern, while allowing EGLE to respond quickly as information develops on the other substances that it has identified.

Recommendations of the Science Advisory Workgroup

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6 https://www.plainfieldmi.org/services/water/gac_filter_project.php

7 https://www.epa.gov/ndwac

8 It is also likely that the initial and ongoing sampling costs associated with the DES proposal will be passed onto customers and should be included in DES' affordability calculation.

ACC/CPTD agrees with the recommendations from the SAWG to establish individual standards for those PFAS for which sufficient information is available. We support the use of allometric scaling for PFAS with short biologic half-lives (*i.e.*, PFHxS, PFBS, HFPO-DA), and urge the Department to apply body-weight scaling to all such PFAS since the available data suggest that these substances are relatively short elimination half-lives. ACC is concerned, however, about several of the decisions the SAWG made in developing its recommendations. These concerns are explained below.

Dosimetric Extrapolation - Use of Pharmacokinetic Data

A key mechanistic issue involved in assessing the health effects of the PFAS is an estimate of the serum elimination half-lives of the chemicals since the half-live is a critical component in extrapolating doses from exposed animals to humans. Since the half-lives for long-chain PFAS like PFOA, PFOS, PFHxS, and PFNA have been found to be significantly longer in humans than in rodents, extrapolation from doses in animals to equivalent dosing in humans (the human equivalent dose, or HED) has involved adjustments to account for the observed half-life differences and/or clearance rates.

For the short-chain PFAS included in the proposal -- PFHxA, PFBS and HFPO-DA -- ACC supports the use of the default approach of body-weight scaling to estimate the HED for the selected animal studies[9] – consistent with EPA guidance[10] and the state of the science in the use of body weight allometric scaling.[11] Although the data may not be sufficient to model external dose and clearance in humans, the information available for these three substances suggest that they are eliminated relatively rapidly and thus will not accumulate -- in contrast to PFOA and PFOS. As a result, body-weight scaling is the most appropriate approach to estimating the HED.

In its assessments for PFOA, PFOS, PFHxS, and PFNA, the SAWG calculated the HED by the adjusting the serum concentration in rodents measured at the drinking water exposure by the rate of clearance (CL) of the substance from the human body. The CL was calculated using the estimated volume of distribution (V_d) and serum elimination half-life. Internal dose ratios predicted by the available physiologically-based pharmacokinetic (PBPK) models for PFOA and PFOS indicate, however, that the interspecies extrapolations for long-chain PFAS are highly

[9] EPA used body-weight scaling for its recent toxicity assessments of hexafluoropropylene oxide dimer acid (GenX) and perfluorobutane sulfonate (PFBS).

[10] EPA. Recommended Use of Body Weight ¾ as the Default Method in Derivation of the Oral Reference Dose. Office of the Science Advisor. Risk Assessment Forum. Washington, DC. EPA/100.R11/001 (2011).

[11] Sharma V and McNeill JH. To scale or not to scale: the principles of dose extrapolation. *Brit J of Pharma* 157(6):907-921 (2009).

dose dependent, and result from nonlinear toxicokinetics.[12] Furthermore, findings from a large data set of 28-day oral gavage rat studies conducted by the National Toxicology Program (NTP) underscore the differences in dose-response relationships between PFOA and PFOS across a wide range of endpoints.[13] These findings further suggest that dosimetry scaling is unlikely to be linear across a broad dose range. As a result, a single interspecies extrapolation factor such as that used by EPA is not scientifically supportable for long-chain PFAS like PFOA or PFOS. Instead an approach that uses chemical-specific adjustment factors (CSAFs)[14] derived from the PBPK models better addresses the issue of nonlinear toxicokinetics for long-chain PFAS and its impact on interspecies extrapolation.[15]

Using such an approach, Health Canada compared dose metrics predicted by the various animal PBPK models to calculate a CL ratio between species (CL_A/CL_H) for PFOA and PFOS.[16] They reasoned that using the model data to derive the CL_A/CL_H allows for a more appropriate comparison of doses of the same magnitude.[17] Using the CL ratio to estimate exposures, Health Canada's analysis indicates that the approach taken by the SAWG underestimates the human clearance rate for PFOA and PFOS and, as a result, leads to dramatic underestimates of human exposures that are 10 to 500 times lower than actual.

To the extent that toxicokinetic data are available for the PFHxS and PFNA, ACC urges EGLE to base the HED on the CL ratio for the relevant dose range, rather than an estimate based on a single extrapolation factor.

Estimating Drinking Water Exposure

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[12] Loccisano AE *et al.* Comparison and evaluation of pharmacokinetics of PFOA and PFOS in the adult rat using a physiologically based pharmacokinetic model. *Reprod Toxicol* 33(4):452-467 (2012).

[13] NTP. Final reports from the PFAS 28-Day toxicity studies TOX-96 and TOX-97 (2019). https://ntp.niehs.nih.gov/whatwestudy/topics/pfas/index.html

[14] World Health Organization (WHO). Chemical specific adjustment factors for interspecies differences and human variability: guidance document for use of data in dose/concentration–response assessment. International Programme on Chemical Safety. World Health Organization. Geneva (2005). http://apps.who.int/iris/bitstream/handle/10665/43294/9241546786_eng.pdf;jsessionid=45918ABD3B07EF944ACD546CF50B974F?sequence=1

[15] Sources of nonlinear toxicokinetics include kidney filtration, protein binding, and other nonlinear processes.

[16] For each species, the PBPK model was used to predict internal doses for a broad range of oral doses. Model simulations were continued until steady-state conditions or expected lifetimes were reached (Loccisano *et al.* 2012).

[17] Health Canada. Guidelines for Canadian Drinking Water Quality – Guideline Technical Document – Perfluorooctanoic Acid (PFOA). Ottawa, Ontario (2018); Health Canada. Guidelines for Canadian Drinking Water Quality – Guideline Technical Document - Perfluorooctane Sulfonate. Ottawa, Ontario (2018).

In estimating drinking water exposure to PFOA, PFOS, PFHxS, and PFNA, the SAWG assumed a relative source contribution (RSC) of 50 percent and used a transgenerational model to estimate exposure over an extended period of time.[18] According to data collected by the Center for Disease Control and Prevention (CDC), mean serum levels of PFOA and PFOS have declined dramatically in the US population between 1999 and 2016 as a result of the phase out of use.[19] (See Figure 1). Given this decline, it is likely that drinking water contributes an even greater percentage of total exposure than the 50 percent assumed by the Workgroup – particularly in areas where drinking water contamination has been detected.

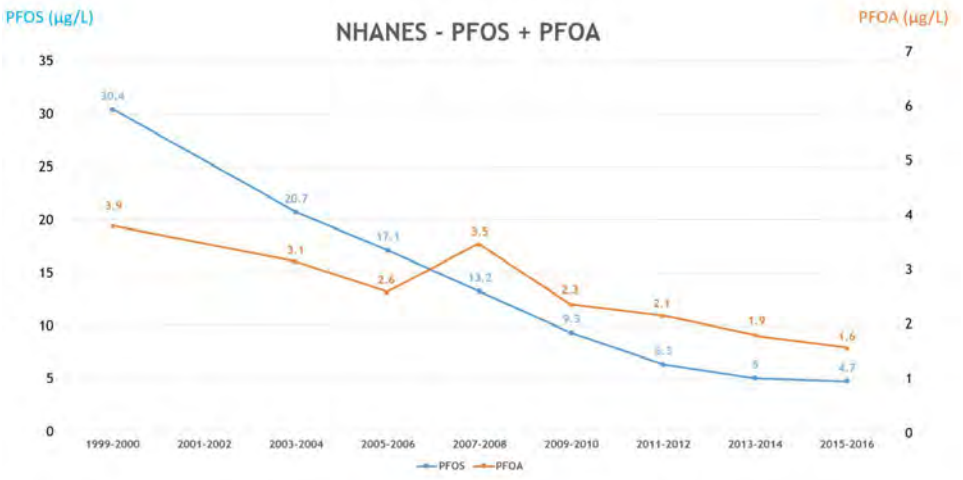

Figure 1. Serum levels of PFOA and PFOS, 1999-2016.[20]

The transgenerational model used by the SAWG attempts to estimate serum levels of long-lived PFAS from birth through adulthood, without adjusting for the nonlinear toxicokinetics described earlier. As a result, it is likely to overestimate serum levels associated with a particular drinking water scenario – particularly related to exposure through breast milk. In fact, the serum levels predicted by the model are well above those from other models that

[18] Goeden HM *et al.* A transgenerational toxicokinetic model and its use in derivation of Minnesota PFOA water guidance. J Exp Sci Environ Epidem 29:183-195 (2019).

[19] CDC. Fourth national report on human exposure to environmental chemicals, updated tables (January 2019). https://www.cdc.gov/exposurereport/index.html. Declines in PFHxS and PFNA serum levels have not been as dramatic.

[20] Human exposure monitoring is conducted as part of CDC's National Health and Nutrition Examination Survey (NHANES).

have been developed,[21] and are inconsistent with the empirical data that are available. While the model used by the workgroup predicts that serum levels stay well above adult concentrations for the first 5 years in a breast-fed infant, Fromme *et al.* (2010) reported that levels dropped significantly after the first 6 months among 40 mother-infant pairs in Germany.[22] A study of participants in the 2013-14 NHANES, moreover, reported that serum levels of PFOA, PFOS, PFHxS, and PFNA in children from 3 to 5 years old were at or below adult levels.[23]

A 2016 study in Norway of toddlers at age 3 pinpointed the conclusion that "transplacental transfer, prenatally, and breastfeeding, postnatally, are among the main determinants of PFOS, PFOA, and PFHxS concentrations in toddlers, while that was not the case for PFNA."[24] Specific relevant trends noted by the Norwegian researchers included the conclusion that, while levels of PFOA in children were related to the length of time the child was breastfed, "PFNA concentrations in children were not associated with either maternal concentrations or breastfeeding duration." This underscores the fact that not all PFAS have the same physical/chemical or toxicokinetic behavior, and generalizing into one transgenerational model for all PFAS is inappropriate.

Workman et al. (2019) found plasma PFAS to be associated with maternal characteristics but PFASs were not associated with developmental effects, with the exception that perfluoroundecanoic acid (PFUA) was *negatively* associated with birth weight.[25] This example of a recent negative study for developmental effects (e.g., finding no human effect that mirrors the potential animal study effect) at relevant levels of human PFAS exposure is an important moderator that has been overlooked as EGLE extrapolates directly from animal studies without regard to the relevance of the dose. Toxicologists would assert that the explanation for this is not only the need for body weight scaling and allometric adjustment, but also a quantitative understanding of the nonlinear kinetics involved in the multiple potential modes of action for the various PFAS chemicals.

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21 Mondal D *et al.* Breastfeeding: a potential excretion route for mothers and implications for infant exposure to perfluoroalkyl acids. *Environ Health Persp* 122(2):187-912 (2014); Mogensen U *et al.* Breastfeeding as an exposure pathway for perfluorinated alkylates. *Environ Sci Technol* 49:10466–73 (2015).

22 Fromme H *et al.* Pre and postnatal exposure to perfluorinated compounds (PFCs). *Environ Sci Tech* 44:7123-7129 (2010).

23 Ye X *et al.* Per- and polyfluoroalkyl substances in sera from children 3 to 11 years of age participating in the National Health and Nutrition Examination Survey 2013-2014. *Intl J Hyg Environ Health* 221:9-16 (2018).

24 Papadopoulou E *et al* Exposure of Norwegian toddlers to PFAS: The association with breastfeeding and maternal PFAS concentrations. *Environ Intl* 94:687-694 (2016).

25 Workman CE *et al.* Associations between concentrations of perfluoroalkyl substances in human plasma and maternal, infant, and home characteristics in Winnipeg, Canada. *Env Pollut* 249:758-766 (2019).

Perfluorooctanoic Acid (PFOA)

The two studies selected as the basis for Michigan's MCL recommendation (Onishchenko *et al.* 2011; Koskela *et al.* 2016) provide results from animals exposed to a single, high dose and do not allow for dose-response modelling. Consequently, they are not appropriate as a basis for establishing a regulatory standard. The animal data suggesting effects in mammary gland development are equivocal, moreover, and do not provide any evidence of possible endocrine effects (and a 3-fold database uncertainty factor).

In the study by Onishchenko *et al.* mild sex-related differences in exploratory behavior patterns were reported after 5 weeks of age. PFOA-exposed males were more active, while PFOA-exposed females were less active, than their respective controls. In the second principal study, Koskela *et al.* (2016) reported mild alterations in bone morphometry and mineral density of femurs and tibias in mice while noting that the biomechanical properties of the bones were not affected. Based on the absence of an impact on mechanical function, the biological significance of bone geometry and mineral density alterations is uncertain and may not be a suitable basis for the MCL calculation. Notably, no increases in the occurrence of malformations/variations were observed in similar studies conducted in rats.[26,27] Koskela *et al.* also appear to have conducted their statistical analysis on a per-fetus basis, rather than per-litter as advised by EPA's guidelines, for assessing developmental toxicity which has been widely critiqued as a study deficiency in the past.[28]

Lau *et al.* (2006)[29] also reported skeletal effects in the offspring of mice exposed to PFOA, but the effects neither increased in a dose-related manner nor in severity and would generally not be considered biological significant.[30] In noting the striking difference between their results and the minor effects reported in the two-generation study in rats by Butenhoff *et al.* (2004), the authors suggest that they are most likely related to toxicokinetic differences between the two species.

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[26] Staples *et al.* The embryo-fetal toxicity and teratogenic potential of ammonium perfluorooctanoate (APFO) in the rat. *Fundam Appl Toxicol* 4(3 Pt 1): 429–440 (1984).

[27] Butenhoff *et al.* The reproductive toxicology of ammonium perfluorooctanoate (APFO) in the rat. *Toxicol* 196(1–2):95–116 (2004).

[28] EPA. Guidelines for developmental toxicity risk assessment. Risk Assessment Forum. EPA/600/FR-91/001(December 1991). (EPA Guidelines 1991). https://www.epa.gov/risk/guidelines-developmental-toxicity-risk-assessment

[29] Lau C *et al.* (2006). Effects of perfluorooctanoic acid exposure during pregnancy in the mouse. *Toxicol Sci* 90(2): 510–518 (2006).

[30] EPA Guidelines 1991, at 13. The 1991 guidelines note that a dose-related increase in variations in skeletal ossification is interpreted as an adverse developmental effect, but assessing the biological significance of the variation must take into account what is known about the developmental stage.

In addition to developmental effects, the SAWG also identified evidence of delayed mammary gland development in the laboratory studies. Research has shown that many metabolic effects of exposure to PFOA in rodents can be explained by the activation of xenosensor nuclear receptors such as the peroxisome proliferator activated receptor alpha (PPARα) in the liver.[31] These effects are of questionable relevance for human health risk assessment since the associated proliferative response in mice has not been observed in humans.[32] While the study by Macon *et al.* (2011),[33] observed a delay in mammary gland development in CD-1 mice, the results in other mouse studies are equivocal and support a PPARα-activated mechanism – not one mediated through endocrine effects. Albrecht *et al.* (2013), for example, did not find alterations in mammary gland development in offspring of wild type, PPARα-null, or PPARα humanized mice following *in utero* exposure to PFOA.[34]

In a multi-generational study in CD-1 mice, moreover, no clear dose-response was reported and the investigators noted that the delay in mammary gland development did not appear to affect lactational support based on normal survival and growth of the second generation (F2) offspring.[35] Based on the weight of the evidence, the available data do not support an association between PFOA exposure and delayed mammary gland development and, therefore, an additional uncertainty factor is not appropriate.

Perfluorooctane Sulfonic Acid (PFOS)

The immune system effects reported by Dong *et al.* (2009), that are the basis of the MCL recommendation, conflict with the findings reported by other researchers. In addition, the decision to focus on immune effects as the basis for its proposed MCL runs directly counter to the specific concerns expressed about these data by both the US Environmental Protection Agency (EPA) and Health Canada.

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[31] See for example: Bjork JA *et al.* Multiplicity of nuclear receptor activation by PFOA and PFOS in primary human and rodent hepatocytes. *Toxicol* 288: 8-17 (2011).

[32] An understanding of the biological functions and role in chemical effects of PPARα has been facilitated by the use of a mouse model that lacks a functional PPARα (the *PPARα*-null mouse). Many of the effects of peroxisome proliferators have been shown to be mediated by PPARα as these effects were not observed in similarly treated *PPARα*-null mice. See Corton JC *et al.* Mode of action framework analysis for receptor-mediated toxicity: the peroxisome proliferator-activated receptor alpha (PPARα) as a case study. *Crit Rev Toxicol* 44(1):1-49 (2014).

[33] Macon MB *et al.* Prenatal perfluorooctanoic acid exposure in CD-1 mice: low dose developmental effects and internal dosimetry. *Toxicol Sci* 122: 134-45 (2011).

[34] Albrecht PP *et al.* A species difference in the peroxisome proliferator-activated receptor α-dependent response to the developmental effects of perfluorooctanoic acid. *Toxicol Sci* 131:568–582 (2013).

[35] White SS *et al.* Gestational and chronic low-dose PFOA exposures and mammary gland growth and differentiation in three generations of CD-1 mice. *Environ Health Persp* 119(8):1070–1076 (2011).

Several studies have investigated potential effects on the immune system -- natural killer (NK) cell activity and plaque forming cell (PFC) response in mice exposed to PFOS. Although the studies reported immune effects, EPA concluded that the differences in the levels at which effects were reported (and conflicts in the direction of the effects) "highlight the need for additional research to confirm the [no-observable-adverse-effect level or NOAEL] and [lowest-observable-adverse-effect level or LOAEL] for the immunological endpoints."[36] Health Canada reached a similar conclusion noting that "[f]urther exploration should be performed to address the nearly two orders of magnitude difference in LOAELs in the studies before these endpoints can be reliably considered as a basis for risk assessment."[37] The inconsistency of these study results is detailed below.

Dong *et al.* reported decreased PFC response in male C57BL/6 mice at 0.083 mg/kg per day by gavage.[38] Terminal serum concentrations of PFOS among these mice was 7,132 nanograms per milliliter (ng/ml). While the authors identified a NOAEL of 0.0083 mg/kg, a subsequent report by the same group did not observe a PFC response at 0.0167 mg/kg per day (2,360 ng/ml) by gavage.[39] Although a gavage study by Peden-Adams *et al.* (2008)[40] identified decreased PFC response in male B6C3F1 mice exposed to a lower dose than that reported by Dong *et al.*, concerns about the reliability of the serum levels reported in the mice make interpretation of the data difficult.[41]

In contrast, a dietary study with B6C3F1 mice did not find a change in PFC response in males exposed to 0.25 mg/kg per day for 28 days, resulting in serum PFOS levels of 12,000 ng/ml.[42] In the only study designed to measure immune effects in rats, moreover, the NOAEL

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36 EPA. Health Effects Support Document for Perfluorooctane Sulfonate (PFOS). EPA 822-R-16-202 (May 2016).

37 Health Canada. Guidelines for Canadian Drinking Water Quality – Guideline Technical Document – Perfluorooctane Sulfonate (PFOS). Ottawa, Ontario (2018).

38 Dong GH *et al.* Chronic effects of perfluorooctanesulfonate (PFOS) exposure on immunotoxicity in adult male C57BL/6 mice. *Arch Toxicol* 83:805–815 (2009)

39 Dong GH *et al.* Sub-chronic effect of perfluorooctanesulfonate (PFOS) on the balance of type 1 and type 2 cytokine in adult C57BL6 mice. *Arch Toxicol* 85(10): 1235–1244 (2011).

40 Peden-Adams MM *et al.* Suppression of humoral immunity in mice following exposure to perfluorooctane sulfonate. *Toxicol Sci* 104(1): 144–154 (2008).

41 Pachkowski B *et al.* The derivation of a reference dose (RfD) for perfluorooctane sulfonate (PFOS) based on immune suppression. *Environ Res* 171:452-469 (2019).

42 Qazi MR *et al.* 28-day dietary exposure of mice to a low total dose (7 mg/kg) of perfluorooctanesulfonate (PFOS) alters neither the cellular compositions of the thymus and spleen nor humoral immune responses: Does the route of administration play a pivotal role in pfos-induced immunotoxicity? *Toxicol* 267, 132–139 (2010).

was several orders of magnitude higher than some of the LOAELs from mouse studies. [43] In addition, a study with PPARα-null 129/Sv mice suggests that immunomodulation in mice was partially dependent on PPARα.[44]

Sensitivity to immunological effects in the animal studies appears to be dependent on several factors – including test species (mice vs rat), route of exposure (gavage vs diet), and exposure duration. Consequently, EPA and Health Canada have stressed the need for more research. However, there are no indications that prenatally exposed animals are more sensitive to apparent PFOS-associated to immunological effects than adults, as changes in PFC response were not observed at ≤1 mg/kg per day in B6F3F1 mice exposed *in utero* on GD 1–17.[45]

Human Immunological Data

Several epidemiology studies have evaluated potential impacts of PFOS exposure on immune suppression (infectious disease and vaccine response). As with the animal data, the human data are inconsistent, as noted by Health Canada which concluded that "associations are observed between PFOS levels and decreases in antibodies against some (but not all) illnesses and the influence of PFOS exposure on demonstrable clinical immunosuppression (i.e., incidence of illnesses) appears to be more tenuous."[46] Health Canada further noted that, while the available animal and human data may indicate immune system changes, "it is unclear whether small variations in these measures are sufficient to result in adverse health effects in humans."

A study of children of the Faroe Islands found an inverse relationship in immune response with exposure to perfluorinated alkyl acids, with maternal cord PFOS levels negatively correlated with anti-diphtheria antibody concentration at 5 years. Children in this population demonstrated increased odds of not reaching protective antibody levels for diphtheria after vaccination at 7 years old (Grandjean *et al.* 2012). [47] A subsequent study of a different birth

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[43] Lefebvre DE *et al.* Immunomodulatory effects of dietary potassium perfluorooctane sulfonate (PFOS) exposure in adult Sprague -Dawley rats. *J Toxicol Environ Health A* 71:1516-1525 (2008).

[44] Qazi MR *et al.* The atrophy and changes in the cellular compositions of the thymus and spleen observed in mice subjected to short-term exposure to perfluorooctane sulfonate are high-dose phenomena mediated in part by peroxisome proliferator-activated receptor-alpha (PPARα). *Toxicol* 260:68–76 (2009)

[45] Keil DE *et al.* Gestational exposure to perfluorooctane sulfonate suppresses immune function in B6C3F1 mice. *Toxicol Sci* 103:77–85 (2008).

[46] Health Canada 2018, at 69.

[47] Grandjean *et al.* Serum vaccine antibody concentrations in children exposed to perfluorinated compounds. *J Am Med Assoc* 307(4): 391–397.

cohort from the same location did not observe a relationship between PFOS exposure and diphtheria antibodies.[48]

Increased PFOS exposure was associated with decreased antibodies against rubella in children from a prospective birth cohort of pregnant women in Norway.[49] Prenatal exposure to PFOS was not associated with hospitalizations for infections in a 2010 Danish cohort study,[50] nor with episodes of common cold, gastroenteritis, eczema or asthma in the Norwegian cohort, although an association with infection and fever has been reported in a few other studies. 2013). In a Taiwanese cohort study, the median serum PFOS concentration was higher in asthmatic children,[51] and prenatal exposure to PFOS was positively correlated with cord blood Immunoglobulin E (IgE) levels, particularly in male children. However, Wang *et al.* (2011) [52] found no association with atopic dermatitis. Cord blood IgE levels, food allergy, eczema, wheezing, or otitis media were not associated with maternal PFOS in female infants in a prospective cohort study of pregnant women in Japan.[53]

Finally, a cohort of 411 adult members of the C8 Health Project in West Virginia was evaluated to determine whether there was an association between serum PFOS levels and antibody response following vaccination with an inactivated trivalent influenza vaccine.[54] Vaccine response, as measured by geometric mean antibody titer rise, was not affected by PFOS exposure. After reviewing the available human data, Health Canada concluded –

> Although some effects on the antibody response have been observed, conflicting results were common in the dataset, which remains relatively small. A low level of consistency was observed across studies, with variations between genders, specific microbial immunoglobins, infections, mother vs. child exposure, and child years, amongst other characteristics. Moreover, the risk of residual

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48 Grandjean P *et al.* Estimated exposures to perfluorinated compounds in infancy predict attenuated vaccine antibody concentrations at age 5-years. *J Immunotox* 14:188–195 (2017).

49 Granum B *et al.* Pre-natal exposure to perfluoroalkyl substances may be associated with altered vaccine antibody levels and immune-related health outcomes in early childhood. *J Immunotox* 10(4): 373–379 (2013).

50 Fei C *et al.* Prenatal exposure to PFOA and PFOS and risk of hospitalization for infectious diseases in early childhood. *Environ Res* 110: 773–777 (2010).

51 Dong GH *et al.* Serum polyfluoroalkyl concentrations, asthma outcomes, and immunological markers in a case–control study of Taiwanese children. *Environ Health Perspect* 121(4): 507–513 (2013).

52 Wang Y *et al.* Modulation of dietary fat on the toxicological effects in thymus and spleen in BALB/c mice exposed to perfluorooctane sulfonate. *Toxicol Lett* 204(2–3): 174–182 (2011).

53 Okada E *et al.* Prenatal exposure to perfluorinated chemicals and relationship with allergies and infectious diseases in infants. *Environ Res* 112: 118–125 (2012).

54 Looker C *et al.* Influenza vaccine response in adults exposed to perfluorooctanoate and perfluorooctanesulfonate. *Toxicol Sci* 138: 76–88 (2014).

> confounding, bias, and chance cannot be discarded. These flaws impede concluding on a causative mechanism, and the nature of the association remains unclear.[55]

In considering these data EPA cautioned that "lack of human dosing information . . . precludes the use of these immunotoxicity data in setting the [reference dose]."[56]

Relevance of the Animal Data to Human Risk

The SAWG analysis suggests that the relevance of reduced PFC response observed in mice to reduced resistance to infection in humans in explaining its rationale for the proposed MCL. Yet, the human studies generally report no increase in infection in children or adults and both EPA and Health Canada have questioned whether the small variations in the antibodies observed in the available studies are sufficient to result in adverse health effects in humans. As the National Toxicology Program (NTP) noted in its review of PFOS the "effects on diverse endpoints such as suppression of the antibody response and increased hypersensitivity may be unrelated."[57] Moreover, while asserting that the SRBC response in mice are "analogous" to decreased vaccine response in humans, the SAWG offers no supporting information and neither EPA nor Health Canada have reached a similar conclusion.

The 2016 NTP systematic review of the animal data concluded that it cannot be confident in the outcome assessment of the Dong *et al.* 2009 study that is the basis for the proposed groundwater criterion.[58] NTP's lack of confidence is supported by the inability of benchmark dose (BMD) modeling of the PFC response data to provide an acceptable fit to any of the dose-response models included in EPA's BMD software. The inability of BMD modeling to yield a valid POD suggests that the 2009 PFC response data reported by Dong *et al.* are not sufficiently robust.

The SAWG decision to focus on immune system effects as the basis for its proposed MCL for PFOS runs directly counter to the specific concerns expressed about these data by both EPA and Health Canada. The analysis provided offers little support for the relevance of the available animal and human data, which NTP's systematic review is clear to caution may not be related to actual health effects in humans.

Perfluorononanoic Acid (PFNA)

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55 Health Canada 2018, at 40.

56 EPA 2016, at 4-7.

57 NTP. Monograph on Immunotoxicity Associated with Exposure to Perfluorooctanoic acid (PFOA) or Perfluorooctanoic Sulfonate (PFOS). Office of Health Assessment and Translation. (September 2016).

58 Ibid, at 133 (Appendix 3. Risk of Bias Heatmaps).

The decreased body weight gain and developmental delays reported in the offspring of mice administered PFNA via gavage in the SAWG-chosen study (Das *et al.* 2015) occurred concomitant with maternal toxicity and therefore, should not be used as the critical effect. Moreover, Wolf *et al.* (2010) did not report changes in pup body weight or postnatal development in mice PPARα-null mice at 2 mg/kg-day, suggesting that these effects are rodent-specific responses to PFNA and of questionable relevance to humans. Reported liver effects in mice exposed to PFNA also may result from PPARα activation of limited relevance to humans, although a possible adaptive response increased liver weight and other effects have been observed in PPARα-null mice.

In addition to concerns about study selection, ACC/CPTD questions the inclusion of a 10-fold database uncertainty factor based on the lack of serum elimination half-life data in humans and "uncertainty for associated effects on other physiological processes including the immune system."[59] According to EPA guidance, database uncertainty factors are typically and properly applied in the absence of reproductive and developmental information. In the case of PFNA, developmental toxicity data do exist which suggest that effects are the result of PPARα activation. As previously discussed, the PPARα relevance to a human response to PFNA is not clear: a lower number of PPARα receptors present in target tissues of humans versus rodents suggests an obvious difference between the sensitivity of laboratory animals and humans that logically should result in *less* concern for PPARα-activated pathways in humans than results might suggest in animal studies. Information on immune effects is available, moreover, and suggests that other health effects (e.g., liver weight) are more sensitive than effects in development or the immune system. Although human serum elimination half-life information is lacking, inclusion of a poorly supported uncertainty factor is clearly not justified since the information that does exist from animal studies suggests a half-life that is equal to or only slightly longer than that of PFOA.[60] In light of the limited data available for PFNA, it may be prudent to defer the development of standards until more data are available.

Perfluorohexanesulfonic acid (PFHxS)

The data selected by the SAWG to derive the MCL come from unpublished research conducted by the federal National Toxicology Program (NTP). As with all research, these results should be subject to peer review before they are used in deriving regulatory standards. ACC agrees with the SAWG that the results reported by Chang *et al.* 2018 do not represent a

[59] Agency for Toxic Substances and Disease Registry. Toxicological Profile for Perfluoroalkyls. Draft for Public Comment. US Department of Health and Human Services. Atlanta, GA (June 2018).

[60] Ibid, at 13.

significant health effect,[61] but questions why the Work Group's report does not discuss the study by Butenhoff *et al.* (2009) which has been used by other groups for assessing the health effects of PFHxS.[62] The SAWG also does not address the suggestion by Butenhoff *et al* that thyroid effects (such as those reported in the NTP study) may be related to hepatocellular hypertrophy caused by PPARα activation leading to hyperplasia of the thyroid that is likely not relevant to human health risk.

Before committing to onerous MCLs based on thyroid effects, EGLE should carefully review human study data on the relevance of thyroid effects and the variability of thyroid hormones are variable across life. A recent French study reports that PFAS levels at birth were not associated with TSH levels later in life,[63] and similar studies are underway to continue to add to the weight of evidence that TSH variance is not a key adverse endpoint, either in the mothers or the children. Previous study data show a lack of strong evidence to suggest PFAS are associated with overall TSH and free T4, and even at the highest levels, any statistical variance in TSH-PFAS concentration correlations does not persist in humans beyond gestational week 10.[64] This would suggest that, even if a potential mechanism of action included possible competition with T4 for binding to transthyretin (a main carrier protein of thyroid hormone in mammals), thus increasing TSH and decreasing free T4, that relevant human exposures to PFAS coming from observational (community epidemiology) studies do not suggest this effect occurs, either in the mother or infant.

The decision to focus on an unpublished study for deriving the proposed MCL reflects the limited amount of toxicity data available for PFHxS. The Working Group's struggle to address PFHxS are further evidenced by the application of a 10-fold data base uncertainty factor based on unspecified concerns about early life sensitivity and the lack of two-generation and immuntoxicity studies. The lack of a two-generation study would justify the use of a 3-fold uncertainty factor, based on EPA guidance. The SAWG's concern about early life sensitivity is addressed by Chang *et al.* who reported no treatment-related effects on postnatal survival of development in offspring exposed *in utero* through PND 36. Although limited, Butenhoff *et al.* did not find evidence of immunotoxicity in rats exposed to up to 10 mg/kg per day by gavage for up to 56 days. If the SAWG does not feel that published reports on the chemical provide a

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61 Chang S *et al.* Reproductive and developmental toxicity of potassium perfluorohexanesulfonate in CD-1 mice. *Reprod Toxicol* 78:150-168 (2018).

62 Butenhoff JL *et al.* 2009. Evaluation of potential reproductive and developmental toxicity of potassium perfluorohexanesulfonate in Sprague Dawley rats. *Reprod Toxicol* 27(3-4):331-341 (2009).

63 Dufour P *et al.* Association between exposure to persistent organic pollutants during pregnancy and thyroid function during childhood: a pilot longitudinal study and literature review. *Rev Med Liege* 75:37-42 (2020).

64 Inoue K *et al.* PFAS and maternal thyroid hormones in early pregnancy: Findings in the Danish National Birth Cohort. *Environ Health Persp* 127:117002 (2019)

sufficient basis for developing an MCL, EGLE should defer establishing standards until more peer reviewed data are available.

ACC's concerns about using the NTP study results, notwithstanding, the SAWG's calculations inappropriately use a benchmark response (BMR) of 20 percent rather than a BMR of one standard deviation directly observed from study results as advised by EPA's benchmark dose (BMD) modeling guidance.[65] The SAWG report suggests that a BMR_{20} provides a more reliable result, citing an analysis by the Minnesota Department of Health, but does not provide the analysis for review by stakeholders.

Perfluorohexanoic acid (PFHxA)

ACC agrees with use of the kidney effects in rats reported by Klauning *et al.* (2015) as the basis for the proposed MCL. We further support the recommendation to use the default body weight scaling to derive the human equivalent dose (HED) from the animal data. The elimination of PFHxA has been shown to scale with body weight and there are no known species-specific mechanisms that alter elimination kinetics between species.

Although the data base of toxicity information for PFHxA is not as robust as for PFOA and PFOS, considerable data do exist for the chemical including toxicity studies with rats and mice and developmental and carcinogenicity studies in one species.[66] In the absence of a 2-generation reproductive toxicity study, a 3-fold data base uncertainty factor – not a 10-fold factor as recommended by the SAWG -- is scientifically appropriate.[67] This generates a drinking water value that is about 3-fold higher than the MCL proposed by EGLE.[68]

Perfluorobutanesulfonic acid (PFBS)

The database for PFBS includes multiple short-term and subchronic-duration toxicity studies of laboratory animals, multiple developmental toxicity studies with mice and rats, and a two-generation reproductive toxicity study with rats. The proposed MCL for PFBS is based on reports of decreases in thyroid hormones in pregnant mice and their female offspring following

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65 EPA. Benchmark Dose Technical Guidance. Risk Assessment Forum. Washington, DC. EPA/100/R-12/001 (June 2012). https://www.epa.gov/sites/production/files/2015-01/documents/benchmark_dose_guidance.pdf

66 Luz AL *et al.* Perfluorohexanoic acid toxicity, part I: development of a chronic human health toxicity value for use in risk assessment. *Reg Tox Pharma* 103:41-55 (2019).

67 Ibid.

68 Anderson JK *et al.* Perfluorohexanoic acid toxicity, part II: application of human health toxicity value for risk characterization. *Reg Tox Pharma* 103:10-20 (2019)

gavage exposure to 200 mg/kg per day from GD1 to 20.[69] Kidney effects have been reported in rats exposed to PFBS by gavage, but the SAWG considered them to be a potential compensatory response and of lesser functional significance.

Since Feng *et al.* (2017) report continuous mouse data, one standard deviation is likely the more appropriate BMR for BMD modeling than the 20-percent response selected by the SAWG, based on EPA guidance.[70] A recent analysis conducted by EPA demonstrates the significant difference in the lower confidence limit (BMDL) that results from the choice of BMR.[71] Since no species-specific elimination mechanisms have been identified for PFBS and the elimination rate among species appears to scale to body weight, moreover, allometric scaling is the appropriate method for deriving the HED – rather than the serum elimination half-life adjusted approach used by the SAWG.

In extrapolating the toxicity value for PFBS from the mouse data, the Work Group included a database uncertainty factor of 10 based on a "lack of neurodevelopmental, immunotoxicological, and chronic studies." For PFBS, however, robust data are available on reproductive and developmental effects, including both a prenatal animal toxicity study and a two-generation animal reproduction study. Although a specific neurodevelopmental study has not been conducted, the available data suggest that the thyroid effects seen in mice used by the SAWG are the more sensitive endpoint.[72] Consequently, a toxicity value that protects against effects on thyroid hormones also will protect against developmental effects, particularly effects on neurodevelopment since it is suggested that perturbations in thyroid hormones may trigger neurodevelopmental effects.[73] Furthermore Dufour *et al.* reported that PFAS levels at birth are not associated with TSH levels later in life, and similar studies are underway to continue to add to the weight of evidence that TSH variance is not a key adverse human endpoint, either in the mothers or the children.

The SAWG echoes EPA's concern for the potential immunotoxicity of PFBS based primarily on suggestions of immunotoxicity for other PFAS. In fact, to date, EPA has critically evaluated the immunotoxicity data for only two PFAS (*i.e.*, PFOA, PFOS). In each case, the Agency has concluded that the available data did not suggest that immune effects are a

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69 Feng X *et al.* Exposure of pregnant mice to perfluorobutanesulfonate causes hypothryoxinemia and developmental abnormalities in female offspring. *Toxicol Sci* 155: 409-419 (2017)

70 EPA, 2012.

71 EPA. Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3). Public Review Draft. EPA-823-R-18-307. Office of Research and Development. Washington, DC (November 2018), at 56

72 Ibid, at 60.

73 Ibid.

particularly sensitive health endpoint.[74] ACC-CPTD is not aware of other data that would suggest that immunotoxicity is a concern for PFBS, which--as clearly demonstrated by EPA's analysis—exhibits dramatically different properties than the two PFAS previously evaluated. While a lack of empirical immunological data with laboratory animals continues to exist, a data uncertainty factor of 3 (not 10) is appropriate. However, significant numbers of assays and studies are underway in 2020, with the likelihood of advanced PFBS immune effects ready for interpretation in the near future to fill this "gap."

The suggestion by EGLE that "some infants born to mothers who drink water containing PFBS in excess of the MCL may experience decreased thyroid hormone levels" does not adequately consider the human data that have now become available, nor has "experience" of (transient, and lifestage-specific) thyroid hormone changes been linked to an adverse effect or human disease state. PFBS thus does not warrant an MCL in Michigan at this time, as no health effects are likely to result to the residents of Michigan at relevant (or toxic) concentrations.

Hexafluoropropylene oxide dimer acid (HFPO-DA)

The proposed MCL for HFPO-DA is based on liver effects reported in a mouse reproductive/developmental toxicity screening study,[75] despite the fact that a 90-day subchronic study is available which provides additional, relevant hepatic measurements.[76] Although evidence for liver hypertrophy is generally considered to be rodent-specific, indications of other histological and clinical pathological changes may warrant additional consideration as to the relevance to humans.[77] Both the reproductive/development and 90-day studies provide information on hepatocyte necrosis, but the 90-day study also includes information on key clinical chemistry measures indicative of hepatotoxicity – including alanine aminotransferase (ALT), alkaline phosphatase (ALP) and aspartate aminotransferase (AST). [78] The elevation of these enzyme levels provides important clinical correlations to the observed changes in pathology.

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[74] EPA Health advisories for PFOA, PFOS.

[75] E.I. du Pont de Nemours and Company. An oral (gavage) reproduction/developmental toxicity screening study of H-28548 in mice. U.S. EPA OPPTS 870.3550; OECD Test Guideline 421. Conducted by WIL Research Laboratories, LLC, Ashland, OH (2010). **DuPont-18405-1037**

[76] E.I. du Pont de Nemours and Company. H-28548: subchronic toxicity 90-day gavage study in mice. OECD Test Guideline 408. E.I. du Pont de Nemours and Company, Newark, DE. (2010). **DuPont-18405-1307**.

[77] Hall AP *et al.* Liver hypertrophy: a review of adaptive (adverse and non-adverse) changes – conclusions from the 3rd international ESTP expert workshop. *Toxicologic Pathol* 40:971-994 (2012).

[78] The results of both of these studies are summarized in the public comment draft of the human health toxicity assessment for HFPODA released by EPA in November 2018. https://www.epa.gov/sites/production/files/2018-11/documents/genx_public_comment_draft_toxicity_assessment_nov2018-508.pdf

The longer exposure time in the 90-day study improve the chances to observe necrosis, despite the smaller sample size.[79] The consistency of the necrosis data with the liver enzyme results, moreover, provides a more complete picture of what is happening in the liver than the more limited data available from the reproductive/developmental study. Importantly, the 90-day study did not report liver necrosis in any of the animals exposed to levels of 0.5 mg/kg-day or less. The minimal necrosis reported at these levels in the reproductive/developmental study may suggest an adaptive, non-adverse reaction in the mice or a response to other stressors.

The findings from the 90-day study support a NOAEL of 0.5 milligrams per kilogram (mg/kg) body weight per day, based on histological changes in the liver, as opposed to a NOAEL of 0.1 mg/kg per day suggested by the 28-day study.

Please do not hesitate to contact me at [redacted]@americanchemistry.com or at [redacted] if you questions about the above information. ACC looks forward to participating in the rulemaking process as it proceeds.

Sincerely,

Steve Risotto

Stephen P. Risotto

[79] 10 animals/exposure group versus 24/group in the reproductive/developmental study.

Smith, Ian (EGLE)

From: Campbell, Laura [redacted]@michfb.com>
Sent: Friday, January 31, 2020 2:22 PM
To: EGLE-PFAS-RuleMaking
Subject: MFB Comments on Proposed Rule 2019-035 EG on PFAS
Attachments: MFB Comments on Proposed Rule 2019-035 EG PFAS Drinking Water Standards.pdf

Dear Ms. Ruch,

Attached please find comments on behalf of Michigan Farm Bureau in response to the proposal to amend Michigan's rules for supplying drinking water to the public, Rule 2019-035 EG. Please feel free to contact me with any questions.

Sincerely,

Laura A. Campbell, Manager
Agricultural Ecology Department
Michigan Farm Bureau
7373 W. Saginaw Hwy
Lansing, MI 48917
Office: [redacted], Cell: [redacted]
[redacted]@michfb.com

January 31, 2020

Suzann Ruch
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
PO Box 30817
Lansing, Michigan 48909-8311
Sent via email to EGLE-PFAS-RuleMaking@Michigan.gov

Dear Ms. Ruch,

Thank you for the opportunity to provide comments on proposed rule 2019-035 EG, amending the Michigan Department of Environment, Great Lakes, and Energy's (MDEGLE) rules on supplying drinking water to the public. Michigan Farm Bureau is our state's largest general agriculture organization, representing more than 40,000 farming families across Michigan. Drinking water standards affect not only many small and rural communities providing municipal supplies, but also several dozen farms and agricultural processors that meet the threshold for community or non-transient noncommunity water supplies regulated by MDEGLE's proposed rule. We support water quality protection for all of Michigan's citizens, while remaining concerned that the added costs of testing and treatment for the seven new per- and polyfluoroalkyl substances (PFAS) added to drinking water testing requirements will present a heavy burden on those small suppliers. We therefore urge that before this proposed rule is finalized, MDEGLE must work with the State of Michigan to provide technical and financial assistance, and extended compliance schedules, for small public water supplies to ensure they can meet the new standards without being driven out of business.

The proposed rule adds Hexafluoropropylene oxide dimer acid (HFPO-DA), Perfluorobutanesulfonic acid (PFBS), Perfluorohexanesulfonic acid (PFHxS), Perfluorohexanoic acid (PFHxA), Perfluorononanoic acid (PFNA), Perfluorooctanesulfonic acid (PFOS), and Perfluorooctanoic acid (PFOA) to the list of organic contaminants for which the best available technology for removal or reduction is granular activated carbon or "an equally efficient technology" (Proposed Rule, pp. 4-5) and for which the following limits are proposed:

Contaminant	Maximum Contaminant Level in ng/l
Hexafluoropropylene oxide dimer acid (HFPO-DA)	**370**
Perfluorobutane sulfonic acid (PFBS)	**420**
Perfluorohexane sulfonic acid (PFHxS)	**51**
Perfluorohexanoic acid (PFHxA)	**400,000**
Perfluorononanoic acid (PFNA)	**6**
Perfluorooctane sulfonic acid (PFOS)	**16**
Perfluorooctanoic acid (PFOA)	**8**

(Proposed Rule, p. 38).

Under proposed R.325.10604g, these contaminants must be tested at every entry point to the distribution system for a groundwater supply, or at one sampling point for each source if combined groundwater and surface water. If one sampling point is in violation of the proposed maximum contaminant levels (MCL), the entire supply is considered in violation of the MCL. Further, if a sampling point produces results higher than the reporting limit, that supplier must test its supply quarterly until demonstrating reliable and consistent levels below the MCL to be given permission to test annually. The samples must be tested by a certified laboratory approved for testing PFAS chemicals, which may be a challenge to access or timely provide samples from rural areas of the state.

The Michigan Office of Administrative Hearings and Rules' Regulatory Impact Statement and Cost-Benefit Analysis (RIS) notes that in addition to added staff time at municipal and business sites to perform the testing, the cost for laboratory analysis of each test averages approximately $300 to $600, which will need to be incurred quarterly or at a minimum annually by each supplier. If a supply tests for these PFAS contaminants and finds they exceed the MCLs, they will either need to find alternate water sources, which is not feasible for many small communities, farms, or businesses, or install treatment. An example listed in the RIS of treatment installed at a small supply of 4,500 gallons per day was $206,000.

Analysis of New Hampshire's installation costs for PFAS treatment ranged between $2.90 per gallon and $8 per gallon treated per day, but this is not a figure that can be divided down to zero for small supplies since costs for installation of systems have a minimum base cost for equipment, construction, and materials. It also does not account for annual replacement of the granular activated carbon or repair of equipment. More instructive is the average figure in the RIS for annual maintenance costs: $352,500, with "no anticipated difference in operations and maintenance costs between large and small systems" (RIS, p. 5).

This cost may be able to be absorbed by a large community supply that can pass on additional costs to many ratepayers to lessen the burden, but for small community supplies and businesses with non-transient noncommunity supplies, there are either few or no ratepayers to absorb those costs. It presents an enormous, and in some cases impossible, burden to maintain for any small supply with PFAS concentrations over MCL limits.

Because of this potentially enormous financial challenge, we urge MDEGLE to work with the State of Michigan to identify: 1) a funding source to provide grants and financial assistance for small community and non-transient noncommunity suppliers that must install treatment systems for their supplies due to non-compliant PFAS levels, 2) staff, materials, and technical assistance to help those small suppliers with the training to properly take samples, find certified laboratory services, and operate and maintain treatment systems, and 3) that small community and non-transient noncommunity supplies be provided additional time to come into compliance both with the new testing requirements and with implementing treatment if needed. This funding and technical assistance must be made available in time for the proposed rule to be amended as needed and finalized, to avoid creating a burden on small suppliers without any means of assistance to comply with the new standards. The RIS states MDEGLE has already included new full-time equivalent (FTE) positions in the 2020 state budget to absorb the additional burden for implementing and administering the additional duties presented by the proposed rules. Therefore, budget approvals should also be provided for small supplier treatment system funding and additional staff and training materials to assist them with compliance.

Safe drinking water is a priority for communities of all sizes and the farms and businesses who provide water for their employees, families, and products. We urge the State of Michigan to recognize both their desire to comply with necessary protections of public health and their need to continue operating their businesses, farms, and small communities. We appreciate the opportunity to provide comments on this proposed rule amendment. Please feel free to contact me with any questions.

Sincerely,

Laura Campbell, Manager

Agricultural Ecology Department

Smith, Ian (EGLE)

From: Rebecca Meuninck [redacted]@ecocenter.org>
Sent: Friday, January 31, 2020 3:47 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS MCL Standards Comments - 2019-35 EG
Attachments: Ecology Center - PFAS MCL Comments.pdf

Dear Ms. Ruch,

Please find the Ecology Center's comments on the proposed MCL standards for PFAS in Michigan's drinking water attached to this email.

The Ecology Center appreciates the opportunity to submit comments on these proposed rules. We are grateful that EGLE is working to set health-protective standards for these seven PFAS.

Sincerely,

Rebecca Meuninck

Rebecca Meuninck, Ph.D. | Deputy Director
Ecology Center

339 E. Liberty St., Suite 300 | Ann Arbor, MI 48104
[redacted]@ecocenter.org | www.ecocenter.org
Office [redacted]

Healthy people and a healthy planet starts with YOU: www.ecocenter.org/give

ECOLOGYCENTER
Healthy People, Healthy Planet

January 31, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311

EGLE-PFAS-RuleMaking@Michigan.gov

Re: Comments on Proposed Administrative Rules Establishing Michigan PFAS Drinking Water Standards (2019-35 EG)

Dear Ms. Ruch,

The Ecology Center appreciates the opportunity to submit comments on the proposed rules establishing maximum contaminant levels (MCLs) for seven per- and polyfluoroalkyl substances (PFAS) in Michigan. PFAS drinking water contamination is a threat to public health in Michigan. We are grateful that the state is considering setting MCLs for seven of these chemicals, especially because of the lack of action at the federal level to set strong standards.

The state should take swift action to set health-protective standards. However, we believe that the proposed standards do not hit the mark to protect our most vulnerable populations in Michigan and should consider the most sensitive health endpoints to ensure everyone in Michigan is protected. Vulnerable populations including children, nursing mothers, the ill, the elderly, and workers experience high levels of exposure and/or low-dose sensitivity not consistently considered in the development of the proposed standards. We also urge the state to use the best available science to set these standards and create a plan to review them periodically when new scientific evidence emerges on the health impacts of these substances. Finally, the state's testing has shown that water systems with PFAS contamination rarely have just one substance present. The standards should consider the cumulative impacts of these chemicals together and use a class-based or at the very least a sub-class based approach to best protect public health. The recommendations should be revised and ultimately lowered, given these considerations.

Considering Vulnerable Populations and Sensitive Health Endpoints

The parameters applied in the development of some of these standards are only relevant to healthy adults, in particular, we are referring to the proposed standards for GenX. When setting MCLs, the state should consider vulnerable populations and sensitive health endpoints. Populations most vulnerable to the impacts of PFAS include fetuses and children, pregnant and nursing mothers, the elderly, the ill, and workers. Vulnerable populations experience more sensitive health endpoints to these toxic chemicals and are often more highly exposed than the healthy adult population.

Scientific studies have shown that fetuses and children are particularly vulnerable to the negative health effects of PFAS as they have very sensitive health endpoints and are exposed at a high rate. Fetuses are highly exposed to PFAS in utero; even a minuscule amount of exposure at a critical time of gestation impacts fetal development.[1] The shift away from long-chain PFAS towards short-chain exacerbates this disruption as short-chain PFAS cross the placenta more easily.[1] After birth, babies and children experience greater exposure via consumption as they eat and drink more per pound than adults. Furthermore, exposure to PFAS has been shown to decrease immune response, which poses a threat to children getting vaccines as it interferes with the way the body's white blood cells recognize vaccines.[2] Reducing the effectiveness of vaccines in children greatly increases their susceptibility to other health problems for years to come.

Studies have also exemplified the significant health risks PFAS exposure (particularly PFOA exposure) poses for nursing mothers and their children. This increased risk is due to the low-dose sensitivity of mammary glands to PFOA, which was not considered in the MCL development process. Linkages have been made between PFOA exposure and changes in mammary gland development, which alters the morphological and functional development of the glands.[3] A nursing mother exposed to PFOA can pass along negative health effects to her children, resulting in delayed mammary gland development, increased risk of breast cancer, and difficulty breastfeeding. In one study, the offspring of rodents exposed to environmentally relevant concentrations of PFOA (comparable to those experienced by humans) had delayed mammary gland development, delayed epithelial cell differentiation, and altered functional development of mammary glands.[3] That same study found gestational exposure to cause delays in mammary gland development across three generations.[3] The passage of these health risks from mother to child compound the risks PFAS already pose directly to babies and children.

Nursing mothers exposed to PFOA also face additional health risks that harm both them and their child. In lab tests, chronic exposure to environmentally relevant levels of PFOA resulted in morphologically abnormal lactation glands; this reduces the number and density of alveoli that produce milk, ultimately reducing the latency periods to peak milk output.[3] Such functional defects show a correlation that may delay a mother's substantial milk output, and result in cessation of breastfeeding before the recommended time, and ultimately delays the child's development and

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6173485/
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6190594/
[3] https://ehp.niehs.nih.gov/doi/10.1289/ehp.1002741

maturation.[4,5] The recommended timeline for breastfeeding is exclusively breastfeeding for the first six months of life and breastfeeding supplemented by complementary foods until the child is one year old.[6] Cessation of breastfeeding before this timeline can negatively affect the child's developmental and overall health. Breast milk is rich in nutrients and antibodies that enhance brain development.[5] Breastfeeding reduces healthcare costs and provides free, naturally renewable complete nutrition for the first six months of a child's life.[5] Moreover, babies that are breastfed have decreased risk of SIDS and necrotizing enterocolitis - the two leading causes of infant death in the United States - and increased academic productivity.[5] Exposure to PFAS harms not only breastfed babies but also their mothers. Exposure to PFAS may reduce a mother's ability to properly breastfeed, putting both mother and child at risk. Breastfeeding reduces a mother's likelihood of developing breast cancer later in life and the inability to breastfeed caused by PFAS exposure compounds that likelihood.[4] Additionally, delays in mammary gland development also caused by exposure to PFAS can result in increased vulnerability to carcinogens, heightening a mother's chances of getting breast cancer.[4] It is clear that exposure to PFAS, even in small amounts, poses significant health risks to fetuses, babies, children, and nursing mothers. These risks need to be taken into account in lowering the MCL standards.

Other vulnerable populations are also particularly susceptible to the negative effects of PFAS exposure, namely the ill and elderly. The threat of exposure to PFAS interacts with other genetic and environmental influences to negatively impact the elderly population. Exposure at any age may exacerbate stress and inflammation, ultimately contributing to the risk of neurological diseases later in life.[7] At any point in life, those who are ill are also at additional risk due to PFAS exposure. Similarly to children, the ill may also experience decreased immune response as an effect of PFAS exposure. Because PFAS acts as an endocrine disruptor, it decreases immunity and makes already sick bodies more susceptible to disease.[8]

Lastly, workers who have high occupational exposure to PFAS on the job are also a particularly vulnerable population that should be considered. In Michigan, some examples of highly exposed workers include those who have worked on chrome-plating for the auto industry, firefighters, pulp and paper processors, and those who are involved in furniture and apparel production. People with high levels of occupational exposure will have an additive source of exposure through their drinking water. While many companies have shifted focus away from long-chain PFAS they are increasingly focused on short-chain PFAS. The use of short-chain PFAS does not decrease the health risks to humans. Short-chain PFAS do not break down in the environment or our bodies and bioaccumulate in the same fashion as long-chain PFAS. Short-chain PFAS, however, are harder to filter out of drinking water than long-chain.[9] The MCLs for short-chain PFAS have been adopted from manufacturing companies and are based on limited studies and flawed assumptions. These limits do not protect the general population, nor manufacturing workers.

[4] https://www.nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf
[5] https://www.ncbi.nlm.nih.gov/pubmed/27179585
[6] https://www.mibreastfeeding.org/wp-content/uploads/2019/06/MIBFN-2019-Advocacy-Overview.pdf
[7] http://www.agehealthy.org/pdf/GBPSRSEHN_HealthyAging1017.pdf
[8] https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf
[9] https://greensciencepolicy.org/wp-content/uploads/2018/06/Myths-vs.-Facts-June-2018.pdf

Endocrine disruptor abnormalities, like those caused by exposure to PFAS, happen in real-time. This means that the risk to workers isn't only related to the duration of exposure or bioaccumulation. Workers exposed to PFAS chemicals can experience negative health effects after one-time acute exposures. This highly exposed population should be considered in setting the MCLs. To protect everyone - including the aforementioned vulnerable populations - the proposed MCLs must be revised and lowered, given these considerations.

Cumulative Impact and a Class-based Approach

In addition to lowering the individual MCLs for PFAS, a class-based approach also needs to be utilized. Currently, there is an emphasis on the regulation of PFOA and PFOS, but gaps remain on the regulation of GenX and other short-chain PFAS. Short-chain PFAS are more easily absorbed by humans, circulated through the bloodstream, and transferred through the placenta and breastmilk.[10] They are also insufficiently removed from drinking water by the current filtration system technology in place.[7] Along with expanding regulations to include additional chemicals, group values for fluorinated carboxylic acids (PFOA, PFNA, PFHxA, and GenX) and sulfonic acids (PFOS, PFHxS, and PFBS) need to be set. The proposed MCLs evaluate PFAS individually without considering the synergistic effects of two or more PFAS. Most drinking water tested in Michigan has been contaminated with more than one PFAS. When setting safe drinking water standards, we must consider these chemicals as a class and acknowledge and address the cumulative effects of exposure to multiple PFAS simultaneously. Regulations need to be expanded to cover all PFAS as a class in order to account for the impacts of exposure to and bioaccumulation of multiple PFAS.

Using the Best Available Science and Establishing a plan to Periodically Reevaluate

The scientific evidence of the health effects of PFAS is rapidly developing. New analyses and findings have been released in recent months that weren't considered in the development of the proposed values. More recent studies are more alarming. They show that PFAS appear to be endocrine disruptors that interfere with the function of normal hormones like estrogen, testosterone, and thyroid. They also suggest a relationship between PFHxS exposure and impaired reproduction.[11] An analysis of research conducted in New Hampshire that was published in September 2019 supports an MCL of 18 ppt for PFHxS - the proposed MCL for Michigan is two and a half times higher at 51 ppt.[12] Given the alarming new evidence that continues to emerge, the proposed standards need to be lowered and coverage needs to be extended to regulate PFAS as a class. Additionally, a plan to reevaluate and strengthen standards as new science emerges must be developed. Updating standards based on the most up-to-date scientific evidence ensures that the MCLs adequately protect Michiganders from any emerging health threats from PFAS exposure.

The Ecology Center is advocating on behalf of all Michiganders by urging EGLE to reassess the recommended health-based MCL values for PFAS. Revision of these standards must consider

[10] https://ehp.niehs.nih.gov/doi/10.1289/ehp.1509934
[11] http://dx.doi.org/10.1016/j.chemosphere.2017.06.024
[12] https://www4.des.state.nh.us/nh-pfas-investigation/?p=1044

the exposure and low-dose sensitivity of vulnerable populations, extend coverage to include class-based regulation of all PFAS chemicals, and incorporate a plan to reevaluate and adjust standards based on new scientific evidence. These considerations warrant lower MCLs to adequately protect all Michiganders.

Sincerely,

Rebecca Meuninck, Ph.D.
Deputy Director

Gillian Z. Miller, Ph.D.
Senior Scientist

Jeff Gearhart, MS
Research Director

Mara Herman, MPH
Health Policy Specialist

Melissa Sargent
Green Living Resources Director

Smith, Ian (EGLE)

From: Carrie O. Coy <[redacted]@ltbbodawa-nsn.gov>
Sent: Friday, January 24, 2020 11:13 AM
To: EGLE-PFAS-RuleMaking
Cc: Caroline E. Moellering
Subject: PFAS MCL Rule Comments
Attachments: Signed Comment Letter - MI EGLE PFAS Standards.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Blue Category

Hello,

Please see the attached comments from Little Traverse Bay Bands of Odawa Indians. Thanks!

Carrie Coy
Great Lakes Policy Specialist
Little Traverse Bay Bands of Odawa Indians
7500 Odawa Circle, Harbor Springs, MI 49740
[redacted]

Little Traverse Bay Bands of Odawa Indians
Natural Resource Department
7500 Odawa Circle
Harbor Springs, MI 49740
Phone: [redacted]
Fax: [redacted]

WAGANAKISING ODAWA

January 17, 2020

Suzann Ruch
Drinking Water and Environmental Health Division
EGLE
P.O. Box 30817
Lansing, MI 48909-8311
EGLE-PFAS-RuleMaking@Michigan.gov

Re: 2019-35 EG

Dear Ms. Ruch,

On behalf of the Little Traverse Bay Bands of Odawa Indians (LTBB), please accept this letter as support and suggestions for the Michigan Department of Environment, Great Lakes, and Energy's proposed rule (2019-35 EG) PFAS Maximum Contaminant Levels (MCLs) for drinking water. LTBB appreciates this significant step forward to protect Michigan's waters.

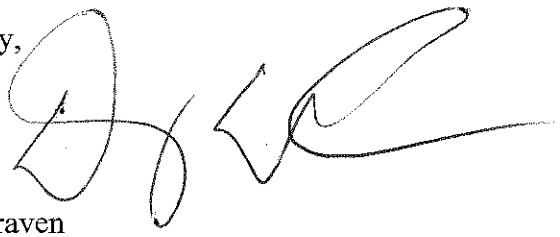
LTBB's traditional way of life, and rights to hunt, fish and gather in the Ceded Territory were reserved in the 1836 Treaty of Washington and reaffirmed by the Federal Court in the case of *United States v. Michigan* (WD MI Case 2: 73 CV 26). LTBB is party to the 2000 Great Lakes and 2007 Inland Consent Decrees entered in that case.

As a supporter, LTBB has questions and suggestions to improve the rule. LTBB would like to see an MCL included for Total PFAS, not only for the standard 7 PFAS compounds in the proposed rule or the few dozen PFAS that are commonly tested, but the many more possible when using non-target analysis techniques. This additional MCL would be more protective, including less studied PFAS which are still potentially dangerous. LTBB would like to see these MCLs reviewed and updated every two years to account for new information. In addition, LTBB would like to see systems that share a source with a system with an exceedance and systems near a system that has an exceedance be monitored more frequently. How often will the best available technologies for filtering systems be updated and replaced? Will public places where a person could access water (i.e. drinking fountain) have notification of an exceedance as well? LTBB would like to see vulnerable populations protected under this rule as well, as our Tribal Elders and youth are very important to our culture. LTBB would also like to see affordable options for testing and treatment for homeowners on well water, as many of our Tribal citizens are not on a municipal system. The proposed MCLs and these considerations will aid in public health on the LTBB reservation and throughout the 1836 ceded territory.

We see the proposed rules as a valuable mechanism to monitor and protect resources from risks associated with PFAS and look forward to potential PFAS MCLs regarding surface and ground

waters. LTBB appreciates this opportunity to comment on State of Michigan proposed rules for the shared purpose of water resource protection and public health.

Sincerely,



Doug Craven
Natural Resources Director
Little Traverse Bay Bands of Odawa Indians

Smith, Ian (EGLE)

From: Nicholas Leonard <[redacted]@glelc.org>
Sent: Friday, January 31, 2020 3:52 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Drinking Water Rules Comment
Attachments: 2020_01_31_EGLE Comment_PFAS Drinking Water Rules.pdf

Good Afternoon,

Please find the attached comments regarding pending rule set # 2019-35 EG. Please let me know if you have any issues with the document.

Nick Leonard
Executive Director
Great Lakes Environmental Law Center
4444 Second Avenue
Detroit, MI 48201
[redacted]

January 31, 2020

Submitted via email to: EGLE-PFAS-RuleMaking@Michigan.gov

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311

Re: Comments on "Proposed PFAS drinking water standards" – Pending Rule Set # 2019-35 EG

Dear Ms. Ruch,

The Michigan Department of Environment, Great Lakes, and Energy has proposed a rule to establish a state drinking water standard per- and polyfluoroalkyl substances, as well as associated monitoring requirements. Comments are being accepted regarding this proposed rule through January 31, 2020. As such, these comments have been submitted in a timely fashion.

Sincerely,

/s/Nicholas Leonard

Nicholas Leonard
Executive Director
Great Lakes Environmental Law Center
4444 Second Avenue
Detroit, MI 48201

[redacted] | [redacted]@glelc.org

I.Ā Introduction

The issue of per- and polyfluoralkyl substances (PFAS) contaminating drinking water delivered by public water systems is one that has been decades in the making. The manufacture and use of PFAS chemicals in the United States dates back to the 1940s, and since then it has been used in a number of products from cookware to firefighting materials. When released into the environment, PFAS tends to remain. Due to strong carbon-fluorine bonds, many PFAS chemicals will refuse to breakdown and remain present in the environment over periods of decades.[1] As a result, PFAS has become a ubiquitous presence in the bodies of humans; it is currently detected in 99% of blood serum samples.[2] While ubiquitous, PFAS are far from innocuous. Exposure to PFAS can lead to serious adverse health effects. The EPA has found suggestive evidence of the carcinogenic potential of PFOA and PFOS.[3] Additionally, liver damage, thyroid disease, and other health effects have been tied to PFAS exposure.[4] Breastfeeding can be an exposure pathway for infants.[5] Pregnant women and infants face unique risks related to PFAS exposure. Numerous studies have linked PFOS and PFNA to increased risks of preeclampsia.[6]

In many instances, PFAS contaminated materials were either improperly used or were improperly disposed of, causing a veritable crisis. PFAS contamination has spread throughout our environment, often without the United States Environmental Protection Agency (EPA) or the Michigan Department of Environment, Great Lakes, and Energy (EGLE) being any the wiser. Now, despite many manufacturers voluntarily phasing out the production of many PFAS chemicals, the threat of PFAS from sites contaminated long-ago is incredibly pressing. Additionally, despite PFAS contamination being present in far too many public water systems, the scientific community's understanding of PFAS and how it may impact exposed individuals is unfortunately still lacking. This scientific uncertainty should not be used as a justification to further delay urgently needed regulatory action. However, it is also important to acknowledge this

[1] United States Environmental Protection Agency, EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan, at 9 (Feb. 2019), available at https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf
[2] Id.
[3] United States Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Toxicological Profile for Perfluoroalkyls, Draft for Public Comment, at 6 (Jun. 2018), available at https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf
[4] Id.
[5] Ulla Mogensen et al., Breastfeeding as an Exposure Pathway for Perfluorinated Alkylates, Environ. Sci Technol. 2015, 49, 17, 10466-10473, available at https://pubs.acs.org/doi/10.1021/acs.est.5b02237
[6] Sverre Wikstrom et al., Early pregnancy serum levels of perfluoroalkyl substances and risk of preeclampsia in Swedish women, Sci. Rep. 2019; 9: 9179, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6591359/#CR7

uncertainty, and to embrace the precautionary principle to ensure that more people are not exposed to harmful levels of PFAS.

We commend the Michigan Department of Environment, Great Lakes, and Energy for being among the first few states to enact enforceable drinking water standards to protect Michigan residents from one of the primary exposure pathways regarding this dangerous group of chemicals. However, we believe the maximum contaminant levels (MCLs) described in the proposed rule fail to meet the statutory directive expressed by the Michigan legislature in the Safe Drinking Water Act (SDWA). Additionally, we believe there must be stronger public notification and education requirements on a quick timeline for public water systems that experience an exceedance of a PFAS.

II.Ā Legal Background

Similar to other major environmental laws, drinking water regulation involves cooperative federalism, with each respective state government working together with the EPA to ensure that all citizens have drinking water that meets basic quality standards. The EPA is primarily responsible for developing MCLS and treatment techniques to limit the concentration of harmful contaminants in the drinking water delivered by public water supplies, and states are primarily responsible for implementing these drinking water standards and ensuring all public water suppliers within the state are complying with them.

However, as with many other federal environmental laws, state policymakers are free to adopt or enforce any law or regulation regarding drinking water or public water systems, so long as that law or regulation is as stringent as the requirements under federal law.[7] This authority has been regularly utilized by Great Lakes states to create MCLs contaminants that are not regulated by the EPA under the federal Safe Drinking Water Act. Below are examples states regulating drinking water contaminants not regulated by the EPA:

- Ā Illinois has adopted MCLs of 0.001 mg/L for aldrin; 0.05 mg/L for DDT, and; 0.001 mg/L for dieldrin. The EPA has expressly decided not to regulate either aldrin or dieldrin, and has not made a regulatory decision regarding DDT.[8]

[7] 42 USC 300g-3(e).
[8] 35 Ill. Adm. Code 611.310.

- Ohio has adopted a treatment technique for microcystins, a contaminant associated with cyanobacteria blooms that is currently unregulated under the federal Safe Drinking Water Act.[9]
- New York has adopted a generic MCL of 0.05 mg/L for any unspecificed organic contaminant (defined as any organic chemical compound not otherwise specified), and a generic MCL of 0.005 mg/L for any principal organic contaminant (defined as any organic chemical compound belonging to specified chemical classes).[10]

The federal Safe Drinking Water Act plainly allows for states to regulate drinking water contaminants not regulated by the EPA, and several state regulators have done so in order to address unique threats to their drinking water. However, when state agencies develop "state-only MCLs" it's important to note that they do so pursuant to state law, not federal law. Therefore, in creating the Proposed Rule at issue here, EGLE relied on its authority as expressed in the Michigan Safe Drinking Water Act, not the federal Safe Drinking Water Act. This is important because there are key differences between the two laws regarding what the rulemaking agency is allowed to consider in developing a MCL.

The federal Safe Drinking Water Act provides very specific directives to the EPA regarding how a MCL is to be developed. Once the EPA has determined that a contaminant presents a public health risk and has decided to create a MCL, it engages in a two-step process. First, the EPA establishes a "maximum contaminant level goal" or "MCLG," which is set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.[11] Second, the EPA then develops a MCL that is set "as close to the maximum contaminant level goal as is feasible."[12] The term "feasibility" is expressly defined in the federal SDWA itself, and requires the EPA to consider available treatment technologies and techniques, as well as the cost of the regulation that will be borne by regulated public water systems.[13] Therefore, in creating the federal SDWA, Congress could not have been clearer: it wanted the EPA to consider costs in creating MCLs.

The process for creating a MCL under the Michigan Safe Drinking Water Act differs significantly from the process described above in the federal Safe Drinking Water Act. The Michigan SDWA does not require EGLE to follow the two-step process

[9] OAC 3745-90-02.
[10] 10 NYCRR 5-1.52, Table 3.
[11] 42 USC 300g-1(b)(4)(A).
[12] 42 USC 300g-1(b)(4)(B).
[13] 42 USC 300g-1(b)(4)(D).

of developing a health-based MCLG, then a MCL that is as close to the MCLG as feasible. Instead, it requires EGLE to develop "state drinking water standards…the attainment and maintenance of which are necessary to protect the public health."[14] Notably missing from the Michigan SDWA is any instruction from the legislature that EGLE consider the costs of compliance to public water systems, which the EPA is expressly required to consider in developing a MCL. Instead, the Michigan SDWA is clear: a MCL promulgated by EGLE pursuant to the Michigan SDWA must be set at a level "necessary to protect the public health."[15] Unlike the federal SDWA, the Michigan SDWA does not direct EGLE to consider costs in creating a MCL.

III.Ā Development of the Rule

The draft PFAS drinking water rule ("Proposed Rule") primarily does three things: it establishes a maximum contaminant level (MCL) for a number of PFAS chemicals; it establishes monitoring requirements, and; it establishes public notification requirements for systems that fail to comply with the Proposed Rule.

In order to develop the MCLs described in R. 325.10604g, Table 1 of the Proposed Rule, EGLE relied on a number of different analyses. In February 2019, the Michigan Department of Health and Human Services published a report titled "Public health drinking water screening levels for PFAS." As its name suggests, this report provided a "public health" perspective regarding the risks of PFAS in drinking water. More specifically, MDHHS conducted a comprehensive review of state and federal agencies' health-based levels, and the used a toxicokinetic model meant to establish levels that are protective of infants to identify levels at which harm can be expected to result.[16] MDHHS stated that its public health drinking water screening levels "have a similar intent as the US EPA Maximum Contaminant Level Goal (MCLG)…"[17] The federal Safe Drinking Water Act defines a "maximum contaminant level goal" as the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[18] As such, MDHHS did not consider any economic costs that may be borne by a public water system if it were to comply with public health drinking water screening levels.

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[14] MCL 325.1005(1)(b).
[15] Id; MCL 325.1002(q).
[16] Michigan Department of Health and Human Services, Public health drinking water screening levels for PFAS (Feb. 22, 2019), available at https://www.michigan.gov/documents/pfasresponse/MDHHS_Public_Health_Drinking_Water_Screening_Levels_for_PFAS_651683_7.pdf
[17] Id.
[18] 42 USC 300g-1(4)(A).

After MDHHS published its PFAS screen levels for drinking water, the Michigan PFAS Action Response Team's Science Advisory Workgroup published its own report titled "Health-Based Drinking Water Value Recommendations for PFAS in Michigan."[19] This report included a number of health-based values for PFAS. Notably, some of the health-based values proposed by the Science Advisory Workgroup are higher than the corresponding public health screening levels proposed by MDHHS. Specifically, while the Science Advisory Workgroup's health-based value for PFOS is 16 parts per trillion, the public health drinking water screening level published by MDHHS was 8 parts per trillion. The MDHHS health-based screening level of 8 parts per trillion was set at a level protective of those most vulnerable to harm, specifically breast-feeding infants. In the Proposed Rule, EGLE selected the Science Advisory Workgroup's value of 16 parts per trillion, as opposed to the public health drinking water screening level published by MDHHS.

It is not clear how the MCL of 16 parts per trillion for PFOS was precisely selected. However, what is clear is that EGLE incorporated "economic considerations" in making its decision regarding what is the most appropriate MCL level for the distinct PFAS chemicals.[20] As stated by EGLE, the consideration of costs can justify the promulgation of a MCL that is higher than the health-based screening levels, which are solely based on the proper regulation of a drinking water contaminant as necessary to protect the public health.

IV. Comments

A. EGLE Impermissibly Considered Costs in Setting the MCLs in the Proposed Rule

As described in Section III above, it is clear that EGLE considered the economic costs that may be associated with compliance in determining the appropriate level for each MCL. This is most clear in regards to the MCL for PFOS. While the MDHHS set a health-based level of 8 parts per trillion, in its Proposed Rule EGLE set the MCL for PFOS at 16 parts per trillion.

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[19] Michigan Science Advisory Workgroup, Health-Based Drinking Water Value Recommendations for PFAS in Michigan (2019), available at https://www.michigan.gov/documents/pfasresponse/Health-Based_Drinking_Water_Value_Recommendations_for_PFAS_in_Michigan_Report_659258_7.pdf

[20] Michigan Department of Health and Human Services, Understanding Risk: What's Behind the Numbers Per- and polyfluoroalkyl substances (PFAS), v.12 (2019), available at https://www.michigan.gov/documents/mdhhs/PFAS_-_Understanding_the_Risk_FINAL_675768_7.pdf

Based on the plain language of the Michigan SDWA, EGLE does not have the authority to consider costs in promulgating a MCL. The Michigan legislature made it very clear what EGLE is to consider when setting MCLs: what is necessary to protect the public health. Unlike the federal SDWA, the Michigan SDWA does not make any reference to costs in the context of MCL setting. This key difference between the federal and Michigan SDWA is accentuated by the fact that Michigan enacted its SDWA in 1976, shortly after the federal SDWA was enacted in 1974. Surely, the Michigan legislature could have modeled the process for how EGLE is to set state MCLs on the process described in the federal SDWA. It chose not to do so. Legislatures do not change the fundamental nature of a regulatory scheme in uncertain or vague terms.[21] When determining the meaning of a statute, it is necessary to consider statutory language not only in the context of the statute itself, but also in its relation to other statutes.[22] In this case, the Michigan legislature adopted by the Michigan Safe Drinking Water Act shortly after Congress had adopted the federal Safe Drinking Water Act. Maximum contaminant levels are the lynchpin of both the federal and Michigan SDWA; they are the maximum levels of contamination legally allowable in drinking water delivered by public water systems. The federal SDWA expressly requires the EPA to consider costs in creating MCLs; the Michigan SDWA does not. Instead, the Michigan SDWA only requires MCLs to be set at levels "necessary to protect the public health." In comparing the federal and Michigan SDWA, the language of the Michigan SDWA becomes clear and unambiguous: EGLE must set MCLs at levels necessary to protect the public health and cannot consider costs. EGLE was bound to follow the unambiguous intent of the Michigan legislature, and by considering costs in the promulgation of the PFAS MCLs it failed to do so and exceeded its statutory authority.

Several court cases have interpreted similar environmental statutes to prohibit the consideration of costs where the legislature unambiguously omitted such factors from those required to be considered. In *Whitman v. American Trucking,* the Supreme Court of the United States considered whether the EPA may consider costs in setting national ambient air quality standards under the Clean Air Act. Similar to the Michigan SDWA, the Clean Air Act instructed to the EPA to set national ambient air quality standards at levels that "are requisite to protect the public health."[23] The Court interpreted this statutory language to "unambiguously bar cost considerations" from the standard setting process, and found it "implausible" such language could be

[21] *Whitman v. Am. Trucking Ass'n,* 531 U.S. 457, 468 (2001)
[22] *See, Toll Northville Ltd. V. Twp. of Northville,* 480 Mich. 6, 17 (2008)
[23] 42 USC 7409(b)(1).

interpreted to authorize an agency to consider costs.[24] This decision has been reinforced by several other courts.[25]

Additionally, the phrase "public health" does not include the consideration of costs. The phrase is undefined in the Michigan SDWA. In situations where a phrase is undefined by statute, dictionary definitions are generally consulted to discern their meaning.[26] The phrase "public health" has been defined by the American Heritage Dictionary as: "[t]he art and science of protecting and improving community health by means of preventative medicine, health education, communicable disease control, and the application of the social and sanitary sciences."[27]

The commenter believes that EGLE has impermissibly considered costs in devising the MCLs described in Rule 604g, Table 1 of the Proposed Rule in excess of its authority under the Michigan SDWA. The commenter asserts that EGLE is required to revise its MCL for PFOS to a level that is protective of public health, regardless of the costs that may be associated with compliance. Additionally, to the extent EGLE considered costs in creating any MCL described in the Proposed Rule, such considerations were in excess of its authority under the Michigan SDWA and any such MCLs should be revised to level necessary to protect the public health regardless of costs.

B.ĀRule 604g - EGLE Should Establish One or More Cumulative PFAS Standards

While PFAS are a broad group of chemicals, many PFAS chemicals share similar characteristics, and cause similar or identical health effects in humans at similar doses as other PFAS chemicals. As such, many states that have established MCLs or screening levels for PFAS not only set thresholds for the allowable concentrations of individual PFAS chemicals in drinking water delivered by public water systems, but also establish one or more cumulative standards for groups of PFAS that share similarities in regards to their chemical structure, and their effects on human health. For example, Vermont has developed health advisory levels for the sum five PFAS chemicals: PFHxS, PFHpA, PFNA, PFOA, and PFOS. In making this determination to regulate these five chemicals cumulatively, Vermont concluded that they are sufficiently similar, are often found together, and elicit similar health effects.[28] As noted by the Vermont Department of

[24] *Whitman v. Am. Trucking Ass'n,* 531 U.S. 457 (2001).
[25] *Murray Energy Corp. v. EPA,* 936 f.3d 597 (D.C. Cir. 2019)
[26] *United Methodist Ret. Cmtys., Inc. v. City of Chelsea,* 2018 Mich. App. LEXIS 2521 (2018)
[27] Id.
[28] Vermont Department of Health, Drinking Water Guidance (May 3, 2019), available at https://www.healthvermont.gov/sites/default/files/documents/pdf/ENV_ECP_GeneralScreeningValues_Water.pdf

Health, there is precedent for establish cumulative MCLs for other chemicals, most notably PCBs (a group chemicals that contain 209 individual compounds) and haloacetic acid disinfection byproducts (which includes dichloroacetic acid, trichloroacetic acid, monochloroacetic acid, bromoacetic acid, and dibromoacetic acid). Setting cumulative values are useful to effectively regulate chemicals that do not have established toxicity values, but are part of a group of chemicals that do have toxicity values. It is also necessary to ensure that the MCLs established by the Proposed Rule are adequately protecting the public health. Without a cumulative standard, it is possible that a person may ingest multiple PFAS at concentrations below each individual MCL, but nonetheless may be exposed to an unacceptable health risk due to the cumulative exposure of multiple PFAS chemicals that elicit similar health effects.

The commenter believe that EGLE should promulgate one or more cumulative PFAS standards that establishes a cumulative limit for a number of PFAS chemicals that are sufficiently similar in their chemical structure, are often found together, and elicit similar health effects. The commenter believes this is necessary both for EGLE to establish state drinking water standards that are necessary to protect the public health, as required by the Michigan SDWA, and in order to account for scientific uncertainty of certain PFAS chemicals.

C. Rule 604g(2)(b) – Reporting Exceedance of PFAS MCL for Water Supplies on Annual Monitoring

According to Rule 717d(9), the Proposed Rule requires all public water systems to monitor for PFAS on quarterly basis unless initial sampling result reveal PFAS concentrations below the specified reporting limits.[29]

Notably, if a public water system on annual monitoring exceeds a PFAS MCL, that exceedance is not regarded as a violation of the MCL.[30] Instead, if a public water system on annual monitoring exceeds a PFAS MCL, they then must conduct quarterly monitoring. Compliance with the MCL is then based on an annual average of the results from each quarter.[31]

Currently, the public notification and education requirements described in Rule 401a, Table 1 apply to violations of a PFAS MCL, or to violations of any monitoring, testing, reporting, or procedure requirements. This does not require public water systems on annual monitoring to conduct any public notification or education in a

[29] Proposed Rule, Mich. Admin. Code R. 325.10717d(9).
[30] Proposed Rule, Mich. Admin. Code R. 325.10604g(2)(b).
[31] Id.

situation where it has exceeded a PFAS MCL. Further, no public notification or education requirements would be required for at least one year until the system determines it has failed to comply with a PFAS MCL based on the average of four quarterly samples. This is true regardless of severity of the exceedance. Hypothetically, a water system that is on annual monitoring may detect PFAS contamination in drinking water that is ten-times the MCL, and this Proposed Rule would not require any public notification or education. This lack of public notification and education could have grave public health consequences, particularly for vulnerable individuals such as infants.

The commenter believes that the Proposed Rule must include more public notification and public education requirements that specifically pertain to instances where a public water system has exceeded a PFAS MCL, but has not yet violated the PFAS MCL in accordance with Rule 604g(2)(b). Any water system that exceeds a PFAS MCL in any sample required by Rule 717d should be required to deliver a written notice of the results of the sample to each consumer within its service territory, and basic health information regarding PFAS contamination in drinking water. Additionally, water systems should be required to disclose any PFAS samples that exceeded a MCL in their consumer confidence reports.

The commenter believes that Rule 717d(9) of the Proposed Rule should be amended to specifically require the result of samples collected under subrules (6), (7), or (8) of the Proposed Rule to be below the reporting limits for all PFAS regulated with a MCL in Rule 604g, Table 1 before allowing a water system to conduct annual monitoring for any individual PFAS chemical.

D. Rule 717d (3), (4), and (5) – Applicability of Sampling Requirements

Rule 717d(3), (4), and (5) of the Proposed Rule describes where a public water system must collect samples for the purpose of determining compliance with the PFAS MCLs. However, it is unclear what type of public water systems these requirements apply to. Presumably, Rule 717d(3), (4), and (5) would apply to community supply, a nontransient noncommunity water supply, and any transient noncommunity supply or Type III supply that is required to conduct PFAS sampling pursuant to Rule 717d(2). However, this is not precisely clear based on the current wording of the rule.

The commenter requests that Rule 717d(3), (4), and (5) be clarified in regards to the applicability of those subsections to different types of water supplies.

E. Rule 717d(10)(a) – Eligibility for Annual Monitoring

Rule 717d(10)(a) requires any water system that detects PFAS above the reporting limit to conduct quarterly monitoring. Such quarterly monitoring must continue until EGLE determines that the water supply is "reliably and consistently below the MCL." At a minimum, a groundwater system must at least 2 quarterly samples, and a surface water system must take at least 4 quarterly samples before EGLE makes a determination that the supply is reliably and consistently below the MCL. It is unclear why EGLE only requires at least 2 quarterly samples for groundwater systems, but 4 quarterly samples for surface water systems.

The commenter believes that EGLE should revise Rule 717(d)(10)(a) to require a groundwater system to take not fewer than 4 quarterly samples before being eligible for a determination by EGLE that the supply is reliably and consistently below the MCL.

Smith, Ian (EGLE)

From: Dale Wynkoop <[redacted]@ect2.com>
Sent: Monday, January 13, 2020 7:59 AM
To: EGLE-PFAS-RuleMaking
Cc: Erica Schmitz
Subject: PFAS Draft Rule comments - Michigan
Attachments: DraftRule-ECT2 Comment.docx

Categories: Blue Category

Hello,

We are providing comments on the proposed rule regarding PFAS.

We have made a couple of changes to "Table 1 Best available technologies for organic contaminants". The first change is to change the column heading from "GAC" to "GAC/IX", and the second is to change the footnote to “Best available technology is IX Resin, GAC or an equally-efficient technology. We have done this in order to promote options to the entity that has to implement treatment. Otherwise, if left as is, the wording appears to preferentially promote GAC.

Ion Exchange is a proven technology for the removal of PFAS from drinking water, and in most cases, is a better total cost of ownership technology versus GAC.

I have attached the document with our changes.

If you have any questions, please let me know.

Dale Wynkoop

Global Director of Sales and Applications

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DEPARTMENT OF ~~ENVIRONMENTAL QUALITY~~ **ENVIRONMENT, GREAT LAKES, AND ENERGY**

DRINKING WATER AND ~~MUNICIPAL ASSISTANCE~~ **ENVIRONMENTAL HEALTH** DIVISION

SUPPLYING WATER TO THE PUBLIC

Filed with the secretary of state on

These rules take effect 7 days after filing with the secretary of state.

(By authority conferred on the department of environmen~~tal~~**, Great Lakes, and energy** ~~quality~~ by section 5 of **the safe drinking water act,** 1976 PA 399, MCL 325.1005)

R 325.10107, R 325.10116, R 325.10308b, R 325.10313, R 325.10401a, R 325.10405, and R 325.12701 of the Michigan Administrative Code are amended, and R 325.10604g, R 325.10717d, R 325.12708, and R 325.12710 are added, as follows:

PART 1. GENERAL PROVISIONS

R 325.10107 Definitions; P, R.

Rule 107. As used in these rules:

(a) "Permit" means a public water supply construction permit that is issued to a supplier of water by the department under section 4 of the act**, MCL 325.1004**.

(b) "Person" means an individual, partnership, copartnership, cooperative, firm, company, public or private association or corporation, political subdivision, agency of the state, agency of the federal government, trust, estate, joint structure company, or any other legal entity, or their legal representative, agent, or assignee.

(c) "PFAS" means per- and polyfluoroalkyl substances.

~~(c)~~ **(d)** "Pitless adapter" means a device or assembly of parts ~~which~~ **that** permits water to pass through the wall of a well casing or extension of a well casing and ~~which~~ **that** provides access to the well and to the parts of the system within the well in a manner that prevents the entrance of contaminants into the well and the water produced.

~~(d)~~ **(e)** "Plans and specifications" means drawings, data, and a true description or representation of an entire waterworks system or parts of the system as it exists or is to be constructed, and a statement of how a waterworks system ~~shall~~ **must** be operated.

~~(e)~~ **(f)** "Plant intake" means the works or structures at the head of a conduit through which water is diverted from a source, for example, river or lake, into the treatment plant.

~~(f)~~ **(g)** "Point-of-entry treatment device (POE)" means a treatment device applied to the drinking water entering a house or building for the purpose of reducing contaminants in the drinking water distributed throughout the house or building.

~~(g)~~ **(h)** "Point-of-use treatment devise (POU)" means a treatment device applied to a single tap used for the purpose of reducing contaminants in drinking water at that 1 tap.

~~(h)~~ **(i)** "Political subdivision" means a city, village, township, charter township, county, district, authority, or portion or combination of any of the entities specified in this subdivision.

~~(i)~~ **(j)** "PQL" means the practical quantitation levels. The PQL is the lowest concentration that can be reliably achieved by well-operated laboratories within specified limits of precision and accuracy during routine laboratory operating conditions.

~~(j)~~ **(k)** "Presedimentation" means a preliminary treatment process used to remove gravel, sand, and other particulate material from the source water through settling before the water enters the primary clarification and filtration processes in a treatment plant.

~~(k)~~ **(l)** "Production well" means a well that has been approved for use for a public water supply ~~in accordance with the provisions of~~ **pursuant to** part 8 of these rules.

~~(l)~~ **(m)** "Public hearing" means a hearing ~~which~~ **that** is conducted by the director of the department on matters relating to the functions and responsibilities of the division and ~~which~~ **that** seeks public input relevant to such functions and responsibilities.

~~(m)~~ **(n)** "Public water supply" or "public water system" means a waterworks system that provides water for drinking or household purposes to persons other than the supplier of the water, and does not include either of the following:

(i) A waterworks system that supplies water to only 1 living unit.

(ii) A waterworks system that consists solely of customer site piping.

~~(n)~~ **(o)** "Pumping water level" means the distance measured from an established datum at or above ground level to the water surface in a well being pumped at a known rate for a known period of time.

~~(o)~~ **(p)** "Rated treatment capacity" means 1 or any combination of the following capacities when water treatment is practiced:

(i) Rated capacity from an approved surface water supply, ground water supply under the direct influence of surface water, or complete treatment system as contained in R 325.11006.

(ii) Firm capacity from an approved ground water supply where firm capacity means the production capability of each respective component of the waterworks system with the largest well, pump, or treatment unit out of service.

(iii) Available capacity obtained under contract and capable of delivery from another approved public water supply.

~~(p)~~ **(q)** "Raw water" means water that is obtained from a source by a public water supply before the public water supply provides any treatment or distributes the water to its customers.

~~(q)~~ **(r)** "Regional administrator" means the EPA region V administrator.

~~(r)~~ **(s)** "Regulated VOCs" means a group of volatile organic chemicals for which state drinking water standards have been promulgated but does not include total trihalomethanes.

~~(s)~~ **(t)** "Removed from service" means physically disconnected from the waterworks system in a manner that would prevent the inadvertent use of the well and would require specific authorization from the public water supply to reconnect.

~~(t)~~ **(u)** "Repeat sample" means a sample that is collected and analyzed in response to a previous coliform-positive sample.

~~(u)~~ **(v)** "Resident" means an individual who owns or occupies a living unit.

~~(v)~~ **(w)** "Routine sample" means a water sample that is collected and analyzed to meet the monitoring requirements for total coliform, as outlined in the written sampling plan.

R 325.10116 Addresses.

Rule 116. The following are addresses and contact information of the department and other organizations referred to in these rules:

(a) Department of ~~Environmental Quality~~ **Environment, Great Lakes, and Energy**, ~~Office of~~ Drinking Water and ~~Municipal Assistance~~ **Environmental Health Division**, 525 West Allegan Street, Post Office Box 30~~241~~**817**, Lansing, MI 48909-~~7741~~**8311**, Telephone 800-662-9278. Internet address: http://www.michigan.gov/~~deq~~**egle**.

(b) National Council ~~O~~**o**n Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3095, Telephone 301-657-2652. Internet address: http://www.ncrponline.org/.

(c) NSF International, P.O Box 130140, 789 North Dixboro Road, Ann Arbor, Michigan 48105, ~~t~~**T**elephone 734-769-8010 or 800-673-6275, email info@nsf.org, Internet address http://www.nsf.org.

(d) Superintendent of Documents, ~~United States Government Printing~~ **U.S. Government Publishing** Office, ~~Post Office~~ **P.O.** Box 979050, St. Louis, MO 63197-9000, Telephone 202-512-1800. Internet address ~~to download documents is http://www.gpoaccess.gov/index.html or~~ to purchase documents online is http://bookstore.gpo.gov.

PART 3. VARIANCES, EXEMPTIONS, AND TREATMENT TECHNOLOGIES

R 325.10308b Best available technology.

Rule 308b. (1) The department identifies the following as the best technology, treatment technique, or other means generally available for achieving compliance with the MCL:

(a) For organic contaminants in R 325.10604b~~ and~~**,** R325.10604d**, and R 325.10604g** the best available technologies, treatment techniques, or other means available for achieving compliance with the MCLs are granular activated carbon (GAC), packed tower aeration (PTA), or oxidation (OX), as listed in table 1 of this rule.

Table 1 Best available technologies for organic contaminants

Contaminant	GAC/IX	PTA	OX
Alachlor	x		
Aldicarb	x		
Aldicarb sulfone	x		
Aldicarb sulfoxide	x		
Atrazine	x		
Benzene	x	x	
Benzo(a)pyrene	x		
Carbofuran	x		
Carbon tetrachloride	x	x	
Chlordane	x		
Dalapon	x		
2,4 D	x		

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Contaminant	GAC/IX	PTA	OX
Di (2 ethylhexyl)adipate	x	x	
Di (2 ethylhexyl)phthalate	x		
Dibromochloropropane (DBCP)	x	x	
o Dichlorobenzene	x	x	
para Dichlorobenzene	x	x	
1,2 Dichloroethane	x	x	
1,1 Dichloroethylene	x	x	
cis 1,2 Dichloroethylene	x	x	
trans 1,2 Dichloroethylene	x	x	
Dichloromethane		x	
1,2 Dichloropropane	x	x	
Dinoseb	x		
Diquat	x		
Endothall	x		
Endrin	x		
Ethylbenzene	x	x	
Ethylene Dibromide (EDB)	x	x	
Glyphosate			x
Heptachlor	x		
Heptachlor epoxide	x		
Hexachlorobenzene	x		
Hexachlorocyclopentadiene	x	x	
Hexafluoropropylene oxide dimer acid (HFPO-DA)	**x[1]**		
Lindane	x		
Methoxychlor	x		
Monochlorobenzene	x	x	
Oxamyl (Vydate)	x		
Pentachlorophenol	x		
Perfluorobutanesulfonic acid (PFBS)	**x[1]**		
Perfluorohexanesulfonic acid (PFHxS)	**x[1]**		
Perfluorohexanoic acid (PFHxA)	**x[1]**		
Perfluorononanoic acid (PFNA)	**x[1]**		
Perfluorooctanesulfonic acid (PFOS)	**x[1]**		
Perfluorooctanoic acid (PFOA)	**x[1]**		
Picloram	x		
Polychlorinated biphenyls(PCB)	x		
Simazine	x		
Styrene	x	x	
2,3,7,8 TCDD (Dioxin)	x		
Tetrachloroethylene	x	x	
Toluene	x	x	
Toxaphene	x		
2,4,5 TP (Silvex)	x		

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Contaminant	GAC/IX	PTA	OX
1,2,4 Trichlorobenzene	x	x	
1,1,1 Trichloroethane	x	x	
1,1,2 Trichloroethane	x	x	
Trichloroethylene	x	x	
Vinyl chloride		x	
Xylene	x	x	

[1]Best available technology is Ion Exchange Resin, GAC or an equally efficient technology.

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(b) For inorganic contaminants in R 325.10604c, the best available technologies, treatment techniques, or other means available for achieving compliance with the MCLs are listed in table 2 of this rule. The affordable technology, treatment technique, or other means available to supplies serving 10,000 or fewer people for achieving compliance with the maximum contaminant level for arsenic are listed in table 3 of this rule.

Table 2 Best available technologies for inorganic contaminants

Chemical name	Best available technologies
Antimony	2,7
Arsenic[4]	1,2, 5,6,7,9,11[5]
Asbestos	2,3,8
Barium	5,6,7,9
Beryllium	1,2,5,6,7
Cadmium	2,5,6,7
Chromium	2,5,6[2],7
Cyanide	5,7,10
Mercury	2[1],4,6[1],7 [1]
Nickel	5,6,7
Nitrate	5,7,9
Nitrite	5,7
Selenium	1,2[3],6,7,9
Thallium	1,5

[1]Best available technology only if influent Hg concentrations are 10 µg/l or less.
[2]Best available technology for chromium III only.
[3]Best available technology for selenium IV only.
[4]BATs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.
[5]To obtain high removals, iron to arsenic ratio ~~shall~~ **must** be at least 20:1.

Key to best available technologies in table:
1 = activated alumina
2 = coagulation/filtration (not BAT for supplies with fewer than 500 service connections)
3 = direct and diatomite filtration
4 = granular activated carbon

5 = ion exchange
6 = lime softening (not BAT for supplies than 500 service connections)
7 = reverse osmosis
8 = corrosion control
9 = electrodialysis
10 = alkaline chlorination (pH greater than or equal to 8.5)
11 = oxidation/filtration

Table 3 Small supplies compliance technologies (SSCTs) for arsenic[1]

Small supply compliance technology	Affordable for listed small supply categories.[2]
Activated alumina (centralized)	All size categories.
Activated alumina (point-of-use)[3]	All size categories.
Coagulation/filtration	501-3,300, 3,301-10,000.
Coagulation-assisted microfiltration	501-3,300, 3,301-10,000.
Electrodialysis reversal	501-3,300, 3,301-10,000.
Enhanced coagulation/filtration	All size categories.
Enhanced lime softening (pH more than 10.5)	All size categories.
Ion exchange	All size categories.
Lime softening	501-3,300, 3,301-10,000.
Oxidation/filtration[4]	All size categories.
Reverse osmosis (centralized)	501-3,300, 3,301-10,000.
Reverse osmosis (point-of-use)[3]	All size categories.

[1] SSCTs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.

[2]Three categories of small supplies are: (i) those serving 25 or more, but fewer than 501, (ii) those serving more than 500, but fewer than 3,301, and (iii) those serving more than 3,300, but fewer than 10,001.

[3]POU ~~shall~~ **must** not be used to obtain a variance.

[4]To obtain high removals, iron to arsenic ratio ~~shall~~ **must** be at least 20:1.

(c) For radionuclide contaminants in R 325.10603, the best available technologies, treatment techniques, or other means available for achieving compliance with the MCLs are listed in table 4 for all size supplies. The affordable technology, treatment technique, or other means available for achieving compliance with the maximum contaminant level are listed in table 5 for supplies serving 10,000 or fewer people as categorized in table 6.

Table 4 Best available technologies for radionuclide contaminants

Contaminant	Best available technologies.
Combined radium 226 and radium 228	Ion exchange, reverse osmosis, lime softening.
Uranium	Ion exchange, reverse osmosis, lime softening, coagulation/filtration.
Gross alpha particle activity (excluding radon and uranium)	Reverse osmosis.

Contaminant	Best available technologies.
Beta particle and proton radioactivity	Ion exchange, reverse osmosis.

Table 5 List of small supplies compliance technologies for radionuclides and limitations to use

Unit Technologies	Limitations (see footnotes)	Operator skill level required *	Raw water quality range and considerations.
1. Ion exchange	(a)	Intermediate	All ground waters.
2. Reverse osmosis (RO)	(b)	Advanced	Surface waters usually require pre-filtration.
3. Lime softening	(c)	Advanced	All waters.
4. Green sand filtration	(d)	Basic	
5. Co-precipitation and Barium sulfate	(e)	Intermediate to Advanced	Ground waters with suitable water quality.
6. Electrodialysis/ electrodialysis reversal	Not applicable	Basic to intermediate	All ground waters.
7. Pre-formed hydrous Manganese oxide filtration.	(f)	Intermediate	All ground waters.
8. Activated alumina	(a), (g)	Advanced	All ground waters; competing anion concentrations may affect regeneration frequency.
9. Enhanced coagulation/ filtration	(h)	Advanced	Can treat a wide range of water qualities.

* An operator with a basic skill level has minimal experience in the water treatment field and can perform the necessary system operation and monitoring if provided with proper instruction. The operator is capable of reading and following explicit directions. An operator with an intermediate skill level understands the principles of water treatment and has a knowledge of the regulatory framework. The operator is capable of making system changes in response to source water fluctuations. An operator with an advanced skill level possesses a thorough understanding of the principles of system operation. The operator is knowledgeable in water treatment and regulatory requirements. The operator may, however, have advanced knowledge of only the particular treatment technology. The operator seeks information, remains informed, and reliably interprets and responds to water fluctuations and system intricacies.

Limitations Footnotes: Technologies for Radionuclides:

a. The regeneration solution contains high concentrations of the contaminant ions. Disposal options ~~shall~~ **must** be carefully considered before choosing this technology.

b. Reject water disposal options ~~shall~~ **must** be carefully considered before choosing this technology.

c. The combination of variable source water quality and the complexity of the water chemistry involved may make this technology too complex for small surface water systems.

d. Removal efficiencies may vary depending on water quality.

e. This technology may be very limited in application to small systems. Since the process requires static mixing, detention basins, and filtration, it is most applicable to systems with sufficiently high sulfate levels that already have a suitable filtration treatment train in place.

f. This technology is most applicable to small systems that already have filtration in place.

g. Handling of chemicals required during regeneration and pH adjustment may be too difficult for small systems without an adequately trained operator.

h. Assumes modification to a coagulation/filtration process already in place.

Table 6 Compliance technologies by supply size category for radionuclide Requirements

Contaminant	Compliance technologies* for supply size categories (population served)		
	25-500	501-3,300	3,301 – 10,000
1. Combined radium 226 and radium 228	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
2. Gross alpha particle activity	2	2	2
3. Beta particle activity and photon activity	1, 2	1, 2	1, 2
4. Uranium	1, 8, 9	1, 2, 3, 8, 9	1, 2, 3, 8, 9

* Numbers correspond to those technologies listed in Table 5 of this rule.

(2) The department shall require community water supplies and nontransient, noncommunity water supplies to employ a treatment method identified in subrule (1) of this rule as a condition for granting a variance, except as provided in subrule (3) of this rule. If, after the treatment method is installed in the system, the supply cannot meet the MCL, then the supply ~~shall be~~ **is** eligible for a variance under this part and section 20 of the act**, MCL 325.1020**.

(3) If a supply demonstrates through comprehensive engineering assessments, which may include pilot plant studies, that the treatment methods identified in subrule (1) of this rule may only achieve a de minimis reduction in contaminants, then the department may issue a schedule of compliance that requires the supply being granted the variance to examine other treatment methods as a condition of obtaining the variance.

(4) If the department determines that a treatment method identified in subrule (3) of this rule is technically feasible, then the department may require the supply to use that treatment method in connection with a compliance schedule issued under section 20 of the act**, MCL 325.1020**. The department's determination **must** ~~shall~~ be based on studies by the supply and other relevant information.

(5) The department may require a community or noncommunity supply to use point-of-use devices, point-of-entry devices, or other means as a condition of granting a variance or an exemption from the requirements of R 325.10603, R 325.10604b, R 325.10604c, ~~or~~ R 325.10604d, **or R325.10604g** to avoid an unreasonable risk to health. The department may require a public water supply to use point-of-use devices or other means, but not point-of-entry devices, as a condition for granting an exemption from corrosion control treatment requirements for lead and copper in R 325.10604f(2) and (3) to avoid an unreasonable risk to health. The department may require a public water supply to use point-of-entry devices as a condition for granting an exemption from the source water and lead service line replacement requirements for lead and copper under R 325.10604f(4) and (5) to avoid an unreasonable risk to health, provided the supply demonstrates that the device will not cause an increased corrosion of lead and copper bearing materials located between the device and the tap that may increase contaminant levels at the tap.

(6) Community or noncommunity water supplies that use point-of-use or point-of-entry devices under this rule shall meet the conditions in R 325.10313.

R 325.10313 Criteria for water supplies using POE, or POU, or both.

Rule 313. (1) Community and noncommunity water supplies shall not use point-of-use devices (POU) or point-of-entry devices (POE) except as required by the department under R 325.10308b or under all of the following provisions with department approval:

(a) Community water supplies may use POE to comply with the maximum contaminant level or treatment technique for organic, inorganic, and radiological contaminants.

(b) Noncommunity water supplies may use POU, or POE, or both, to comply with maximum contaminant levels or treatment techniques for organic and inorganic contaminants.

(c) An alternative source of water that meets state drinking water standards is not available.

(2) Supplies that use POU or POE, or both, shall meet all of the following requirements:

(a) The supply shall operate and maintain the POU, or POE, or both.

(b) Before POU, or POE, or both, are installed, the supply shall obtain department approval of a monitoring plan that ensures that the devices provide health protection equivalent to that provided by central water treatment. If the POU, or POE, or both, are being used to comply with maximum contaminant levels or treatment techniques, then "equivalent" means that the water ~~shall~~ **must** meet all state drinking water standards and ~~shall~~ **must** be of acceptable quality similar to water distributed by a well-operated central treatment plant. At a minimum, the monitoring plan ~~shall~~ **must** include all of the following:

(i) Contaminants and parameters to be analyzed.

(ii) Physical measurements and observations, such as total flow treated and mechanical condition of the treatment equipment.

(iii) Location of sampling sites.

(iv) Frequency of sampling. Approximately 10% of the treatment units ~~shall~~ **must** be sampled at regular intervals so that all the POE or POU are monitored at least as frequently as required in part 7 for a particular contaminant. For example, for a contaminant that is required to be sampled every 3 years, 10% of the POE or POU ~~shall~~ **must** be monitored quarterly so that in 3 years time all of the POE or POU have been monitored. The department may approve an alternate frequency that better represents the rate of degradation of the POE or POU.

(c) Before POU, or POE, or both, are installed, the supply shall obtain department approval of a technology plan that ensures that effective technology is applied and that the microbiological safety of the water is maintained at all times. At a minimum, the technology plan ~~shall~~ **must** include all of the following:

(i) The POU, or POE, or both, ~~shall~~ **must** be equipped with mechanical warnings to ensure that customers are automatically notified of operational problems.

(ii) If a specific type of POU or POE has been independently certified to comply with the maximum contaminant level or treatment technique in accordance with the American ~~a~~**N**ational ~~s~~**S**tandards ~~i~~**I**nstitute/~~a~~**N**ational ~~s~~**S**anitation ~~f~~**F**oundation standards 44, 53, 58, or 62, as adopted by reference in R 325.10112, then individual units of that type ~~shall~~ **must** be used to comply with the maximum contaminant level or treatment technique. A supply may use an alternate type of POU or POE if the supply demonstrates to the department, using pilot plant studies or other means, that the alternative POU or POE consistently complies with the maximum contaminant level or treatment technique and the department approves the use of the POU or POE.

(iii) The design and application of the POU, or POE, or both, ~~shall~~ **must** consider the potential for increasing concentrations of heterotrophic bacteria in water treated with activated carbon. Frequent backwashing, post-contactor disinfection, and heterotrophic plate count monitoring may ensure that the microbiological safety of the water is not compromised.

(d) The supply shall demonstrate that buildings connected to the system have sufficient POU, or POE, or both, that are properly installed, maintained, and monitored such that all ~~of~~ customers ~~shall be~~ **are** protected.

(e) If the POU, or POE, or both, are used to meet an MCL or treatment technique, then the supply shall replace or repair the POU or POE when the contaminant for which the device is intended to control is above the maximum contaminant level in a confirmed sample.

(3) Compliance with the maximum contaminant level ~~shall~~ **must** be determined based on the analytical results obtained at each POU or POE, also known as **the** "sampling point". **The** ~~C~~**c**ompliance determination ~~shall~~ **must** be made under R 325.10604b(2) for volatile organic contaminants, R 325.10604c(2) for inorganic contaminants, ~~or~~ R 325.10604d(2) for synthetic organic chemicals**, or R 325.10604g(2) for per- and polyfluoroalkyl substances**.

(4) Supplies that violate the MCL shall notify the department under part 7 of these rules and shall notify the public under part 4 of these rules. The supply may limit the distribution of the public notice to only persons served by the POU or POE that is out of compliance.

PART 4. PUBLIC NOTIFICATION AND PUBLIC EDUCATION

R 325.10401a General public notification requirements.

Rule 401a. (1) Each community water supply, nontransient noncommunity water supply, or transient noncommunity water supply shall give notice for violations of the maximum contaminant level (MCL), maximum residual disinfection level (MRDL), treatment technique (TT), monitoring requirements, testing procedures in these rules, and for other situations, as listed in the following provisions:

(a) Violations and other situations requiring public notice, including all of the following:

(i) Failure to comply with an applicable maximum contaminant level (MCL) or maximum residual disinfectant level (MRDL).

(ii) Failure to comply with a prescribed treatment technique (TT).

(iii) Failure to perform water quality monitoring, as required by part 7 of these rules.

(iv) Failure to comply with testing procedures as prescribed by part 6 of these rules.

(b) Variance**s** and exemptions under part 3 of these rules, including both of the following:

(i) Operation under a variance or an exemption.

(ii) Failure to comply with the requirements of a schedule that has been set under a variance or exemption.

(c) Special public notices, including all of the following:

(i) Occurrence of a waterborne disease outbreak or other waterborne emergency.

(ii) Exceedance of the nitrate MCL by noncommunity water supplies, where granted permission by the department.

(iii) Fluoride level above 2.0 mg/l as specified in R 325.10408a.

(iv) Availability of unregulated contaminant monitoring data.

(v) Other violations and situations ~~which~~ **that** are determined by the department to require a public notice under this part and ~~which~~ **that** are not already listed in table 1 of this rule. The tier assignment for each specific violation or situation requiring a public notice is identified in table 1 of this rule. Community and noncommunity water supplies are also considered "water supplies" or "supplies" in this rule, R 325.10402 to R 325.10407, and R 325.10408a to R 325.10409.

(2) Public notice requirements are divided into 3 tiers to take into account the seriousness of the violation or situation and of the potential adverse health effects that may be involved. The public notice requirements for each violation or situation listed in subrule (1) of this rule are determined by the tier to which the violation or situation is assigned. The definition of each tier is provided in the following provisions:

(a) Tier 1 public notice is required for violations and situations that have significant potential to have serious adverse effects on human health as a result of short term exposure.

(b) Tier 2 public notice is required for all other violations and situations that have potential to have serious adverse effects on human health.

(c) Tier 3 public notice is required for all other violations and situations not included in tier 1 and tier 2. The tier assignment for each specific violation or situation is identified in table 1 of this rule.

(3) Supplies shall provide public notice to the following:

(a) Each supply shall provide public notice to persons served by the supply as specified in this part. Supplies that sell or otherwise provide drinking water to other public water supplies, such as to consecutive supplies, shall give public notice to the consecutive supply. The consecutive supply shall provide public notice to the persons it serves.

(b) If a public water supply has a violation in a portion of the distribution system that is physically or hydraulically isolated from other parts of the distribution system, then the department may grant permission, which ~~shall~~ **must** be in writing, to the supply to limit distribution of the public notice to only persons served by that portion of the system ~~which~~ **that** is out of compliance. To be **considered** physically ~~separated~~ **isolated**, the supply shall show that the affected portion of the distribution system is separated from other parts of the distribution system with no interconnections. To be considered hydraulically ~~separated~~ **isolated**, the supply shall show that the design of the distribution system or the system operation, or both, created a situation where water in the affected portion is effectively isolated from the water in all other parts of the distribution system because of projected water flow patterns and water pressure zones.

(4) The supply, within 10 days of completing the public notification requirements under this part for the initial public notice and applicable repeat notices, shall submit to the department a certification that it fully complied with the public notification regulations. The supply shall include with this certification a representative copy of each type of notice distributed, published, posted, and made available to the persons served by the supply and to the media.

Table 1 Violations and other situations requiring public notice

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
I. Violations of MCL, MRDL, treatment technique, monitoring and reporting, and testing procedure requirements:				
A. Microbiological contaminants				
Total coliform until March 31, 2016	2	R 325.10602**(1)**(a) and (b)	3	R 325.10704 to R 325.10707a R 325.10702(2) R 325.10707b(4)
Total coliform (TT violations resulting from failure to perform assessments or corrective actions, monitoring violations, and reporting violations) beginning April 1, 2016	2	R 325.10704j(2)(a)	3	R 325.10704j(3) R 325.10704j(4)(a)

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Seasonal supply failure to follow department-approved start-up plan before serving water to the public or failure to provide certification to the department beginning April 1, 2016	2	R 325.10704j(2)(b)	3	R 325.10704j(4)(c)
Fecal coliform/E. coli until March 31, 2016	1	R 325.10602**(1)**(c)	1, 3 [2]	R 325.10704(3) R 325.10707b(4)
E. coli (MCL, monitoring, and reporting violations) beginning April 1, 2016	1	R 325.10704j(1)	3	R 325.10704j(3)(b) R 325.10704j(4)(a) R 325.10704j(4)(b)
E. coli (TT violations resulting from failure to perform level 2 assessments or corrective action) beginning April 1, 2016	2	R 325.10704j(2)(a)	n/a	n/a
Turbidity (for TT violations resulting from a single exceedance of maximum allowable turbidity level)	2, 1 [3]	R 325.10611b	3	R 325.10605 R 325.10720(2)(a) and (b)
Violations, other than violations resulting from single exceedance of max. allowable turbidity level (TT)	2	R 325.10611, R 325.10611a, and R 325.10611b	3	R 325.10605 R 325.10720(2)(c) and (d)
Violations of disinfection profiling and benchmarking	N/A	N/A	3	R 325.10722
Violations of filter backwash recycling provisions	2	R 325.10611c	3	R 325.1**1**507

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Violations of enhanced treatment for cryptosporidium	2	R 325.10611e to R 325.10611m	2, 3	40 CFR §141.701 to §141.705, as adopted by reference in R 325.10720b, R 325.10720c and R 325.10720d. Failure to collect 3 or more samples for Cryptosporidium analysis is a ~~T~~tier 2 violation requiring special notice as required in R 325.10408d. All other monitoring and testing procedure violations are ~~T~~tier 3.
Violations of rules for ground water supplies subject to R 325.10612	2	R 325.10612b	3	R 325.10739(7) R 325.10739a(5)
B. Inorganic chemicals (IOC)				
Antimony	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Arsenic	2	R 325.10604c(1)	3	R 325.10710(4) and (5) R 325.10605
Asbestos (fibers longer than 10 µm)	2	R 325.10604c(1)	3	R 325.10710(4), (6)
Barium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Beryllium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Cadmium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Chromium (total)	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Cyanide (free)	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Fluoride	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Mercury (inorganic)	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Nitrate (as nitrogen)	1	R 325.10604c(1)	1, 3 [4]	R 325.10710(3), (4), (7), and (9)(b)
Nitrite (as nitrogen)	1	R 325.10604c(1)	1, 3 [4]	R 325.10710(3), (4), (8), and (9)(b)

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Total nitrate and nitrite (as nitrogen)	1	R 325.10604c(1)	3	R 325.10710(4)
Selenium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Thallium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
C. Lead and copper (action level for lead is 0.015 mg/l through December 31, 2024 and 0.012 mg/l beginning January 1, 2025; action level for copper is 1.3 mg/l)				
Lead and copper rule (TT)	2	R 325.10604f(1) – (5) R 325.10410(2) and (3)	3	R 325.10710a to R 325.10710c and R 325.10605
D. Synthetic organic chemicals (SOC)				
2,4-D	2	R 325.10604d(1)	3	R 325.10717
2,4,5-TP (silvex)	2	R 325.10604d(1)	3	R 325.10717
Alachlor	2	R 325.10604d(1)	3	R 325.10717
Atrazine	2	R 325.10604d(1)	3	R 325.10717
Benzo(a)pyrene (PAHs)	2	R 325.10604d(1)	3	R 325.10717
Carbofuran	2	R 325.10604d(1)	3	R 325.10717
Chlordane	2	R 325.10604d(1)	3	R 325.10717
Dalapon	2	R 325.10604d(1)	3	R 325.10717
Di (2-ethylhexyl) adipate	2	R 325.10604d(1)	3	R 325.10717
Di (2-ethylhexyl) phthalate	2	R 325.10604d(1)	3	R 325.10717
Dibromochloropropane	2	R 325.10604d(1)	3	R 325.10717
Dinoseb	2	R 325.10604d(1)	3	R 325.10717
Dioxin (2,3,7,8-TCDD)	2	R 325.10604d(1)	3	R 325.10717
Diquat	2	R 325.10604d(1)	3	R 325.10717
Endothall	2	R 325.10604d(1)	3	R 325.10717
Endrin	2	R 325.10604d(1)	3	R 325.10717
Ethylene dibromide	2	R 325.10604d(1)	3	R 325.10717
Glyphosate	2	R 325.10604d(1)	3	R 325.10717
Heptachlor	2	R 325.10604d(1)	3	R 325.10717
Heptachlor epoxide	2	R 325.10604d(1)	3	R 325.10717
Hexachlorobenzene	2	R 325.10604d(1)	3	R 325.10717
Hexachlorocyclo-pentadiene	2	R 325.10604d(1)	3	R 325.10717
Lindane	2	R 325.10604d(1)	3	R 325.10717
Methoxychlor	2	R 325.10604d(1)	3	R 325.10717
Oxamyl (vydate)	2	R 325.10604d(1)	3	R 325.10717
Pentachlorophenol	2	R 325.10604d(1)	3	R 325.10717
Picloram	2	R 325.10604d(1)	3	R 325.10717
Polychlorinated biphenyls [PCBs]	2	R 325.10604d(1)	3	R 325.10717
Simazine	2	R 325.10604d(1)	3	R 325.10717
Toxaphene	2	R 325.10604d(1)	3	R 325.10717
E. Volatile organic chemicals (VOC)				
Benzene	2	R 325.10604b(1)	3	R 325.10716
Carbon tetrachloride	2	R 325.10604b(1)	3	R 325.10716
Chlorobenzene (monochloro-benzene)	2	R 325.10604b(1)	3	R 325.10716

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
O-dichlorobenzene	2	R 325.10604b(1)	3	R 325.10716
P-dichlorobenzene	2	R 325.10604b(1)	3	R 325.10716
1,2-dichloroethane	2	R 325.10604b(1)	3	R 325.10716
1,1-dichloroethylene	2	R 325.10604b(1)	3	R 325.10716
Cis-1,2-dichloroethylene	2	R 325.10604b(1)	3	R 325.10716
Trans-1,2-dichloroethylene	2	R 325.10604b(1)	3	R 325.10716
Dichloromethane	2	R 325.10604b(1)	3	R 325.10716
1,2-dichloropropane	2	R 325.10604b(1)	3	R 325.10716
Ethylbenzene	2	R 325.10604b(1)	3	R 325.10716
Styrene	2	R 325.10604b(1)	3	R 325.10716
Tetrachloro-ethylene	2	R 325.10604b(1)	3	R 325.10716
Toluene	2	R 325.10604b(1)	3	R 325.10716
1,2,4-trichlorobenzene	2	R 325.10604b(1)	3	R 325.10716
1,1,1-trichloroethane	2	R 325.10604b(1)	3	R 325.10716
1,1,2-trichloroethane	2	R 325.10604b(1)	3	R 325.10716
Trichloroethylene	2	R 325.10604b(1)	3	R 325.10716
Vinyl chloride	2	R 325.10604b(1)	3	R 325.10716
Xylenes (total)	2	R 325.10604b(1)	3	R 325.10716
F. per- and polyfluoroalkyl substances (PFAS)				
Hexafluoropropylene oxide dimer acid (HFPO-DA)	**2**	**R 325.10604g(1)**	**3**	**R 325.10717d**
Perfluorobutane sulfonic acid (PFBS)	**2**	**R 325.10604g(1)**	**3**	**R 325.10717d**
Perfluorohexane sulfonic acid (PFHxS)	**2**	**R 325.10604g(1)**	**3**	**R 325.10717d**
Perfluorohexanoic acid (PFHxA)	**2**	**R 325.10604g(1)**	**3**	**R 325.10717d**
Perfluorononanoic acid (PFNA)	**2**	**R 325.10604g(1)**	**3**	**R 325.10717d**
Perfluorooctane sulfonic acid (PFOS)	**2**	**R 325.10604g(1)**	**3**	**R 325.10717d**
Perfluorooctanoic acid (PFOA)	**2**	**R 325.10604g(1)**	**3**	**R 325.10717d**
~~F~~ **G**. Radioactive contaminants				
Beta/photon emitters	2	R 325.10603(2)(c)	3	R 325.10605 R 325.10725 R 325.10730
Alpha emitters (gross alpha)	2	R 325.10603(2)(b)	3	R 325.10605 R 325.10725 R 325.10726 R 325.10728 R 325.10729
Combined radium (226 & 228)	2	R 325.10603(2)(a)	3	R 325.10605 R 325.10725 R 325.10726 R 325.10728 R 325.10729

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Uranium (pCi/L)	2	R 325.10603(2)(d)	3	R 325.10605 R 325.10725 R 325.10726 R 325.10728 R 325.10729
~~G~~ **H**. Disinfection byproducts (DBP), byproduct precursors, disinfectant residuals. Where disinfection is used in the treatment of drinking water, disinfectants combine with organic and inorganic matter present in water to form chemicals called disinfection byproducts (DBP). The department sets standards for controlling the levels of disinfectants and DBPs in drinking water, including trihalomethanes (THM) and haloacetic acids (HAA). See R 325.10610 to R 325.10610d, and R 325.10719e to R 325.10719n for disinfection byproduct MCLs, disinfectant MRDLs, and related monitoring requirements.				
Total trihalomethanes (TTHM)	2	R 325.10610(2) R 325.10610b(2)(a)	3	R 325.10610d, R 325.10719e(1) and (2)(a), and R 325.10719h to R 325.10719n
Haloacetic acids (HAA)	2	R 325.10610(2) R 325.10610b(2)(a)	3	R 325.10610d, R 325.10719e(1) and (2)(a), and R 325.10719h to R 325.10719n
Bromate	2	R 325.10610 R 325.10610b(2)(b)	3	R 325.10719e(1) and (2)(c)
Chloramine (MRDL)	2	R 325.10610a R 325.10610b(3)(a)	3	R 325.10719e(1) and (3)
Chlorine (MRDL)	2	R 325.10610a R 325.10610b(3)(a)	3	R 325.10719e(1) and (3)
Chlorite	2	R 325.10610 R 325.10610b(2)(c)	3	R 325.10719e(1) and (2)(b)
Chlorine dioxide (MRDL), where any 2 consecutive daily samples at entrance to distribution system only are above MRDL	2	R 325.10610a R 325.10610b(3)(b)(ii)	2 *, 3	R 325.10719e(1), (3)(b)(i) and (iii)
	* Failure to monitor for chlorine dioxide at the entrance to the distribution system the day after exceeding the MRDL at the entrance to the distribution system is a tier 2 violation.			
Chlorine dioxide (MRDL), where sample(s) in distribution system the next day are also above MRDL	1 *	R 325.10610a R 325.10610b(3)(b)(i)	1	R 325.10719e(1), (3)(b)(ii) and (iii)
	* If any daily sample taken at the entrance to the distribution system exceeds the MRDL for chlorine dioxide and 1 or more samples taken in the distribution system the next day exceed the MRDL, tier 1 notification is required. Failure to take the required samples in the distribution system after the MRDL is exceeded at the entry point also triggers tier 1 notification.			
Control of DBP precursors—TOC (TT)	2	R 325.10610b(4) R 325.10610c	3	R 325.10719e(1) and (4)
Bench marking and disinfection profiling	N/A	N/A	3	R 325.10722
Development of monitoring plan	N/A	N/A	3	R 325.10719e(5)
~~H~~ **I**. Other treatment techniques				
Acrylamide (TT)	2	R 325.10604e	N/A	N/A

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Epichlorohydrin (TT)	2	R 325.10604e	N/A	N/A
II. Other monitoring:				
Unregulated contaminants	N/A	N/A	3	40 CFR §141.40 [5]
Nickel	N/A	N/A	3	R 325.10710(4), (5), and (9)
III. Public notification for variances and exemptions:				
Operation under a variance or exemption	3	R 325.10302	N/A	N/A
Violation of conditions of a variance or exemption	2	R 325.10312	N/A	N/A
IV. Other situations requiring public notification:				
Fluoride level above 2.0 mg/l	3	R 325.10408a(1)	N/A	N/A
Exceedance of nitrate MCL for noncommunity supplies, as allowed by the department	1	R 325.10604c(3)	N/A	N/A
Availability of unregulated contaminant monitoring data	3	R 325.10407	N/A	N/A
Waterborne disease outbreak	1	R 325.10734(4)	N/A	N/A
Source water sample positive for ~~F~~fecal ~~I~~indicator: E.coli, enterococci, or coliphage	1	R 325.10739(6)	N/A	N/A
Other waterborne emergencies and other situations as determined by the department	1 or 2 or 3 *	N/A	N/A	N/A
	* Waterborne emergencies require a tier 1 public notice. The department may place other situations in any tier it determines appropriate, based on threat to public health.			

[1]MCL - Maximum contaminant level, MRDL - maximum residual disinfectant level, TT - treatment technique.

[2]Failure to test for fecal coliform or E. coli is a tier 1 violation if testing is not done after any repeat sample tests positive for coliform. All other total coliform monitoring and testing procedure violations are tier 3.

[3]Supplies with treatment technique violations involving a single exceedance of a maximum turbidity limit under R 325.10611b(1) are required to initiate consultation with the department within 24 hours after learning of the violation. Based on this consultation, the department may subsequently decide to elevate the violation to tier 1. If a supply is unable to make contact with the department in the 24-hour period, the violation is automatically elevated to tier 1.

[4]Failure to take a confirmation sample within 24 hours for nitrate or nitrite after an initial sample exceeds the MCL is a tier 1 violation. Other monitoring violations for nitrate are tier 3.

[5]~~Title 40 CFR part 141 Section 40, being~~ 40 CFR §141.40,~~(2014),~~ which pertains to unregulated contaminant monitoring, is contained in Title 40 CFR parts 136 to 149 and is available for purchase for $67.00 from the superintendent of documents at the address in R 325.10116. The material is available for inspection from the offices of the department at the address in R 325.10116(a) or available on the ~~I~~internet at http://www.ecfr.gov/.

R 325.10405 Content of public notice.

Rule 405. (1) If a community or noncommunity water supply that is subject to R 325.10401a has a violation or situation requiring public notification, then each public notice ~~shall~~ **must** include all of the following elements:

(a) A description of the violation or situation, including the contaminant or contaminants of concern, and, as applicable, the contaminant level or levels.

(b) When the violation or situation occurred.

(c) The potential adverse health effects from the violation or situation, including the standard language under subrule (4)(a) or (b) of this rule, whichever is applicable.

(d) The population at risk, including subpopulations particularly vulnerable if exposed to the contaminant in their drinking water.

(e) If alternative water supplies should be used.

(f) What actions consumers should take, including when they should seek medical help, if known.

(g) What the supply is doing to correct the violation or situation.

(h) When the supply expects to return to compliance or resolve the situation.

(i) The name, business address, and phone number of the supply or designee of the supply as a source of additional information concerning the notice.

(j) A statement to encourage the notice recipient to distribute the public notice to other persons served, using the standard language under subrule (4)(c) of this rule, where applicable.

(2) All of the following elements ~~shall~~ **must** be included in the public notice for public water supplies operating under a variance or exemption:

(a) If a public water supply has been granted a variance or an exemption, then the public notice ~~shall~~ **must** contain all of the following elements:

(i) An explanation of the reasons for the variance or exemption.

(ii) The date on which the variance or exemption was issued.

(iii) A brief status report on the steps the supply is taking to install treatment, find alternative sources of water, or otherwise comply with the terms and schedules of the variance or exemption.

(iv) A notice of opportunities for public input in the review of the variance or exemption.

(b) If a public water supply violates the conditions of a variance or exemption, then the public notice ~~shall~~ **must** contain the 10 elements listed in subrule (1) of this rule.

(3) The public notice ~~shall~~ **must** be presented in the following manner:

(a) Each public notice required by this part ~~shall~~ **must** meet all of the following criteria:

(i) ~~Shall~~ **Must** be displayed in a conspicuous way when printed or posted.

(ii) ~~Shall~~ **Must** not contain overly technical language or very small print.

(iii) ~~Shall~~ **Must** not be formatted in a way that defeats the purpose of the notice.

(iv) ~~Shall~~ **Must** not contain language ~~which~~ **that** nullifies the purpose of the notice.

(b) In communities where more than 10% of the consumers are non-English speaking consumers, the public notice ~~shall~~ **must** contain information in the appropriate language or languages regarding the importance of the notice or contain a telephone number or address where persons served may contact the supply to obtain a translated copy of the notice or to request assistance in the appropriate language.

(4) The supply shall include the following standard language in the public notice:

(a) The supply shall include in each public notice the health effects language specified in table 1 of this rule corresponding to each MCL, MRDL, and treatment technique violation listed in table 1 of R 325.10401a, and for each violation of a condition of a variance or exemption.

(b) The supply shall include the following language in the notice, including the language necessary to fill in the blanks, for all monitoring and testing procedure violations listed in table 1 of R 325.10401a: "We are required to monitor your drinking water for specific contaminants on a regular basis. Results of regular monitoring are an indicator of whether or not your drinking water meets health standards. During [compliance period], we 'did not monitor or test' or 'did not complete all monitoring or testing' for [contaminant or contaminants], and therefore cannot be sure of the quality of your drinking water during that time."

(c) The supply shall include in the notice the following language, where applicable, to encourage the distribution of the public notice to all persons served: "Please share this information with all the other people who drink this water, especially those who may not have received this notice directly (for example, people in apartments, nursing homes, schools, and businesses). You can do this by posting this notice in a public place or distributing copies by hand or mail."

Table 1 Regulated contaminants

Key

AL=Action level
MCL=Maximum contaminant level
MCLG=Maximum contaminant level goal
mfl=Million fibers per liter
MRDL=Maximum residual disinfectant level
MRDLG=Maximum residual disinfectant level goal
mrem/year=Millirems per year (a measure of radiation absorbed by the body)
N/A=Not applicable
NTU=Nephelometric turbidity units (a measure of water clarity)
pci/l=Picocuries per liter (a measure of radioactivity)
ppm=Parts per million, or milligrams per liter (mg/l)
ppb=Parts per billion, or micrograms per liter (µg/l)
ppt=Parts per trillion, or nanograms per liter
ppq=Parts per quadrillion, or picograms per liter
TT=Treatment technique

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Microbiological contaminants						
Total coliform bacteria until March 31, 2016	MCL: For water supplies analyzing 40 or more samples per month, not more than 5.0% of the monthly samples may be positive for total coliform. For supplies analyzing fewer than 40 samples per month, not more than 1 sample per month may be positive for total coliform.			zero	Naturally present in the environment	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, bacteria may be present. Coliforms were found in more samples than allowed and this was a warning of potential problems.
Total coliform bacteria beginning April 1, 2016. This row applies to Consumer Confidence Reporting.	TT	No conversion necessary	TT	N/A	Naturally present in the environment	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system.
Fecal coliform and E. coli until March 31, 2016	zero	No conversion necessary	zero	zero	Human and animal fecal waste	Fecal coliforms and E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
E. coli beginning April 1, 2016	MCL: Routine and repeat samples are total coliform-positive and either is E. coli-positive or supply fails to take all required repeat samples following E. coli-positive routine sample or supply fails to analyze total coliform-positive repeat sample for E. coli			zero	Human and animal fecal waste	E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely-compromised immune systems.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Coliform Assessment ~~and~~/or Corrective Action Violations**, or both,** beginning April 1, 2016. This row applies to public notification. For Consumer Confidence Reporting, see R 325.10413(12)(g)(i).	N/A	No conversion necessary	TT	N/A	N/A	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system. We found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct assessments to identify problems and to correct any problems that are found. [THE SUPPLY MUST USE 1 OF THE FOLLOWING APPLICABLE SENTENCES:] We failed to conduct the required assessment. We failed to correct all identified sanitary defects that were found during the assessment(s).
E. coli Assessment ~~and~~/or Corrective Action Violations**, or both,** beginning April 1, 2106. This row applies to public notification. For Consumer Confidence Reporting, see R 325.10413(12)(g)(ii).	N/A	No conversion necessary	TT	N/A	N/A	E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely compromised immune systems. We violated the standard for E. coli, indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct a detailed assessment to identify problems and to correct any problems that are found. [THE SUPPLY MUST USE 1 OF THE FOLLOWING APPLICABLE SENTENCES:] We failed to conduct the required assessment. We failed to correct all identified sanitary defects that were found during the assessment that we conducted.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Seasonal Supply Treatment Technique Violations of the Total Coliform Rule beginning April 1, 2016.	N/A	No conversion necessary	TT	N/A	N/A	When this violation includes the failure to monitor for total coliforms or E. coli prior to serving water to the public, the mandatory language found at R 325.10405(4)(b) ~~shall~~ **must** be used. When this violation includes failure to complete other actions, the appropriate public notice elements found in R 325.10405(1) ~~shall~~ **must** be used.
Fecal indicator under groundwater requirements in R 325.10612 et. al: - E.coli - enterococci or - coliphage)	TT	No conversion necessary	TT	E.coli: zero Others: N/A	Human and animal fecal waste	Fecal indicators are microbes whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term health effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
Violations of rules for ground water supplies subject to R 325.10612	TT	No conversion necessary	TT	N/A	N/A	Inadequately treated or inadequately protected water may contain disease-causing organisms. These organisms can cause symptoms such as diarrhea, nausea, cramps, and associated headaches.
Turbidity (ntu)	TT	No conversion necessary	TT	N/A	Soil runoff	Turbidity has no health effects. However, turbidity can interfere with disinfection and provide a medium for microbial growth. Turbidity may indicate the presence of disease-causing organisms. These organisms include bacteria, viruses, and parasites that can cause symptoms such as nausea, cramps, diarrhea, and associated headaches.
Other microbiological contaminants						
Giardia lamblia, viruses, heterotrophic plate count (HPC) bacteria, legionella, cryptosporidium	TT*	No conversion necessary	TT*	zero	Naturally present in the environment	Inadequately treated water may contain disease-causing organisms. These organisms include bacteria, viruses, and parasites which can cause symptoms such as nausea, cramps, diarrhea, and associated headaches.
	* The treatment technique violations that involve turbidity exceedances may use health effects language for turbidity instead.					
Inorganic contaminants						

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Antimony (ppb)	0.006	1000	6	6	Discharge from petroleum refineries; fire retardants; ceramics; electronics; solder	Some people who drink water containing antimony well in excess of the MCL over many years could experience increases in blood cholesterol and decreases in blood sugar.
Arsenic (ppb)	0.010	1000	10	0	Erosion of natural deposits; runoff from orchards; runoff from glass and electronics production wastes	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.
Asbestos [fibers longer than 10 µm] (mfl)	7 mfl	No conversion necessary	7	7	Decay of asbestos cement water mains; erosion of natural deposits	Some people who drink water containing asbestos in excess of the MCL over many years may have an increased risk of developing benign intestinal polyps.
Barium (ppm)	2	No conversion necessary	2	2	Discharge of drilling wastes; discharge from metal refineries; erosion of natural deposits	Some people who drink water containing barium in excess of the MCL over many years could experience an increase in their blood pressure.
Beryllium (ppb)	0.004	1000	4	4	Discharge from metal refineries and coal-burning factories; discharge from electrical, aerospace, and defense industries	Some people who drink water containing beryllium well in excess of the MCL over many years could develop intestinal lesions.
Cadmium (ppb)	0.005	1000	5	5	Corrosion of galvanized pipes; erosion of natural deposits; discharge from metal refineries; runoff from waste batteries and paints	Some people who drink water containing cadmium in excess of the MCL over many years could experience kidney damage.
Chromium [total] (ppb)	0.1	1000	100	100	Discharge from steel and pulp mills; erosion of natural deposits	Some people who use water containing chromium well in excess of the MCL over many years could experience allergic dermatitis.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Cyanide [free] (ppb)	0.2	1000	200	200	Discharge from steel/metal factories; discharge from plastic and fertilizer factories	Some people who drink water containing cyanide well in excess of the MCL over many years could experience nerve damage or problems with their thyroid.
Fluoride (ppm)	4.0	No conversion necessary	4.0	4.0	Erosion of natural deposits; water additive that promotes strong teeth; discharge from fertilizer and aluminum factories	Some people who drink water containing fluoride in excess of the MCL over many years could get bone disease, including pain and tenderness of the bones. Fluoride in drinking water at half the MCL or more may cause mottling of children's teeth, usually in children less than 9 years old. Mottling, also known as dental fluorosis, may include brown staining ~~and/~~or pitting of the teeth, **or both,** and occurs only in developing teeth before they erupt from the gums.
Mercury [inorganic] (ppb)	0.002	1000	2	2	Erosion of natural deposits; discharge from refineries and factories; runoff from landfills; runoff from cropland	Some people who drink water containing inorganic mercury well in excess of the MCL over many years could experience kidney damage.
Nitrate [as nitrogen] (ppm)	10	No conversion necessary	10	10	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	Infants below the age of 6 months who drink water containing nitrate in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.
Nitrite [as nitrogen] (ppm)	1	No conversion necessary	1	1	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	Infants below the age of 6 months who drink water containing nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.
Total nitrate and nitrite [as nitrogen] (ppm)	10	No conversion necessary	10	10	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	Infants below the age of 6 months who drink water containing nitrate and nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Selenium (ppb)	0.05	1000	50	50	Discharge from petroleum and metal refineries; erosion of natural deposits; discharge from mines	Selenium is an essential nutrient. However, some people who drink water containing selenium in excess of the MCL over many years could experience hair or fingernail losses, numbness in fingers or toes, or problems with their circulation.
Thallium (ppb)	0.002	1000	2	0.5	Leaching from ore-processing sites; discharge from electronics, glass, and drug factories	Some people who drink water containing thallium in excess of the MCL over many years could experience hair loss, changes in their blood, or problems with their kidneys, intestines, or liver.
Lead and copper						
Lead (ppb)	AL=0.015 through December 31, 2024; AL= 0.012 beginning January 1, 2025.	1000	AL=15 through December 31, 2024; AL=12 beginning January 1, 2025. (TT)	zero	Lead services lines, corrosion of household plumbing including fittings and fixtures; erosion of natural deposits	Infants and children who drink water containing lead could experience delays in their physical or mental development. Children could show slight deficits in attention span and learning abilities. Adults who drink this water over many years could develop kidney problems or high blood pressure.
Copper (ppm)	AL=1.3	No conversion necessary	AL=1.3 (TT)	1.3	Corrosion of household plumbing systems; erosion of natural deposits	Copper is an essential nutrient, but some people who drink water containing copper in excess of the action level over a relatively short amount of time could experience gastrointestinal distress. Some people who drink water containing copper in excess of the action level over many years could suffer liver or kidney damage. People with Wilson's disease should consult their personal doctor.
Synthetic organic contaminants including pesticides and herbicides						
2,4-D (ppb)	0.07	1000	70	70	Runoff from herbicide used on row crops	Some people who drink water containing the weed killer 2,4-d well in excess of the MCL over many years could experience problems with their kidneys, liver, or adrenal glands.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
2,4,5-TP [silvex] (ppb)	0.05	1000	50	50	Residue of banned herbicide	Some people who drink water containing silvex in excess of the MCL over many years could experience liver problems.
Alachlor (ppb)	0.002	1000	2	zero	Runoff from herbicide used on row crops	Some people who drink water containing alachlor in excess of the MCL over many years could have problems with their eyes, liver, kidneys, or spleen, or experience anemia, and may have an increased risk of getting cancer.
Atrazine (ppb)	0.003	1000	3	3	Runoff from herbicide used on row crops	Some people who drink water containing atrazine well in excess of the MCL over many years could experience problems with their cardiovascular system or reproductive difficulties.
Benzo(a)pyrene [PAHs] (ppt)	0.0002	1,000,000	200	zero	Leaching from linings of water storage tanks and distribution lines	Some people who drink water containing benzo(a)pyrene in excess of the MCL over many years may experience reproductive difficulties and may have an increased risk of getting cancer.
Carbofuran (ppb)	0.04	1000	40	40	Leaching of soil fumigant used on rice and alfalfa	Some people who drink water containing carbofuran in excess of the MCL over many years could experience problems with their blood or nervous or reproductive systems.
Chlordane (ppb)	0.002	1000	2	zero	Residue of banned termiticide	Some people who drink water containing chlordane in excess of the ~~mcl~~ **MCL** over many years could experience problems with their liver or nervous system, and may have an increased risk of getting cancer.
Dalapon (ppb)	0.2	1000	200	200	Runoff from herbicide used on rights of way	Some people who drink water containing dalapon well in excess of the MCL over many years could experience minor kidney changes.
Di(2-ethylhexyl) adipate (ppb)	0.4	1000	400	400	Discharge from chemical factories	Some people who drink water containing di (2-ethylhexyl) adipate well in excess of the MCL over many years could experience toxic effects such as weight loss, liver enlargement, or possible reproductive difficulties.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Di(2-ethylhexyl) phthalate (ppb)	0.006	1000	6	zero	Discharge from rubber and chemical factories	Some people who drink water containing di (2-ethylhexyl) phthalate well in excess of the MCL over many years may have problems with their liver, or experience reproductive difficulties, and may have an increased risk of getting cancer.
Dibromochloropropane [DBCP] (ppt)	0.0002	1,000,000	200	zero	Runoff/leaching from soil fumigant used on soybeans, cotton, pineapples, and orchards	Some people who drink water containing DBCP in excess of the MCL over many years could experience reproductive difficulties and may have an increased risk of getting cancer.
Dinoseb (ppb)	0.007	1000	7	7	Runoff from herbicide used on soybeans and vegetables	Some people who drink water containing dinoseb well in excess of the MCL over many years could experience reproductive difficulties.
Dioxin [2,3,7,8-TCDD] (ppq)	0.00000003	1,000,000,000	30	zero	Emissions from waste incineration and other combustion; discharge from chemical factories	Some people who drink water containing dioxin in excess of the MCL over many years could experience reproductive difficulties and may have an increased risk of getting cancer.
Diquat (ppb)	0.02	1000	20	20	Runoff from herbicide use	Some people who drink water containing diquat in excess of the MCL over many years could get cataracts.
Endothall (ppb)	0.1	1000	100	100	Runoff from herbicide use	Some people who drink water containing endothall in excess of the MCL over many years could experience problems with their stomach or intestines.
Endrin (ppb)	0.002	1000	2	2	Residue of banned insecticide	Some people who drink water containing endrin in excess of the MCL over many years could experience liver problems.
Ethylene dibromide (ppt)	0.00005	1,000,000	50	zero	Discharge from petroleum refineries	Some people who drink water containing ethylene dibromide in excess of the MCL over many years could experience problems with their liver, stomach, reproductive system, or kidneys, and may have an increased risk of getting cancer.
Glyphosate (ppb)	0.7	1000	700	700	Runoff from herbicide use	Some people who drink water containing glyphosate in excess of the MCL over many years could experience problems with their kidneys or reproductive difficulties.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Heptachlor (ppt)	0.0004	1,000,000	400	zero	Residue of banned pesticide	Some people who drink water containing heptachlor in excess of the MCL over many years could experience liver damage and may have an increased risk of getting cancer.
Heptachlor epoxide (ppt)	0.0002	1,000,000	200	zero	Breakdown of heptachlor	Some people who drink water containing heptachlor epoxide in excess of the MCL over many years could experience liver damage, and may have an increased risk of getting cancer.
Hexachlorobenzene (ppb)	0.001	1000	1	zero	Discharge from metal refineries and agricultural chemical factories	Some people who drink water containing hexachlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys, or adverse reproductive effects, and may have an increased risk of getting cancer.
Hexachlorocyclopentadiene (ppb)	0.05	1000	50	50	Discharge from chemical factories	Some people who drink water containing hexachlorocyclopentadiene well in excess of the MCL over many years could experience problems with their kidneys or stomach.
Lindane (ppt)	0.0002	1,000,000	200	200	Runoff/leaching from insecticide used on cattle, lumber, gardens	Some people who drink water containing lindane in excess of the MCL over many years could experience problems with their kidneys or liver.
Methoxychlor (ppb)	0.04	1000	40	40	Runoff/leaching from insecticide used on fruits, vegetables, alfalfa, livestock	Some people who drink water containing methoxychlor in excess of the MCL over many years could experience reproductive difficulties.
Oxamyl [vydate] (ppb)	0.2	1000	200	200	Runoff/leaching from insecticide used on apples, potatoes, and tomatoes	Some people who drink water containing oxamyl in excess of the MCL over many years could experience slight nervous system effects.
Pentachlorophenol (ppb)	0.001	1000	1	zero	Discharge from wood preserving factories	Some people who drink water containing pentachlorophenol in excess of the MCL over many years could experience problems with their liver or kidneys, and may have an increased risk of getting cancer.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Picloram (ppb)	0.5	1000	500	500	Herbicide runoff	Some people who drink water containing picloram in excess of the MCL over many years could experience problems with their liver.
Polychlorinated biphenyls [PCBs] (ppt)	0.0005	1,000,000	500	zero	Runoff from landfills; discharge of waste chemicals	Some people who drink water containing PCBs in excess of the MCL over many years could experience changes in their skin, problems with their thymus gland, immune deficiencies, or reproductive or nervous system difficulties, and may have an increased risk of getting cancer.
Simazine (ppb)	0.004	1000	4	4	Herbicide runoff	Some people who drink water containing simazine in excess of the MCL over many years could experience problems with their blood.
Toxaphene (ppb)	0.003	1000	3	zero	Runoff/leaching from insecticide used on cotton and cattle	Some people who drink water containing toxaphene in excess of the MCL over many years could have problems with their kidneys, liver, or thyroid, and may have an increased risk of getting cancer.
Per- and polyfluoroalkyl substances (PFAS)						
Hexafluoropropylene oxide dimer acid (HFPO-DA) (ppt)	**370 ppt (ng/l)**	**No conversion necessary**	**370**	**N/A**	**Discharge and waste from industrial facilities utilizing the Gen X chemical process**	**Some people who drink water containing HFPO-DA in excess of the MCL could experience problems with their liver. Some fetuses of pregnant women and infants born to mothers who drink water containing HFPO-DA in excess of the MCL may experience developmental effects.**
Perfluorobutane sulfonic acid (PFBS) (ppt)	**420 ppt (ng/l)**	**No conversion necessary**	**420**	**N/A**	**Discharge and waste from industrial facilities; stain-resistant treatments**	**Some infants born to mothers who drink water containing PFBS in excess of the MCL may experience decreased thyroid hormone levels.**
Perfluorohexane sulfonic acid (PFHxS) (ppt)	**51 ppt (ng/l)**	**No conversion necessary**	**51**	**N/A**	**Firefighting foam; discharge and waste from industrial facilities**	**Some people who drink water containing PFHxS in excess of the MCL could experience problems with their thyroid, liver, and cholesterol levels.**

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Perfluorohexanoic acid (PFHxA) (ppt)	**400,000 ppt (ng/l)**	**No conversion necessary**	**400,000**	**N/A**	**Firefighting foam; discharge and waste from industrial facilities**	**Some people who drink water containing PFHxA in excess of the MCL could experience problems with their liver and kidneys.**
Perfluorononanoic acid (PFNA) (ppt)	**6 ppt (ng/l)**	**No conversion necessary**	**6**	**N/A**	**Discharge and waste from industrial facilities; breakdown of precursor compounds**	**Some fetuses of pregnant women and infants born to mothers who drink water containing PFNA in excess of the MCL may experience developmental delays and decreased body weight gain.**
Perfluorooctane sulfonic acid (PFOS) (ppt)	**16 ppt (ng/l)**	**No conversion necessary**	**16**	**N/A**	**Firefighting foam; discharge from electroplating facilities; discharge and waste from industrial facilities**	**Some fetuses of pregnant women and infants born to mothers who drink water containing PFOS in excess of the MCL may experience developmental delays and decreased body weight gain.**
Perfluorooctanoic acid (PFOA) (ppt)	**8 ppt (ng/l)**	**No conversion necessary**	**8**	**N/A**	**Discharge and waste from industrial facilities; stain-resistant treatments**	**Some fetuses of pregnant women and infants born to mothers who drink water containing PFOA in excess of the MCL may experience neurodevelopmental effects and skeletal effects.**
Volatile organic contaminants						
Benzene (ppb)	0.005	1000	5	zero	Discharge from factories; leaching from gas storage tanks and landfills	Some people who drink water containing benzene in excess of the MCL over many years could experience anemia or a decrease in blood platelets, and may have an increased risk of getting cancer.
Carbon tetrachloride (ppb)	0.005	1000	5	zero	Discharge from chemical plants and other industrial activities	Some people who drink water containing carbon tetrachloride in excess of the MCL over many years could experience problems with their liver and may have an increased risk of getting cancer.
Chlorobenzene (ppb)	0.1	1000	100	100	Discharge from chemical and agricultural chemical factories	Some people who drink water containing chlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
O-dichlorobenzene (ppb)	0.6	1000	600	600	Discharge from industrial chemical factories	Some people who drink water containing o-dichlorobenzene well in excess of the MCL over many years could experience problems with their liver, kidneys, or circulatory systems.
P-dichlorobenzene (ppb)	0.075	1000	75	75	Discharge from industrial chemical factories	Some people who drink water containing p-dichlorobenzene in excess of the MCL over many years could experience anemia, damage to their liver, kidneys, or spleen, or changes in their blood.
1,2-dichloroethane (ppb)	0.005	1000	5	zero	Discharge from industrial chemical factories	Some people who drink water containing 1,2-dichloroethane in excess of the MCL over many years may have an increased risk of getting cancer.
1,1-dichloroethylene (ppb)	0.007	1000	7	7	Discharge from industrial chemical factories	Some people who drink water containing 1,1-dichloroethylene in excess of the MCL over many years could experience problems with their liver.
Cis-1,2-dichloroethylene (ppb)	0.07	1000	70	70	Discharge from industrial chemical factories	Some people who drink water containing cis-1,2-dichloroethylene in excess of the MCL over many years could experience problems with their liver.
Trans-1,2-dichloroethylene (ppb)	0.1	1000	100	100	Discharge from industrial chemical factories	Some people who drink water containing trans-1,2-dichloroethylene well in excess of the MCL over many years could experience problems with their liver.
Dichloromethane (ppb)	0.005	1000	5	zero	Discharge from pharmaceutical and chemical factories	Some people who drink water containing dichloromethane in excess of the MCL over many years could have liver problems and may have an increased risk of getting cancer.
1,2-dichloropropane (ppb)	0.005	1000	5	zero	Discharge from industrial chemical factories	Some people who drink water containing 1,2-dichloropropane in excess of the MCL over many years may have an increased risk of getting cancer.
Ethylbenzene (ppb)	0.7	1000	700	700	Discharge from petroleum refineries	Some people who drink water containing ethylbenzene well in excess of the MCL over many years could experience problems with their liver or kidneys.
Styrene (ppb)	0.1	1000	100	100	Discharge from rubber and plastic factories; leaching from landfills	Some people who drink water containing styrene well in excess of the MCL over many years could have problems with their liver, kidneys, or circulatory system.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Tetrachloro-ethylene (ppb)	0.005	1000	5	~~Z~~zero	Discharge from factories and dry cleaners	Some people who drink water containing tetrachloroethylene in excess of the MCL over many years could have problems with their liver, and may have an increased risk of getting cancer.
Toluene (ppm)	1	No conversion necessary	1	1	Discharge from petroleum factories	Some people who drink water containing toluene well in excess of the MCL over many years could have problems with their nervous system, kidneys, or liver.
1,2,4-trichlorobenzene (ppb)	0.07	1000	70	70	Discharge from textile-finishing factories	Some people who drink water containing 1,2,4-trichlorobenzene well in excess of the MCL over many years could experience changes in their adrenal glands.
1,1,1-trichloroethane (ppb)	0.2	1000	200	200	Discharge from metal degreasing sites and other factories	Some people who drink water containing 1,1,1-trichloroethane in excess of the MCL over many years could experience problems with their liver, nervous system, or circulatory system.
1,1,2-trichloroethane (ppb)	0.005	1000	5	3	Discharge from industrial chemical factories	Some people who drink water containing 1,1,2-trichloroethane well in excess of the MCL over many years could have problems with their liver, kidneys, or immune systems.
Trichloroethylene (ppb)	0.005	1000	5	zero	Discharge from metal degreasing sites and other factories	Some people who drink water containing trichloroethylene in excess of the MCL over many years could experience problems with their liver and may have an increased risk of getting cancer.
Vinyl chloride (ppb)	0.002	1000	2	zero	Leaching from PVC piping; discharge from plastics factories	Some people who drink water containing vinyl chloride in excess of the MCL over many years may have an increased risk of getting cancer.
Xylenes [total] (ppm)	10	No conversion necessary	10	10	Discharge from petroleum factories; discharge from chemical factories	Some people who drink water containing xylenes in excess of the MCL over many years could experience damage to their nervous system.
Radioactive contaminants						

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Beta/photon emitters (mrem/yr)	4 mrem/yr	No conversion necessary	4	zero	Decay of natural and man-made deposits	Certain minerals are radioactive and may emit forms of radiation known as photons and beta radiation. Some people who drink water containing beta particle and photon radioactivity in excess of the MCL over many years may have an increased risk of getting cancer.
Alpha emitters [gross alpha] (pci/l)	15 pCi/L	No conversion necessary	15	zero	Erosion of natural deposits	Certain minerals are radioactive and may emit a form of radiation known as alpha radiation. Some people who drink water containing alpha emitters in excess of the MCL over many years may have an increased risk of getting cancer.
Combined radium [226 & 228] (pci/l)	5 pCi/L	No conversion necessary	5	zero	Erosion of natural deposits	Some people who drink water containing radium 226 or 228 in excess of the MCL over many years may have an increased risk of getting cancer.
Uranium (pCi/L)	30 ug/L	No conversion necessary	30	~~Z~~zero	Erosion of natural deposits	Some people who drink water containing uranium in excess of the MCL over many years may have an increased risk of getting cancer and kidney toxicity.
Disinfection byproducts (DBP), byproduct precursors, and disinfectant residuals: where disinfection is used in the treatment of drinking water, disinfectants combine with organic and inorganic matter present in water to form chemicals called disinfection byproducts (DBP). The department sets standards for controlling the levels of disinfectants and DBP in drinking water, including trihalomethanes (THM) and haloacetic acids (HAA). See R 325.10610 to R 325.10610d and R 325.10719e to R 325.10719n for disinfection byproduct MCLs, disinfectant MRDLs, and related monitoring requirements.						
Total trihalomethanes [TTHM] (ppb)	0.080*	1000	80*	N/A	By-product of drinking water disinfection	Some people who drink water containing trihalomethanes in excess of the MCL over many years may experience problems with their liver, kidneys, or central nervous system, and may have an increased risk of getting cancer.
	* The MCL for total trihalomethanes is the sum of the concentrations of the individual trihalomethanes.					
Haloacetic acids (HAAs) (ppb)	0.060*	1000	60*	N/A	By-product of drinking water disinfection	Some people who drink water containing haloacetic acids in excess of the MCL over many years may have an increased risk of getting cancer.
	* The MCL for haloacetic acids is the sum of the concentrations of the individual haloacetic acids.					
Bromate (ppb)	0.010	1000	10	zero	By-product of drinking water disinfection	Some people who drink water containing bromate in excess of the MCL over many years may have an increased risk of getting cancer.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Chloramines (ppm)	MRDL = 4	No conversion necessary	MRDL = 4	MRDLG = 4	Water additive used to control microbes	Some people who use water containing chloramines well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chloramines well in excess of the MRDL could experience stomach discomfort or anemia.
Chlorine (ppm)	MRDL = 4	No conversion necessary	MRDL = 4	MRDLG = 4	Water additive used to control microbes	Some people who use water containing chlorine well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chlorine well in excess of the MRDL could experience stomach discomfort.
Chlorite (ppm)	1	No conversion necessary	1	0.8	By-product of drinking water disinfection	Some infants and young children who drink water containing chlorite in excess of the MCL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorite in excess of the MCL. Some people may experience anemia.
Chlorine dioxide (ppb)	MRDL = 0.8	1000	MRDL = 800	MRDLG = 800	Water additive used to control microbes	Some infants and young children who drink water containing chlorine dioxide in excess of the MRDL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorine dioxide in excess of the MRDL. Some people may experience anemia.
	Add the following only to public notification where any 2 consecutive daily samples taken at the entrance to the distribution system are above the MRDL: "The chlorine dioxide violations reported today are the result of exceedances at the treatment facility only, not within the distribution system which delivers water to consumers. Continued compliance with chlorine dioxide levels within the distribution system minimizes the potential risk of these violations to consumers." Add the following only to public notification where 1 or more distribution system samples are above the MRDL: "The chlorine dioxide violations reported today include exceedances of the drinking water standard within the distribution system which delivers water to consumers. Violations of the chlorine dioxide standard within the distribution system may harm human health based on short-term exposures. Certain groups, including fetuses, infants, and young children, may be especially susceptible to nervous system effects from excessive chlorine dioxide exposure."					

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Total organic carbon [TOC - control of DBP precursors] (ppm)	TT	No conversion necessary	TT	None	Naturally present in the environment	Total organic carbon (TOC) has no health effects. However, total organic carbon provides a medium for the formation of disinfection byproducts. These byproducts include trihalomethanes (THM) and haloacetic acids (HAA). Drinking water containing these byproducts in excess of the MCL may lead to adverse health effects, liver or kidney problems, or nervous system effects, and may lead to an increased risk of getting cancer.
Other treatment techniques						
Acrylamide	TT	No conversion necessary	TT	zero	Added to water during sewage/ wastewater treatment	Some people who drink water containing high levels of acrylamide over a long period of time could have problems with their nervous system or blood, and may have an increased risk of getting cancer.
Epichlorohydrin	TT	No conversion necessary	TT	zero	Discharge from industrial chemical factories; an impurity of some water treatment chemicals	Some people who drink water containing high levels of epichlorohydrin over a long period of time could experience stomach problems, and may have an increased risk of getting cancer.

PART 6. STATE DRINKING WATER STANDARDS AND ANALYTICAL METHODS

R 325.10604g MCLs for per- and polyfluoroalkyl substances.

Rule 604g. (1) The maximum contaminant levels and effective dates for per- and polyfluoroalkyl substances in table 1 of this rule apply to community and nontransient noncommunity water supplies.

Table 1 MCLs for per and polyfluoroalkyl substances

Contaminant	Maximum Contaminant Level in ng/l	Effective Date
Hexafluoropropylene oxide dimer acid (HFPO-DA)	370	[effective date of this rule]
Perfluorobutane sulfonic acid (PFBS)	420	[effective date of this rule]
Perfluorohexane sulfonic acid (PFHxS)	51	[effective date of this rule]
Perfluorohexanoic acid (PFHxA)	400,000	[effective date of this rule]
Perfluorononanoic acid (PFNA)	6	[effective date of this rule]
Perfluorooctane sulfonic acid (PFOS)	16	[effective date of this rule]
Perfluorooctanoic acid (PFOA)	8	[effective date of this rule]

(2) Compliance with the MCLs in table 1 of this rule must be determined based on the analytical results obtained at each sampling point. If 1 sampling point is in violation of an MCL, then the supply is in violation of the MCL. All of the following provisions apply:

(a) For supplies monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point.

(b) Supplies monitoring annually whose sample result exceeds an MCL in table 1 of this rule shall begin quarterly sampling. Compliance with the MCL must be based on the running annual average. For the purpose of calculating the running annual average, the initial exceedance must be the result for the first quarter. If the department requires a confirmation sample under R 325.10717d(12), then the average of the initial exceedance and the confirmation sample must be the result for the first quarter, unless the department determines a sample should be excluded per R 325.10717d(12). The supply shall not be in violation of the MCL until it has completed 1 year of quarterly sampling.

(c) If any sample result causes the running annual average to exceed the MCL at any sampling point, then the supply is out of compliance with the MCL immediately.

(d) If a supply fails to collect the required number of samples, then compliance must be based on the total number of samples collected.

(e) If a sample result is less than the reporting limit, then zero must be used to calculate the annual average.

PART 7. SURVEILLANCE, INSPECTION, AND MONITORING

R 325.10717d Collection and analysis of samples for per- and polyfluoroalkyl substances.

Rule 717d. (1) Suppliers of community and nontransient noncommunity water supplies shall collect samples and cause analyses to be made under this rule for per- and polyfluoroalkyl substances to determine compliance with the state drinking water standards in R 325.10604g. Each supplier shall monitor at the time designated by the department.

(2) For transient noncommunity and type III public water supplies, the department may require samples to be collected and analyzed at prescribed frequencies for per- and polyfluoroalkyl substances.

(3) A groundwater supplier shall take at least 1 sample at every entry point to the distribution system that is representative of each well after treatment, also known as sampling point. Each sample must be taken at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

(4) A surface water supplier, or combined surface water and ground water, shall take at least 1 sample at points in the distribution system that are representative of each source or at each entry point to the distribution system after treatment, also known as sampling point. Each sample must be taken at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

(5) If a system draws water from more than 1 source and the sources are combined before distribution, then the supplier shall sample at an entry point to the distribution system during periods of normal operating conditions when water that is representative of all sources is being used.

(6) An existing supplier with one or more samples taken at each sampling point described in subrules (3), (4), or (5) of this rule as part of the State of Michigan's 2018/2019 Statewide PFAS Survey shall conduct initial sampling as follows:

(a) A supplier with one or more sample results greater than 50% of the MCL for a contaminant listed in rule 10604g shall collect samples from each sampling point beginning the first full quarter following the effective date of this rule.

(b) A supplier with no detection or a detection less than or equal to 50% of the MCL for a contaminant listed in rule 10604g shall collect at least 1 sample from each sampling point within 6 months of the effective date of this rule.

(7) An existing supplier without sampling conducted under subrule (6) of this rule, shall collect samples beginning the first full quarter following the effective date of this rule.

(8) A new community or nontransient noncommunity water supply shall collect samples beginning the first full quarter following the initiation of operations.

(9) If the results of samples collected under subrules (6), (7), or (8) of this rule are below the reporting limits specified in R 325.12708, the department may allow the water supply to monitor annually.

(10) If a contaminant in R 325.10604g is detected above the reporting limit in any sample, then all of the following provisions apply:

(a) Each supply shall monitor quarterly at each sampling point that resulted in a detection. The department may decrease the quarterly monitoring requirement specified in this subrule if it has determined that the supply is reliably and consistently below the MCL. A groundwater supplier shall take not fewer than 2 quarterly samples and a surface water supplier shall take not fewer than 4 quarterly samples before this determination.

(b) After the department determines that the supply is reliably and consistently below the MCL, the department may allow the supply to monitor annually.

(11) A supplier that violates R 325.10604g shall monitor quarterly. If not fewer than 4 quarterly samples show that the supply is in compliance and the department determines the supply is reliably and consistently below the MCL, then the department may allow the supply to monitor annually.

(12) The department may require confirmation sampling for positive or negative results. If confirmation sampling is required, then the results must be averaged with the first sampling result and the average must be used for the compliance determination. The department may exclude results of obvious sampling errors from this calculation.

(13) The department may increase the required monitoring to detect variations within the system.

(14) All new supplies or supplies that use a new source of water shall demonstrate compliance with the MCLs before serving water to the public. The supply shall also comply with the initial sampling frequencies specified by the department.

PART 27. LABORATORY CERTIFICATION

R 325.12701 Purpose.

Rule 2701. An analytical result that is used to determine compliance with a state drinking water standard established in part 6 **must** ~~shall~~ be the result of an analysis performed by a department or EPA certified laboratory, except that measurements for alkalinity, bromide, calcium, daily chlorite samples at the entrance to the distribution system, conductivity, magnesium, orthophosphate, pH, residual disinfectant concentration, silica, specific ultraviolet absorbance, temperature, **chloride, sulfate,** and turbidity may be performed by personnel acceptable to the department. This part sets forth requirements established by the federal act for laboratory certification.

R 325.12708 Certification for PFAS analyses.

Rule 2708. To qualify for certification to conduct analyses for the PFASs in table 1 of R 325.10604g, a laboratory must be in compliance with the following provisions:

(a) Samples must be collected and analyzed in accordance with EPA method 537.1 or other methods as approved by the department.

(b) The minimum reporting limit must be 2 ng/l.

(c) Analytical results must be reported to the nearest ng/l.

(d) The laboratory must analyze performance evaluation samples that include the PFASs in table 1 of this rule and are acquired from a third party proficiency test provider approved by the department at least once per year.

(e) For each regulated PFAS contaminant included in the performance evaluation sample, the laboratory must achieve quantitative results on the analyses that are within the acceptance limits listed in table 1 of this rule.

Table 1 Acceptance limits

Contaminant	Chemical Abstract Services Registry Number	Acceptance Limits (percent)
Hexafluoropropylene oxide dimer acid (HFPO-DA)	13252-13-6	± 30% (GV) [1]
Perfluorobutane sulfonic acid (PFBS)	373-73-5	± 30% (GV) [1]
Perfluorohexane sulfonic acid (PFHxS)	335-46-4	± 30% (GV) [1]
Perfluorohexanoic acid (PFHxA)	307-24-4	± 30% (GV) [1]
Perfluorononanoic acid (PFNA)	375-95-1	± 30% (GV)[1]
Perfluorooctane sulfonic acid (PFOS)	1763-23-1	± 30% (GV) [1]
Perfluorooctanoic acid (PFOA)	335-67-1	± 30% (GV) [1]

[1]Gravimetric value

R 325.12710 Suspension or revocation of certification.

Rule 2710. (1) If the department determines that a laboratory certified under the act and these rules is not operating in an approved manner, is reporting results that do not meet state laboratory certification requirements, or is operating in a manner that may cause a hazard to the public health, the department may move to suspend or revoke the certification of the laboratory pursuant to the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

(2) Reasons for suspension of a laboratory's certification, in part or whole, or the denial of an initial certification request include, but are not limited to the following:

(a) Failure to pay certification fees.

(b) Failure to pass a laboratory inspection.

(c) Failure to meet proficiency test requirements.

(d) Failure to respond to a laboratory inspection report within the allotted timeframe.

(e) Persistent failure to report compliance data to the public water system or the state drinking water program in a timely manner, thereby preventing timely compliance determination with federal or state regulations and endangering public health.

(f) Failure to correct deficiencies noted in an on-site inspection report.

(g) Refusal to participate in an on-site inspection conducted by the certifying agency.

(h) Failure to make records pertaining to the analysis of regulated drinking water contaminants available for review or copying by the laboratory certification program.

(3) Suspension of a laboratory's certification remains in effect until the laboratory provides documentation that the reason or reasons for the suspension have been corrected.

(4) Reasons for revocation of a laboratory's certification include but are not limited to:

(a) Falsification of the certification application or certification renewal application.

(b) Fraud or other criminal activity.

(c) Falsification of records or analytical results.

(d) Reporting results not meeting the federal act, the act and administrative rules promulgated thereunder, or method requirements.

(e) Reporting proficiency test data from another laboratory as its own.

(f) Using analytical methodology not listed on the laboratory's certification letter for reporting regulated drinking water contaminants.

(g) A written notification from the laboratory that it is voluntarily relinquishing certification.

Smith, Ian (EGLE)

From: Marjorie Smallfield [redacted]@gmail.com>
Sent: Sunday, January 12, 2020 5:00 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Comment
Attachments: fullsizeoutput_8160.jpeg; fullsizeoutput_8161.jpeg; hw0NlE4JSiO+pAs9oIXpXA.jpg; YgjxWQ6USQWj1hh7rRikKw.jpg

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Red Category

I was able to attend the meeting at the Eberhard Center last week. I was able to hear the presentation but could not stay for comments. Thank you for holding this meeting it was informative.

I believe the time for limits is the sooner the better. I think the numbers have been reduced a lot in your proposals BUT, the real question is would you like to drink a little poison or a lot of poison. I think **no poison** is the only way to go. The companies that created these chemicals need to contribute enough money to invent a filter **to take all of their poisons** out of the public waters. I also think these companies need to pay for people who have wells to have their well water tested at least once a year and create filters to clean up the well water too. We are all victims of their corporate greed and the irresponsible creation of these poisons.

At this time I have witnessed a builder and apparently realtors ignoring the danger of building homes on the Boulder Creek toxic landfill. They are continuing to endanger the future or present home owners as they continue building homes on the shores of the contaminated ponds. One home is about 15 ft. from the shore and the builder put sand in as if it is a beach. Anyone swimming in this filth will be exposed to high concentrations of PFAS. And yet the building continues. The development called The Preserve is also now building homes right near the pond that is used for irrigation that was tested and has very high PFAS levels. Irrigation also means the sprinklers shoot contaminated water onto the golf course regularly. I am sure your agency knows all about this stuff, you also probably know much more that I know. I am attaching photos of the homes I am describing. I have emailed with Karen Vorce, and even met with her and other staff personnel. And yet the building continues?????

If your agency is so powerless to protect the community perhaps you need to hire some lawyers to sue the state. It is like the emperor's new clothes. We all see it but no one can change anything. People have died from this poison and will continue to die.

I have no personal connection to Boulder Creek. I drive by this development almost every day and each house they build makes me very afraid for the people living there. Human nature tends to try and avoid bad thoughts and there is a sense all is good now with Plainfield water. I don't entirely believe it is fixed. If I lived in that township I would be asking for water test results weekly. Please help the people you can right now, and let's get that poison out of our waters.

Thank you,
Margie Smallfield


CATCH &
EAT FISH

Smith, Ian (EGLE)

From: Herasanna Richards <[redacted]@mml.org>
Sent: Thursday, January 16, 2020 2:33 PM
To: EGLE-PFAS-RuleMaking
Subject: MML Public Comment on proposed rule set 2019 – 35 EG
Attachments: 20MML_PublicHearing1.15.pdf

Categories: Blue Category

Good Afternoon,

Please see the attached letter and below text from the Michigan Municipal League on the PFAS draft rules for providing drinking water to the public.

Thank you,
Herasanna Richards

To the Department of Energy, Great Lakes and Environment:

Thank you for the opportunity to provide comment on proposed rule set (2019 – 35 EG). Over the past 10 months, in coordination with EGLE, MPART, the Science Advisory Workgroup, and participating stakeholders, the Michigan Municipal League has worked to better understand and address PFAS contamination in Michigan. Delivering affordable, clean, quality drinking water to our residents is of utmost importance to Michigan's communities. It is a charge and responsibility that we take with tremendous care, and we are immensely proud of the many communities throughout Michigan that have already taken independent steps to mitigate existing PFAS contamination within their respective water supplies.

As we continue to discuss the adoption and implementation of these rules, we hope you recognize our communities are still learning how to address the financial costs of contamination and cleanup. Many communities, especially Michigan's smaller cities and villages, will require substantial new investment in new treatment technologies, sampling, staffing and more – many of which that can be estimated, and others that are unknown.

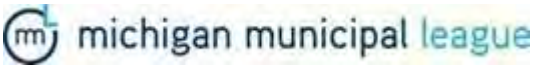
While it is helpful the state has provided cost estimates for implementation and utilization of effective treatment techniques, there are still many other costs and steps needed down the road that are not that are not entirely covered in Regulatory Impact Statement. We believe that an in depth conversation to address and understand the costs to communities and their ratepayers is still necessary. PFAS is still an emerging contaminate, and as our knowledge develops, we must remain aware that flexibility will be required to make this an achievable expectation for our local water suppliers.

The League looks forward to continuing our work as a cooperative partner in this process. We appreciate the opportunity to work in partnership to provide quality, accessible drinking water, balanced with effective asset management for the residents of Michigan.

Respectfully,

The Michigan Municipal League

Herasanna Richards
Legislative Associate, State & Federal Affairs
Ph: [redacted] I Cell: [redacted]
208 N. Capitol Ave., 1st Floor, Lansing MI 48933
www.mml.org



michigan municipal league

208 N Capitol Avenue, First Floor
Lansing, MI 48933-1354

T [redacted]
F
mml.org

To the Department of Energy, Great Lakes and Environment:

Thank you for the opportunity to provide comment on proposed rule set (2019 – 35 EG). Over the past 10 months, in coordination with EGLE, MPART, the Science Advisory Workgroup, and participating stakeholders, the Michigan Municipal League has worked to better understand and address PFAS contamination in Michigan. Delivering affordable, clean, quality drinking water to our residents is of utmost importance to Michigan's communities. It is a charge and responsibility that we take with tremendous care, and we are immensely proud of the many communities throughout Michigan that have already taken independent steps to mitigate existing PFAS contamination within their respective water supplies.

As we continue to discuss the adoption and implementation of these rules, we hope you recognize our communities are still learning how to address the financial costs of contamination and cleanup. Many communities, especially Michigan's smaller cities and villages, will require substantial new investment in new treatment technologies, sampling, staffing and more – many of which that can be estimated, and others that are unknown.

While it is helpful the state has provided cost estimates for implementation and utilization of effective treatment techniques, there are still many other costs and steps needed down the road that are not that are not entirely covered in Regulatory Impact Statement. We believe that an in depth conversation to address and understand the costs to communities and their ratepayers is still necessary. PFAS is still an emerging contaminate, and as our knowledge develops, we must remain aware that flexibility will be required to make this an achievable expectation for our local water suppliers.

The League looks forward to continuing our work as a cooperative partner in this process. We appreciate the opportunity to work in partnership to provide quality, accessible drinking water, balanced with effective asset management for the residents of Michigan.

Respectfully,

The Michigan Municipal League

Smith, Ian (EGLE)

From: John Dulmes [redacted]@michiganchemistry.com>
Sent: Friday, January 31, 2020 3:58 PM
To: EGLE-PFAS-RuleMaking
Subject: Michigan Chemistry Council comments on proposed PFAS drinking water rule
Attachments: Michigan Chemistry Council PFAS MCL comments - 1.31.20.pdf

--
John Dulmes
Executive Director
Michigan Chemistry Council
[redacted]@michiganchemistry.com

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy

RE: 2019-35 EG –Supplying Water to the Public Rule, Promulgated Pursuant to the Michigan Safe Drinking Water Act, 1976 PA 399

The Michigan Chemistry Council (MCC) appreciate the opportunity to provide public comments in response to the proposed maximum contaminant levels (MCLs) for seven per- and poly-fluoroalkyl substances (PFAS). The MCC represents numerous chemistry companies that manufacture or do business in Michigan, employing tens of thousands of Michigan residents and contributing to countless areas of our economy. The MCC is proud to be a constructive partner with EGLE, state legislators, and other stakeholders in stewardship of Michigan's natural resources and environment.

As a fundamental principle, the MCC supports the use of sound science when developing regulatory policy. Science-driven policymaking ensures protection of human health and the environment while also appropriately considering risks. PFAS is a challenging issue given many remaining information gaps, and so the MCC encourages the state to continue to be transparent and deliberative in its decision-making processes.

When assessing this new drinking water rule, it should be noted that Michigan's first-in-the-nation study of all public water systems revealed no widespread, elevated contamination across the state.[1] MPART's Phase 1 study of more than 1,500 supplies showed that ninety percent were non-detect for any PFAS, even given minute detection levels. Another seven percent of systems tested for less than 10 parts per trillion (ppt) of total PFAS. Just three percent of systems were in a "middle range" of more than 10ppt but below the EPA's Lifetime Health Advisory (LHA) of 70 ppt for PFOA and PFOS. Finally, just two systems exceeded the EPA's LHA, with both systems being swiftly remedied through both emergency and long-term water supply solutions.

Given this context, the MCC continues to urge the development of uniform federal standards. In general, federal rules avoid conflicts of regulatory standards across various states, and mitigate risk communication challenges resulting from such conflicts. Further, the U.S. EPA is much better-positioned to establish drinking water standards, with greater resources to conduct the requisite risk assessments, technology reviews, cost-benefit analyses, and more. While allowing that the federal process is not as expeditious, it should be noted that the U.S. EPA continues to move forward with a drinking water MCL determination as part of its PFAS Action Plan[2]. In contrast, Michigan has never before established its own MCL, a fact that has led to lingering confusion about this process. Because Michigan's public water utilities are only at the beginning stages of responding to PFAS, there will also be many data gathered and lessons learned that may not be able to be reflected in this hastened rule.

[1] "2018 PFAS Sampling of Drinking Water Supplies in Michigan" – July 26, 2019
[2] "EPA Moves Forward on Key Drinking Water Priority Under PFAS Action Plan" – December 4, 2019

In general, the Department should be commended for following a constructive process, including the convening of an independent science advisory panel, the development of a full report with science-based justifications for public review, and a subsequent stakeholder review to provide input and comment on the proposed rules.

Still, the MCC continues to have concerns about the Department's accelerated timeline and the potential for unforeseen and unintended consequences. This rulemaking did not fully follow the robust process of the federal Safe Drinking Water Act and falls short in several areas:

- First, the Science Advisory Workgroup (SAWG) process was completed in less than three months, and was limited to an evaluation of proposed drinking water standards or screening levels from other bodies[3]. A number of these standards remained – at that time or at present - in draft form, and it is understood that Michigan's workgroup did not fully review comments provided by third parties on these other standards[4]. The use of unpublished studies and draft reports is – in general – an MCC concern with these proposed standards.
- Additionally, there was no dedicated peer review or formal public comment process on the SAWG's proposed standards. MPART subsequently voted to "accept" the SAWG's recommendations as initially proposed, but in so doing merely acknowledged the interim "input" received without providing any formal responses.[5]
  Accordingly, this has left unaddressed a number of inconsistent or questionable scientific decisions reflected in the proposed standards. It is imperative that our state's rules be grounded in sound science informed by robust review. The MCC looks forward to reviewing the Department's response to public comments on the proposed standards.
- In several other aspects, the Department's regulatory review falls likewise short of the EPA's process and criteria for making a regulatory determination[6].
  - In its regulatory impact statement, the Department continues to underestimate the costs to smaller water systems and the impact on local ratepayers, including residents and businesses.[7] These smaller systems will bear a disproportionately greater burden for installing and maintaining expensive treatment systems whose costs cannot be as easily shared by a larger customer base.
    While the Department makes only a passing attempt at a quantitative cost-benefit analysis, it does not evaluate any other regulatory alternatives that may be equally protective but more cost-effective.[8]
  - The Department also does not valuate whether the proposed contaminants are "known to occur or there is a substantial likelihood that the contaminant will occur in public health systems with a frequency and at levels of public health concern," as is required by the federal SDWA. This is especially true of the proposed standards for three short-chain PFAS compounds: PFHxA, PFBS, and HFPO-DA.
    Michigan's standards for these three compounds would the first of their kind, despite the fact that the statewide sampling revealed scattered levels only at extremely low proportions to the proposed standards (in the case of PFHxA and PFBS), or no measured levels (HFPO-DA).[9]

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[3] "Health-Based Drinking Water Value Recommendations For PFAS In Michigan" – June 27, 2019
[4] Including, but not limited to: ATSDR Draft Toxicological Profile for Perfluoroalkyls, New Jersey Drinking Water Quality Institute (DWQI) proposed MCLs, and EPA Draft Toxicity Assessments for GenX Chemicals and PFBS
[5] Michigan PFAS Action Response Team agenda - September 27, 2019
[6] Federal Safe Drinking Water Act (SDWA), Section 1412
[7] Regulatory Impact Statement, #13, #14 and #16
[8] Regulatory Impact Statement, #35
[9] "2018 PFAS Sampling of Drinking Water Supplies in Michigan" – July 26, 2019

Instead of regulating a multitude of compounds for appearances' sake, the MCC believes that the Department should prioritize the development and enforcement of those standards that bear an actual relation to our known PFAS levels in the state, and that are backed by appropriate science.

- Further, the Department readily acknowledges its inability to quantify the benefits of the proposed rule[10], and arguably does not demonstrate that "regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems." This is particularly true of the short-chain compounds that do not currently present concerns at known levels in Michigan water supplies, as previously noted, and have even less scientific underpinning for regulation.

One notable recommendation from the SAWG reflected in the proposed rules is that the compounds be regulated individually, rather than grouped into one drinking water value. The MCC firmly supports this recommendation, as explained by the SAWG that "there is no consensus from the scientific community on which PFAS should be grouped or the basis of that grouping."[11] There are important differences between different PFAS compounds, and the current scientific understanding of the critical toxicological endpoints and toxicokinetics of various PFAS do not support a class-based approach.

Finally, it should be recognized that these proposed standards are already extremely conservative, in part driven by risk assessment methodologies that utilize the most protective endpoints and multiple uncertainty factors. In particular, most of the proposed standards were based on a transgenerational toxicokinetic model that considers already full life stage exposure, including placental transfer, infant exposure through 12 months of exclusive breastfeeding, and into adulthood[12]. This reflects extremely conservative assumptions to be protective of the most vulnerable populations, but results in some of the nation's strictest standards.

For the sake of comparison, the lowest proposed standard (6ppt for PFNA, also recommended as a default screening level for other long-chain PFAS) equates to about 1 drop of water in seven Olympic-size swimming pools, or one second every five thousand years. Indeed, the rule would establish certain regulatory triggers at levels barely above the minimum reporting levels for most laboratories. As such, the MCC encourages the Department to carefully account for the rule's entire costs, and continue to work with local water systems to ensure sensible implementation of these standards.

The MCC looks forward to continuing to work with the Department to ensure that the rule is well-grounded and is ultimately part of the state's successful response to this complex issue.

Respectfully submitted,

John Dulmes

John Dulmes
Executive Director

[10] Regulatory Impact Statement, #31
[11] "Health-Based Drinking Water Value Recommendations For PFAS In Michigan" – June 27, 2019
[12] "Health-Based Drinking Water Value Recommendations For PFAS In Michigan" – June 27, 2019

Smith, Ian (EGLE)

From: Kindra Weid <[redacted]@miairmihealth.org>
Sent: Friday, January 31, 2020 4:09 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS MCL Standards Comments - 2019-35 EG
Attachments: PFAS MCL Comments - Health and Lactation Advocates.pdf

ATTN: Suzann Ruch

Dear Ms. Ruch,

Please find attached the following comments from health professionals on the proposed MCL standards for PFAS in Michigan's drinking water.

As nurses, lactation consultants, obstetricians and midwives, we all appreciate this opportunity to provide feedback on these proposed rules and are grateful that EGLE is working to improve water quality in our state.

Thank you for your time,
Kindra Weid

--
Kindra Weid, RN, BSN, MPH
MI Air MI Health, Coalition Coordinator
miairmihealth.org
Cell: [redacted]
Email: [redacted]@miairmihealth.org

January 31, 2019

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311

Comment to: State of Michigan's Department of Environment Great Lakes and Energy regarding proposed PFAS MCL standards

Dear Ms Ruch,

The undersigned breastfeeding advocates, nurse-midwifes, nurses, obstetricians, and lactation consultants urge the State of Michigan's Department of Environment Great Lakes and Energy to reevaluate the recommended health-based values for the maximum contaminant levels (MCLs) of PFAS chemicals permitted under Michigan's regulatory drinking water standards and take into account the potential impacts of PFAS chemicals, particularly PFOA, on mammary gland development. The current recommendations are too high and will not adequately protect the women and children of Michigan. Emerging science warns of the negative impacts PFAS chemicals may have on mammary gland development and the significant health risks they pose for both mothers and children. In lab tests, scientists have found that mammary glands have a low-dose sensitivity to PFOA, which was not previously considered in the development of the current MCL recommendations. These recommendations should be revised, and ultimately lowered, given the critical nature of mammary gland development as it relates to breastfeeding ability, children's health and development, and new mothers' health.

Studies have exemplified the linkages between exposure to PFOA and changes in mammary gland development which alters the morphological and functional development of mammary glands.[1] In lab tests, chronic exposure to environmentally relevant levels of PFOA, comparable to those experienced by humans, has resulted in morphologically abnormal lactation glands.[2] This abnormal development of mammary glands may reduce the number and density of alveoli that produce milk, increasing the latency period to peak milk output.[1] This functional defect

[1] https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.1002741?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed
[2] https://www.nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf

delays substantial milk output, resulting in cessation of breastfeeding before the recommended time frame and ultimately delays the nursing child's maturation.[2] The cessation of breastfeeding before the recommended time frame (exclusively breastfeeding for the first six months of life, followed by breastfeeding supplemented by complementary foods until the child's first birthday) can negatively affect the child's fundamental development and overall health.[3]

According to the Michigan Breastfeeding Network, breastfeeding children reduces the risk of SIDS and necrotizing enterocolitis - the two leading causes of infant death in the country. In addition, consuming breast milk that is rich in nutrients and antibodies enhances children's brain development, reduces healthcare costs, improves academic productivity, and provides a free, naturally renewable source of complete nutrition for the first six months of life.[3] Along with these benefits for the nursing child, breastfeeding also provides benefits to mothers. Mothers who breastfeed their children are less likely to develop breast cancer later in life.[2] Exposure to PFAS may reduce a mother's ability to properly breastfeed her young child, preventing both of them from experiencing the benefits of breastfeeding.

In addition to the negative effects PFAS exposure has on the ability to adequately breastfeed, it can also put the mother at further risk for health problems. Delays in mammary gland development could result in a prolonged window of increased vulnerability to carcinogens.[2] This increased exposure heightens the mother's chances of being diagnosed with breast cancer throughout her life.

Finally, studies have demonstrated links between prenatal and/or gestational exposure to PFOA and various negative impacts on offspring health and development. Research that exposed rodents to environmentally relevant concentrations of PFOA, comparable to those experienced by humans, resulted in delayed mammary gland development, delayed epithelial cell differentiation, and alteration of functional mammary gland cell differentiation in offspring.[4] This means a mother's exposure to PFOA could potentially pass along negative health effects to her children, resulting in delayed mammary gland development and, ultimately, an increased risk of breast cancer and difficulty breastfeeding. One study even found gestational exposure to induce delays in mammary gland development across three generations.[1] These lasting impacts on

[3] https://www.mibreastfeeding.org/wp-content/uploads/2019/06/MIBFN-2019-Advocacy-Overview.pdf
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6173485/

mother, child, and future generations of offspring are cause for concern when determining the acceptable amount of exposure to PFAS chemicals.

We are advocating on behalf of mothers and children across Michigan by urging EGLE to reassess the recommended health-based MCL values, this time considering the evidence of the impacts PFAS has on mammary gland development. Studies have indicated the numerous adverse health effects that exposure to these chemicals can have on mothers and children for years into the future. We ask that the proposed health-based values be reevaluated with the careful consideration for Michigan mothers and children. The low-dose sensitivity of mammary glands to PFAS should warrant lower MCLs that adequately protect all Michiganders, especially the most vulnerable, including women and children.

Sincerely,

Brittney Batalucco, RN, BSN
Nurse
[redacted]
Taylor, MI 48180

Jezreel Vedua-Cardenas, RD, CLS
Certified Lactation Consultant
[redacted]
Kalamazoo, MI 49008

Melissa X. Garcia, MPH, CLS
Certified Latation Consultant
[redacted]
Woodhaven, MI 48183

Fatima Jibrel, MD
Obstetrician
[redacted]
Ann Arbor, MI 48104

Kathleen A. Moriarty, Ph.D., CNM, CAFCI, FACNM
Certified Nurse Midwife
[redacted]
Novi, MI 48375

Kindra Weid, RN, BSN, MPH
Nurse
[redacted]
Manchester, MI 48158

Smith, Ian (EGLE)

From: Mary Beth Whitton <[redacted]@gmail.com>
Sent: Thursday, January 30, 2020 5:15 PM
To: EGLE-PFAS-RuleMaking
Subject: Input on PFAS in Mi.'s drinking water

I welcome the opportunity to share my concerns on the dire state of these cancer causing chemicals in our water in Michigan.
I recently read a news report that states as the army and our state agencies argue over who is responsible for the clean up of a close base in Eastern mid Mi as the fire fighting chemical leach into a nearby river AND into Lake Huron.
I hope your new proposed rules can address clean up at this sight immediately
Sincerely
Mary Beth Whitton

Smith, Ian (EGLE)

From: Samantha Nellis <[redacted]@huronpines.org>
Sent: Friday, January 31, 2020 1:17 PM
To: EGLE-PFAS-RuleMaking
Cc: Gary Vetter; Duane Brooks; David Smith; Christine LaFontaine; mikemac2008@yahoo.com; Robert Dixon Grayling Twsp; LMPOA- Harry Wojcik; Carolyn"; Mike Bushre; Marcia Koppa; Thielrouston@gmail.com; cheryl alef
Subject: Proposed PFAS Drinking Water Standards Public Comment
Attachments: RAB_MCL_PublicComment.pdf

Ms. Ruch,

I have attached the public comment from the Camp Grayling JMTC Restoration Advisory Board regarding the proposed PFAS drinking regulations. Please contact me if you have any questions. We appreciate you taking our comments into consideration.

Sincerely,
Samantha Nellis

--
Samantha Nellis
Watershed Project Manager

Huron Pines
4241 Old US 27 South, Suite 2
Gaylord, MI 49735
[redacted]@huronpines.org
www.huronpines.org

Samantha Nellis
Camp Grayling JMTC Restoration Advisory Board
[redacted]@huronpines.org

January 31, 2020

Suzann Ruch
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
PO Box 30817
Lansing, Michigan 48909-8311

Re: Proposed Drinking Water Standards for PFAS in Michigan

Dear Ms. Ruch,
I am writing on behalf of the Camp Grayling Joint Maneuver Training Center Restoration Advisory Board (RAB) Community Representatives. The RAB was formed to give the Grayling community the opportunity to provide input and discuss the cleanup at Camp Grayling. The primary goals of the RAB members are to serve as community liaisons, provide solution-focused input to regulators and to review and comment on technical documents. Many members of the RAB have been directly affected by PFAS contamination in their homes or businesses and we are all motivated to work toward improving communications with communities and finding solutions for the health of Michigan's residents and natural resources.

The Community Representatives on the RAB would like to express support of the proposed drinking water standards for PFAS. We feel that establishing enforceable limits for Michigan's public water supplies is an important step in protecting the health of citizens. However, as the science and technology evolves and as we gain a more accurate and wider understanding of PFAS and its effects on humans, we need to have the flexibility to change this standard. We suggest a minimum of a two-year review be built into this proposed regulation. People continue to be exposed to these chemicals, including those most vulnerable to these toxins, and we feel that swift action will be needed in in response to new developments.

We hope that these proposed levels and any future standards are developed with those that are most vulnerable in mind- pregnant and nursing mothers, fetuses and developing children. Studies are showing that exposure at this time in a person's life can have the greatest impact that can result in lifelong health issues.

Thank you for taking our comments into consideration.
Sincerely,

Samantha Nellis
Community Co-chair
Camp Grayling JMTC Restoration Advisory Board

Smith, Ian (EGLE)

From: Joshua Lunger [redacted]@grandrapids.org>
Sent: Friday, January 31, 2020 3:48 PM
To: EGLE-PFAS-RuleMaking
Subject: 2019-35 EG Comments
Attachments: GRC Comments 2019-35 EG.pdf

Please see the attached comments from the Grand Rapids Area Chamber of Commerce.

Thank you,

Joshua Lunger
Senior Director of Government Affairs

P |[redacted]
A |250 Monroe Ave. NW, Suite 150, Grand Rapids, MI 49503

Not yet a Chamber Member? Read about our membership offerings: https://bit.ly/2T5nF6K

Click here for conference room reservations!

GRAND RAPIDS CHAMBER

GRAND
RAPIDS
CHAMBER

January 31, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311

RE: Comments to Rule Set 2019-35 EG

Dear Ms. Ruch:

On behalf of the Grand Rapids Area Chamber of Commerce, I would like to submit the following comments on Rule Set 2019-35 EG to set the maximum contaminant levels for certain per- and polyfluoroalkyl substances.

We support the Department's focus on public health and safety. The largest questions we ask you to consider are the impacts this rule will have on the determination and cleanup of contaminated sites in Michigan, the long-term effects on public water systems and their ratepayers, and the certainty of the science and proper regulatory approach for emerging contaminants.

Michigan is a state built on a legacy of industry and manufacturing and West Michigan has benefitted greatly from the reinvestment and cleanup of contaminated and blighted sites. Much of this work is difficult, costly and can take a significant amount of time to return sites to clean, active use. The proposed rule further injects uncertainty into how it will impact cleanup criteria and Part 201. It is not clear how the inconsistency between this rule and Part 201 will impact closed sites or those undergoing remediation, and how many new sites will be "created" due to the rule change.

The Department should examine and deliberate on the unintended consequences of the proposed rule. The Department is setting standards for emerging chemicals at a time when the science remains uncertain. In these instances, a better regulatory method would be to create flexibility in how to achieve compliance or explore incremental approaches rather than creating an extremely stringent number that will be difficult for communities to meet across the state.

We appreciate the Department's work to protect Michigan's citizens and communities. We urge you to consider and seek to resolve the uncertainty and potential unintended consequences caused by this rule.

Sincerely,

Joshua Lunger

Joshua Lunger
Senior Director of Government Affairs

250 MONROE AVE. NW SUITE 150
GRAND RAPIDS, MI 49503

WWW.GRANDRAPIDS.ORG

Smith, Ian (EGLE)

From: guven witteveen [redacted]@hotmail.com>
Sent: Saturday, December 14, 2019 8:05 AM
To: PFAS MCL Comments
Subject: Michigan needs the strongest possible MCL for PFAS

Dear PFAS MCL Comments,

Dear Representative Hood,

Thanks for representing us in the Northeast of Grand Rapids. You are already engaged in PFAS matters, but urged by my friends at cleanwateraction.org I am adding my name to express support for Michigan to set a good example for other states to follow in its MCL (containment levels) in the several flavors of PFAS hazardous wastes in our soil and water.
- G P Witteveen, Grand Rapids

Sincerely,
guven witteveen
[redacted]
grand rapids, MI 49505

Smith, Ian (EGLE)

From: Petka, Keith [redacted]@chemours.com>
Sent: Friday, January 31, 2020 12:43 PM
To: EGLE-PFAS-RuleMaking
Cc: Ei, Tom
Subject: The Chemours Company Comments on Draft PFAS Drinking Water Rulemaking (2019-35 EG)
Attachments: The Chemours Company comments to Michigan EGLE on PFAS DW DraftRule- January 31 2020.pdf

Please see the attached comments and thank you for your consideration of this information.

Keith Petka
Regulatory Advocacy Leader – North America | Fluoroproducts
+1 [redacted] o
+1 [redacted] m
The Chemours Company
1007 Market Street—626-3
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[redacted]t
chemours.com

January 31, 2020

Ms. Suzann Ruch
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Submitted via email to EGLE-PFAS-RuleMaking@michigan.gov

Re: Draft PFAS Drinking Water Rulemaking (2019-35 EG)

Dear Ms. Ruch,

The Chemours Company appreciates the opportunity to provide comments on the draft rule to add PFAS-related drinking water standards and related sampling and response requirements to Michigan's Supplying Water to the Public rules. Specifically, Chemours provides the following comments regarding the draft MCL for 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoic acid (HFPO-DA, sometimes referred to as GenX) in Michigan.

Uses of HFPO-DA

In the table on page 31, the "major source" for HFPO-DA in drinking water is listed as "discharge and waste from industrial facilities utilizing the Gen X chemical process". Chemours understands the description "GenX chemical process" to mean the intentional use of HFPO-DA as a polymerization processing aid for fluoropolymers, which is our patented technology. Chemours has no such operations in Michigan, and is unaware of any facility in Michigan that utilizes a "GenX chemical process".

Additional Polymerization Processing Aids

As part of the PFOA Stewardship Program with the U.S. Environmental Protection Agency (EPA), participating companies, including DuPont, Daikin, Asahi Glass (AGC), Arkema, 3M/Dyneon and Solvay Solexis, stopped manufacturing and importing long-chain polymerization processing aids and transitioned to alternative short-chain processing aids.

We would like to make you aware of some these short-chain processing aids registered for use by other commercial manufacturers that are not included in your draft MCL. These include the following:

Substance Name	CAS No.	Publicly Available Reference
Perfluoro[(2-ethyloxy-ethoxy)acetic acid], ammonium salt,	908020-52-0	EFSA, EFSA Panel on food contact materials. Scientific opinion on the safety evaluation of the substance, perfluoro[(2-ethyloxy-ethoxy)acetic acid], ammonium salt, CAS No. 908020-52-0,for use in food contact materials. EFSA J 2011a;9(6):2183. http://dx.doi.org/10.2903/j.efsa.2011.2183
3H-perfluoro-3-[(3-methoxypropoxy)propanoic acid], ammonium salt (aka ADONA)	958445-44-8	Gordon SC. Toxicological evaluation of ammonium4,8-dioxa-3H-perfluorononanoate, a new emulsifier to replace ammonium perfluorooctanoate in fluoropolymer manufacturing. Regul Toxicol Pharmacol

		2011;59(1):64–80. http://dx.doi.org/10.1016/j.yrtph.2010.09.008
Perfluoro acetic acid, α-substituted with the copolymer of perfluoro-1,2-propylene glycol and perfluoro-1,1- ethylene glycol, terminated with chlorohexafluoropropyloxy groups	329238-24-6	EFSA, EFSA Panel on food contact materials. Scientific opinion on the safety evaluation of the substance perfluoro acetic aci... EFSA J 2010;8(2):1519. http://dx.doi.org/10.2903/j.efsa.2010.1519
Difluoro{[2,2,4,5-tetrafluoro-5-(trifluoromethoxy)-1,3-dioxolan-4-yl]oxy}acetic acid	1190931-41-9	Difluoro{[2,2,4,5-tetrafluoro-5-(trifluorometho... - Registration Dossier https://echa.europa.eu/registration-dossier/-/registered-dossier/5331/1

If sampling for short-chain HFPO-DA will be performed in the future, EGLE should include these other short-chain processing aids as well.

Health Effects of HFPO-DA

Regarding the information presented in the table concerning "Health Effects language", we understand it was derived from the "*Health-Based Drinking Water Value Recommendations for PFAS In Michigan*" report issued by the Michigan Science Advisory Workgroup. We further understand the recommended health level used the draft U.S. EPA "*Human Health Toxicity Values for HFPO*". This draft document should not be relied upon in identifying final health effects as it explicitly states in the toxicity assessment:

> This document is a public comment draft for review purposes only. This information is distributed solely for the purpose of public comment. It has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency determination or policy.[1]

If EGLE does decide to move forward with using draft research information from the U.S. EPA, we strongly encourage there be a provision within the MCL that requires any health value to be reviewed and updated automatically upon issuance by EPA of a final value. A similar approach was recently adopted in S.1790, National Defense Authorization Act of 2020 that was passed in December 2019.

Furthermore, from a toxicological standpoint, the key study noted decreased pup weights as a critical effect. The decrease pup weights are likely related to the activation of PPAR alpha in the dams and fetal livers but this mode of action is not relevant to humans. The wording used in the Health Effect Language implies a strong link between the effects noted in rodents and potential effects in humans that is not supported by the available science.

Over a decade of scientific data has been collected regarding the safety profile of HFPO-DA. The data were collected from studies designed to identify potential effects from short-term and long-term exposures, including studies on genetic material, fetal development, reproductive performance and cancer. These studies demonstrated that HFPO-DA as a polymerization processing

[1] U.S. Environmental Protection Agency, *Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037- 80-3) Also Known as "GenX Chemicals"*. https://www.epa.gov/sites/production/files/2018-11/documents/genx_public_comment_draft_toxicity_assessment_nov2018-508.pdf

aid is safe for its intended use and, at the low levels found in the environment, does not pose a risk to human health.

A recent publication by Thompson, et al. considered all the available data as of October 11, 2018 on HFPO-DA and calculated a reference dose for this substance using the same methods as the EPA uses.[2] The results of this work show a probabilistic reference dose of 0.01 mg/kg/day and a corresponding maximum contaminant level goal of 70,000 ppt.

For more information, please see the below peer-reviewed scientific literature:

Caverly Rae JM, Craig L, Slone TW, Frame SR, Buxton LW, Kennedy GL. Evaluation of chronic toxicity and carcinogenicity of ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoate in Sprague-Dawley rats. Toxicol Rep. 2015 Jun 30;2:939-949. doi: 10.1016/j.toxrep.2015.06.001. eCollection 2015. PubMed PMID: 28962433; PubMed Central PMCID: PMC5598527.

Gannon SA, Fasano WJ, Mawn MP, Nabb DL, Buck RC, Buxton LW, Jepson GW, Frame SR. Absorption, distribution, metabolism, excretion, and kinetics of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid ammonium salt following a single dose in rat, mouse, and cynomolgus monkey. Toxicology. 2016 Jan 18;340:1-9. doi: 10.1016/j.tox.2015.12.006. Epub 2015 Dec 29. PubMed PMID: 26743852.

Hoke RA, Ferrell BD, Sloman TL, Buck RC, Buxton LW. Aquatic hazard, bioaccumulation and screening risk assessment for ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoate. Chemosphere. 2016 Apr;149:336-42. doi: 10.1016/j.chemosphere.2016.01.009. Epub 2016 Feb 11. PubMed PMID: 26874062.

Thompson CM, Fitch SE, Ring C, Rish W, Cullen JM, Haws LC. Development of an oral reference dose for the perfluorinated compound GenX. J Appl Toxicol. 2019 Sep;39(9):1267-1282. doi: 10.1002/jat.3812. Epub 2019 Jun 18. PubMed PMID: 31215065.

* * * *

Thank you for your consideration of this information.

Sincerely,

Keith Petka

Regulatory Advocacy Leader – North America | Fluoroproducts

[2] Thompson CM, Fitch SE, Ring C, Rish W, Cullen JM, Haws LC. Development of an oral reference dose for the perfluorinated compound GenX. J Appl Toxicol. 2019 Sep;39(9):1267-1282. doi: 10.1002/jat.3812. Epub 2019 Jun 18. PubMed PMID: 31215065.

Smith, Ian (EGLE)

From: Dave Greco <[redacted]@mimfg.org>
Sent: Friday, January 31, 2020 4:11 PM
To: EGLE-PFAS-RuleMaking
Subject: Supplying Water to the Public / Proposed Rule Set 2019-35 EG "PFAS"
Attachments: MMA Formal Comments - Supplying Water to the Public Proposed Rule Set 2019-35 EG PFAS.pdf

Ms. Suzann Ruch,

The Michigan Manufacturers Association respectfully submits these comments on proposed rule set 2019-35 EG, otherwise known as "Supplying Water to the Public." We submitted comments with the constructive intent of being part of the solution.

Thank you,

Dave

Dave Greco, III | **Regulatory & Environmental Affairs Director** | **Michigan Manufacturers Association**
620 S. Capitol Ave ● Lansing Michigan ● 48933
Tel: [redacted] | **Cell:** [redacted] | **Fax:** 5[redacted] | **Email:** [redacted]@mimfg.org

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Michigan Manufacturers Association

January 31, 2020

Mr. Eric Oswald
Director, Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
P.O. Box 30817
Lansing, Michigan 48909

RE: Supplying Water to the Public / Proposed Rule Set 2019-35 EG "PFAS"

Dear Mr. Oswald,

The Michigan Manufacturers Association (MMA) respectfully submits these comments on proposed rule set 2019-35 EG, otherwise known as "Supplying Water to the Public."

MMA has served manufacturers and related industries for nearly 120 years. MMA's membership represents approximately 1,700 manufacturers located in every corner of the state. These members include small, medium, and large manufacturers, with 85 percent employing 100 or fewer employees.

Manufacturing represents Michigan's largest economic sector. It drives Michigan's economy and provides livelihoods for more than 635,000 Michigan citizens and their families. Manufacturing generates nearly 20 percent of state GDP.

MMA has been actively engaged for more than two years in discussions on per- and poly-fluoroalkyl substances (PFAS) with state regulators, legislators, local communities, and our members. **We all agree the safety of public drinking water supplies is paramount, as is public confidence in drinking water safety**.

We believe the state can both protect the public health and its economic competitiveness; these are not mutually exclusive goals. As such, **MMA welcomes being part of the solution** to what clearly is a complex challenge.

To meaningfully contribute to the state's rulemaking process, **MMA commissioned an independent peer review by leading PFAS researchers of the draft ruleset.** As directed by MMA, the purpose of the peer review is to provide technical comments on the Science Advisor Workgroup's (SAW) recommendations to the Department of Environment, Great Lakes, and Energy (EGLE) that were used to establish the health-based drinking water values (HBVs) for PFAS.

MMA's intent in providing this peer review is that it will aid in the rulemaking process by providing scientific, technical information for SAW, EGLE, and the Environmental Rules Review Committee (ERRC) to take into consideration before proceeding to promulgate rules.

Professional Qualifications of Peer Review Scientists

The technical review was completed by Dr. Michael L. Dourson, former U.S. Environmental Protection Agency (EPA) Advisor and current Director of Science for Toxicology Excellence for Risk Assessment (TERA); Dr. Edward J. Calabrese, professor at the University of Massachusetts-Amherst, and Mr. Richard J. Welsh, Director for ASTI Environmental, Inc.

Dr. Michael L. Dourson of Toxicology Excellence for Risk Assessment (TERA)

Michael Dourson has a PhD in toxicology from the University of Cincinnati, College of Medicine, and is a board-certified toxicologist (Diplomate of the American Board of Toxicology - DABT).

Dourson currently serves as the Director of Science at the 501c3 nonprofit organization TERA. Prior to this, he was Senior Advisor in the Office of the Administrator at the EPA. Before this, he was a Professor in the Risk Science Center at the University of Cincinnati, College of Medicine.

He was awarded the Arnold J. Lehman award from the Society of Toxicology, the International Achievement Award by the International Society of Regulatory Toxicology and Pharmacology, and four bronze medals by the EPA. He has been elected as a Fellow of the Academy of Toxicological Sciences and as a Fellow for the Society for Risk Analysis.

Dourson has co-published more than 150 papers on risk assessment methods or chemical-specific analyses, and co-authored well over 100 government risk assessment documents, many of them risk assessment guidance texts. He is a well-respected and frequently invited presenter within this specialization, chairing over 150 sessions at scientific meetings and independent peer reviews.

Dourson has been elected to multiple officer positions in the American Board of Toxicology (including its president), the Society of Toxicology (including the presidency of three specialty sections), the Society for Risk Analysis (including its secretary), and is currently president of the Toxicology Education Foundation, a nonprofit organization with a vision to assist public understanding of toxicology. In addition to numerous appointments on government panels, such as EPA's Science Advisory Board, he is a current member on the editorial board of Regulatory Toxicology and Pharmacology and Human and Experimental Toxicology.

Dr. Edward J. Calabrese of University of Massachusetts

Edward J. Calabrese is a Professor of Toxicology at the University of Massachusetts, School of Public Health and Health Sciences, Amherst. Calabrese has extensively researched host factors affecting susceptibility to pollutants, and is the author of over 900 papers in scholarly journals, and more than 10 books, including Principles of Animal Extrapolation; Nutrition and Environmental Health, Vols. I and II; Ecogenetics; Multiple Chemical Interaction; Air Toxics and Risk Assessment; and Biological Effects of Low Level Exposures to Chemical and Radiation. Along with Mark Mattson (NIH) he is a co-

editor of the recently published book entitled Hormesis: A Revolution in Biology, Toxicology and Medicine.

Calabrese has been a member of the U.S. National Academy of Sciences and NATO Countries Safe Drinking Water committees, and on the Board of Scientific Counselors for the Agency for Toxic Substances and Disease Registry (ATSDR). He serves as chair of the Biological Effects of Low-Level Exposures (BELLE) and as director of the Northeast Regional Environmental Public Health Center at the University of Massachusetts.

Calabrese was awarded the 2009 Marie Curie Prize for his body of work on hormesis. He is the recipient of the International Society for Cell Communication and Signaling-Springer award for 2010. He was awarded an Honorary Doctor of Science Degree from McMaster University in 2013. In 2014 he was awarded the Peter Beckmann Award from Doctors for Disaster Preparedness.

Over the past 20 years, Professor Calabrese has redirected his research to understanding the nature of dose response in the low dose zone and underlying adaptive explanatory mechanisms. This research has led to important discoveries which indicate that the most fundamental dose response in toxicology and pharmacology is the hormetic-biphasic dose response relationship. These observations are leading to major transformations in improving drug discovery, development, and in the efficiency of the clinical trial, as well as the scientific foundations for risk assessment and environmental regulation for radiation and chemicals.

Mr. Richard J. Welsh of ASTI Environmental

Mr. Welsh is a board-certified toxicologist (DABT) and environmental chemist with over 30 years of environmental consulting and litigation support experience in disciplines including human health risk assessment, exposure assessment and ecological risk assessment. He holds a Master of Science degree in Pharmacology and Toxicology from the University of California, Davis. He is currently a director at ASTI Environmental, Inc.

Welsh has completed his career of work under the State Comprehensive Environmental Response, Compensation, & Liability Act, the Resource Conservation and Recovery Act, as well as a range of other state and international regulatory regimes. He has developed quantitative criteria and qualitative goals for soil, groundwater, sediments and air as well as supporting chemical fate and transport evaluations for a range of projects and environmental contaminants. Welsh has worked throughout the US, as well as in Western, Central & Eastern Europe, South America, the Middle East and Africa. His work includes contaminant groups PFAS, dioxins, PCBs, petroleum hydrocarbons (e.g., BTEX, PAHs & coal tar), metals (e.g., lead, chromium, mercury), industrial solvents (e.g., PCE), explosives, and agricultural chemicals.

Overview of Findings

In summary, the technical peer review identified the following:

- **Key studies were not referenced or discussed** by the Science Advisory Workgroup (SAW) in its risk assessment calculations;
- **Significant data gaps and scientific uncertainty are evident in** the SAW's calculations;

- **Curious conclusions and assumptions are evident** in calculations for the Health-Based Values (HBVs); and
- **SAW deviated from accepted standard practice** when developing its Maximum Contaminant Levels (MCLs).
- **There is an inadequate assessment of the compliance costs of the proposed rule that, ultimately, the public will bear.** The absence of a robust assessment may weaken acceptance and support for the proposed criteria.

Recommendations

Based on the findings of the independent peer review, MMA encourages the following recommendations:

1. **Ensure public confidence in the process:** SAW should address and resolve any key scientific uncertainties and shortcomings that have been identified during the public comment period and subsequent to the development of proposed rules. MMA trusts that the peer review information provided here will assist in addressing some of the information gaps and questions that remain.

2. **Rely on settled science to develop MCLs:** Michigan should rely upon universally settled science when developing MCLs and ensure that Michigan is using a scientific community-consensus database. EGLE should refrain from developing MCLs on a class basis due the unique and varying effects of different PFAS constituents. As the body of scientific knowledge on exposure continues to grow, Michigan should reassess its previous determinations, consider adding other individual PFAS constituents, or modify the compliance requirements.

3. **Lead with regulation-ready rules:** Promulgate rules that are legally defensible and provide clarity, consistency, and certainty. The ruleset must also establish the proper mechanisms to ensure that EGLE, individuals, communities, and industry can understand, adapt to, and comply with the rules. *Regulation-ready* rules must include a screening and review process, as well as a site-specific plan approach for any testing site that registers a level that results in further action.

4. **Fully account for the cost:** Properly account for the costs to be incurred by employers, municipal water systems and their citizens by identifying the cost for retrofitting for existing municipal water supply systems of differing scale, costs as they relate to Industrial Pretreatment Programs, and for disposal cost elimination of PFAS material remaining after treatment. The Regulatory Impact Statement (RIS) also did not appropriately account for the ongoing operating costs, including a full assessment of the compliance monitoring costs, for municipal systems. Lastly, SAW should fully identify and consider costs when establishing HBVs, which does not appear to have been included in the overall assessment.

With EGLE's implementation of these recommendations, Michigan can be a credible leader in PFAS-related safe drinking water standards, which the State has indicated as its goal.

Peer Review Technical comments

Again, MMA appreciates the opportunity to provide formal comments on the proposed rules, and we trust the peer review will aid EGLE in using settled science as the foundation for setting standards, allowing the Department to establish regulation-ready standards to properly and confidently implement a credible, safe drinking water standard.

Since this is the first time that Michigan has established an MCL without one first being established by EPA, MMA's objective is to see that Michigan implements a sustainable and defensible regulation. While the work of SAW is considerable and significant, an obvious weakness is the absence of **a robust peer review as part of the SAW rule development process.** A robust, properly credentialed peer review protocol is required practice for the EPA when it establishes an MCL, and Michigan should follow this example in some credible manner.

As SAW did not include a proper peer review phase in its process, MMA believed it essential to engage an expert review so as to properly and credibly inform our organization and its members of proposed rulesets soundness, and also to provide SAW with a foundational peer review for ensuring the soundness of the final rules package. While SAW relied on studies employed by other states, the different selections of information and the unique amalgamated result was not peer reviewed by other scientists or technical experts.

Further, recognizing the state's commitment to ensuring safe public drinking water supplies, and by doing so, looking to establish MCLs prior to any established by the EPA, EGLE must consider the following:

- SAW should expand the pool of experts used in developing the MCLs. **SAW lacks the multidisciplinary pool to properly determine and establish MCLs and requires additional expert assistance for properly rooting the development of MCLs.** For example, EPA used more than 30 different scientists from multiple disciples to develop its health advisory standard – that is 10 times more than those used by SAW. Moreover, the budget and technical resources of EPA far exceed the ability of any individual state to set an MCL. (*See,* page 22; Section 3.25 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

- To properly establish an MCL and gain the public confidence that is necessary on this issue, SAW must expand its review and reevaluate the HBVs that it established. Alternatively, **EGLE should proceed to regulate what is based on settled and established science** and continue to consult and incorporate **ongoing research conducted by the EPA and others** to enable access to critical new findings as PFAS science evolves.

- SAW did not consider some of the newest science, nor did it consider human clinical studies that are available. SAW should further evaluate the more than 2,000-plus studies on PFOA and PFOS, as well as the 400 human epidemiological studies (or at **a minimum discuss why it chose not to use the other available scientific studies.)** (*See,* page 24; Section 3.26 of Independent Technical

Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

- Since the SAW report lacked a peer review process, it **lacked the proper professional evaluation needed for establishing HBVs**. With a proper scientific, technical peer review the **SAW could have corrected scientifically curious assumptions and removed uncertainty from many aspects of the review used to establish HBVs**. (*See*, page 20; Section 3.19 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

  To expand on the scientifically unsettled assumptions and approach, **SAW relied on scientific uncertainty** by embedding uncertainty factors into many equations to establish HBVs **rather than looking to settled and established science**. By relying on the inclusion of subjective uncertainty factors to address scientific questions of toxicity and exposure rather than a settled-science based determination.

  To emphasize: due to the multiple layers of uncertainty factors that were added, the proposed MCLs have a similar Point of Departure to many other chemicals with established MCLs, but those other chemicals have MCLs in the parts-per-million or parts-per-billion. Put another way, human exposure via drinking water of methyl mercury or perchlorate have radically higher safe dose levels even though it is well established that these chemicals have known adverse, toxic effects. (*See*, romanette page vii of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

  In addition, SAW also used uncertainty factors in place of available data for establishing dosage levels. At a minimum, SAW needs to **further explain the reason for favoring scientifically curious data gaps rather than using well established and measured data.** *(see,* page 9, 16, 22-23; Section 3.3, 3.12, 3.22 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

  Of significant concern, **SAW's confidence statement failed to identify all the scientific uncertainty factors** it used in lieu of established, settled science in its report establishing the HBVs. Moreover, SAW utilized uncertainty factors at a 10-fold multiple rather than filling in database deficiencies with settled science to establish its robust database. As such, **SAW report omits appropriate criteria for assessing scientific uncertainty and ensuring a proper peer review and evaluation has been conducted**. (*See,* pages 12, 15, 19, 20-21, 23; Sections 3.6, 3.7, 3.10, 3.15, 3.19-3.21, 3.23 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020). To alleviate the scientifically curious approach, SAW must at least **modify its report to discuss why it chose not to use the other available scientific information available.**

- **SAW did not properly match the exposure scenario needs to the exposure that caused the critical effect.**

  For example, SAW's use of the breast-fed infant exposure as the target population in its review is incorrect. The critical effect occurs for in-utero exposure and not in the postnatal pups. Since SAW had this data gap, it added an uncertainty factor to try to address critical effect. SAW, however, added additional levels of uncertainty factors when proper data would have been available. **SAW must address these issues to better understand the proper critical effect and how that determines appropriate HBVs.** (*See,* page 15-16; Section 3.11 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

- **SAW did not follow EPA's established, accepted standard practices when developing its MCLs**.

  For example, **SAW deviated from standard EPA practice** when it used a benchmark dose, lower confidence limit (BMDL) rather than a Benchmark Dose (BMD), No Observed Adverse Effect Level (NOAEL) or Lowest Observed Adverse Effect Level (LOAEL) when estimating the Point of Departure. (*See*, romanette page vii of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

- **SAW failed to use a Concentration maximum (CMax) for proper dose adjustment** from mice to humans when calculating its HBVs.

  More specifically, EPA **guidelines highlight CMax as the standard, default dosimetric adjustment for critical effect when developing toxicity levels**. (*see,* pages 6, 15, 19; Sections 3.1, 3.9, 3.17 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

- **SAW did not follow the EPA standard process as it relates to a cost analysis when generating proposed HBVs**.

  The Safe Drinking Water Act (SDWA) requires the EPA to prepare a health risk reduction and cost analysis in support of any National Primary Drinking Water Regulations. While EGLE did include some minimal estimate of the costs when preparing its Regulatory Impact Statement (RIS), SAW failed to provide a similar analysis.

  As a result, **SAW failed to analyze the quantifiable and non-quantifiable benefits that are likely to occur as a result of compliance with the proposed standards**. *(See,* pages 12-14, 24; Sections 3.8, 3.26 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

  For example, the prevalence of PFAS in consumer products combined with the exceedingly low proposed MCLs, as well as the still developing laboratory standards will establish higher

compliance costs and likely result in false positive results that will require water suppliers to commit technical and monetary resources on issues that may not actually exist.

The lack of a complete accounting for the cost of any proposed drinking water rules is of major concern for the public and the regulated community to assess the benefits of this proposal relative to the costs all will be asked to bear. It is also of concern for municipalities as represented by the Michigan Municipal League's formal comments filed with the ERRC. In addition, the RIS excluded the costs filtration systems from municipal water systems in Ann Arbor and Plainfield Township; and according to news reports, the combined cost of for those systems exceed $3 million.

The State should not move forward without fully knowing and accounting for the financial impact on communities and their citizens on the cost of implementing safe drinking water standards. Nor should the state move forward without properly addressing and identifying the costs on industry for Industrial Pretreatment Plans and Part 201 cleanup criteria.

Peer reviewers also highlighted numerous areas where the scientific community remains without consensus on what is settled science. Unfortunately, this meant that **SAW had to consistently use scientific uncertainty to fill in gaps in place of technical information and data.**

As consensus and further understanding on the impacts of PFAS continues to evolve, the state should focus its regulatory efforts around what is already settled. To highlight the lack of scientific certainty and the gaps in data that remain, the independent review noted the following:

- Due to the lack of settled and certain science on PFAS, there is still considerable debate – among both scientists and governments – on safe dose exposure. To wit, there **is a more than 500-fold difference in projected safe dose levels for PFOA by different governments**, with Australia setting a safe dose level at 160 parts-per-trillion (ppt) and the UK setting a safe dose at 1,500 ppt. (*See,* romanette page v of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

  Moreover, SAW had a more than 40,000-fold difference in safe doses based on the different PFAS constituents. (*See,* pages 2, 17, 19; Sections 3.13, 3.16 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020). Arguably, the **safe dose levels vary so greatly due to data gaps and certainty**, supporting the need for Michigan to remain credibly in step with leading knowledge as it continues to evolve.

- The **scientific community continues to study and ascertain the amount of time certain PFAS compounds remain in and interact in humans.** Specifically, scientific evaluation is still ongoing as it relates to prolonged exposure of PFAS compounds in human serum and how albumin protein impacts how long it takes for the exposure to be eliminated from the body. (*See,* page 11; Section 3.5 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

We must first understand the interactions of PFAS and the human body and only establish HBVs and MCLs on compounds where we have an established consensus based on settled science. MMA **recommends that to best ensure public confidence and protect human health, the state consult and incorporate research conducted by the EPA** and others to enable Michigan to access critical new findings as PFAS science evolves and not regulate in areas where the science is still unsettled.

Scientific studies, including one utilized by SAW, on dose levels use exceptionally high dosages, resulting in overtly toxic levels. While this has been a historically accepted practice, it is important to note that the **high doses along with scientifically unusual assumptions and uncertainty factors are driving the HBVs for establishing MCLs, rather than settled science to properly determine proper, safe HBVs.** (*See,* page 17-18; Section 3.14 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

- Recognizing that 8-carbon PFAS are no longer in production and the science on other short chain carbon continues to evolve, the scientific community continues to further evaluate the impacts of the different constituents. As a result, moving toward **a class designation is premature and would likely generate rules that are not regulation ready**. Michigan needs to include a screening and review process for exceedance findings. Due to the changing nature of the settled science, the database of established science will grow over time.

  Having **an additional level of review and evaluation embedded into the ruleset will allow for the state, as well as communities and industry to adjust and adapt as the body of settled science grows.** (*See,* page 23; Section 3.24 of Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan, January 30, 2020).

Regulatory Review comments

As noted above, the **EPA has historically developed MCLs because it is best equipped with the resources and expertise to provide the basis for addressing these complex public health questions**. EPA has shown through its actions that it has been actively engaged in understanding and addressing PFAS public health concerns. To highlight this point, in 2016, EPA developed and released health advisories for PFOA and PFOS. (*See,* 81 Fed Reg. 101 (May 25, 2016). EPA has since issued its 2019 PFAS Action Plan, which includes EPA conducting an Integrated Risk Information System (IRIS) assessments of multiple PFAS constituents and developing MCLs for PFOA and PFOS under the SDWA. (*See,* U.S. EPA Per- and Polyfluoroalkyl Substances (PFAS) Action Plan (February 2019)). The agency has also recently issued interim recommendations for groundwater contamination due to PFOA and PFOS. (*See,* Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS (December 20, 2019)). EPA's objective is to properly develop a unified regulatory mechanism for protecting the public health.

Moreover, while the **EPA is working through its long-established rulemaking process for MCLs, Congress is also working diligently to ensure that EPA promulgates a national drinking water standard for PFAS constituents**. (*See,* National Defense Authorization Act (NDAA) (P.L. 116-92) and (H.R. 535)). It is important that M**ichigan continues to monitor the extensive research conducted by the EPA**, as well as the actions of Congress to enable Michigan to access and use critical new findings as PFAS science and regulations evolve.

Many states and the Federal government have recognized the importance of addressing this complex issue. It is imperative to **remember that the SDWA provides little direction other than the adoption of federal MCLs**, and that EGLE is authorized to promulgate rules that include drinking water standards and monitoring requirements, necessary to protect the public health. (*See,* MCL 325.1005(1)(b)).

Moreover, the law establishing the ERRC provides that draft rules are to be evaluated against certain criteria including that the rules do not exceed their statutory authorization; the rules reasonably implement and apply the relevant law; the rules are necessary and **suitable to achieve their purposes in proportion to their burdens on individuals and businesses**; and the **rules are based on sound and objective scientific reasoning.** (*See,* MCL 24.266(4)(a)-(e)).

Given the gaps in information described both above and in the attached technical review, it is not clear that the **proposed standards have ensured that SAW used settled science necessary to establish MCLs**. This is further highlighted by **SAW's own report, which stated in part that there "remains significant scientific uncertainty"** relating to the values selected and that additional study was warranted. (*See,* page 9, Health-Based Drinking Water Value Recommendations for PFAS in Michigan, June 27, 2019).

Further, for reasons discussed above and below, there is a significant concern **that these rules do not take into account economic reasonableness and the necessity of these particular standards in proportion to the burdens on individuals, local communities, municipal water systems, and businesses** that would result from the adoption and imposition of these standards.

As previously noted, this is the first time that Michigan has developed its own MCLs. In fact, **the SAW report specifically states that the most stringent HBV proposed – the 6 ppt level for PFNA – that was adopted into the rule should "be used as a screening level."** (*See,* page 25, Health-Based Drinking Water Value Recommendations for PFAS in Michigan, June 27, 2019).

Recognizing and understanding that the SAW had a more than 40,000-fold difference in safe doses based on the different PFAS constituents, **EGLE should not use SAW's proposed levels as an automatic trigger as a point of violation as is proposed in draft ruleset**. Rather than adopting these levels as MCLs which could result in fines, penalties, and even the termination of water services pursuant to the SDWA, we urge **EGLE to entertain a slight revision to the proposed rules and use SAW's report to set monitoring, attainment, and maintenance requirements through regular screening as empowered to do under the SDWA**. This would ensure continued sampling while also utilizing state and federal data and standards over time.

Due to the evolving and growing understanding of PFAS, **the ruleset should not adopt MCLs, but instead, should provide for the proposed sampling as proposed and then provide for significant and robust evaluation and study of each specific situation before taking any enforcement actions** regarding the detected results and a process whereby only drinking water systems with consistent detections of PFAS rather than intermittent detections would be required to provide a site-specific demonstration that the levels detected do not pose a human health risk with review by a review panel, or alternatively address EGLE's concerns through a source or system modification.

Summary

MMA and its members universally agree that the safety of Michigan's public drinking water supplies is the top priority. We also believe that the public's confidence is achieved by ensuring the integrity and soundness of the process and information used as the solid foundation for setting safety standards. Anything less subjects regulators, drinking water systems and others to potential skepticism and lack of confidence in drinking water safety.

Michigan cannot and should not find itself in such position, especially in light of PFAS rule related litigation and implementation delays being experienced in other states that have failed to properly underpin standards and account for costs.

MMA believes the state has endeavored to establish appropriate standards, though our peer review identified some areas lacking in the kind of robust scientific and technical integrity to fully complete the effort. We believe the issues identified in the peer review report we are submitting, and associated recommendations, if implemented, should result in the state's rule making initiative achieving the process and confidence milestones expected of state agencies.

MMA looks forward to working with EGLE to properly develop a ruleset that ensures the safety of public drinking water supplies and the public's confidence in its drinking water. Doing so properly guarantees we protect the public health, while also ensuring Michigan's continued economic vitality.

Respectfully,

Mike Johnston

Vice President, Government Affairs

Attachments: 1

Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan

January 30, 2020

Report Prepared For:
Michigan Manufacturers Association
620 S. Capitol Ave.
Lansing, MI 48933

Report Prepared By:
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ASTI ENVIRONMENTAL

TERA

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Executive Summary

An independent technical review was conducted for the primary studies used by Michigan per- and poly-fluoroalkyl substances (PFAS) Action Response Team (MPART), Science Advisory Workgroup (SAW) to calculate the MPART 2019 PFAS Health Based Values (HBVs), and in turn proposed Michigan Maximum Contaminant Levels (MCLs) for Seven PFAS (including the 8-Carbon Perfluorooctanoic acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) as well as the primary studies used by the United States Environmental Protection Agency (USEPA) to calculate the 2016 USEPA Drinking Water Health Advisory for PFOA and PFOS. The review was completed by Dr. Michael L. Dourson of Toxicology Excellence for Risk Assessment (TERA), Dr. Edward J. Calabrese of University of Massachusetts, and Mr. Richard J. Welsh of ASTI Environmental. The review identified:

- Key studies not discussed by the MPART in their risk assessment calculations;
- Significant data gaps in the calculations; and
- Questionable conclusions and assumptions used by SAW in calculating the HBVs and the USEPA in the Drinking Water Health Advisory.

The range of PFAS drinking water values being generated in the USA as well as throughout the World shows there is considerable debate taking place within the scientific community and that the PFAS science is anything but settled (there is little scientific consensus). To get a sense of the breath of scientific uncertainty, refer to the 500-fold differences in the projected safe dose of PFOA by different national authorities shown in Table 1, or perhaps review the abstracts from a recent international conference on PFAS (SETAC, 2019, see: https://pfas.setac.org).

Table 1. The Primary Issue: Risks Among National Authorities Are Widely Disparate: "Safe" PFOA Doses

Agency	UK-COT (2009)	Health Canada (2018)	USEPA (2016)	Australian FASANZ (2017)	US ATSDR (2018)
Study	Mouse fetal (Lau et al., 2006)	Perkins et al. (2004)	Mouse fetal (Lau et al., 2006)	Mouse fetal (Lau et al., 2006)	Mouse fetal (Koskela et al., 2016)
Critical Effect	Liver effects in pups & adults	Rat liver hypertrophy	Reduced pup ossification, accelerated puberty	Fetal toxicity	Altered pup activity; skeletal alterations
Human Dose (mg/kg-day)	0.08 (MMDL of 0.3 ÷ 4)	0.00052	0.0053	0.0049	0.000821
Uncertainty Factor	50 (200 ÷ 4)	25	300	30	300
Safe Dose (ug/kg-day)	1.5	0.02	0.02	0.16	0.003

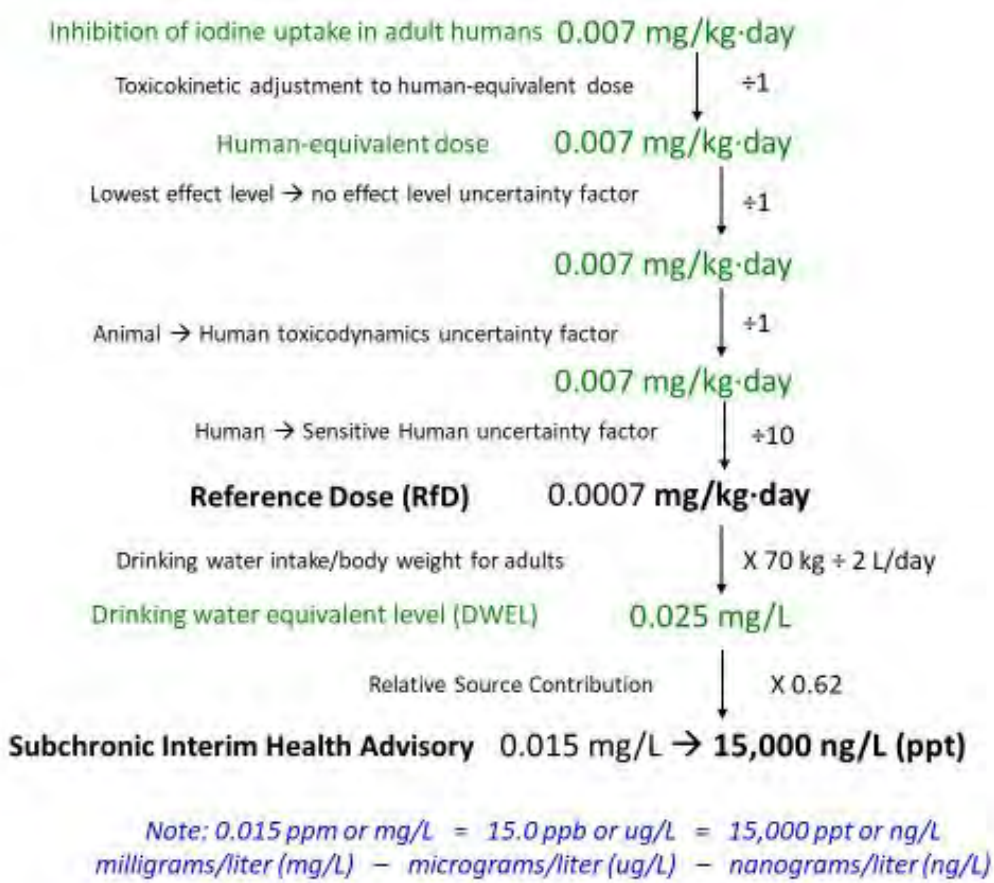
500- Fold Difference in Safe Dose

Another observation, the estimated safe dose for PFHxA is ~ 40,000-fold higher than other safe doses. A critical question is left unanswered here: Are the PFAS sufficiently different in toxicity among a 6 carbon PFAS, 8 carbon PFAS and 9 carbon PFAS to warrant such an extreme difference in HBVs? One conclusion is that the PFAS science is not yet settled, even basic information on the mechanisms of action are not known.

We looked at other MCLs generated by the USEPA and their Point of Departure (POD). It is curious from a "gut-check" perspective that the POD doses identified for PFAS are similar to many of the chemicals with existing MCLs, yet these other chemicals have much higher MCLs in the parts-per-million (ppm) or parts-per-billion range (ppb); versus parts-per-trillion (ppt) levels for the HBVs. From a scientific perspective, a ppt is an extremely low concentration (e.g., 1 second in 32,000 years, or traveling 6 inches out of a 93 million-mile journey toward the sun) and PFAS are very unlikely to be toxic in this range. Furthermore, this is not being communicated effectively to the public.

For comparison purposes, consider perchlorate. Although starting with a lower, more toxic, point of departure, perchlorate has a radically higher drinking water health advisory versus PFAS drinking water health advisory (Figure 1).

Figure 1, USEPA Health Advisory Level for Perchlorate

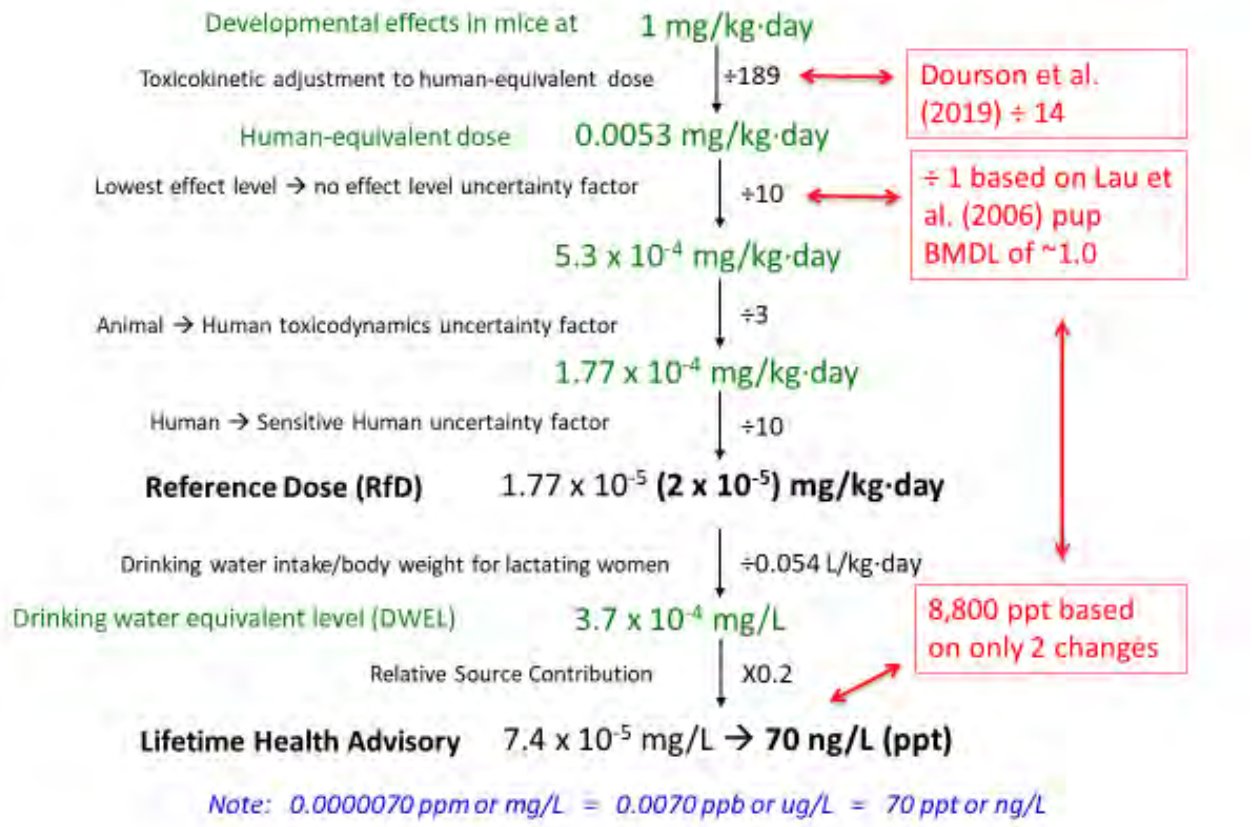


It is understood that SAW proposed select changes to the traditional risk assessment approach (e.g., drinking water intake values for assessing development effects), however, such a radical departure from other past Health Advisory or MCL calculations (especially for chemicals arguably much more toxic than PFAS) needs further evaluation by the scientific community. To illustrate this point, consider methyl mercury. Methyl mercury is known to damage the developing brains of human fetuses and, in human children, result in deficits in attention, behavior, cognition and motor skills. Yet, the HBV for methyl mercury, the USEPA reference dose, is much higher, indicating that methyl mercury is less toxic, than all the PFAS toxicity factors, less one.

As an example of studies not discussed by SAW in the HBVs, there is a human clinical cancer treatment dosing study for PFOA (Elcombe et al., 2013), and published in part by Convertino et al. (2018). Dourson et al. (2019) also conducted a review of this clinical study, and recently received an award for best paper of the year from the Society of Toxicology's Regulatory and Safety Evaluation Specialty Section. The study provides data on PFOA blood serum levels at various dose levels given to cancer patients. This study also provides badly needed data on how long it takes for humans to clear PFAS from their bodies (called the "half-life" in humans).

Thus, using actual human clinical data (instead of the calculations and assumptions) and a Benchmark Dose approach for PFOA (two reasonable changes), the USEPA Drinking Water Health Advisory would be recalculated to be 8,800 ppt instead of 70 ppt (See Figure 2 below). As elaborated further in this review, the benchmark dose, lower confidence limit (BMDL) rather than a no-observed-adverse-effect-level (NOAEL) or lowest-observed-adverse-effect-level (LOAEL) is generally preferred by the USEPA for estimating the Point of Departure (POD).

Figure 2. Example Calculations for Alternate Health Advisory Level for PFOA



As discussed, this report goes on to identify other significant data gaps in the calculations as well as other questionable conclusions and assumptions used by SAW in calculating the HBVs and the Drinking Water Health Advisory. Addressing these issues will further raise the calculated acceptable drinking water levels. For example, we provided examples (there are many more) of reduced toxic responses of PFAS at low dose levels (called hormesis). In other words, what is happening at the high dose levels in laboratory animal studies does not predict whether a chemical is toxic at low (ppt) dose levels. This needs to be further debated by the scientific community and then addressed in the HBVs.

Also consider that the USEPA PFAS Drinking Water Health Advisory, by definition, does not include a cost-benefit analysis, but the MCL process does. This analysis appears to be missing from the current HBV discussions. Note that California recently had its hexavalent

chromium MCL rescinded, and now New Hampshire has had its PFAS MCL blocked by State Courts, due to inadequate assessment of the cost for compliance.

Lastly, we compared the risk assessment process for generating the HBVs (and thus the upcoming State of Michigan MCL) to the typical process used by the USEPA in generating their MCLs. Simply put, there is and will be a large difference in level of effort and budget for the upcoming comprehensive USEPA MCL process. This level of effort, once completed, is anticipated to produce significantly higher USEPA MCL values than the SAW HBVs. It also needs to be determined whether multiple MCLs be developed for the higher 8-carbon PFAS versus the replacement lower carbon PFAS based on differences with both their toxicities, toxicokinetics and chemistries.

The independent technical review does not provide recommended MCLs, but instead highlights areas where the SAW had data gaps and indefensible or questionable conclusions and assumptions. The take-away from this review is that it is the scientifically unusual assumptions and uncertainty factors used in the SAW calculations that are driving the HBVs into the parts-per-trillion range, not the underlying science.

1.0 INTRODUCTION

At the direction of the Michigan per- and poly-fluoroalkyl substances (PFAS) Action Response Team (MPART), the document entitled "Health-based drinking water value recommendations for PFAS in Michigan" dated June 27, 2019 was prepared by Michigan Science Advisory Workgroup (SAW). The SAW Approach (MPART 2019) included that:

- *Given the relatively short timeframe for which to accomplish the tasks set forth within Charge, the Workgroup confirmed that the focus of the effort was to utilize the existing and proposed national- and state-derived PFAS assessments to inform its decision-making process as opposed to conducting a full systematic review of the available scientific literature on PFAS.*

- *Based on guidance from the Director of EGLE's Drinking Water and Environmental Health Division, PFAS chemical summary sheets were used to capture the necessary information for the MCL rulemaking process. The Workgroup and MPART staff used this format to provide maximum transparency on the decisions and rationale for drinking water health-based value development for each PFAS. The chemical summary sheets describe:*

    - *The critical study or studies, point of departure from each study, and conversion to a human equivalent dose;*
    - *Uncertainty factors and a calculated toxicity value;*
    - *Exposure parameters, and methodology for calculation of a drinking water health-based value.*

The 2019 SAW report provides Health Based Values (HBVs) recommendations for seven PFAS compounds as shown in Table 2:

Table 2. SAW Health Based Values (HBVs)

Specific PFAS	SAW Drinking Water Health Based Value
PFNA – Perfluorononanoic acid	6 ng/L (ppt)
PFOA – Perfluorooctanoic acid	8 ng/L (ppt)
PFHxA – Perfluorohexanoic acid	400,000 ng/L (ppt)
PFOS – Perfluorooctanesulfonic acid	16 ng/L (ppt)
PFHxS – Perfluorohexanesulfonic acid	51 ng/L (ppt)
PFBS – Perfluorobutanesulfonic acid	420 ng/L (ppt)
GenX (HFPO-DA) – Hexafluoropropylene oxide dimer acid	370 ng/L (ppt)

ng/L – nanograms per liter
ppt – parts-per-trillion

The objectives of this Independent PFAS Review Report are to provide:

- A technical review of the "PFAS Chemical Summary Sheets" generated by SAW and the associated key study (or studies) used by SAW to develop the seven individual PFAS HBVs as well as the USEPA May 2016 Drinking Water Health Advisory for PFOS and PFOA (with emphasis on the toxic endpoints, point of departure, human equivalent dose calculations, exposure parameters, uncertainty factors, etc.).
- A technical review of additional key studies (not address in the 2019 SAW Report) to provide further information and clarifications to the HBV calculations.
- An assessment of the HBVs relative to the typical drinking water maximum contaminant level (MCL) process used by the United States Environmental Protection Agency (USEPA) including cost of implementation.

The results of the independent technical review are presented below after a brief overview of the team Biographies.

2.0 TEAM BIOGRAPHIES

The independent technical review was completed by Dr. Michael L. Dourson of Toxicology Excellence for Risk Assessment (TERA), Dr. Edward J. Calabrese of University of Massachusetts, and Mr. Richard J. Welsh of ASTI Environmental.

Dr. Michael L. Dourson of Toxicology Excellence for Risk Assessment (TERA)

Michael Dourson has a PhD in toxicology from the University of Cincinnati, College of Medicine, and is a board-certified toxicologist (i.e., Diplomate of the American Board of Toxicology - DABT) serving as the Director of Science at the 501c3 nonprofit organization Toxicology Excellence for Risk Assessment (TERA). Prior to this, he was Senior Advisor in the Office of the Administrator at the USEPA. Before this, he was a Professor in the Risk Science Center at the University of Cincinnati, College of Medicine and also worked at TERA and USEPA.

He has been awarded the Arnold J. Lehman award from the Society of Toxicology, the International Achievement Award by the International Society of Regulatory Toxicology and Pharmacology, and 4 bronze medals from the USEPA. He has been elected as a Fellow of the Academy of Toxicological Sciences (i.e., FATS) and as a Fellow for the Society for Risk Analysis (i.e., FSRA).

He has co-published more than 150 papers on risk assessment methods or chemical-specific analyses, and co-authored well over 100 government risk assessment documents, many of them risk assessment guidance texts. He has made over 150 invited presentations to a variety of organizations and has chaired over 150 sessions at scientific meetings and independent peer reviews. He has been elected to multiple officer positions in the American Board of Toxicology (including its President), the Society of Toxicology (including the presidency of 3 specialty sections), the Society for Risk Analysis (including its Secretary), and is currently the President of the Toxicology Education Foundation, a nonprofit organization with a vision to help our public understand the essentials of toxicology. In addition to numerous appointments

on government panels, such as USEPA's Science Advisory Board, he is a current member on the editorial board of Regulatory Toxicology and Pharmacology and Human and Experimental Toxicology.

Dr. Edward J. Calabrese of University of Massachusetts

Edward J. Calabrese is a Professor of Toxicology at the University of Massachusetts, School of Public Health and Health Sciences, Amherst. Dr. Calabrese has researched extensively in the area of host factors affecting susceptibility to pollutants, and is the author of over 900 papers in scholarly journals, as well as more than 10 books, including Principles of Animal Extrapolation; Nutrition and Environmental Health, Vols. I and II; Ecogenetics; Multiple Chemical Interaction; Air Toxics and Risk Assessment; and Biological Effects of Low Level Exposures to Chemical and Radiation. Along with Mark Mattson (NIH) he is a co-editor of the recently published book entitled Hormesis: A Revolution in Biology, Toxicology and Medicine. He has been a member of the U.S. National Academy of Sciences and NATO Countries Safe Drinking Water committees, and on the Board of Scientific Counselors for the Agency for Toxic Substances and Disease Registry (ATSDR). Dr. Calabrese also serves as Chairman of the Biological Effects of Low Level Exposures (BELLE) and as Director of the Northeast Regional Environmental Public Health Center at the University of Massachusetts. Dr. Calabrese was awarded the 2009 Marie Curie Prize for his body of work on hormesis. He is the recipient of the International Society for Cell Communication and Signaling-Springer award for 2010. He was awarded an Honorary Doctor of Science Degree from McMaster University in 2013. In 2014 he was awarded the Peter Beckmann Award from Doctors for Disaster Preparedness. Over the past 20 years Professor Calabrese has redirected his research to understanding the nature of the dose response in the low dose zone and underlying adaptive explanatory mechanisms. Of particular note is that this research has led to important discoveries which indicate that the most fundamental dose response in toxicology and pharmacology is the hormetic-biphasic dose response relationship. These observations are leading to a major transformation in improving drug discovery, development, and in the efficiency of the clinical trial, as well as the scientific foundations for risk assessment and environmental regulation for radiation and chemicals.

Mr. Richard J. Welsh of ASTI Environmental

Mr. Welsh is a board-certified toxicologist (i.e., Diplomate of the American Board of Toxicology - DABT) and Environmental Chemist with over 30 years toxicology and environmental consulting support experience in a range of disciplines including human health risk assessment, exposure assessment and ecological risk assessment. He has a Master of Science (MSc) degree in Pharmacology and Toxicology from the University of California, Davis. He is currently a Director at ASTI Environmental, Inc. Mr. Welsh has conducted much of his work under the State Comprehensive Environmental Response, Compensation, & Liability Act, the Resource Conservation and Recovery Act, as well as a range of other State and Worldwide regulatory regimes. He has developed quantitative criteria and qualitative goals for soil, groundwater, sediments and air as well as supporting chemical fate and transport evaluations for a range of projects and environmental contaminants. Geographically, he has worked throughout the USA as well as in Western, Central & Eastern Europe, South America, the Middle East and Africa. The contaminant groups he has worked with include PFAS, dioxins, PCBs, petroleum hydrocarbons (e.g., BTEX, PAHs & coal tar), metals (e.g., lead, chromium, mercury), industrial solvents (e.g., PCE), explosives, and agricultural chemicals.

3.0 SPECIFIC COMMENTS ON 2019 SAW HBVS

Provided below are comments to the SAW report and the individual HBVs.

3.1 Actual Human Data versus Estimated Human Equivalent Dose (HED): Pages 10, 12, 16, & 18

Key Finding: A clinical human cancer treatment study by Elcombe et al. (2013) provides actual human PFOA dosing and Cmax blood serum concentrations. These measured data should be used instead of the Human Equivalent Dose (HED) calculated estimates by SAW. We recommend that SAW review this information and update the HBVs accordingly.

A key paper, Elcombe et al. (2013), and published in part by Convertino et al. (2018), appears to have not been reviewed in the analysis described in the 2019 SAW report.

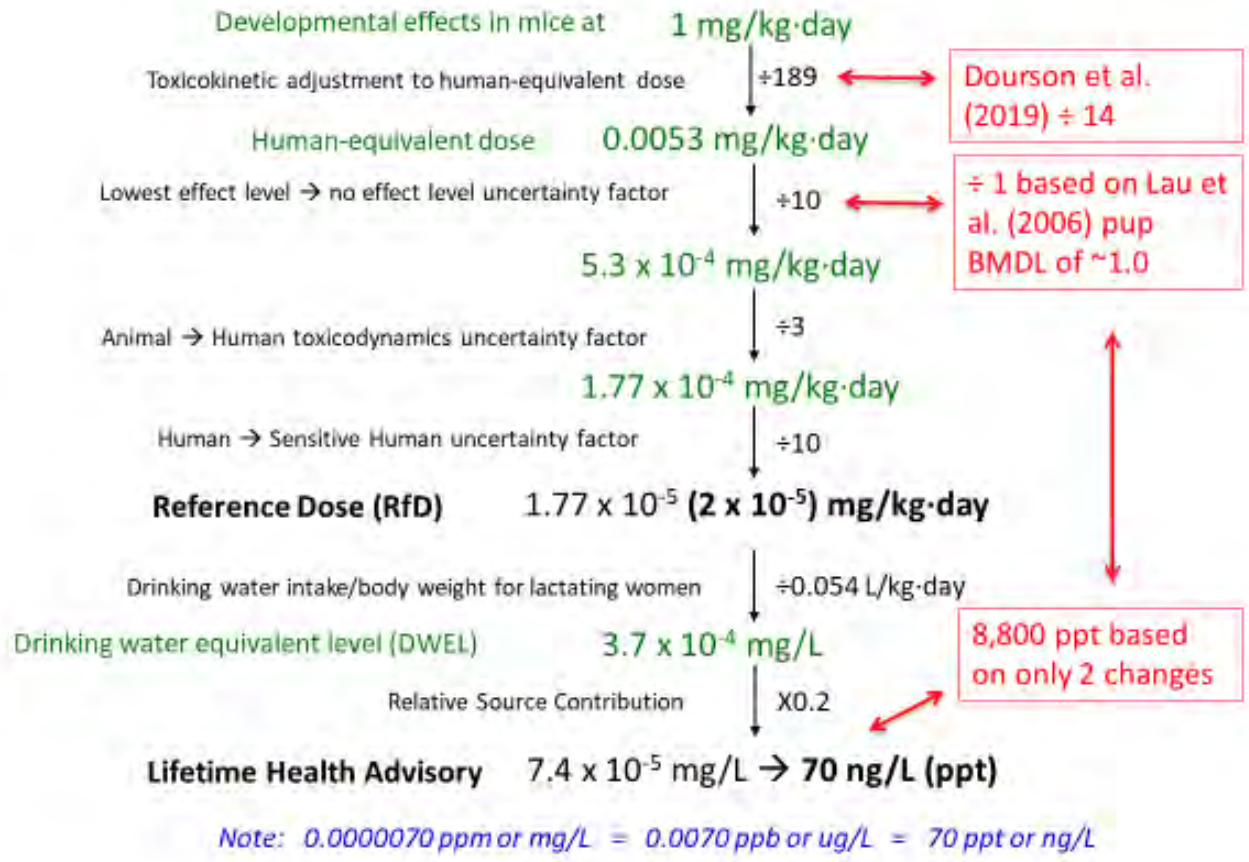
Elcombe et al. (2013) is a phase one, human clinical study where PFOA was used as a cancer chemotherapeutic agent. While the 40+ patients were in various stages of cancer, acceptance into the study necessitated good liver and kidney function, and kinetics were carefully monitored. The data are described in a "*Patent Application*" are complex.

Note, the human PFOA clinical trial data reported in Elcombe et al. (2013) and in Appendix A of the report hint at a much lower human elimination half-life (i.e., 70 to 136 days) for PFOA than previous studies (e.g., 2 to 3 years), and the half-life data from the Elcombe study would support a higher HBV for PFOA. However, this was a phase one clinical trial of often very sick patients, some of whom did not survive for the duration of the trial. Consequently, it is possible that other factors influenced PFOA elimination and thus the derived half-lives. Regardless, these data warrant careful consideration since they show good kinetic data in humans over 6 weeks of exposure and sometimes beyond. Moreover, entry into the study necessitated good liver and kidney functions.

Dourson et al. (2019) provides an analysis of the Elcombe human clinical data with the intent to compare them with relevant kinetic data in mice. This comparison can then be used to consider whether Cmax (maximum plasma concentration) is the relevant dosimenter, rather than area under the curve or AUC (useful for calculating the average plasma concentration over time) as per USEPA (1991) developmental toxicity guidelines. This paper by Dourson et al. (2019) will receive the award for best paper of the year from the Society of Toxicology's Society of Toxicology's Regulatory and Safety Evaluation Specialty Section in March of 2020.

As illustrated in Figure 2 below, using actual human clinical data (instead of the calculations and assumptions) and a Benchmark Dose for PFOA (two reasonable changes), the USEPA Drinking Water Health Advisory would be recalculated to be 8,800 ppt instead of 70 ppt:

Figure 2. Example Calculations for Alternate Health Advisory Level for PFOA



These human dosing data can also be used to develop some initial quantitative findings of PFOA half-life in humans, which appears to be under one-year (see Appendix A), and which is consistent with initial work done by Dr. Harvey Clewell [Harvey Clewell, personal communication, Alliance for Risk Assessment-Beyond Science and Decisions Workshop, TCEQ, February (ARA, 2019)].

This is all in contrast to using observational human studies by SAW to estimate half-life and thus Human Equivalent Dose (HED). Pages 10, 12, 16, & 18 from the 2019 SAW Report converted the blood serum concentrations in laboratory animals to the serum concentrations in Humans based on the following calculation (instead of the actual human data):

NOAEL (or LOAEL) = TWA Serum Concentration * Ke * Vd
Where:
TWA = Time Weighted Average Serum Concentrations
Ke = Human Elimination Rate Constant
Vd = Human Volume of Distribution

This methodology breaks down (compared to the actual human data) in that observational data (a human blood ½ life of 2.3 years) was used to estimate the Ke. The SAW report uses scientific uncertainty in place of technical information resulting in unjustified lower HBV.

Note also that while the previous observational human studies are useful to get a sense of PFAS half-lives in humans, it appears several of them may not have addressed other exposure pathways to PFAS in items such as house-hold dust and commercial products. If so, then estimates of half-lives from such observational studies would be longer, and perhaps significantly longer, than the actual human dosing / half-life data.

Note, many PFAS half-life studies in humans do not appear to address other sources of exposure (i.e., food or house dust) beyond drinking water, and by not accounting for these additional exposure routes, the derived serum elimination half-lives are biased high. For example, the PFOS half-life derived by Li et al. (2018) and used in the SAW PFOA assessment appears not to have been corrected for general background exposure, meaning that the estimated PFOS half-life is likely an overestimate. However, it may be that additional background sources are sufficiently low as to not be biasing the

half-lives to a large extent. For example, serum half-lives are often derived from occupationally exposed cohorts or from populations exposed to elevated PFAS due to contaminated drinking water. In these cohorts the occupational exposure or drinking water exposure might account for most of the PFAS exposure, and other sources contributing to general exposure (i.e., dust or food) might be relatively minor. Regardless, it makes sense to carefully check these human observational studies in light of the clinical findings of Elcombe et al. (2013) and Convertino et al. (2018).

3.2 PFNA POD and Cmax, Page 10

Key Finding: SAW did not use the appropriate dose adjustment from mice to humans based on USEPA (1991) guidelines. Refer to Section 2.2 below for recalculated HBV.

According to USEPA (1991) the default dosimetric adjustment for critical effects that are developmental toxicity is Cmax ("**C**oncentration **max**imum" or peak PFAS blood serum concentration). Here the critical effects appear to be related to in-utero exposures, with possible exposure postnatally via suckling. Choices other than this default dosimeter, such as area under the curve represented by half-life, need to be based on data specific for the critical effect. The resulting safe dose for PFNA would be much different with the choice of Cmax as the dosimeter. See Section 3.3 below, a recent publication on this very topic by Dourson et al. (2019) where PFOA is used as a case study.

3.3 PFOA Use of Benchmark Dose instead of LOAEL: Page 12

Key Finding: USEPA's 2009 draft of its PFOA Health Advisory used a Benchmark Dose (BMD) as its point of departure, based in part on finding from authors of the critical study. This changed in its USEPA's 2016 final document due to the review of other developmental toxicity effects in this critical study. The use of the low dose of the critical study as a LOAEL, rather than a BMD from the authors of the critical study lowered the health advisory by 10-fold regardless of other changes.

3.4 PFAS Exposure Prenatal / Breast Feeding, Bottom Paragraph, Page 8

Key Finding: *"These traditional equations do not consider the PFAS body-burden at birth or any transfer of maternal PFAS through breastmilk " (SAW 2019 page 8)*. Yes, breast feeding would result in greater exposure to the young infant. But it would not pertain later in life for a mother's exposure during pregnancy, and it is during pregnancy when the critical effect occurs. Thus, this calculation is flawed. When evaluating development effects to the fetus, it is only the exposure to the pregnant mother that is significant. Indeed, this is the only exposure to the fetus.

This statement, while true, is not accurate in that it does not consider if the critical effect is found to be from a certain type/route of exposure (e.g., developmental toxicity from exposure to pregnant animals). If studies are available that evaluate effects from other exposures (e.g., 2-gen reproductive study that monitors suckling pups), then the appropriate exposure for developing an HBV is the one associated with the critical effect; that is, the pregnant animal. In this case, studies for developmental toxicity from exposure to pregnant animals as well as a 2-generation reproductive study that monitored for postnatal effects (i.e., suckling pups) are available and the developmental endpoints should be considered. The SAW report deviated from appropriate scientific process.

Therefore, the use of the Goeden et al. (2019) model would be inappropriate when developmental toxicity is the critical effect and effects from breast-feeding are already monitored (as generally in a 2-gen study), because it is the exposure to the dam that evoked the critical effect in the pups. If the 2-gen study is missing, then an uncertainty factor for an incomplete database is often used based in part of the work of Dourson et al. (1992). Either way, the exposure scenario is still based on that of the critical effect, in this case maternal exposure causing the fetal effect.

3.5 Serum Half-Life and Interspecies Differences

Key Finding: The Elcombe et al., (2013) human PFAS study cited above provides unique empirical information on serum half-life. However, one of the key concerns has been how to relate serum half-life for PFAS in animal models to humans. While there are multiple factors that may contribute to the occurrence of the differences in human versus mouse half-lives, one may be the difference in serum albumin half-life.

PFAS compounds are principally bound to serum proteins, such as serum albumin being about 97-99% bound. Of particular interest is that the albumin half-life in the adult mouse has been estimated to be 0.87 days as compared to the 21-day estimate for human adults. In addition, the quantity of serum in neonatal mice is in a hypo-condition for most serum proteins, including albumin, which displays about 50% of adult values by the end of the first week of postnatal life, reaching adult values by about one month (Zaias et al., 2009). While there are multiple factors that may contribute to the occurrence of the differences in human versus mouse half-lives one may be the difference in serum albumin half-life. Since the human adult displays about a 20-25 fold greater serum albumin half-life than the adult mouse this may account for a large proportion of the difference in half-life.

The difference becomes even greater when the human adult half-life is compared to the neonatal mouse. Since the PFAS are so tightly bound to serum proteins these agents are prevented from entering into cells during this binding period (e.g., no accumulation in red blood cells). The approximately 20 fold difference in serum albumin levels would reasonably well correspond to the difference in lifespan between mice and humans, and would correspond roughly with a 14-fold factor developed by Dourson et al. (2019) for extrapolating the findings of developmental toxicity in mice to pregnant humans. Thus, while there has been considerable concern raised about the prolonged human serum half-life for the PFAS class of compounds relative to the mouse, a consideration of the role of serum proteins seems to allometrically integrate the animal and human findings, enhancing toxicological interpretations.

3.6 Confidence Statement, 1st paragraph, Page 9

Key Finding: Not all of the scientific uncertainties have been listed.

Absent from the list of general uncertainties in the SAW report are those associated with assumptions of kinetic parameters among species. For specific thoughts on these uncertainties, please see below in Section 3.7.

3.7 Confidence Statement, 2nd paragraph, Page 9

Key Finding: Not all of the scientific uncertainties have been listed. Important ones described below are missing. SAW report omits appropriate criteria for assessing scientific uncertainty.

Absent from this list of specific scientific uncertainties are those associated with:

- The assumption of experimental animal parameters in lieu of human information on kinetics when compared with the kinetics of experimental animals; differences among species are large; and existing information on humans is sparse. This is a large uncertainty that needs to be highlighted;
- Uncertainties in the estimation of human half-life of certain PFAS chemicals based on human observational studies that may not have accounted for all sources of PFAS; and
- The use of LOAELs instead of benchmark doses in the development of HBVs (e.g., for USEPA's PFOA).

3.8 PFNA & PFOS, Dose Response Issues, Pages 10 & 16

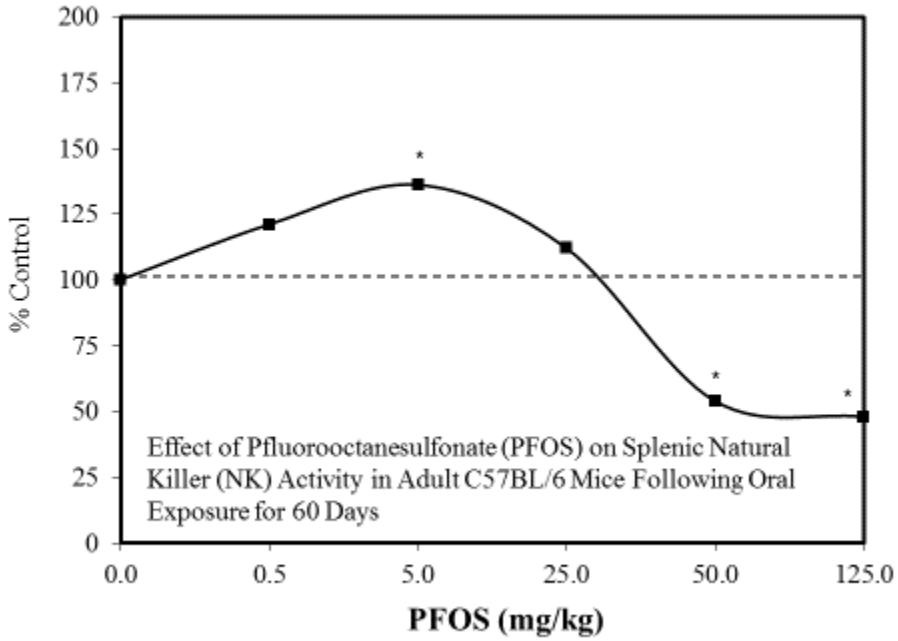
Key Finding: Key studies used by SAW to develop the HBVs did not discuss observations of reduced response and toxicity at low dose levels (known as Hormesis) including Dong et al. (2009) and Das et al. (2015). The implications of this are profound

as this would radically change the HBV calculations, since existing safe doses appear to be well below the hormetic dose range (i.e., the range of enhanced performance).

The report of Dong et al. (2009) provided evidence of a possible hormetic dose response with respect to NK cells (thus lower toxicity / response at low doses). The hormetic response occurred at the same dosage as the changes in plaque forming cell response and increased liver mass. However, the hormetic response was still observed at 0.5 mg/kg, the dosage selected for the NOAEL. Thus, the issue of whether a potential beneficial response may have been occurring was not addressed in the assessment of the SAW.

A second hormetic dose response was also discussed above with respect to the eye opening endpoint (Abbott et al., 2007). In the case of the NK endpoint, the authors of the study did not discuss these findings (Figure 3). The authors appear to have focused on apparent adverse effects at higher doses.

Figure 3. Effect of Pfluorooctanesulfonate (PFOS) on Splenic Natural Killer (NK) Activity in Adult C57Bl/6 mice following oral exposure for 60 days (based on Dong et al., 2009)

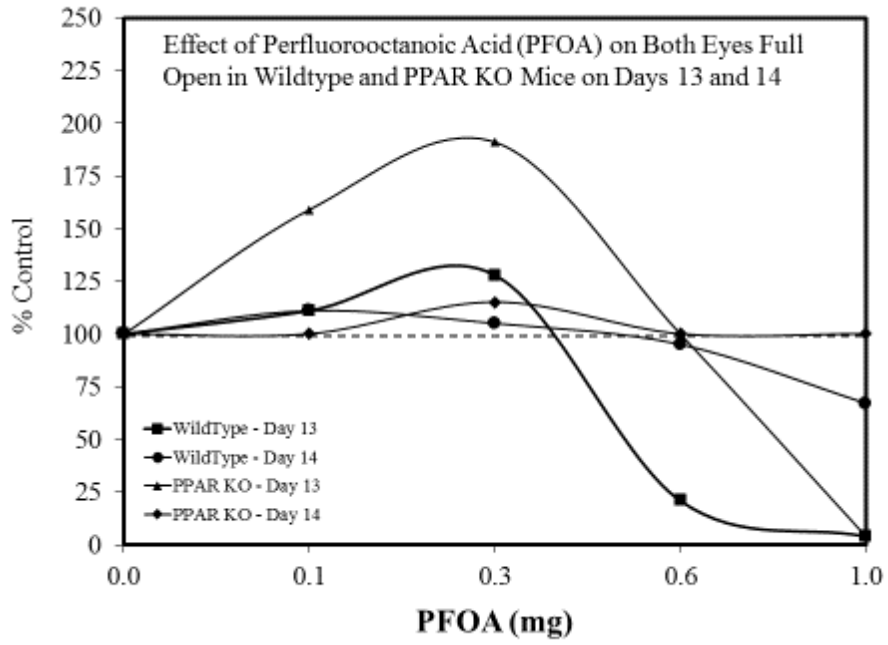


In the report of Das et al. (2015) a key endpoint to be assessed was the occurrence of both eyes opening. It is a measure of developmental performance and maturity. The PFAS treatment at high doses delayed the eye opening. However, in another study (Abbott et al.,

2007) with PFOA, one not cited as a key study - using a broader range of exposures, reported that eye opening in the low dose groups occurred earlier than in the control group (Figure 4). This indicated not only a threshold response but also a potentially enhanced performance at doses below the threshold. For example, this may be similar to when a child starts to walk at 10 months of age rather than at 12 months.

The intention of this discussion is, in part, to illustrate the importance of assessing a broad dose response spectrum. Failure to do so can led to the exclusion of hormetic responses regardless of whether they show a harmful or beneficial response. The hormetic findings for eyelid opening with PFOA suggest the need for PFNA to have been tested over a lower dosage range.

Figure 4. Effect of perfluorooctanoic acid (PFOA) on both eyes full open in Wiltype and PPAR KO mice on Days 13 and 14 (based on Abbott et al., 2007)



3.9 PFNA Human Equivalent Dose (HED), Page 10

Key Finding: As discussed in Sections 3.1, 3.2 & 3.3. SAW failed to discuss the use of the appropriate dose adjustment from mice to humans based on USEPA (1991) guidelines.

These estimations of half-life will not be needed if the appropriate dosimetric adjustment is Cmax, as stated above. Otherwise, the work group needs to carefully consider whether all sources of PFNA were addressed in the Zhang et al. (2013) paper. At a recent Society of Environmental Toxicology and Chemistry (SETAC) meeting, it was demonstrated that unexpected sources of PFAS were potentially house-hold dust and commercial products. Consideration of household dust and commercial products, if not already included, would result in shorter and more appropriate half-lives than suggested by Zhang et al. or other human observational studies. Shorter half-lives would result in the use of smaller uncertainty factors and higher safe doses.

3.10 PFNA Toxicity Value, Page 11

Key Finding: Using uncertainty factors on internal doses needs justification.

This division assumes that the kinetics are linear from the extrapolated serum Point of Departure or POD to the serum level associated with the HBV. Are they? If so, then this division is appropriate. If not, then the appropriate adjustment might be either greater or smaller. Irrespective of the outcome, the SAW needs to address and justify the approach to allow others to determine if the uncertainty was appropriate.

3.11 PFNA Exposure Parameters, Page 11

Key Finding: The exposure scenario needs to match the exposure that caused the critical effect.

The choice of a breast-fed infant exposure as the target subpopulation is not correct. The critical effect occurs in the fetus on an in-utero exposure and not in pups from postnatal

exposure via breast-milk. In fact, exposures to breast feeding infants were not investigated, making adverse effects to this target subpopulation speculation. However, this lack of data appears to be one reason for the 10-fold uncertainty factor for incomplete database, and therefore, reliance on a breast-milk exposure is again not needed since this data gap is addressed in the use of this uncertainty factor. In other words, the SAW appears to have added additional levels uncertainty factors when it was unnecessary.

3.12 PFOA Use of One Dose, Page 12

> **Key Finding**: ATSDR's choice of study is not supportable due to small n, only one dose, and likely pup-based statistics.

The use of a single dose Koskela et al. (2016) is particularly of concern in a study that employed a very modest sample size, that is, only 8-10 mice/treatment per comparison and when there was no information provided concerning historical control group responses for the endpoints studied. Furthermore, this is the only key study used by SAW in which the animals received the dosing more normally via food rather than via a gavage like process. These two reasons raised substantial concerns over the use by SAW of such a limited study for generation of the HBVs. Furthermore, the decreased time spent in the darkened area by the PFOS males as reported in this study does not have to be interpreted as a negative or adverse effect. The response of these males could be interpreted as displaying heighten caution, rather than the opposite of enhanced exploratory behavior had they exceeded the response of the control. A cautionary response may be an adaptive response in specific biological contexts.

In contrast, the study used by USEPA, Lau et al. (2006), is recommended because of more animals, more doses and a more standard design. However, consider developing a benchmark dose, lower confidence limit (BMDL) rather than a LOAEL from the Lau et al. (2006) study as the point of departure.

3.13 PFHxA, Page 14

Key Finding: This is a simple general observation: How can the HBV developed for this chemical be 40,000-fold different than its closely related analogs?

The toxicology database for PFHxA is robust and consists of multiple acute toxicity studies, three subchronic studies (one 28-day and two 90-day studies all conducted in rats), two developmental/reproductive toxicity studies (one in mice and one in rats), one two-year carcinogenicity study (in rats), and multiple toxicokinetics studies [see Luz et al. (2019) for a review of the PFHxA toxicology database], however, as SAW incorrectly states "no additional developmental data in a second species, as part of their rationale for applying a database uncertainty factor of 10.

Iwai and Hoberman (2014) conducted a combined reproductive and developmental toxicity study in mice, while Loveless et al. (2009) conducted reproductive and developmental toxicity studies in rats. A database uncertainty factor of 3-fold would be a better judgment.

In addition, SAW leaves a critical question unanswered: Are the chemistries sufficiently different in toxicity among a 6 carbon PFAS, 8 carbon PFAS and 9 carbon PFAS to warrant such an extreme difference in HBVs? The estimated safe dose for this PFHxA is ~ 40,000-fold higher than others. Differences in toxicity due to small changes in closely related structures are not uncommon (e.g., ethanol versus methanol). However, the proposed magnitude difference needs to be carefully investigated, since it implies that one or more of these proposed safe doses are not done correctly. Note: the toxicity value should be 0.083 mg/kg-day.

3.14 PFOS, High Dose Levels, Page 16

Key Finding: The comments below are simply a general observation, likely not known to the public.

The dose range used in the key studies by SAW for the generation of the HBVs ranged from 0.5 to 500 mg/kg.

Example studies include:

- Dong et al., (2009) administered PFOS to mice daily for 60 days at doses of 0, 0.5, 5, 25, 50, and 125 mg/kg. The laboratory animals at 25, 50, and 125 mg/kg dose levels showed significant weight loss, thus stress (acute toxicity).

- Lau et al., (2005) administered PFOS to mice from gestational day 1 to 17 at doses of 1, 3, 5, 10, 20, and 40 mg/kg. The laboratory animals at 10, 20 and 40mg/kg dose levels showed significant weight loss, thus stress (acute toxicity to the mothers).

A dose of 40 mg/kg for a human weighing 80 kg (175 pounds) is relative equivalent to a human consuming 2400 mg of PFAS per day or about a teaspoon of PFAS per day. Doses of approximately 10 to 20 mg/kg were generally associated with significant weight loss by these laboratory animals. In other words, these animals were significantly stressed.

Dose levels approximately one order of magnitude below these overtly toxic levels are then generally used to identify potential toxicity endpoints in the laboratory animals. It is understood that this is accepted standard of practice in toxicology.

The observation is whether the public is aware of the relatively high doses of PFAS being fed to laboratory animals to elicit toxic effects. Then, is the public really aware of the layers of calculations and uncertainty factors that are applied to that dose level (e.g., equivalent to eating a teaspoon of PFAS per day in humans) to calculate in a HBV of a part-per-trillion.

The answer is likely no. Again, the take-away from this independent technical review is that it is the scientifically unusual assumptions and uncertainty factors used in the SAW calculations that are driving the HBVs into the parts-per-trillion range, not the underlying science.

In conclusion, it is reasonable to assume that the normal defense mechanisms (e.g., repair mechanisms, metabolism, immune responses, etc.) are being overwhelmed at these high doses being fed to laboratory animals (i.e., a human consuming close to a teaspoon of PFAS per day).

3.15 PFOS Toxicity Value and Exposure Parameters, Page 17

Key Finding: Same comments as for PFNA (i.e. 3.10 above).

For the toxicity value section, an assumption is being made that the kinetics are linear from the extrapolated serum Point of Departure or POD to the serum level associated with the HBV. Are they? Otherwise, the uncertainty factors used may not be appropriate. For the exposure parameters section, if the critical effect is in adults and an uncertainty factor for database factor is not being used, why is the breast-fed infant exposure being used? The appropriate exposure scenario is the adult.

3.16 PFHxS, Page 18

Key Finding: How can the health value developed for this chemical be ~8,000-fold lower than its acid analog? This does not appear to make biological sense.

How is it possible that the acid, PFHxA, is so much less toxic than the associated sulfate as shown here? This difference is ~8,000-fold. The SAW needs to address this difference. Otherwise, it gives the impression that it was missed. If missed, then the SAW should consider whether such a large difference makes biological sense.

3.17 PFHxS Human Equivalent Dose (HED), Page 18

Key Finding: SAW needs to confirm that AUC and not Cmax is the appropriate dosimeter.

SAW determined that the critical effect, decreased serum free thyroxin (T4) levels, is associated with AUC as the dosimeter, and not Cmax. Is that correct? Has the gavage nature of the exposure been considered? Furthermore, the recent Society of Environmental Toxicology and Chemistry (SETAC) meeting describe PFAS exposures is pervasive. Did the human observational study of Sundstrom et al. (2012) account for all exposures? If not, then the stated half-life might be too long because the population might be receiving a continuous source of PFAS. A more scientifically appropriate half-life might result in a higher safe dose.

3.18 PFHxS Uncertainty Factors, Page 19

Key Finding: Rats are more sensitive to thyroid hormone changes than humans. This uncertainty factor is not appropriate.

The choice of a toxicodynamic factor of 3 is not consistent with the underlying biological differences between rat and human for thyroid hormone disturbance. Because rats are more sensitive than humans to thyroid effects, rats need 10 times the replacement T4 than humans, due to human binding of T4 in the serum (Casarett and Doull 2018). This 3-fold factor could be proposed as 0.1, as it was in many independent peer reviews during USEPA's RfD development for perchlorate.

USEPA actually used a value of 1.0. Thus, the safe dose would be 3-fold higher with USEPA's choice or 30-fold higher with the recommendation from the peer review.

3.19 PFHxS Toxicity Value and Exposure Parameters, Page 19

Key Finding: Same comments as for PFNA (i.e. 3.10 above).

For the toxicity value section, an assumption is being made that the kinetics are linear from the extrapolated serum Point of Departure or POD to the serum level associated with the health based value. Are they? Otherwise, the uncertainty factors used may not be appropriate. For the exposure parameters section, if the critical effect is in adults and an uncertainty factor for database factor is not being used, why is the breast fed infant exposure being used? The appropriate exposure scenario is the adult.

3.20 PFBS Human Equivalent Dose (HED), Toxicity Value, Exposure Parameters, Page 21

Key Finding: Same comments as for PFNA (i.e. 3.10 above).

For the human equivalent dose section, SAW used a dosimetric adjustment factor of 316 (i.e., the ratio of the human half-life to the mouse half-life) to derive the Human Equivalent Dose (HED). This approach may not be warranted based on USEPA who has derived toxicity values for PFBS on two separate occasions. In 2014, USEPA derived a Provisional Peer-Reviewed Toxicity Value for PFBS, and in 2018 USEPA released their draft toxicity assessment for PFBS. For both assessments, USEPA determined that allometric body-weight scaling to the 3/4 power was the most appropriate method to derive the HED, which resulted in use of a factor of approximately 4. Allometric body-weight scaling appears to be the most appropriate method for deriving an HED for PFBS, and use of an allometric body-weight scaling factor would increase the PFBS toxicity value and subsequent HBV by approximately a factor of 75. At a minimum, the SAW must explain why it departed from USEPA practice.

For the toxicity value section, an assumption is being made that the kinetics are linear from the extrapolated serum Point of Departure or POD to the serum level associated with the health based value. Are they? Otherwise, the uncertainty factors used may not be appropriate. For the exposure parameters section, if the critical effect is in newborns after day 1, then the effect is most likely from in utero exposure and the exposure scenario to the pregnant dam should be used, not breast-fed infants.

3.21 GenX Uncertainty Factors, Page 23

Key Finding: SAW needs to confirm its understanding of uncertainty factor justification.

The lack of epidemiological information is not a basis for this use of a database uncertainty factor. That said, the other stated gaps are sufficient to suggest the use of 3-fold (thus, no difference to the HBV).

3.22 Laboratory Animal Studies – Stress & Behavioral Effects

Key Finding: Standard operating procedures were not provided to address the potential for stress and behavioral effects in the laboratory animals. These study design limitations can have profound effects on the results of the toxicological studies.

Use of Controls, Animal Husbandry, Animal Stress

The key studies used by SAW to develop the HBVs did not provide standard operating procedures to address the potential for induced stress and potential for exasperated toxicological effects. This includes the studies by Das et al., (2015); Dong et al., (2009); Feng et al., (2017); and Klaunig et al., (2015). The implications of this study design limitation would create the possibility that these study protocols may have exacerbated the chemical toxicity by an undetermined amount and done so in a differential manner across control and treatment groups affecting study validity thereby compromising the use of these experiments for regulatory applications. Refer to Appendix B for further discussion.

Reporting and Controlling for Aggressive Behavior in Laboratory Animals

The key studies used by SAW to develop the HBVs, including Klaunig et al., (2015), did not provide standard operating procedures for reporting and controlling for aggressive behavior in laboratory animals. Of importance is that these actions can lead to profound changes in stress physiology, immune responses following wounding and other altered physiological processes. Thus, there is the possibility that these study protocols may have exacerbated the chemical toxicity by an undetermined amount and done so in a differential manner across control and treatment groups affecting study validity thereby compromising the use of these experiments for regulatory applications. Refer to Appendix B for further discussion.

Technician Variability

The key studies used by SAW to develop the HBVs did not provide standard operating procedures for addressing technician variability. These procedures affect laboratory animal behavior and thus numerous biological processes. Thus, there is the possibility that these

study protocols may have exacerbated the chemical toxicity by an undetermined amount and done so in a differential manner across control and treatment groups affecting study validity thereby compromising the use of these experiments for regulatory applications. Refer to Appendix B for further discussion.

3.23 Uncertainty Factors for Database Deficiencies

Key Finding: Uncertainty factors for database deficiencies of up to 10x are used by SAW for many of the HBVs. This reduction in the HBV (or future MCL) by 10-fold can be obviated by the generation of a robust database. Studies that could be helpful included developmental toxicity studies in two species, a two-generation reproductive study and standard toxicity studies in different species.

3.24 Relative Source Contribution

Key Finding: Given the 8-carbon PFAS are no longer in production, and thus no longer in commercial products used by the public, when will a higher RSCs of 0.8 or 1.0 be used in the future HBV or MCL calculations? Based on this consideration, should separate HBVs (and thus MCLs) be produced for the 8-carbon PFAS versus the smaller replacement PFAS?

3.25 USEPA MCL Process

Key Finding: The risk assessment process for generating the HBVs (and thus upcoming State of Michigan MCL) was compared to the typical process used by the USEPA in generating their MCLs. Simply put, there is and will be a significant difference level of effort and budget for the upcoming USEPA MCL process. This level of effort, once completed, is anticipated to produce significantly higher MCL value(s) than the SAW HBVs.

Noteworthy is the approximately 30 scientists and toxicologists employed to generate the USEPA Drinking Water Health Advisory. The USEPA effort will be expected to increase significantly during development of their upcoming PFAS MCL(s). Tens of scientists and peer

review candidates are usually deployed for the effort. Considerable budgets will also be set aside, budgets that are typically not available within individual U.S. States. There are over 2000 studies alone on PFOA and PFOS as well as over 400 human epidemiology studies. The pool of multidisciplinary scientists and toxicologists needed to review the PFAS literature will undoubtably also include several of the known, for lack of better words, premier toxicologists. As with other professions such as medicine and engineering, there are also a range of different toxicologist specialties that will need to be consulted as a part of this effort. As the science of PFAS is highly unsettled, it will take this level of effort and budget to resolve many of the key technical issues identified in the HBV calculations. Part of this effort will also be in completing the ongoing studies being conducted, or proposed, by the USEPA and the world scientific community to fill identified data gaps in the PFAS literature. Using scientifically unusual calculations and assumptions as well as questionable uncertainty factors is not the interim answer.

3.26 MCL Process, Cost Analysis

> **Key Finding:** A cost analysis consistent with the USEPA MCL process does not appear to have been addressed by SAW in generating the proposed HBVs (and thus future MCL).

The Safe Drinking Water Act (SDWA) requires USEPA to prepare a health risk reduction and cost analysis (HRRCA) in support of any National Primary Drinking Water Regulations (NPDWR). Under the SDWA, the USEPA must analyze the quantifiable and non-quantifiable benefits that are likely to occur as the result of compliance with the proposed standard. The USEPA must also analyze certain increased costs that will result from the proposed drinking water standard.

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APPENDICES

Appendix A
Human Clinical Dosing Study, Elcombe et al. (2013)

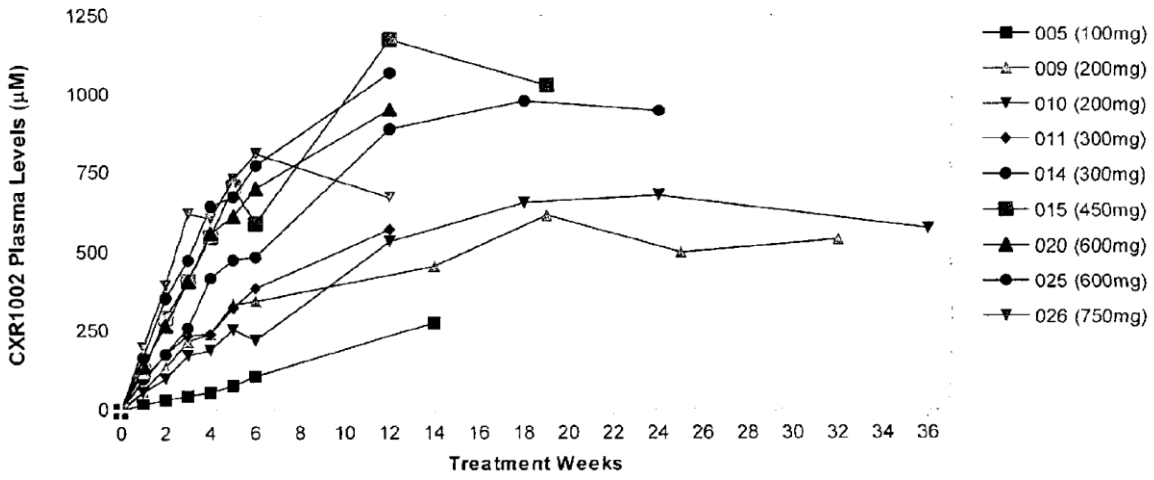
Forty-three patients in the Elcombe et al. (2013) study received PFOA once a week by capsule for 6 weeks at different doses. Nine of them continued after 6 weeks and an apparent plateau was reach as shown in the figure below. Tentative conclusion from this figure is that the apparent half-life of PFOA is 5 weeks (~1/5th the plateau time).

Elcombe et al. (2013) weekly doses in excess of 6 weeks, shown as Figure 78 of their text.

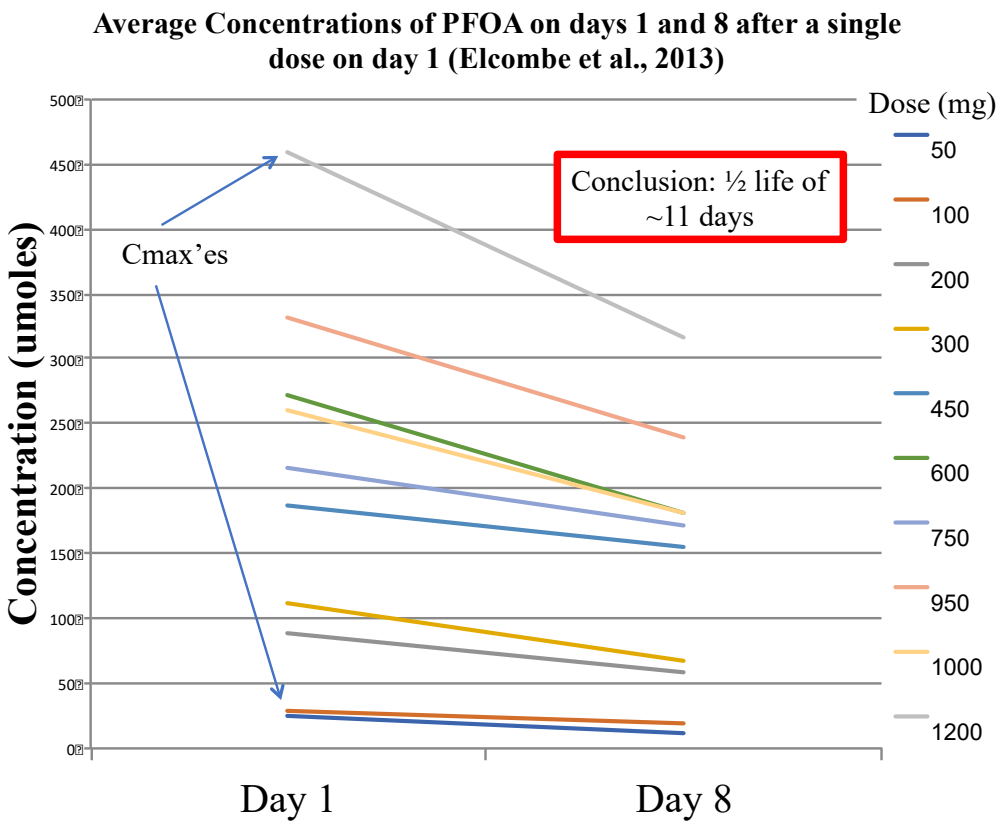
Conclusion: ½ life is 5 weeks

Figure 78

CXR1002 Plasma Exposure Levels beyond the Initial 6-week Assessment Period



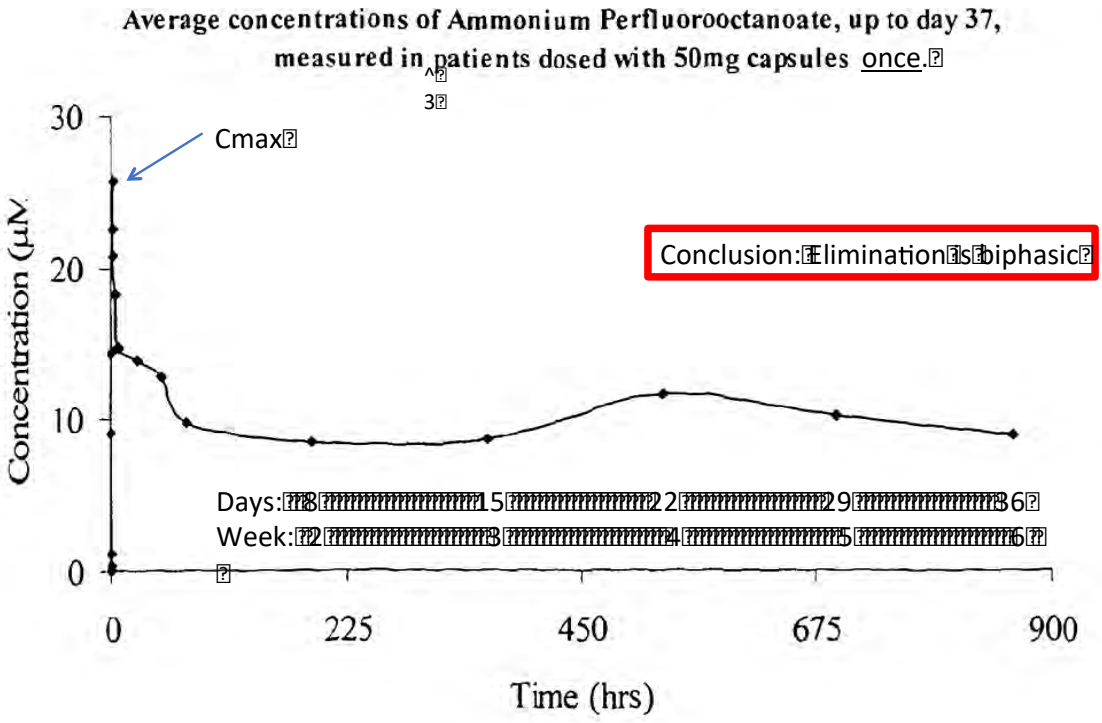
Forty-three patients in the Elcombe et al. (2013) study received PFOA once a week by capsule for 6 weeks at different doses. The figure below shows the average decrease in PFOA in each dose group over the first week, that is from the first dose to the time just before the second dose. The apparent half-life is 11 days, very different from the previous figure. Why the difference?



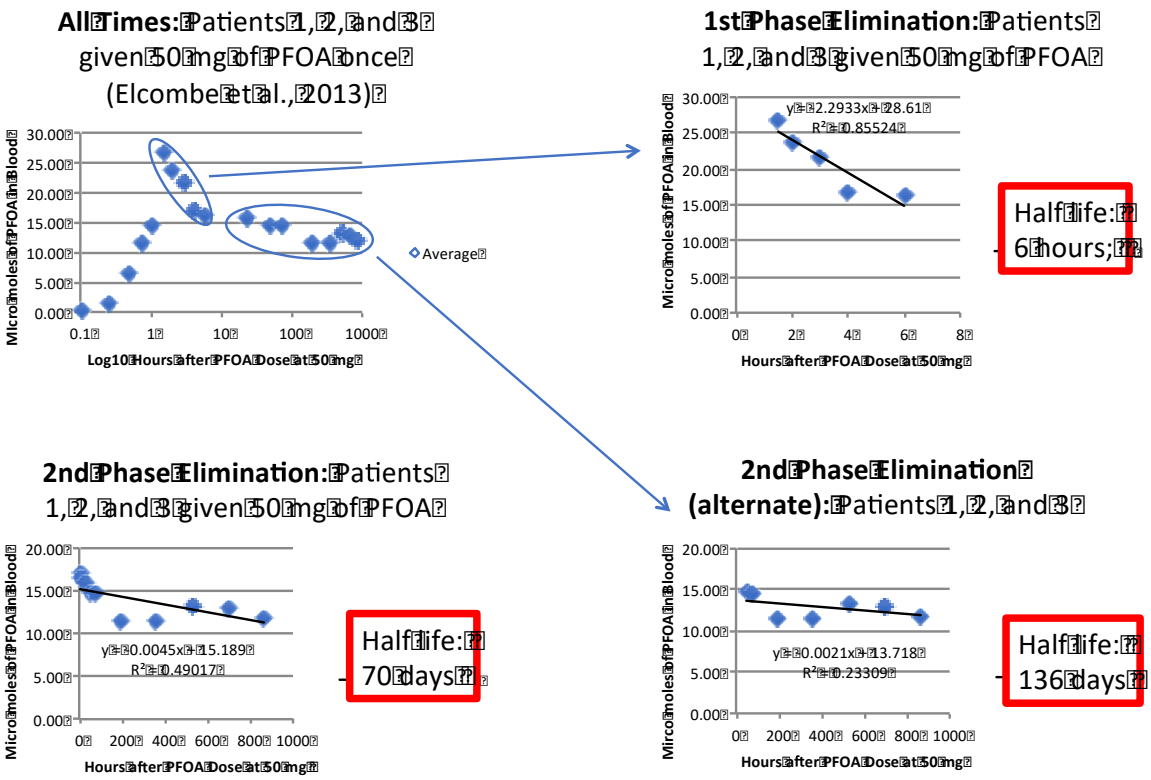
Three patients in the Elcombe et al. (2013) study received only one dose of PFOA at 50 mg and were followed for 6 weeks. The average decline in serum concentration is shown below. The tentative conclusion from this figure is that the apparent half-life of PFOA is biphasic, which helps explain why the estimated half-lives from the first two figures were different.

Figure 14

Elcombe et al. (2013)



A tentative analysis of kinetic information from the three patients of the previous figure is possible. The half-life of the initial phase appears to be 6 hours. The half-life of the second phase appears to be 70 to 140 days.



Appendix B
Laboratory Animal Studies – Stress & Behavioral Effects

Use of Controls, Animal Husbandry, Animal Stress

The process of picking up and handing the animal induces stress. The fact that one employs a vehicle control that is gavaged does not have the potential to detect if there is an interaction between the chemical treatment and the induced stress. The control group addresses the issue of the stress, but not for potential stress-chemical interaction. That handling stress could interact with chemical induced toxicity enhancing toxicity beyond that of the chemical treatment alone was reported by Calabrese (2001). This study reported that prior handling of rats before carbon tetrachloride exposure enhanced liver toxicity by 3-fold. In that study, the handling process was dissected into multiple components to determine which part of the handling process may have affected the increase in toxicity. In the study, all that was required to enhance toxicity was the act of briefly picking up the rat for several days prior to treatment. The toxicity was not further enhanced by additional handling, placing the rat in a restraining plexiglass frame, modestly warming the tail, taking blood from the tail vein and other procedures.

Reporting and Controlling for Aggressive Behavior in Laboratory Animals

According to Deacon (2006), male mice housed in groups often display aggressive behaviors, as well as fighting, biting and wounding. The biting/wounding typically would occur on the back, tail and genitals. Substantial literature indicates that many factors can contribute to such aggressive behaviors and fighting/wounding, including strain specific genetic factors, gender, age, cage size, animal density in the cages, presence or absence of environmental enrichment and other factors. Of importance is that these actions can lead to profound changes in stress physiology, immune responses following wounding and other altered physiological processes. Some of the key studies provided a focus on immune parameters. There was no information provided concerning how the key studies reported any information on these behavior parameters. Furthermore, several of the studies included periodic random selection/removal of animals for testing. However, each mouse caging condition is expected

to have a unique social hierarchy. In the selection of random animals from each cage, it is unlikely that the selected animals would have the same social status as in other cages. These conditions reintroduce a new round of aggressive behaviors, including fighting, biting and wounding. This would have the potential to create another new variable between the various treatment groups and the control group. Some of the key studies in fact employed well-recognized aggressive mouse strains such as the CD-1 stain.

Hierarchy in the mouse cage can affect both behavior and gene expression for hypothalamus corticotropin releasing hormone (CRH) and hippocampal serotonin receptor subtypes in the male C57/BL/6 mouse model used in several of the key studies (Horii et al., 2017). CRH can suppress appetite, increase anxiety and enhance inflammation amongst many physiological changes that could impact the reported study endpoints. CRH is also synthesized in T-lymphocytes, a cell of particular relevance to immune endpoints. The increased synthesis of hypothalamus serotonin has the capacity affect dietary behavior, inflammatory responses and broad spectrum of behavioral responses.

In the Klaunig et al. 2015 rat study the animals were in single cages (i.e., one rat/cage). Rats are highly social and single rat housing, especially for a prolonged time as in this study, leads to considerable stress in the animals. In such cases, the adrenals enlarge, corticosterone rises, and the rats become physiologically somewhat abnormal (Deacon, 2006).

Technician Variabilities that Go Unreported

The technician/animal handler and others in the room with the animals can have a major impact on the outcome of an experiment. Rodents can be very sensitive to many features of people that are underappreciated. For example, their sense of smell is approximately 100,000 times more sensitive than that of humans (Deacon, 2006). Thus, rodents can perceive and be affected by various perfumes of differing strengths and deodorants. This is also the case for creating noise of considerably different types and intensities (Deacon, 2006). In no case did the published papers indicate any information about whether the technicians were instructed not to use perfumes, deodorants other detectable materials. There is no information on whether the same technician handled all the treatment groups as well as the

control groups. There was no information provided concerning how the animals were picked up. It is well known that mice are calmer when picked up by hand and cupped rather than by the tail (Charles River, 2012; Hurst and West, 2010). There was no information provided concerning how they were picked up and any variation between animals, cages, treatments and technicians. There is no information concerning how many different technicians were used and when during these key studies. There was also no information concerning the possibility of fire alarms occurring (i.e., due to maintenance accidental occurrences and other circumstances) during the studies. If these occurred then it would be important to know when, how often, the decibel level and the duration of the exposures.

The key studies used by SAW in generating the HBVs did not provide (with one exception) information on bedding and how often it was changed. This was also the case for cage cleaning. Yet, studies indicate that these findings can markedly affect aggressive behaviors in mice (Lidster et al., 2019). For example, cage cleaning alters scent marks, which can disrupt social hierarchy and decrease social stability, leading to more fighting. As for bedding, there is much variation in how it may be handled. Some studies throw out soiled bedding, others transfer it, amongst other practices. All of these options affect behavior and numerous biological processes. The SAW report did not document the practices and to assess how it may be affected the outcome of the study.

Smith, Ian (EGLE)

From: Tina Porzondek [redacted]@plainfieldmi.org>
Sent: Tuesday, January 28, 2020 1:23 PM
To: EGLE-PFAS-RuleMaking
Cc: Cameron VanWyngarden
Subject: Resolution for PFAS MCL Support -Plainfield Charter Township
Attachments: 2020-02 Resolution for PFAS MCL Support.pdf

Categories: Blue Category

Dear Ms. Ruch,

Attached is a copy of Plainfield Charter Township's Resolution for PFAS MCL Support adopted on January 28, 2020. A certified hard copy of the resolution was mailed out to you this afternoon. Please except this resolution as part of the public record.

Sincerely,

Tina Porzondek
Deputy Clerk/ Manager of Records and Elections/FOIA Coordinator
6161 Belmont Ave. NE/Belmont, MI 49306
Office ph: [redacted] /Direct ph: [redacted] /Fax [redacted]
www.plainfieldmi.org

PLAINFIELD CHARTER TOWNSHIP
KENT COUNTY, MICHIGAN

RESOLUTION NO. 2020-02

At a regular meeting of the Township Board of the Charter Township of Plainfield, held in the Township Offices, 6161 Belmont Avenue NE, Belmont, Michigan, on the 27th day of January 2020, at 7:00 PM., the following resolution was offered by Member Greene and supported by Member Pfaff:

WHEREAS, Plainfield Charter Township has in recent years been at the epicenter of one of the largest known per- and polyfluoroalkyl substances (PFAS) contamination sites in the State of Michigan; and,

WHEREAS, Residents of Plainfield Charter Township have been negatively affected by PFAS contamination by exposure through private wells and through the public municipal water system; and,

WHEREAS, Plainfield Charter Township has been a statewide leader in investigating, measuring, and treating municipal drinking water for the presence of per- and polyfluoroalkyl substances (PFAS); and,

WHEREAS, Plainfield Charter Township has implemented a granular activated carbon (GAC) system at the Township Water Treatment Plant that has proven to safely and effectively reduce or eliminate the presence of PFAS levels in drinking water; and,

WHEREAS, there are currently no uniform standards to regulate and monitor drinking water for the presence of per- and polyfluoroalkyl substances in drinking water; and,

WHEREAS, the Michigan PFAS Action Response Team (MPART) has proposed the development of health-based Maximum Containment Levels (MCLs) to monitor for the presence of seven per- and polyfluoroalkyl substances (PFAS) in municipal drinking water; and,

WHEREAS, in January 2020 the Michigan Department of Environment, Great Lakes, and Energy (EGLE), Drinking Water and Environmental Health Division, is accepting public comments on the proposed Maximum Contaminant Levels developed by MPART; and,

WHEREAS, as a leader in PFAS mitigation, Plainfield Charter Township supports the efforts of the State of Michigan, EGLE, and MPART in the establishment and continued research to develop MCLs for the purpose of ensuring safe drinking water by establishing maximum contaminant levels, sampling requirements, public notification requirements, and laboratory certification criteria.

NOW, THEREFORE BE IT RESOLVED, that the Plainfield Township Board of Trustees supports the State of Michigan, EGLE, and MPART in their efforts to establish health-based maximum contaminant levels, sampling requirements, public notification requirements, and laboratory certification criteria that are supported by sound science to ensure safe municipal drinking water.

BE IT FURTHER RESOLVED, that the Clerk of Plainfield Charter Township submit this Resolution, as approved by the Plainfield Charter Township Board of Trustees on January 27, 2020 to the State of Michigan, Michigan Department of Environment, Great Lakes, and Energy, to be a part of the public record received by 5pm on January 31, 2020 to the distribution address stated below.

Distribution Address:
State of Michigan
Department of Environment, Great Lakes, and Energy
Drinking Water and Environmental Health Division
Attention: Suzann Ruch
P.O. Box 3081
Lansing, MI 48909-8311
EGLE-PFAS-RuleMaking@Michigan.gov

YEAS: Homan, Morrow, Pfaff, Brinkman, Hagedorn, Greene, Postmus

NAYS: None

ABSENT: None

ABSTAIN: None

RESOLUTION 2020-02 DECLARED ADOPTED.

Cathleen Postmus

Cathleen Postmus
Plainfield Charter Township Clerk

Smith, Ian (EGLE)

From: Samantha Nellis <[redacted]@huronpines.org>
Sent: Thursday, January 30, 2020 4:08 PM
To: EGLE-PFAS-RuleMaking
Cc: [redacted]@gmail.com
Subject: RE: Proposed PFAS Drinking Water Standards Public Comment Period
Attachments: HuronPines_PublicComment_Jan2020.pdf

Ms. Ruch,

I have attached the public comment from Huron Pines regarding the proposed PFAS drinking regulations. Please contact me if you have any questions. We appreciate you taking our comments into consideration.

Sincerely,
Samantha Nellis
--
Samantha Nellis
Watershed Project Manager

Huron Pines
4241 Old US 27 South, Suite 2
Gaylord, MI 49735
[redacted]@huronpines.org
www.huronpines.org

Huron Pines

4241 Old US 27 South, Suite 2
Gaylord, MI 49735
[redacted]
huronpines.org

January 29, 2020

Suzann Ruch
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
PO Box 30817
Lansing, Michigan 48909-8311

Re: Proposed Drinking Water Standards for PFAS in Michigan

Dear Ms. Ruch,

Huron Pines is a conservation non-profit serving Northern Michigan. It is our mission at Huron Pines to conserve and enhance Northern Michigan's natural resources to ensure healthy water, protected places and vibrant communities. For over 45 years, Huron Pines has worked to improve economic, environmental, educational and recreational opportunities. Engaging people in conservation stewardship supports sustainable, empowered communities rich with protected natural resources.

As a major environmental contaminant to our soil and water, Huron Pines has been following the developments concerning PFAS contamination and has been engaging with affected communities. In 2019, we became an active member of the Camp Grayling Joint Maneuver Training Center Restoration Advisory Board (RAB) in a natural resource advisory role to discuss PFAS water contamination concerns and possible solutions. Through this role we have heard the concerns and difficulties that private citizens face regarding their water.

Huron Pines supports the proposed Maximum Contaminate Level regulation proposed by EGLE. We feel it is a necessary first step in order to monitor public drinking supplies and provide clean water to citizens. However, due to the rapidly evolving science and understanding of PFAS, we support and reiterate the suggestion made by others that this rule change needs to incorporate, at minimum, a two-year review process. This review must incorporate new knowledge on the health risks of the 7 proposed compounds and add compounds to be regulated as toxicity becomes evident.

While Michigan has been leading the way to address these forever chemicals, there is still a long road ahead. Assistance and guidance to the many households on private wells is of the utmost importance and it is our hope that EGLE work closely with local Health Departments to address these challenges. We need to move beyond merely filtering drinking water and find solutions to remove these compounds from the environment for safe consumption and to ensure safe recreation such as swimming, fishing and hunting. Huron Pines is committed to monitoring advancements in restoration and removal techniques in order to protect natural resources.

We hope that you will take our suggestions under consideration.

Sincerely,

Ned Caveney
Huron Pines Policy Committee Chair

Smith, Ian (EGLE)

From: Rep. Donna Lasinski (District 52) <DonnaLasinski@house.mi.gov>
Sent: Thursday, January 30, 2020 1:07 PM
To: EGLE-PFAS-RuleMaking
Subject: State Representative Donna Lasinski's Comment on the proposed PFAS Rule
Attachments: PFASRulePublicComment.Rep.Lasinski.pdf

I strongly urge the Dept. of Environment, Great Lakes and Energy to formalize the proposed PFAS rule. I have attached my comment and included it in the body of my email.

January 30, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311

Dear Michigan Department of Environment, Great Lakes and Energy,

Ensuring that we have safe, clean and healthy drinking water for all residents and communities throughout the state of Michigan is one of my top priorities. I am pleased to see the Michigan Department of Environment, Great Lakes and Energy (EGLE) moving in the right direction to protect our water from harmful contaminants such as PFAS.

The proposed rule by EGLE to establish enforceable drinking water standards for seven different types of PFAS is a necessary step to protect our drinking water across Michigan. Within my own 52nd House District we are faced with PFAS water contaminants, and we must take strong action to prevent future contaminations and hold those accountable to clean up.

This proposed rule is such an important step to take in keeping our drinking water safe, but there is so much more to be done and that can be done to prevent PFAS contaminants in our drinking water. I will continue to fight and work hard to prevent further PFAS contamination of our drinking water and I encourage EGLE to implement the proposed rule and take increased action in the fight against PFAS contaminants.

Sincerely,

Donna Lasinski
State Representative
52nd House District

52ND DISTRICT
STATE CAPITOL
P.O. BOX 30014
LANSING, MI 48909-7514
PHONE: (517) 373-0828
FAX: (517) 373-5783
E-MAIL: donnalasinski@house.mi.gov

MICHIGAN HOUSE OF REPRESENTATIVES
DONNA LASINSKI
STATE REPRESENTATIVE

COMMITTEES:
ENERGY POLICY,
MINORITY VICE CHAIR
COMMUNICATIONS
AND TECHNOLOGY
INSURANCE

January 30, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311

Dear Michigan Department of Environment, Great Lakes and Energy,

Ensuring that we have safe, clean and healthy drinking water for all residents and communities throughout the state of Michigan is one of my top priorities. I am pleased to see the Michigan Department of Environment, Great Lakes and Energy (EGLE) moving in the right direction to protect our water from harmful contaminants such as PFAS.

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This proposed rule is an important step to take in keeping our drinking water safe, but there is so much more to be done and that can be done to prevent PFAS contaminants in our drinking water. I will continue to fight and work hard to prevent further PFAS contamination of our drinking water and I encourage EGLE to implement the proposed rule and take increased action in the fight against PFAS contaminants.

Sincerely,

Donna Lasinski
State Representative
52nd House District

Smith, Ian (EGLE)

From: Scott Harvey [redacted]@gmail.com>
Sent: Tuesday, January 7, 2020 11:27 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Rule
Attachments: Plainfield Contamination Rev 7.docx

Follow Up Flag: Follow up
Flag Status: Flagged

I plan on sharing my support and concerns at the PFAS Rule public comment in Grand Rapids. I am attaching the Plainfield Charter Township Ground Water Contamination Chronology document I will be sharing at this hearing.

Sincerely

Kennth Scott Harvey

PLAINFIELD CHARTER TOWNSHIP

GROUND WATER CONTAMINATION

CHRONOLOGY

PREPARED BY KENNETH SCOTT HARVEY
Former Plainfield Charter Township Clerk 2008 to 2013
Email: [redacted]@prodigy.net
Phone: [redacted]

OVERVIEW:

The following chronology has been prepared to provide from excerpts of Township Board and Committee meetings. These are highlights of the reporting by Plainfield Charter Township on the contamination of the aquifers by industrial liquid waste from the State Disposal Landfill EPA Superfund site. The ground water being used by the Plainfield Municipal Water Department has been polluted for decades. Volatile Organic Compounds (VOC's) emanating from the toxic plume generated from the industrial liquid wastes dump at this site from the 1960's to mid 1970's contaminated drinking water wells and the township municipal wells.

After the VOC's were discovered Waste Management Inc. and Plainfield Charter Township installed an Air Stripper at the municipal water plant to remove most of these toxic chemicals. This process does not remove the PFAS chemicals discovered throughout Norther Kent County.

PFAS chemicals are present in the what is known as the Versluis Wellfield. This was a major source for drinking water to this municipal water system. This has resulted in these residents being exposed to a toxic chemical cocktail that includes these emergent PFAS contaminants.

There is a proposed settlement between the State of Michigan, Plainfield Charter, Algoma Township and Wolverine World Wide Inc. to provide Plainfield Municipal water to around 1,000 additional households. This water currently is treated to remove PFAS and VOC's.

My concern is that in the event the proposed consent decree is approved; Plainfield Charter Township will continue to use the wellfields exposed to these toxic chemicals. Should the agreement not require the cleanup of the dump sites scattered throughout Northern Kent County will remain contaminated and present future generations with potential health concerns.

I support the adoption of the proposed PFAS Rule for Michigan, but encourage continued health studies to insure these bio-accumulating compounds are being regulated at levels that are harmless to the health of future generations.

Chronology of the discovery of contamination of the Plainfield Charter Township Municipal water

I. Township Board Notified

A special meeting of the Plainfield Charter Township Board was called to order at 7:30pm on **December 14, 1987** at Township Hall; Belmont; MI by Supervisor Rekeny.

2. Members present: Supervisor Rekeny, Clerk Morrow, Treasurer Goodspeed, Trustees Groenleer; Malkewitz, Meek, and Vonk.

3. Water Director Vincent Ferrarese reviewed the results of water sampling of the township wells located at Versluis Park. None of these wells are presently in use and the levels of certain chemicals which had caused some concern are extremely low; well within the acceptable 1imits for the public water. The reason the wells are not being used is to give the Kent County Health Department time to test private wells in the area and to try to determine the source of the contamination. Tests will be conducted at the site of old landfills on the East Beltline and on Four Mile. The results of the tests will be available in four to six weeks.

II. Investigation to find alternatives to contaminated water begins

The regular meeting of the Plainfield Charter Township Board was called to order at 8:00pm on **May 16, 1988** at Township Hall, Belmont, MI by Supervisor Rekeny.

11. Mr. Meek reported for the water and sewer committee. The committee recommends that Supervisor Rekeny send a letter to the City of Grand Rapids expressing an interest in the proposed pipeline and the possible connection to their system at some time in the future. She is to request costs and any other information which might be of interest to Plainfield Township. The purpose of this letter is to keep the communication lines open but the letter should not be construed as a proposal to change the operation of our system. Mr. Meek also reported that Prein and Newhof would like to drill five more exploratory wells in the area of the contaminated water in order to continue to try to find the source

and the path of the contamination. Mr. Meek moved, supported by Mrs. Morrow, that five additional wells be drilled to continue to explore the source of contamination of some of the wells in the township. Ayes 6. Nays O. Motion carried.

III. Contamination of residential wells between Superfund site and Versluis wellfields discovered

The regular meeting of the Plainfield Charter Township Board was called to order at 8:00pm on **January 19, 1988** at Township Hall, Belmont, MI by Supervisor Rekeny.

22. Mr. Groenleer submitted the report for the water and sewer committee. The water department continues to monitor the township wells. Some of the water samples on homes on Grand River have been returned to the Kent County Health Department and show no signs of contamination, however, several samples on Hordyk do show contamination. It is the responsibility of the Kent County Health Department to furnish water to the contaminated homes.

VI. Monitoring wells installed

The regular meeting of the Plainfield Charter Township Board was called to order at 8:00pm on **March 21, 1988** at Township Hall, Belmont, MI by Supervisor Rekeny.

15. Mr. Groenleer reported for the water and sewer committee. Monitor wells are being installed and a pattern of contamination is trying to be established which will show the source which is affecting the homes on Hordyk and Walnut Creek. A second monitoring well has been approved for the area east of Grand Rapids Gravel on Grand River Drive. The second phase of Sierra Estates is ready for water installation.

IV. Assistance from the GGREAT requested

A special meeting of the Plainfield Charter Township Board was called to order at 7:30pm on **April 11, 1988** at Township Hall, Belmont, MI by Supervisor Rekeny.

3. Following discussion the Board agreed that the following concerns would be recommended to GGREAT for 1988:

WATER SUPPLY AND QUALITY Plainfield Charter Township operates its own water system and is presently experiencing contamination difficulties in some of the wells which supply water to the entire system. We request assistance in studying the entire system, its source, and the quality of the water produced.

V. Contaminated Versluis well used to supplement to meet increased demand

A special meeting of the Plainfield Charter Township Board was called to order at 7:30pm on **July 11, 1988** at Township Hall, Belmont, MI by Supervisor Rekeny.

4. Water Director Vince Ferrarese explained the history of the restrictions which are now in effect. He reviewed the flyer which has been distributed in both Plainfield and Alpine Townships. There is a shut-off notice with the first warning so that the customer is informed of action which could result if a second call is necessary. Mr. Ferrarese stated that the plant capacity is satisfactory. We do have a problem during peak hours in the early evening and therefore, that is why the hours of 4:00pm to 10:00pm were chosen for the ban. The pond and well levels in mid-June were compared with today. The pond is down two feet from 1982 and 8" from mid-June• The 1eve1 in the cluster well is 35' below the top of the casing and the pumps shut off automatically at 38' below the top of the casing. There are three pumps in the cluster wells and the shallowest has not operated for three weeks. Only two pumps are being used. Also it has been necessary to use the number one well at Versluis Park. In summary: there is no problem with plant capacity some problems with storage (Westgate tank), and all wells at Versluis Park have contamination at low levels.

VII. **Testing and pricing the connection to Grand Rapids continues**

The regular meeting of the Plainfield Charter Township Board was called to order at 8:00pm on **November 21, 1988** at Township Hall, Belmont, MI by Supervisor Rekeny.

13. Mr. Groenleer reported for the water and sewer committee. The committee has met with Mr. and Mrs. Ergang regarding their situation with a 200-front footage assessment for water hookup and suggested that they begin application to rezone their property to R-l residential. The plant will begin the discharge of lime sludge into the Coit Avenue Gravel Company's pond in 1989. The fee for the discharge is less than the cost to have the lime hauled away. Well sampling is being done again by Prein and Newhof for an update of conditions one year after the test wells were drilled. Ed Prein is still trying to get an estimated cost of hooking up to the city of Grand Rapids' water system. The Department of Public Works will begin flow testing the Rockford sewer line on November 27, 1988 to try to determine if infiltration exists between Rockford and the Belmont lift station.

VI. Township desires to remain an independent Municipal Water System

A special meeting of the Plainfield Charter Township Board was called to order at 7:30pm on **December 12, 1988** at Township Hall, Belmont, MI by Supervisor Rekeny.

Mrs. Morrow moved, supported by Mr. Goodspeed, that the Supervisor convey to the city of Grand Rapids that Plainfield's intentions regarding future water requirements are to make every effort to remain independent. Ayes 7. Nays o. Motion carried•

The Board will not make the final decision regarding possible connection to the city water system until the completion of the geophysical study.

VII. **Waste Management proposes to install VOC reducing Air Stripper**

The regular meeting of the Plainfield Charter Township Board was called to order by Supervisor Rekeny at 7:40 p.m. on **November 15, 1993**, at Township Hall, Belmont, MI.

13. The Board carefully reviewed a revised copy of the agreement between SC Holdings (Waste Management) and the Township regarding an air stripper and land transfer. Tom Kerns of SC Holdings answered questions and pledged to work with the Township to supply safe drinking water from the Versluis Park well field. Mrs. Siebers moved, supported by Mr. Groenleer, that Resolution 93-59 an agreement, with corrections, regarding an air stripper, land transfer, and the Versluis well field, be authorized for signatures. Ayes: 6. Nays: o. Motion carried. Bob Vander Male, engineer from Prein & Newhof, was instructed to proceed with the plans for an elevated tank at this location.

VIII. **Air Stripper approved**

The regular meeting of the Plainfield Charter Township Board was called to order by Supervisor Rekeny at 7:30 p.m. on **August 15, 1994**, at Township Hall, Belmont, MI.

Mr. Groenleer reported for the Water and Sewer Committee. The Committee met on August 10 to discuss the need for an 8" water main in West River Drive between Pine Island Drive and Wakefield Avenue. The Committee also considered the following: replacement of sidewalk in Northgate Plat using Community Block Grant funds, plans for construction of an air stripper at the water plant, water main agreements with Alpine Township and with the City of Walker, and a request from Rockford Paper Mill for water main.

XI. Air Stripper approved

The regular meeting of the Plainfield Charter Township Board was called to order by Clerk Morrow at 7:30 p.m., on **February 22, 1994**, at Township Hall, Belmont, MI.

Mrs. Slot moved, supported by Mr. Vonk, to award Contract No.1 - Water Plant Expansion to Triangle Associates, Inc., as recommended by Prein & Newhof, for the adjusted contract amount of $7,326,360.13. Roll call vote. Ayes: Briggs, Groenleer, Morrow, Slot, Vonk, and Siebers. Nays: None. Motion carried.

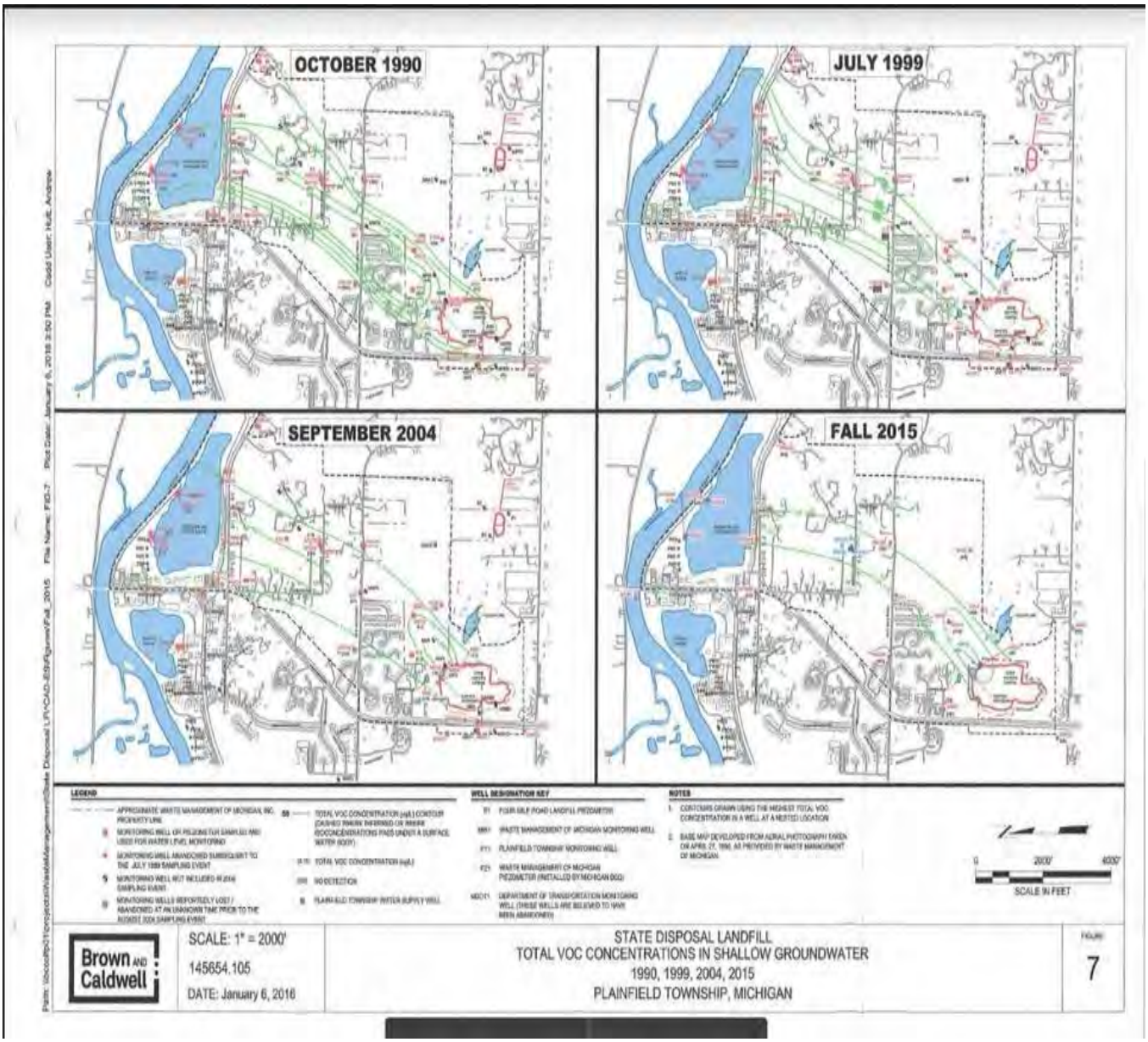
XII. SC Holdings(Waste Management) holds a Public Hearing concerning the Air Stripper

A special meeting of the Plainfield Charter Township Board was called to order by Supervisor Rekeny at 7:30 p.m. on **July 10, 1995**, at Township Hall, 6161 Belmont Avenue, Belmont, MI 49306.

Approve Triangle Associates' Change Order Air Stripper No. lA for an increase of $300,000.00 and Change Order No. 3 for an increase of $19,588.00 and approve Payment Estimate No. 15 in the amount of$261,389.00 to Triangle Associates, Inc. for Contract No. 1--water plant expansion.

Approve waiver of the $50.00 Community Center rental fee for SC Holdings' use of the center to hold a public hearing on August 2, 1995, regarding the air stripper which is being built at the water plant.

XIII. State Disposal Landfill Plume maps



XIV. Plainfield Charter Township begins to be transparent about the PFC contamination

INFRASTRUCTURE COMMITTEE MEETING MINUTES **JULY 14, 2016**

Versluis Well Field PFCs
Staff provided an update on the PFC issue. The Township has begun to receive media calls on this issue.

XV. Toxins reported in the Water Quality reports

XVI. SUBSTANCE (UNIT OF MEASURE)	YEAR SAMPLED	MCL [MRDL]	MCLG [MRDLG]	AMOUNT DETECTED	RANGE LOW-HIGH	VIOLATION	TYPICAL SOURCE
Chlorine (ppm)	2013	[4]	[4]	0.77	0.19–1.25	No	Water additive used to control microbes
Chromium (ppb)	2013	100	100	0.5	0.4–0.5	No	Discharge from steel and pulp mills; Erosion of natural deposits
Fluoride (ppm)	2013	4	4	1.3	0.4–1.3	No	Erosion of natural deposits; Water additive which promotes strong teeth; Discharge from fertilizer and aluminum factories
Haloacetic Acids [HAA]–Stage 2 (ppb)	2013	60	NA	14.4	5.9–21.1	No	By-product of drinking water disinfection
Nitrate (ppm)	2013	10	10	1.17	1.17–1.17	No	Runoff from fertilizer use; Leaching from septic tanks, sewage; Erosion of natural deposits
TTHMs [Total Trihalomethanes]–Stage 2 (ppb)	2013	80	NA	64.2	42.7–65.5	No	By-product of drinking water disinfection
Total Coliform Bacteria (% positive samples)	2013	5% of monthly samples are positive	0	2	NA	No	Naturally present in the environment
Total Organic Carbon (ppm)	2013	TT	NA	2.06	1.61–2.06	No	Naturally present in the environment

Turbidity (Lowest monthly percent of samples meeting limit)	2013	TT=95% of samples <0.3 NTU	NA	100	NA	No	Soil runoff	

Tap water samples were collected for lead and copper analyses from sample sites throughout the community

SUBSTANCE	YEAR			AMOUNT DETECTED	SITES ABOVE AL/		
(UNIT OF MEASURE)	SAMPLED	AL	MCLG	(90TH%TILE)	TOTAL SITES	VIOLATION	TYPICAL SOURCE
Copper (ppm)	2013	1.3	1.3	0	0/31	No	Corrosion of household plumbing systems; Erosion of natural deposits
Lead (ppb)	2013	15	0	4	0/31	No	Corrosion of household plumbing systems; Erosion of natural deposits

SUBSTANCE (UNIT OF MEASURE)	YEAR SAMPLED	AMOUNT DETECTED	RANGE LOW-HIGH	TYPICAL SOURCE
1,1-Dichloroethane (ppb)	2013	0.05	0.03–0.05	Industrial chemical
Calcium (ppm)	2013	38.0	19.0–38.0	Naturally present in ground water
Chloride (ppm)	2013	97.5	52.5–97.5	Runoff from fertilizer use; Leaching from septic tanks, sewage; Erosion of natural deposits
Hardness (ppm)	2013	188	128–188	Naturally present in ground water
Iron (ppm)	2013	0.039	0.039–0.039	Leaching from natural deposits; Industrial wastes
Magnesium (ppm)	2013	30	16–30	Naturally present in ground water
Sodium (ppm)	2013	37.8	37.8–37.8	Naturally present in ground water
Sulfate (ppm)	2013	47.6	47.6–47.6	Naturally present in ground water

SUBSTANCE (UNIT OF MEASURE)	YEAR SAMPLED	AMOUNT DETECTED	RANGE LOW-HIGH	TYPICAL SOURCE
1,4 Dioxane (ppb)	2013	0.86	0.14–0.86	Industrial chemical
Chromium Hexavalent (ppb)	2013	0.56	0.42–0.56	Naural deposits of ores
Molybdenum (ppb)	2013	1.1	<1.0–1.1	Naturally occurring mineral element
Perfluorooctane Sulfonate (ppb)	2013	0.06	0.05–0.06	Industrial chemical
Strontium (ppb)	2013	100	91–100	Naturally occurring mineral element
Vanadium (ppb)	2013	0.6	0.5–0.6	Naturally occurring mineral element

SUBSTANCE (UNIT OF MEASURE)	YEAR SAMPLED	AMOUNT DETECTED	RANGE LOW-HIGH	TYPICAL SOURCE
1,1-Dichloroethane (ppb)	2014	0.04	0.04–0.04	Industrial chemical
Calcium (ppm)	2014	36.0	20.0–36.0	Naturally present in the ground water
Chloride (ppm)	2014	97.5	70.0–97.5	Runoff from fertilizer use; Leaching from septic tanks, sewage; Erosion of natural deposits
Hardness (ppm)	2014	180	124.0–180.0	Naturally present in the ground water
Iron (ppm)	2014	0.04	0.04–0.04	Leaching from natural deposits; Industrial wastes
Magnesium (ppm)	2014	27.0	16.0–27.0	Naturally present in ground water
Sodium (ppm)	2014	39.1	39.1–39.1	Naturally present in ground water
Sulfate (ppm)	2014	51.1	51.1–51.1	Naturally present in ground water

SUBSTANCE (UNIT OF MEASURE)	YEAR SAMPLED	AMOUNT DETECTED	RANGE LOW-HIGH	TYPICAL SOURCE
1,4 Dioxane (ppb)	2014	0.20	0.20–0.20	Industrial chemical
Chromium Hexavalent (ppb)	2014	0.51	0.40–0.51	Naural deposits of ores
Strontium (ppb)	2014	110.0	110.0–110.0	Naturally occurring mineral element
Vanadium (ppb)	2014	0.6	0.5–0.6	Naturally occurring mineral element

SUBSTANCE (UNIT OF MEASURE)	YEAR SAMPLED	AMOUNT DETECTED	RANGE LOW-HIGH	TYPICAL SOURCE
Calcium (ppm)	2016	32	21–32	Naturally present in the ground water
Chloride (ppm)	2016	98.5	72.5–98.5	Runoff from fertilizer use; Leaching from septic tanks, sewage; Erosion of natural deposits
Hardness (ppm)	2016	178	116–178	Naturally present in the ground water
Iron (ppm)	2016	0.032	0.032–0.032	Leaching from natural deposits; Industrial wastes
Magnesium (ppm)	2016	26	13–26	Naturally present in the ground water
Perfluorobutanesulfonic Acid [PFBS] (ppt)	2016	5.1	4.7–5.1	Consumer products such as Teflon, Scotch Guard, Stain Master, and firefighting foam
Perfluoroheptanoic Acid [PFHpA] (ppt)	2016	3.6	2.3–3.6	Consumer Products such as Teflon, Scotch Guard, Stain Master, and firefighting foam
Perfluorohexanesulfonic Acid [PFHxS] (ppt)	2016	3.1	2.4–3.1	Consumer products such as Teflon, Scotch Guard, Stain Master, and firefighting foam
Perfluorooctanesulfonate Acid [PFOS] (ppt)	2016	7.9	4.9–7.9	Consumer products such as Teflon, Scotch Guard, Stain Master, and fire fighting foam
Perfluorooctanoic Acid [PFOA] (ppt)	2016	2.6	2.1–2.6	Consumer products such as Teflon, Scotch Guard, Stain Master, and firefighting foams
Sodium (ppm)	2016	43.7	43.7–43.7	Naturally present in ground water
Sulfate (ppm)	2016	54.5	54.5–54.5	Naturally present in the ground water

Smith, Ian (EGLE)

From: Olivia Lewis <[redacted]@michiganfoundations.org>
Sent: Thursday, January 30, 2020 12:52 PM
To: EGLE-PFAS-RuleMaking
Cc: Regina Bell; Kyle Caldwell
Subject: PFAS Response
Attachments: Public Comment on PFAS.pdf

Hello,

Attached you will find public comments provided on behalf of the Council of Michigan Foundations regarding proposed PFAS in drinking water rules.

Best,
Olivia Lewis

Olivia Lewis, MPP
Public Policy Fellow
Council of Michigan Foundations
300 River Place Ste 6600,Detroit, MI 48207
p. [redacted]
f. [redacted]

Council of Michigan Foundations

Growing the impact of Michigan philanthropy

January 30, 2020

Attention: Suzann Ruch
Department of Environment, Great Lakes and Energy
Drinking Water and Environmental Health Division
P.O. Box 30817
Lansing, MI 48909-8311

Dear Suzann Ruch,

The Council of Michigan Foundations is a community of philanthropists committed to improving outcomes for Michigan and beyond. Our members make strategic investments in and partner with communities across the state. Several of our members and their grantee partners have been working to educate residents and businesses about the health and environmental impacts of PFAS.

It is on their behalf that the Council of Michigan Foundations would like to offer public comment on the state's plan to regulate PFAS chemicals in drinking water.

We recognize that the U.S. Environmental Protection Agency and the Michigan Department of Environment, Great Lakes, and Energy have the authority to regulate PFAS, which includes but is not limited to setting drinking water standards, setting cleanup standards and procedures, and limiting use of the 4,000+ chemicals that PFAS contains. The Council of Michigan Foundations recommends the adoption of standards and proactive measures that protect and improve the health and well-being of our communities and limit the exposure to PFAS contaminants.

Understanding that research is needed to determine the extent of PFAS' impact and produce solutions to combat this contaminant, we believe that appropriate drinking water standards coupled with timely and accurate public notification, as well as the focus on long-term solutions to address water contaminants, will go a long way in supporting the health and well-being of Michigan's residents and our environment.

As partners, we will continue to raise awareness about the negative environmental consequences and public health effects of PFAS. We can learn from the devastating impact of the Flint Water Crisis on our state. Appropriate regulations with a strategic and focused approach is the right direction to take.

Thank you for the opportunity to offer feedback.

Sincerely,

Kyle Caldwell
President and CEO

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www.michiganfoundations.org

Smith, Ian (EGLE)

From: Helminski, Tammy [redacted]@btlaw.com>
Sent: Friday, January 31, 2020 4:31 PM
To: EGLE-PFAS-RuleMaking
Cc: Longsworth, Jeffrey
Subject: PFAS Regulatory Coalition Comments on Proposed MCL Rulemaking
Attachments: 2020-01-31 Michigan Proposed Rulemaking Comments.pdf

Ms. Ruch,
Attached are comments submitted on behalf of the PFAS Regulatory Coalition on EGLE's proposed administrative rule amendments establishing MCLs for certain PFAS compounds. Please reach out to Jeff Longsworth or me if you have any questions.

VCard | Bio | Dept Info

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January 31, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
P.O. Box 30817
Lansing, Michigan 48909-8311
EGLE-PFAS-RuleMaking@Michigan.gov

Re: Comments of the PFAS Regulatory Coalition
Supplying Water to the Public, R 325.10101 R 325.12820
Rule Set No: 2019-35 EG

Dear Ms. Ruch:

The PFAS Regulatory Coalition (Coalition) appreciates the opportunity to file comments regarding the Michigan Department of Environment, Great Lakes, and Energy's (EGLE or State) proposed rulemaking 2019-35 EG titled "Supplying Water to the Public," which amends and adds provisions to the Michigan Administrative Code.

I. The Coalition's Interest

The Coalition is a group of industrial companies, municipal entities, and trade associations that are directly affected by the State's development of policies and regulations related to per- and polyfluoroalkyl substances (PFAS). Coalition membership includes entities in the automobile, coke and coal, iron and steel, municipal, paper, petroleum, and other sectors. Coalition members, for purposes of these comments, include: American Coke and Coal Chemicals Institute; American Forest and Paper Association; American Iron and Steel Institute; Barr Engineering; Brown & Caldwell; Gary Sanitary District (IN); North Shore Water Reclamation District (IL); Pueblo, CO; Tempe, AZ; Toyota; Trihydro, and, Yucaipa Valley Water District (CA).

Coalition members support the State's efforts to identify potential sources of those individual PFAS that pose risks to human health and the environment, and to prioritize the protection of drinking water sources for vulnerable populations. In pursuing such regulations, the Coalition emphasizes that state regulators must ensure that final standards are scientifically supported, cost-effective, and achievable.

II. Proposed Rulemaking

On March 26, 2019, the EGLE submitted a request for rulemaking 2019-35 EG, "Supplying Water to the Public," to establish enforceable drinking water standards for certain PFAS compounds found during the 2018 sampling of Michigan's public drinking water supplies. The proposed rules would establish drinking water maximum contaminant levels as follows:

- Perfluorononanoic Acid (PFNA): 6 ng/L (ppt)
- Perfluorooctanoic Acid (PFOA): 8 ng/L (ppt)
- Perfluorohexanoic acid (PFHxA): 400,000 ng/L (ppt)
- Perfluorooctane Sulfonic Acid (PFOS): 16 ng/L (ppt)
- Perfluorohexane Sulfonic Acid (PFHxS): 51 ng/L (ppt)
- Perfluorobutane Sulfonic Acid (PFBS): 420 ng/L (ppt)
- GenX: 370 ng/L (ppt)

The proposed rules would require the monitoring of selected PFAS chemicals and, in the event the chemicals exceed the established limit, a response to lower exposure below that limit. The proposed rules also would require quarterly samples that are averaged over a year in order to address seasonal and source variations. Additionally, the proposed rules would require a violation for exceedances of the MCL but do not stipulate a required strategy or timeline to return to compliance.

The Coalition appreciates the work that the Michigan PFAS Action Response Team (MPART) has done and continues to do to address the concerns about PFAS in Michigan. As reflected in the comments below, the Coalition highly encourages Michigan to work towards supporting the federal rulemaking process. Many of our members have interests in multiple states and it is important to have uniformity and consistency on standards, not just for business operations but for risk communication, as well. If finalized, Michigan's proposed rules would make this already complex regulatory landscape only more complex. The Regulatory Impact Statement (RIS) for the proposed rules states that "Michigan's proposed levels are similar to standards being developed by other states." But, this statement is misleading when you look at the compounds for which Michigan is proposing MCLs.

For example, Michigan's proposed 6 ppt MCL for PFNA is less than half the 13 ppt promulgated by New Jersey. Also, Michigan is proposing an MCL for PFHxA and the GenX compounds; we are not aware of any other state that has proposed MCLs for these. Michigan's proposed MCL of 8 ppt for PFOA is lower than we have seen in proposals from any other state, with the range being between 8 and 20 ppt.

As described below, USEPA is taking action to address PFAS in drinking water. Michigan can still address those public drinking water systems where PFAS has been found,[1] while assisting USEPA in its efforts for national uniformity.

III. Coalition Analysis and Recommendations

In the comments below, the Coalition recognizes and summarizes some of the challenges that the State faces in attempting to promulgate enforceable regulations, as well as some of the challenges that Coalition members face if states promulgate standards that vary from any existing or future federal standards. The Coalition appreciates the State's desire to act to protect its citizens from potential risks associated with exposure to certain PFAS compounds, but urges the various states and federal government to work closely together to develop a cohesive national strategy to help ensure national uniformity. The prospect of a patchwork set of state-specific standards that vary widely is likely to cause significantly more confusion and overwhelming challenges for Coalition members that operate in multiple states or nationwide.

A. The Scientific Community Does Not Agree on Human Health Toxicity Values for PFAS

The term "PFAS" refers to a group of man-made chemicals that include perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), GenX,[2] and other fluorinated compounds. The most prevalent and available science regarding the incidence and potential health effects of PFAS is based on PFOA and PFOS, two compounds that are no longer manufactured in the United States due to voluntary phase outs. For replacement chemicals, industry has begun using shorter-chain PFAS that have different physical, chemical, and toxicological properties from the long-chain PFOA and PFOS. The scientific understanding of how PFAS impacts people and the environment is still developing and, for thousands of PFAS compounds, much remains unknown. From a toxicological perspective, states must have adequate science for determining health-based values before promulgating individual compound standards, limits, and related regulations.

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[1] According to EGLE, in the statewide drinking water testing it has conducted, 36 out of approximately 1400 Type I Community Water Systems and 48 out of approximately 1300 Type II Noncommunity Water Systems had total PFAS above 10 ppt. EGLE "Information Session Proposed Administrative Rule Revisions" dated January 8, 2020, available at: https://www.michigan.gov/documents/egle/egle-tou-dwehd-PFAS-rule-presentation_676317_7.pdf (last visited January 27, 2020).

[2] Note that GenX is a trade name for a specific PFAS compound, ammonium, 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate. ITRC "Naming Conventions and Physical and Chemical Properties of Per- and Polyfluoroalkyl Substances (PFAS)," at 12, *available at* https://pfas-1.itrcweb.org/wp-content/uploads/2018/03/pfas_fact_sheet_naming_conventions__3_16_18.pdf (last visited January 23, 2020). More generically, GenX can be denoted by the abbreviation, "HFPO-DA."

Toxicologists, whether they work for various state agencies, USEPA, international standards-setting organizations, academia, or in private practice, have not yet established specific methodologies, resources, or even agreed on which of the hundreds of studies of PFAS compounds are the appropriate or critical components that must or should support appropriate regulatory "standards." Different methodologies, levels of experience, procedural prerequisites to standards-setting, and even local political pressures can and have led to considerations of highly variable standards in different states or at USEPA. Accordingly, the Coalition recommends that states work with one another and with USEPA to continue developing science and methodologies to inform and encourage a more uniform approach to federal and state PFAS regulatory mandates.

B. Federal Action on PFAS

USEPA has issued "Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS."[3] Those recommendations provide clear and consistent guidance for federal cleanup sites being evaluated and addressed under federal programs, including the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA). The screening levels followed under such cleanups are risk-based values that are used to determine if levels of contamination may warrant further investigation at a site. The recommendations are intended to be used as guidance for states to evaluate state cleanup and corrective action sites. The interim guidance recommends in relevant part:

- Using a screening level of 40 parts per trillion (ppt) to determine if either PFOA, or PFOS, or both, is present at a site and may warrant further attention.
- Using USEPA's PFOA and PFOS Lifetime Drinking Water Health Advisory level of 70 ppt as the preliminary remediation goal (PRG) for contaminated groundwater that is a current or potential source of drinking water, where no state or tribal MCL or other applicable or relevant and appropriate requirements (ARARs) are available or sufficiently protective.

In addition, USEPA is focusing significant resources on developing appropriate regulatory mechanisms related to various PFAS compounds. For example, USEPA has developed a PFAS Action Plan, which provides a multi-media, multi-program, national research, and risk communication plan to address emerging PFAS challenge.[4] Part of USEPA's PFAS Action Plan involves expanding the scientific foundation for understanding and managing risk from PFAS, including researching improved detection

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[3] USEPA Office of Land and Emergency Management, OLEM Directive No. 9283.1-47 (December 19, 2019), *available at* https://www.epa.gov/sites/production/files/2019-12/text_version_epas_interim_recommendations_for_addressing_groundwater_contaminated_with_pfoa_and_pfos_dec_2019.txt.

[4] *See* USEPA "EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan" (February 2019) *available at* https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.

and measurement methods, generating additional information about PFAS presence in the environment and drinking water, improving the understanding of effective treatment and remediation methods, and developing more information regarding the potential toxicity of a broader set of PFAS. In turn, USEPA expects that this information will help states and others better manage PFAS risks.

USEPA is also moving towards possible Maximum Contaminant Level (MCL) standards for PFOA and PFOS—two of the most well-known and prevalent PFAS chemicals. The Agency has sent "regulatory determinations" for PFOA and PFOS to the White House Office of Management and Budget, Office of Information and Regulatory Affairs (OMB-OIRA) for approval.[5] As stated in its proposed regulatory determination, "[p]roposing a regulatory determination is the next step in the maximum contaminant level [] rulemaking process under the Safe Drinking Water Act; it enables the USEPA to propose and solicit comment on information critical to regulatory decision-making towards protecting public health and communities across the nation."[6] Additionally, USEPA is gathering and evaluating information to determine if similar regulations are appropriate for a broader number of PFAS compounds.

While USEPA is working through its long-established processes and rulemaking procedures, Congress is considering ways to expedite and fund various national standards-setting approaches. Recently, the House of Representatives passed the PFAS Action Act (H.R. 535), which would require, among other things, that USEPA promulgate a national primary drinking water regulation for certain PFAS and a health advisory for other PFAS not subject to a national primary drinking water regulation. Also, Congress passed and then the President signed into law the National Defense Authorization Act (NDAA) (P.L. 116-92) that mandates additional federal actions to regulate and manage various risks associated with many PFAS. While we recognize that not all states and stakeholders can agree on specific priorities or approaches to PFAS regulations, these congressional actions combined with USEPA's efforts, are important national developments that should be supported by the states through their contribution of expertise, resources, and efforts as the Nation works to respond to the PFAS exposure risks.

Indeed, a patchwork of 50 different state solutions is unworkable and contrary to how the U.S. has previously addressed similar emerging contaminant issues. While some limited variations related to groundwater, surface water, or soil cleanup levels may be expected and appropriate, the highly variable regulatory health advisories, action levels, and drinking water standards currently being developed or under consideration across the country create unnecessary confusion and complexity for the public and the regulated community.

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[5] RIN: 2040-AF93 *available at* https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=2040-AF93 (last visited January 26, 2020).
[6] *Id.*

The Coalition recognizes that states have elected to utilize different methods and processes for communicating risks to their populations. However, standards-setting must reflect more national and uniform collaboration and cohesion. We must work to avoid the undesirable solution of 50 separate state rules, particularly with regard to drinking water standards. With this in mind, we urge the states to work closely with USEPA to establish science-based and peer-reviewed federal standards that serve as the basis for comparable state standards. Such an approach is consistent with how USEPA and the states have addressed environmental and human health risks since the inception of USEPA.

In addition, the Coalition can foresee challenges to states that choose to develop their own unique and varying drinking water standards. Many jurisdictions, including Michigan,[7] have existing laws or rules that prohibit the state from promulgating regulations that are more stringent than the federal rules. When USEPA does promulgate national primary drinking water regulations, such states may be in conflict with their legislature's clearly stated policy. States that promulgate their own drinking water standards ahead of USEPA may be required to amend such state-specific PFAS regulations when USEPA completes its work in this regard. Antibacksliding provisions may further limit states' abilities to change their standards to conform with federal rules.

Considering the above, implementation of any future federal standards likely will be more complex and resource-consuming for states that set their own limits in advance of federal action. Indeed, the purpose of federal law is to protect against a patchwork of state law. Accordingly, the State should clearly articulate how forthcoming federal drinking water standards may impact this state-specific proposed rulemaking, how the State will help to foster consistency and uniformity with neighboring states, and how the State will defer to federal standards or revise standards based on future federal action and improved scientific understanding about exposure, dose, and toxicology.

The Coalition encourages the State to use its resources to support the development of science upon which USEPA can base its federal standards, heed the non-binding recommendations of USEPA's Federal Health Advisory of 70 ppt (for PFOA and PFOS combined), and, ultimately, work to implement any forthcoming national primary drinking water standards. This will protect the State from expending resources on establishing and enforcing individual PFAS drinking water standards that are inconsistent both with other states and with federal science-based and peer-reviewed standards.

C. Reliance on the ATSDR Values

The United States Agency for Toxic Substances and Disease Registry (ATSDR), part of the federal Center for Disease Control, and many states have reviewed the toxicity information available for PFOA and PFOS and opined on appropriate dosages that reflect highly conservative assumptions designed to protect human health, including the most susceptible subpopulations. ASTDR values are derived through different methods than

[7] Mich. Comp. L. 24.232(8).

USEPA's MCL (and Health Advisory) values and the two are not directly comparable.[8] These variabilities in how various health recommendations are derived must be considered and addressed to ensure that any final standards are scientifically justified and corroborated.

Moreover, the ATSDR has only finalized the Toxicological Profile for two PFAS compounds, PFOA and PFOS. The profiles for two additional PFAS—Hexafluoropropylene Oxide (HFPO) Dimer Acid, more commonly referred to as the ''GenX Chemicals,'' and Perfluorobutane Sulfonic Acid/Potassium Perfluorobutane Sulfonate, referred to as PFBS—are still only in draft form. ATSDR made the Toxicological Profiles for these additional PFAS available for public comment in 2018, and the Profiles have not been finalized yet.

Considering the above, the Coalition recommends that the State base any rulemaking on any forthcoming national primary drinking water standards, rather than the draft ATSDR report. And, even if the State still seeks to base its rulemaking on the ASTDR reference doses, the Coalition recommends that it wait until ATSDR finalizes its Toxicological Profiles, as the science supporting ATSDR's reference doses is not fully developed and not generally agreed-upon in the scientific community. Moreover, ATSDR has not even drafted profiles for some of the compounds that the State is proposing to regulate.

The State, at best, must avoid underpinning regulations on information that the scientific community is still debating, or using science not yet fully developed enough for ATSDR to draft recommendations. USEPA is actively working on developing its own assessments for these and other PFAS compounds and, consequently, final standards-setting is still premature.

D. Specificity in the Type of Regulated PFAS

Generally, future PFAS regulations should clearly specify the individual compounds of PFAS that it seeks to regulate. Given the wide variations in toxicities and other characteristics exhibited by different PFAS chemicals, it is not scientifically appropriate to group all PFAS together for purposes of risk assessment or to assume that exposures to mixtures of PFAS necessarily bioaccumulate in one's body in interchangeable 1:1 ratios.

Accordingly, the Coalition supports the proposed rulemaking's specificity in identifying which PFAS compounds are regulated and recommends that the regulation of individual PFAS substances reflect peer-reviewed science regarding the physical,

[8] *See* ATSDR Public Health Assessment Guidance Manual (2005) at Appendix F: Derivation of Comparison Values (https://www.atsdr.cdc.gov/hac/phamanual/appf.html) ("MCLs represent more realistic assumptions about toxicity and contain fewer uncertainty factors than the very conservative ATSDR environmental guidelines.")

chemical, and toxicological properties of each compound. Similarly, the Coalition recommends against including any combined PFAS standards or limits unless science clearly demonstrates that the mixture of the PFAS compounds subject to the combined limit results in bioaccumulation in hazardous concentrations.

E. Testing Capabilities and Reliability

The Coalition urges the State to consider the capabilities and reliability of laboratories that test for PFAS. In other words, there is limited capacity nationally to perform all of the analytical laboratory work and limited reliability on any given sample result due to potential lab error, cross contamination, or other factor that could impact results in the very low parts per trillion levels being considered. There is little doubt that the closer the State sets a limit or standard to the detection limit, analytical sampling and related lab results become increasingly unreliable.

For example, Coalition members who have sent split samples to multiple labs report receiving highly variable results. Such anecdotal evidence demonstrates the potential difficulty and unreliability of performing testing at limits that approach the detection limit. Considering that the State can potentially impose fines, costly corrective action, or other penalties for failing to meet regulatory limits, the regulated community must have the ability to accurately measure PFAS to demonstrate compliance. Subjecting the regulated community to fines, corrective action, and other penalties based on potentially unreliable testing raises due process concerns. Accordingly, the Coalition urges the State to consider testing capabilities and set limits and impose a regulatory scheme that account for the variability in and limits of current laboratory testing.

F. Availability of Testing and Disposal

A limited number of established laboratories in the country have robust experiecnce testing and reporting PFAS results. The State's rulemaking should account for the limited number of testing laboratories in the region. The Coalition recommends, for example, that in regions where testing capacity is limited that the rule provide for a delayed effective date or phased implementation that allows for laboritories to develop the expertise necessary to reliably accommodate the increased testing that the rule will require.

Similarly, treatment technologies for PFAS are still being developed, and there is limited capacity for the disposal of byproducts from newly-developed technologies. For example, absorption technologies such as granular activated carbon (GAC) are being developed as potential response measures to achieve compliance with new drinking water standards for PFAS. The regulated community will need to safely dispose of the byproducts of such treatment technologies used to treat PFAS in drinking water. Again, this is another area where USEPA is taking action.

Congress, in the NDAA, mandated that USEPA, not later than one year after enactment, "publish interim guidance on the destruction and disposal of perfluoroalkyl and

polyfluoroalkyl substances and materials containing perfluoroalkyl and polyfluoroalkyl substances," which includes guidance on "spent filters, membranes, resins, granular carbon, and other waste from water treatment."[9] The Coalition urges the State to use its resources to support the development of USEPA's interim guidance documents prior to independently establishing MCLs.

G. EGLE Should Consider the Rulemaking's True Costs

The RIS fails to take into account this developing nature of treatment technologies and availability of disposal or other treatment endpoints. The basis of the costs descibed in sections 13 and 14 of the RIS is limited to only one report from the State of New Hampshire. EGLE should do a more robust analysis to determine the true costs of this proposed regulation. There is more information available about the variable costs of treatment systems installed at locations around the country that could be considered. The RIS also relies on the New Hampshire study for operation and maintenance costs and discusses that the granular actived carbon media will need to replaced is an important variable, but this does not acknowledge the uncertainty and costs associated with how to handle that media. In Michigan, a treatment system may not be able to find a landfill to take the spent media, and incineration of the media is currently subject to criticism and further study. As stated in Section H above, Congress has directed USEPA to develop guidance to specially address these issues.

The RIS also ignores the effect the drinking water standards have on remediation sites under Part of 201 of Michigan's Natural Resources and Environmental Protection Act. For sites with impacted groundwater, these drinking water standards can become the remediation standards, unless it can be demonstrated that there is in fact no one drinking water and such exposure pathway is subject to an institutional control. Likewise, sites being remediated under federal programs, such as Superfund, could have to address the MCLs as applicable or relevant and appropriate requirements (ARARS) to meet as remediation standards. For Department of Defense (DOD) sites, the NDAA requires that cooperative agreements with states include that the DOD "shall meet or exceed the most stringent . . . standards for PFAS in any environmental media," including an enforceable drinking water standard. NDAA Sec. 332(a)(2).

The costs to remediate to these proposed MCLs is not included anywhere in the regulatory analysis. These are certainly substantial costs for the state, municipalities and private parties that are conducting these cleanups. There are many remediation projects underway in Michigan and across the country with data that could be used to conduct this analysis. Without it, the regulatory analysis is significantly flawed.

In sum, this regulation, if it becomes final before there is more certainty of the necessary underlying questions of treatment and disposal, then a more robust cost analysis

[9] NDAA Sec. 7631(4).

must be conducted to account for the potential costs, including remediation and the range of true disposal and ongoing operation and maintenance costs.

V. Conclusion

The Coalition appreciates the opportunity to submit these comments concerning the proposed rulemaking. We look forward to working closely with the State regarding developing appropriate, reasonable, and scientifically-defensible state drinking water levels. Please feel free to call or e-mail if you have any questions, or if you would like any additional information concerning the issues raised in these comments.

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I would like to start by saying I'm very pleased to see EGLE considering establishing a new maximum amount of PFAS permitted in drinking water. It should be noted that the current maximums under the EPA of 70 parts per trillion are based on evidence from before 2008 that is not complete. The 70ppt maximum could be up to 100 times what is actually safe to consume[1]. That said, I would also like to encourage the state to adopt a maximum amount of PFAS permitted in production on a per year basis. PFAS are some of the meanest most persistent compounds[2], and as of now, the only real way to deal with PFAS contaminated soil is to remove it. There are remediative measures being developed, but they face non-trivial efficacy and/or logistic limitations[3]. This is especially important because of the intrinsic link between groundwater and surface water. Say there's a drum of dumped PFAS, eventually the contaminant will leach into the soil. From the soil it will be transported either to an aquifer where we get water, or to a river/stream/lake where we also get our water. Projections for climate change in the midwest point to increased frequency and intensity of precipitation events[4]. That means an acceleration in the transport of these compounds, either over land or through the ground. In addition to all of that, studies are suggesting that the atmosphere plays a role in the transport and deposition of these compounds[5]. This is not a role that we currently understand, and I must suggest that in the spirit of caution we limit the available sources. In a situation like this it just makes less sense to invest in a bulletproof vest, and more sense to simply take the bullets out of the gun.

I thank EGLE for their time and I would be happy to pass along the resources I collected in my research for this statement.

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Andrew Pennock

Hi, Eric Piehl, [redacted], Ada Township, here in Kent County. [redacted]

This PFAS issue should not have happened. We should be testing and evaluating chemicals **before** large-scale production and use, instead of waiting until **after** we have a body count. But that's not the way we do things in America. Until we change that. Regardless, now that we find ourselves in our current situation, we have to "do what we can, with what we have, where we are."

I read your 42-page draft rules, and I like them a lot. It seems you took an existing document, which handles a bunch of other drinking water situations, and expanded it to handle PFAS stuff. Awesome, assuming the structure can hold it.

On first read, your architecture and expansions look very good.

More good stuff:

- Your proposed changes neatly define PFAS. Thank you! Hard subject. Nice job.

- Your proposed changes say that PFAS in water can be treated with granular activated carbon. Seems reasonable to me, based on their chemical structures. Until I find out differently, I will assume this to be true. Nice job!

- You change the word "shall" to "must". As an engineer, I was taught they mean the same—mandatory, not optional. And I hear that lawyers are taught the same. But if "must" clarifies things, allowing engineers, lawyers and the general public to understand the text the same way, I support this. Great job.

Then some problematical stuff:

- You use the term "MCL" to refer to two different things: "Maximum Contaminant Level" and what I eventually found to be "Michigan Compiled Laws". Please try to make your text clear which meaning you intend, in each context. And you use similar terms—"MRDL maximum residual disinfectant level." And more terms adding "Goal" to both MRDL and MCL. Uh-oh, I need a scorecard to keep these straight. Fortunately, you have such a scorecard before Table 1. But it doesn't include terms not used in that table, including "Michigan Compiled Laws." Maybe move all these to the Definitions section at the beginning?

- In the chart in Parts 5 and 6, do I read this correctly: In any particular location, if you find a PFAS in excess of 6 to 400,000 ppt (depending on the particular PFAS), you intend to treat that location, bringing the PFAS level down to that same level of 6 to 400,000 ppt? Not down to some other level?

- Why were these levels of 6 to 400,000 ppt chosen? Presumably, these levels are based on science? You have sources on this? Until I find out differently, I will assume you do. (Huge range, by the way—five orders of magnitude. Must be a good story there interesting to us chemistry geeks.)

So I am greatly in favor of your draft rules. Good job. Go do that! And thank you for being open and transparent about this, and holding these public hearings! Great job.

But I have a fear. 25 years ago, I lived in Brighton, Michigan, in Livingston County. And we had an old plastics factory, south of town right by US-23, that had a plume of toxic TCE (or PCE—it's been a while) expanding underground from its site. As I recall, MDNR had plans to treat this plume, using the same granular activated carbon process proposed here for PFAS. But then we got a new governor—Engler, in this case—whose DNR then changed the levels—the "Maximum Contaminant Level" presumably—on TCE or PCE, so the DNR no longer had to clean up the site. With the wave of a hand, poof, the toxic plume was gone. Even though to the people of Brighton, we still had this toxic plume expanding from the site, still taking out 3 or 4 family wells each year on its way toward Hamburg and the Huron River, still causing the City of Brighton's water department to extend its lines to new neighborhoods way out of town, eventually sinking a new well and building a new water tower. These were large costs, for our little town of 7,000 people. I don't know what you can do about it, but I do have this fear that if things get going well to treat our PFAS problems, that somehow someone might kick it off the rails.

Uh, oh, I just used "toxic" the same way you do. But my biology geek buddies say that that to a biologist, toxins are produced by biology. TCE and PCE and PFAS are produced by people, which would make them "poisons," not "toxins." Maybe the medical community is different? I don't know.

As I recall, TCE and PCE are also carcinogens and teratogens—they cause cancer and birth defects! Which brings up the question, I assume PFAS are poisons—substances that can cause death, injury or harm to organisms. Are PFAS also carcinogens or teratogens? I don't know—I didn't even think of this until a couple hours ago.

Do you have a schedule? When will we see concrete and steel going up? Anything you can tell us?

Thank you! Best wishes to you all, keeping our drinking water safe for us, our kids, and our grandkids.

-30- Eric D. Pratt

2020-01-08

Good evening. My name is Jaime Fleming. I work for the City of Wyoming as the laboratory manager for the Utilities Department. I am also the chair-elect for the Michigan Section of the American Water Works Association and I am here today in that capacity.

I was able to participate the in the rulemaking process via the stakeholder listening sessions. I appreciated the transparency, active listening, and cooperative spirit on the part of EGLE's representatives. Throughout the conversations, it was evident that everyone in the room, no matter the group they represented, was approaching the rules from the perspective of what is in the best interest of public health. The listening sessions were conversational, with open dialogue, not just about the rules at hand, but also stretching into the tough questions and challenges that remain ahead of us.

As for the feedback given on the rules, much of what was brought to the table from the stakeholders in the sessions I attended was reflected in the final form. We understand that it is not possible to create rules that are a perfect fit for every interested group. But, the proposed rules appear to be straightforward and follow a format that utilities are familiar with as they utilize existing regulatory patterns for other organic compounds. Additionally, there are key places where the rule language is appropriately flexible – for instance, in the allowable treatment technologies or for approval of alternative testing methods. Because our understanding of the science is developing alongside these rules, and will continue after they are in place, this flexibility is crucial.

EGLE has been forthcoming with details of implementation, intention, and application that can't be detailed in the regulatory framework. It is clear EGLE has done a significant amount of work to anticipate challenges and questions that will arise as the rules go into effect.

Jaime Fleming

As many voices have shared, there are some key points that must remain in the forefront of the broader PFAS conversation.

Michigan has done great things through the work of MPART. Their efforts have put public health first, while being grounded in science. Our understanding of PFAS is unfolding and will continue to unfold well past the implementation of rules for seven of the compounds. It is imperative that we continue to approach PFAS in a science forward way, always focusing on what is best for public health. In the realm of drinking water, that will mean carefully assessing and balancing PFAS with other elements of water quality.

Protecting public health comes with a price tag. I know that drinking water professionals across the State take up this responsibility with the utmost of care and dedication. But, make no mistake, the cost of additional requirements for monitoring and in some cases implementing treatment is not insignificant, especially for small systems. In the end, water supplies must balance competing priorities, and most often it falls to the ratepayers to fund these efforts. As we move forward with these rules, and with others already in place, the availability of funding sources must continue to be an ongoing, important discussion in order to provide safe drinking water in an affordable, equitable way.

Creating drinking water standards for PFAS is just one piece of the PFAS puzzle. These standards cannot stand alone without real, enforceable protections for our source water. We must find a way to break the PFAS cycle. This requires that we continue the holistic approaches through bodies like MPART.

Michigan is leading the way. We look forward to the continuation of that work.

Michigan Department of Environment, Great Lakes, and Energy

The Wolverine Community Advisory Group represents concerned citizens that have been impacted by PFAS contamination from the Wolverine World Wide Tannery in Rockford, Michigan and their disposal sites at House Street & the Wolven/Jewell neighborhoods. The contaminated area covers 25 square miles and PFAS compounds have been detected in 800+ residential wells and the Plainfield Township municipal water supply which serves over 40,000 people. Given the urgency of the PFAS crisis and need for drinking water standards that are protective of human health, we support the Maximum Contaminant Levels (MCLs) currently recommended by MPART and feel these values are an important first step in the restoration and protection of our water supplies. Since the science related to PFAS is rapidly evolving, we recommend that future considerations be given to the concerns described below.

PFAS is a class of chemicals that includes 4000+ compounds and we should be regulating PFAS as a class of chemicals. The regulation of individual PFAS chemicals, in this case the 7 MCLs considered by MPART, is not protective against the likelihood of additive or synergistic effects from exposure to the chemical mixtures encountered in the environment. Water testing results usually show that individuals are exposed to multiple PFAS compounds in their water and Michigan should establish a future value for total PFAS and/or chemical classes (C6, C8, etc.). Please consider the work that the State of Massachusetts has done to support their proposed MCL of 20 ppt for Total PFAS Compounds.

Michigan should endeavor to reflect the best science in its assessment of drinking water standards protective of public health and give special consideration to the most vulnerable populations exposed to PFAS. Fetuses, children, pregnant women, and other susceptible populations such as the elderly and individuals suffering from chronic illness and suppressed immune systems are more sensitive to contaminants due to physiological and developmental differences from healthy adults.

Richard
Redmile

The Wolverine Community Advisory Group appreciates the opportunity to comment on this important legislation. Setting MCLs for the seven PFAS compounds is overdue and in the absence of federal safeguards, Michigan must act to protect drinking water and reduce public health risks. The widespread occurrence of PFAS chemicals in Michigan's drinking water, their persistence, and ability to bioaccumulate/circulate in blood serum underscore the need for swift adoption of the proposed MCLs.

Sincerely,

The Wolverine Community Advisory Group

Richard R. Rediske, Ph.D., Leadership Committee Co-Chair

[redacted]
Allendale, MI 49401
[redacted]@gvsu.edu

PFAS DRINKING WATER RULE

MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

PUBLIC COMMENTS SUBMITTED ON JANUARY 14, 2020
YPSILANTI, MICHIGAN

ELAINE G. CHOTTINER, M.D.
[redacted]
PLYMOUTH (SALEM TOWNSHIP), MI 48170

[redacted]@UMICH.EDU

My name is Elaine Chottiner. I'm a retired hematology/oncology physician. I spent 30 years caring for patients with blood disorders and cancer, many linked to pesticides, workplace exposures and other environmental toxins. As part of a Health Leaders Fellowship with the Ecology Center, I performed a comprehensive literature review on the health effects of PFAS with a focus on the newer, short-chain chemicals. I was shocked by what I learned. In my profession, drugs don't come to market until they have undergone rigorous testing and are proven to be safe and efficacious. In the world of industrial chemicals, it appears that these safeguards don't apply until harms emerge and the public demands accountability.

I applaud the work that MPART is doing. However, I am concerned about the proposed MCLs and want to make the following points:

Evolving studies suggest that PFAS pose the highest risks for the most vulnerable populations – pregnant and lactating women, the developing fetus, and infants and children.

Older epidemiologic data from studies such as the C8 Project suggested links to various diseases. Recent studies are more alarming. PFAS appear to be endocrine disruptors that interfere with the function of normal hormones including estrogen, testosterone and thyroid. They impact pregnancy and fetal development, fertility and thyroid function. PFAS also appear to impair immunity, particularly in children – possibly by interfering with the way white blood cells recognize vaccines and foreign substances. These abnormalities occur in real time. This means that unlike cancer, these risks are not necessarily related to duration of exposure or bioaccumulation, but that ANY level of exposure to PFAS at critical times can cause potentially devastating health problems.

Shorter is not better.

The introduction of GenX and other short-chain PFAS was based upon inadequate and misleading scientific studies. Most of the assumptions regarding their limited toxicity have been disproven. As your own experts have noted, we have very scant information on short-chain PFAS. They are easily absorbed in humans, circulate in the bloodstream, cross the placenta, appear in semen and breast milk, and bioaccumulate. They pose an even greater risk, since current filtration systems do not adequately remove them. The proposed MCLs for the short-chain PFAS are far too high.

PFAS should be regulated as a class

It is rare that we see contamination by single chemicals, and the health hazards are magnified by cumulative exposure.

PFAS don't belong in our water, our wildlife, our food chain, our bodies or our children. I urge you to reexamine and significantly lower the recommended regulatory levels for all PFAS including short-chain compounds, to expand the regulations to cover all PFAS as a class, and to commit to regular reviews of emerging scientific studies in order to update these standards as needed.

Good Evening, thank you for your efforts today. I realize that it is your job however, it is the sincerity with which you perform the functions of your assignments that is appreciated by those of us who come to you today.

My name is Jim Egged and I come to you this evening as a retired firefighter and grandfather. This is Hailee and she is one of the reasons I am here.

As a firefighter I was placed on the Western Wayne Hazardous Incident Response Team. In the course of executing the functions of my sworn duties I have had the occasion to use AFFF firefighting foam. As a firefighter it was my sworn duty to protect those who look to us for their safety. I regret that as firefighter I have failed in my obligation to protect the most vulnerable who look to me to protect them. In the use of AFFF I have poisoned her water with one of the PFAS chemicals.
As a firefighter and hazardous incident responder I should be painstakingly aware of the chemicals we are dealing with and use.

As you know, PFAS builds up in the body over time and can lead to significant health complications, like cancers, thyroid conditions, auto-immune diseases and reproductive issues. I am 60 years old, she is only 8, you can only imagine the damage to children as they grow to become adults, these chemicals can do their bodies.

That is why I am here. Now that we are aware of the consequences of the use and longterm effects of the PFAS family of chemicals I want to work with the Department of Environment, Great Lakes and Energy to ensure that the levels of this family of chemicals be adopted in the proposed rule changes. The state is considering limits for the following chemicals:

- PFNA (6-parts per trillion)
- PFOA (8-parts per trillion)
- PFOS (16-parts per trillion)
- PFHxS (51-parts per trillion)
- GenX (370-parts per trillion)
- PFBS (420-parts per trillion)
- PFHxA (400,000-parts per trillion)

These science-based limits for PFAS contaminants are a significant step forward for ensuring Michiganders have safe, clean drinking water.
Furthermore, the state should set a combined total limit for all of the toxic contaminants, instead of smaller limits for each chemical. Establishing a combined total standard for PFAS contaminants will set the baseline for ensuring Michiganders have safe, clean water to drink.

As concerned protectors of those who cannot defend themselves, we need to guard against the resistance that would be profiteers who will fight these proposed protections. This is why I am entering my comments into the public record, to ensure the state hears our priorities as they move forward in the process and protect the most vulnerable among us.

Pollutants in Michigan's Environment is contrary to Michigan's Economic health

- GDP
  - ✓ From time to time over 2 decades, I have been questioning GDP, Gross Domestic Product, as an accurate measure of real economic health.
  - ✓ In my parent's and grandparent's age, when American corporations were national and not international, there was a more fulsome correlation between corporate earnings and take home pay. This is no longer case.
  - ✓ Many of saw this in the years after 2008 financial crisis as the metrics of federal economic health were repaired, yet most Americans were not made whole.
  - ✓ A handful of economists around the world saw this too.
- Joseph Stiglitz
  - ✓ Professor of Economics at Columbia University, received the Nobel Prize for his published work: The Price of Inequality. Before and Since this 2012 noted work, Stiglitz has been defining the limits of GDP and exploring alternatives.
  - ✓ This book was my introduction.
- SEEA (System of Environmental Economic Accounting)
  - ✓ UN Statistical Accounts established this framework in 2009. Although refinement and development remain, but it has produced policy worthy concepts capturing interactions between environment and economy. It is a way forward out of an old model that assumes unlimited resources to one that deals with the reality of sustainability.
- Michigan Policy and Legislative Makers need to connect the dots to answer revolving issues. For example, let's link: demographic trends, business decision matrix, and whether or not Michigan's water is fit to drink.
  - Demographics: Michigan has one of the oldest populations in the USA
  - Trend: Michigan has a brain-drain problem and difficulty attracting business AND this is a regulation problem—but not one of too much regulation. It is a problem of too little.
  - Decision Matrix: Appeal/Suitability is of top concern when a business considers locating to Michigan, because it has direct implications of attracting and retaining talent.
  - Indeed, Michigan Public Schools are in the top 10—but if you can't drink the water why even attack the list.
  - Today there are large swaths of Michigan I would never raise my family because it could kill them or set them up for chronic disease later in life.
  - PFAS is poison.

- I thank my State Legislators, Rabhi and Irwin, and my Congressional Leader, Dingell, for not sweeping PFAS under the rug.

Lisa Patrell
Washtenaw350
[redacted]@gmail.com
[redacted]

EGLE MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

(1)

Michigan.gov/EGLE | 800-662-9278

My name is Sue Shink, I'm a Washtenaw County Commissioner. I thank EGLE and the State of Michigan for addressing this issue.

The people in my ~~point~~ district ~~do not want to be poisoned~~ and in this county do not want to be poisoned by PFAS and are asking ~~for your help~~ you to use your power to protect us, including the frail, the pregnant and the unborn.

These chemicals were and are produced as part of a profit-making enterprise. ~~The~~ Their emissions is an unacceptable externalization of costs. The people and governments are paying the cost through health problems, ~~and~~ clean up costs and losing the ability to eat the fish of our rivers, and our peace of mind.

Susan Shink
[redacted] [redacted]
Ann Arbor, MI 48105
[redacted]@washtenaw.org

(2)

EGLE MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

Michigan.gov/EGLE | 800-662-9278

I understand this is not within your purview but the legislatures.

~~Clearly, while the draft~~

Clearly the precautionary principal would be appropriate and would help avoid these tragedies.

Polluter Pay is also appropriate considering that profit making enterprises have taken their profits and left the people and government to pay the costs.

Thank you Senator Jeff Irwin and Rep. Youssef Rabhi for championing these bills.

Technical and financial help is going to be needed for some water providers

Visit us at *Michigan.gov/EGLEconnect* to sign up for email updates, follow us on Twitter, or subscribe to our YouTube channel.

Susan Shenk
[redacted]
Ann Arbor, MI 48105
[redacted]@washtenaw.org

EGLE MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

Michigan.gov/EGLE | 800-662-9278

Regarding benefit/cost analysis.

The people of this State pay far too high a cost with our health, quality of life, and our lives because polluters use our State's water, land and air as their trash can.

We have asthma.
We have liver disease
We experience low fertility and low birthweights
. . .

Please do not undervalue our health.

And I think that if you actually tried to quantify the impact to our economy it would be astonishing-

Susan Shunk
[redacted]
Ann Arbor, MI 48105
[redacted]@washtenaw.org

(44)

EGLE MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

Michigan.gov/EGLE | 800-662-9278

I urge you to use the boldest possible standards in protecting our health. As detailed by the Michigan League of Conservation Voters, other states have higher standards. Our people do not deserve less.

I would also urge you to use at least a 50% relatives source contribution. We are exposed by PFAS chemicals by many routes - most without our knowledge or permission. A total MCL standard would also be appropriate, as would more research into synergystic effects.

There are likely other chemicals present in our drinking water sources of which we are not yet aware.

Susan Shink
[redacted]
Ann Arbor, MI 48105
[redacted]@washtenaw.org

(5)

EGLE MICHIGAN DEPARTMENT OF ENVIRONMENT, GREAT LAKES, AND ENERGY

Michigan.gov/EGLE | 800-662-9278

I urge you to protect us by promulgating the most protective standards possible.

Susan Shenk, Washtenaw Cty. Commissioner
[redacted]
Ann Arbor, MI 48105
[redacted]@washtenaw.org

As a WCC I have been working very hard to try to figure out the best approach to deal with a problem exacerbated by a lackluster State response - the destruction of an aquifer by dioxane pollution - Gelman.

Please be bold. Please be strong. Please protect us.

Susan Shunk
[redacted]
Ann Arbor, MI 48105
[redacted]@washtenaw.org

Comments from William Creal, January 14, 2020

I support the proposed PFAS rules and urge their adoption. This is another example of the crisis that results when we do not require proper testing of chemicals before they are widely used in our society. There is an alphabet soup of such examples - PCB, DDT, TCE to name a few of the other chemicals that have caused us problems in the past. I realized that you have to address this latest crisis, but I also urge you to take some of the energy that is generated from this crisis to help put in place the necessary chemical testing requirements to prevent the next crisis. Without this prevention step in place, we are doomed to keep repeating this crisis as the next chemical emerges.

NEED OUR WATER

Date: January 16, 2020

Addressed to: EGLE/ERRC Committee

Subject: MCL Rules Public Hearing

I would like to thank EGLE for this opportunity to speak here this evening on such a life changing matter as it relates to PFAS contamination in the State of Michigan today.

We in Oscoda and surrounding areas have been dealing with what I believe is a very difficult situation with respect to PFAS contamination in our area that was created decades ago by the Department of Defense/Air Force. In our case, the Air Force has made, in my opinion, too many broken commitments and promises to remediate the PFAS contamination on and around Wurtsmith Air Force Base with far too little progress to date hiding behind their so called "CERCLA process". They have diverted resources and funding originally assigned to Wurtsmith Air Force Base for remediating PFAS at and around the base to other areas within the Department of Defense as the government in which, we as taxpayers, entrusted have let us down again and feel that a closed Air Force base is not a top priority on their list for PFAS remediation.

Just so you know the PFAS contamination created by the Air Force in our area has resulted in increased health concerns thru out the community, lowered property values, decreased tourism and vacational rental activity, as well as fish and wildlife contamination. All of these items have greatly affected Oscoda and surrounding areas revenue stream but that does not seem to matter to the Department of Defense and the Air Force.

I truly believe it is extremely important that the new proposed MCL guidelines being discussed here today be approved and passed into Michigan law swiftly in order to hold the Department of Defense and private sector industries accountable to remediate the PFAS contamination at Wurtsmith Air Force base and all across the State of Michigan thus not allowing the Air Force, in our case, to drag their feet any longer on such an important issue as they have done in the past.

I also suggest that EGLE and the ERRC committee work with Governor Whitmer and the Attorney General's office to investigate what legal actions will need to be taken by the State of Michigan in order to enforce the new MCL guidelines and learn from other states such as New Hampshire and New Jersey that have adapted their reduced MCL guidelines into state law and have been told by the Department of Defense that they do not recognize the state mandated lower MCL guidelines and therefore are not planning to adhere to individual state reduced MCL's at this point in time and will continued to use the 70ppt guideline.

It is time for Michigan to stand up and be recognized as a state that WILL NOT tolerate the Federal Government and private businesses to continue to contaminate our state land and water resources.

Thank you for your time.

David C. Winn Sr. – Oscoda resident

EGLE COPY

NOW

NEED OUR WATER

Comments for Public Hearing

I hope you set the level at the lowest possible number, to protect the citizens of Michigan. As far as putting all the PFAS contaminants into one MCL, I feel I would leave that decision up to EGLE. If EGLE recommends to do just a part of the contaminants, I would hope as the science comes in, EGLE would address the remaining PFAS chemicals. Immediate action by our State to assign additional MCL's at a timely rate, would get my support. BEWARE we will be holding you accountable for your actions.

Thank you, Greg Cole of the NOW- (Need Our Water).

EGLE - Drinking Water and Environmental Health Division
Attention: Suzann Ruch
P.O. Box 30817
Lansing MI 48909-8311

PFAS Amendment

14th January · 2020

Michigan should consider the current EPA health advisory standard of 70ppt to be deficient. Even the Centers for Disease Control and Prevention has said the exposure to concentrations less than 70ppt can be a cause for concern. Some states feel the EPA is "dragging its feet" and some are concerned that we are returning to a system where industry and agriculture will be policing themselves. We are continually finding more contaminated areas in Michigan. It is imperative that we set a stricter level than the current one expounded by the EPA. We in Michigan have demonstrated in the past (Michigan led the country in establishing a wetland protection program with requirements that exceeded the Federal Government's) that we are concerned about our citizens. We must continue to look out for our own best interests.

Due to chemical contamination in areas like Toms River, New Jersey, Love Canal in New York, and several locations (Hooker Chemical Company), including Muskegon, Michigan, we learned what our industrial leaders, sometimes with aid from local, state, and federal government, could do to citizens mental and physical health. There were many decades spent resolving the contamination issues. One result was the Federal Government setting "safe" levels of chemicals in the environment.

Arrogance, greed, revenge - these are some of the immoral characteristics that played like vultures on the ground and water that people needed for living. Some of those vultures developed a conscience while the non-repetent wanted to continue with their attitudes. Fortunately, the people with the good traits prevailed. There have been many successes due to the regulations created by the various levels of government. I have read that, today, (reported in 2019) the disasterous Toms River area has become "among the municipalities where low-income people have experienced the greatest increases in lifespans."

This current issue with PFAS is a complex one but we must dedicate ourselves to finding answers. We in Michigan should have a high standard of permissible PFAS levels in order to protect ourselves while we continue to search for answers.

Rec'd 1/17/20

Respectfully submitted,
Susan Ford Marshall
[redacted]
Rockford MI 49341

Rec'd
1/17/20
SR

53RD DISTRICT
STATE CAPITOL
P.O. BOX 30014
LANSING, MI 48909-7514
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FAX: (517) 373-5808
E-MAIL: yousefrabhi@house.mi.gov

MICHIGAN HOUSE OF REPRESENTATIVES

YOUSEF RABHI

STATE REPRESENTATIVE

January 14, 2019

Drinking Water and Environmental Health Division, EGLE
Re: Proposed Rule Set 2019 35-EG
Attn: Suzann Ruch
PO Box 30817
Lansing, MI 48909-8311

To Whom it May Concern:

I am glad to see our regulators proposing standards to protect the people of Michigan from toxic PFAS, which build up in the environment and our bodies. But these draft rules do not go far enough to protect human health.

For too long, we have given polluters the benefit of the doubt, allowing them to put millions of tons of chemicals out into our environment without any safety testing. Only once entire communities had already been poisoned did regulators propose drinking water limits and cleanup rules. Due to the negligence of polluters, the inaction of previous administrations, and the willful dismantling of environmental protection by lawmakers, communities like Ann Arbor have been left on the hook for costly water service improvements.

That's obviously the wrong way around. The proposed rule would set MCLs for 20 PFAS compounds. But there are an estimated 4700 PFAS compounds. How long would it take to do testing and administrative rulemaking on each one? Longer than the lifetimes of the people whose health will be ruined, though unfortunately probably not longer than these compounds will persist in our soil, streams, and rivers. We must regulate PFAS as a class now to prevent this entirely predictable environmental and public health catastrophe.

These proposed MCLs are a step in the right direction, but we can do much better than that for the people of our state.

Please enter this comment into the public comment record for Proposed Rule Set 2019 35-EG.

Sincerely,

Yousef Rabhi
Representative, 53rd District

Smith, Ian (EGLE)

From: Potocki Bob [redacted]@potockitransport.us>
Sent: Thursday, January 23, 2020 4:38 PM
To: EGLE-PFAS-RuleMaking
Cc: 003 McIntosh; Anthony M. Spaniola; A.J. Birkbeck; Aaron Weed; Christina Schroeder; Connie Boris; Daniel Brown; Daniel Buyze; David Lipscomb; David Winn; Elizabeth Hauptman; Gale Dugan; Gary Pettyjohn; Jeffrey Dutton; Jennifer Carney; Kate Gislason; Kenneth Harvey; Lea Dyga; Matthew Farrar; Pam McQueer; Patti Baldwin; Renae Mata; Potocki Bob; Sandy Wynn-Stelt; Shellene Thurston; Sliver, Steve (EGLE); Theresa Landrum; William Barnett; William Creal
Subject: Comments -EGLE-PFAS Rulemaking

Categories: Blue Category

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
PO Box 30817
Lansing, Michigan 48909-8311

Attention: Suzann Ruch

Dear Officials:

The common fault of Flint and PFAS is a **failure to share** knowledge of chemicals in our water.

1. Our foods identify chemical content in required labeling. (Federal)
2. Water is the essential food.
3. In both Flint and PFAS, public officials did not share knowledge of harmful chemicals in our waters (drinking, surface and ground).

Government's obligation to health and safety should provide **immediate and broad sharing of presence and concentrations of harmful chemicals** to the public. No testing should be avoided or hidden for political or economic reasons. The health of our children, pets and the community depend on it.

Robert Potocki
[redacted]
Brighton, Mi 48114

Smith, Ian (EGLE)

From: LDA of Michigan <[redacted]@gmail.com>
Sent: Friday, January 31, 2020 10:26 AM
To: EGLE-PFAS-RuleMaking
Subject: Comment to Proposed PFAS MCL Standards
Attachments: PFAS MCL Standards - comments from LDA MI Jan 2020.pdf

Ms. Ruch,
We greatly appreciate the opportunity to comment on the proposed rule related to PFAS MCL standards.

Learning Disabilities Association (LDA) of Michigan is proud to have been a part of LDA America's Healthy Children's Project for over a decade. Through our nationwide network, we work to protect children's health and reduce toxic exposures that may lead to learning disabilities in current and future generations.

On behalf of Michigan's children, we urge the committee to use the best available science to help us protect our families from harmful chemicals such as PFAS.

Attached, please find our comment with explanation including data for support. Thank you again,

Amy Barto
LDA of Michigan
Healthy Children's Project Coordinator

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At LDA of Michigan, our vision is that the causes of learning disabilities will be understood and addressed and the individuals with learning disabilities will thrive and participate fully in society.
http://ldaofmichigan.org
[redacted]
LDA of MI on Facebook
LDA of MI on Twitter

Learning Disabilities Association of Michigan

2428 Burton St SE, Grand Rapids, MI 49546 | [redacted]@gmail.com

January 31, 2019

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311

Comment to: State of Michigan's Department of Environment Great Lakes and Energy regarding proposed PFAS MCL standards

Thank you for the opportunity to comment on this proposed rule. The Learning Disabilities Association of Michigan urges the State of Michigan's Department of Environment Great Lakes and Energy to reevaluate the recommended values for the maximum contaminant levels (MCLs) of PFAS chemicals permitted under Michigan's regulatory drinking water standards. We ask that these standards, in order to be truly health protective, take into account the potential impacts of PFAS chemicals on child development.

Approximately 13% of children in the United States have a developmental disability[1]. The CDC now estimates that 1 in 59 children in the United States have an autism spectrum disorder[2]. The incidence of these types of disabilities is rising every year at an alarming pace, especially for autism and ADHD.

In Michigan, children eligible for special education include 58,509 identified with a Specific Learning Disability (3.73% of all MI school-age students) and 21,550 identified with autism (1.37% of MI students).[3] While ADHD is harder to document, the Center for Health and Research Transformation out of University of Michigan reported in 2013 that approximately 6.3 percent (approximately 17,000 patients) of children aged 4 to 17 living in Michigan had a claim related to ADHD[4]. In addition, the Special Education for Otherwise Health Impaired (OHI) in 2018-2019 children which can include children with ADHD eligible for special education and lead poisoned children had 28,426 students (another 1.81% of children) receiving special education services.

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[1] *Health Care Use and Health and Functional Impact of Developmental Disabilities Among US Children*, 1997-2005, Sheree L. Boulet, DrPH, MPH; Coleen A. Boyle, PhD; Laura A. Schieve, PhD

[2] National Center for Learning Disabilities, https://www.cdc.gov/ncbddd/autism/data.html

[3] Michigan School Data Website, https://www.mischooldata.org/SpecialEducationEarlyOn2/DataPortraits/DataPortraitsDisability.aspx

[4] Center for Health and Research Transformation https://chrt.org/publication/child-adhd-michigan/

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The National Academy of Sciences Committee on Developmental Toxicology, estimates that at least 28% of developmental defects are caused in whole or part by environmental exposures to toxic chemicals [6]. These are **PREVENTABLE causes** of these disabilities.

Per- and polyfluoralkyl substances, also known as PFAS chemicals, are man-made chemicals that are found in our food, water, air and products. They are used to make products more resistant to stains, grease and water. There are nearly 5000 PFAS chemicals and they are used in many products including food containers, electronics, cleaning products, textiles, and some firefighting foams.

The proposed standards do not adequately consider the impact of PFAS on the most vulnerable populations in our state. In particular, PFAS pose significant health risks for pregnant women and children. PFAS are nicknamed "forever chemicals" because they are bio accumulative and don't break down (also known as PBT chemicals - Persistent, Bioaccumulative and Toxic). There is widespread human exposure and can stay in our bodies for years. They are such a concern that the EPA has set a lifetime health advisory level for a few of these chemicals.

People are exposed to PFAS through contaminated food, water and air, from products containing these chemicals, and worker related exposures. PFAS are linked to many health concerns including certain types of cancer, disrupting the immune system including poor response to vaccines[7], impaired liver function, high cholesterol, preeclampsia (potentially fatal pregnancy complication with high blood pressure), and birth defects.

Of particular concern for the LDA of MI are the developmental effects of in utero exposure to Hexafluoropropylene oxide dimer acid (HFPO-DA) which has been associated with negative developmental effects, Perfluorobutane sulfonic acid (PFBS) associated thyroid hormone disruption, Perfluorononanoic acid (PFNA) and Perfluorooctane sulfonic acid (PFOS) both with links to developmental delays, decreased body weight gain, and Perfluorooctanoic acid (PFOA) and it's associate with neurodevelopmental effects.

Studies of the above chemicals have linked PFAS to impaired fetal development as well as interfering with the thyroid and low birth weight, which can then affect children's brains. The CDC states that some studies in people have shown certain PFAS chemicals may affect "learning, and behavior of infants and older children"[8].

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[6] Scientific Frontiers in Developmental Toxicology and Risk Assessment, Executive Summary, http://www.nap.edu/openbook.php?record_id=9871&page=1, National Academy of Sciences Committee on Developmental Toxicology

[7] Grandjean P, Heilmann C, Weihe P, Nielsen F, Mogensen UB, Timmermann A, Budtz-Jørgensen E. 2017. Estimated exposures to perfluorinated compounds in infancy predict attenuated vaccine antibody concentrations at age 5-years. J Immunotoxicol. 14(1):188–195.

[8] Center for Disease Control and Prevention, September 2019, CDC and ATSDR Award $7 Million to Begin Multi-Site PFAS Study, https://www.cdc.gov/media/releases/2019/p0923-cdc-atsdr-award-pfas-study.html

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In addition, scientific studies have shown the effects of PFAS chemicals on mammary gland development, harming both children and their mothers[9]. Lab tests show that mammary glands have a low-dose sensitivity to PFOA. In the proposed Michigan standard for PFOA, mammary gland development was not considered as a health end point. Mammary gland development is critical to the ability of mothers being able to breast feed, and support healthy child development.

Biomonitoring studies have shown that nearly every person in the US, including newborns, have PFAS in their bloodstream. Drinking water and other dietary sources are considered to be the largest exposure pathway to PFAS.

To tackle contamination by PFAS that are harming our families, the state must first set MCLs that are truly health protective, taking into account the most sensitive health end points, cumulative exposure to more than one of the seven PFAS considered here at a time, and synergistic harmful effects of PFAS with other chemicals that can harm brain development. The proposed levels are too high and will not protect pregnant women or children.

On behalf of Michigan children, Learning Disabilities Association urges this committee to consider the most vulnerable populations and most sensitive health end points for each chemical, consider cumulative exposures to these chemicals, and use the best available science to set and periodically evaluate these standards. In doing this, Michigan can better protect all families from unnecessary harmful chemicals such as PFAS.

Sincerely,

Amy Barto, M. Ed.
Learning Disabilities Association of Michigan
Healthy Children's Project Coordinator
[redacted]@gmail.com
[redacted]

[9] https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.1002741?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%3dpubmed
https://www.nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf
https://www.mibreastfeeding.org/wp-content/uploads/2019/06/MIBFN-2019-Advocacy-Overview.pdf

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Georgia Donovan <[redacted]@everyactioncustom.com>
Sent: Monday, January 13, 2020 9:47 PM
To: EGLE-PFAS-RuleMaking
Subject: Comment on PFAS levels in our water

Dear Drinking Water and Environmental Health Division Suzann Ruch,

As vice-president of the Michigan Chapter of the Izaak Walton League, I care about our water and environmental health. Our group in the Rockford area has many new young families that are very concerned about water purity.
I am hoping you'll move quickly to set a strong standard for PFAS that is based on the best available science and is protective of public health. We are the Water State! We cannot wait for federal action; we have the right and the interest, to deal appropriately with our own State's situation.

If your studies have indicated that these are reasonable levels, please follow through with these limits, or a combination of them:
PFNA (6-parts per trillion) •PFOA (8-parts per trillion) •PFOS (16-parts per trillion) •PFHxS (51-parts per trillion) •GenX (370-parts per trillion) •PFBS (420-parts per trillion) •PFHxA (400,000-parts per trillion)

PFAS contamination impacts the drinking water of more than 1.9 million Michiganders, and we can't delay action on protecting the health of our communities. We know PFAS causes health impacts, and we know where it is coming from, which is why the state must move swiftly to pass a standard that is protective of public health.

Michigan should be a leader on addressing the PFAS contamination crisis, and that starts with strong standards for these toxic chemicals.

The PFAS limits proposed by the state are a step in the right direction, but key changes need to be made to ensure they protect the health of Michigan communities.

Those include:

-Taking a class-based approach that sets a standard for the combined total of the various PFAS chemicals instead of individual limits for each.

-Ensuring the standards are protective of our most vulnerable populations, like developing infants and children.

-Basing the standards on the best and most recent science.

Michigan should be leading the country on setting the toughest standards for toxic PFAS chemicals in our water. This is a vitally important issue and will only get worse if we don't start action now!

Sincerely,

Georgia Donovan,

Dwight Lydell chapter, Izaak Walton League of America Belmont, MI

Sincerely,
Georgia Donovan
[redacted] Rockford, MI 49341-9592 [redacted]@gmail.com

Smith, Ian (EGLE)

From: Ethan Lowenstein <[redacted]@emich.edu>
Sent: Wednesday, January 29, 2020 4:42 PM
To: EGLE-PFAS-RuleMaking
Subject: Comment on proposed PFAS rules

Categories: Blue Category

To Whom It May Concern:

I am glad to see our regulators proposing standards to protect the people of Michigan from toxic PFAS, which build up in the environment and our bodies. But these draft rules do not go far enough to protect human health.

For too long we have given polluters the benefit of the doubt, allowing them to put millions of tons of chemicals out into our environment without any safety testing. Only once entire communities had already been poisoned did regulators propose drinking water limits and cleanup rules. Due to the negligence of polluters, the inaction of previous administrations and the willful dismantling of environmental protection by lawmakers, communities like Ann Arbor have been left on the hook for costly water service improvements.

That's obviously the wrong way around. The proposed rule would set MCLs for seven PFAS compounds. But there are an estimated 4,700 PFAS compounds. How long would it take to do testing and administrative rulemaking on each one? Longer than the lifetimes of the people whose health will be ruined, though unfortunately probably not longer than these compounds will persist in our soil, streams and rivers. We must regulate PFAS as a class now to prevent this entirely predictable environmental and public health catastrophe.

These proposed MCLs are a step in the right direction but we can do much better than that for the people of our state.

Thanks for listening!!!!!

All the best,

Ethan Lowenstein

Ethan Lowenstein, Ph.D.
Professor of Curriculum and Instruction, EMU
Director, Southeast Michigan Stewardship Coalition (SEMIS)
Connect with me: www.semiscoalition.org
Facebook: https://www.facebook.com/semiscoalition/

Smith, Ian (EGLE)

From: Josh Kofflin [redacted]@gmail.com>
Sent: Tuesday, January 14, 2020 6:45 PM
To: EGLE-PFAS-RuleMaking
Subject: Comment

Categories: Blue Category

Please increase scope of the rules for all the chemicals related to pfas issues.

Smith, Ian (EGLE)

From: Susan Rock [redacted]@gmail.com>
Sent: Thursday, January 30, 2020 6:13 PM
To: EGLE-PFAS-RuleMaking
Subject: Comment

Per- and polyfluoroalkyl substances (PFAS) are a large group of man-made chemicals that include perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS). PFAS have been used globally during the past century in manufacturing, firefighting and thousands of common household and other consumer products. These chemicals are persistent in the environment and in the human body – meaning they don't break down and they can accumulate over time. In recent years, experts have become increasingly concerned by the potential effects of high concentrations of PFAS on human health.

I want tough laws to keep PFAS out of our water supply. Our most precious asset in Michigan is our water.

Susan Rock
[redacted]
Redford, Michigan 48239
[redacted]

Smith, Ian (EGLE)

From: Sue Popma [redacted]@yahoo.com>
Sent: Saturday, January 25, 2020 9:38 AM
To: EGLE-PFAS-RuleMaking
Subject: Comment

Categories: Blue Category

Because Wolverine World Wide has already spent the money they saved by NOT properly disposing the Forever Chemicals, they still owe that money for cleanup of wells and water systems.
They must be held to the highest standard of cleanup to keep our current and future taxpayers healthy so we can continue to pay our taxes.
Thank You,
Sue Popma
[redacted]
Rockford MI 49341
[redacted]

Smith, Ian (EGLE)

From: ELIZABET [redacted]@comcast.net>
Sent: Friday, January 31, 2020 12:44 PM
To: EGLE-PFAS-RuleMaking
Subject: Clean Water

I live in Harrison Township. I never thought I would see the day when the water flowing from the faucets in my home could contain undisclosed contamination. The recent report that Selfridge ANG Base legally dumps PFAS into our water is shocking and unacceptable. EGLE must take action to set tough limits for all toxic contaminants in drinking water. The goal should be zero. This crisis is an opportunity for EGLE to demonstrate to the people of our state it's commitment to its mission: "To protect Michigan's environment and public health ..."
Elizabeth Miriani

Sent from Xfinity Connect Application

Smith, Ian (EGLE)

From: Suzanne Dixon <[redacted]@aol.com>
Sent: Monday, January 27, 2020 5:22 PM
To: EGLE-PFAS-RuleMaking
Subject: Comments on proposed PFAS regulations

Thank you for taking up this investigation on what we know and need to do about chemicals know as PFAS.
Our President and Senate has indicated that they will not be taking up for consideration recently passed bills from the House. Michigan must act to control exposure to these toxic chemicals.
Michigan has gone beyond some state efforts in establishing limits for 7 chemicals in the PFAS family, however we know others are also toxic. Establishing a cumulative limit, such as Vermont and New Hampshire has, will be more protective and I believe can be established with the present science.
Establishing a 2 year review process will allow Michigan to stay current with an evolving information base.
We know that conditions at the time of the testing can produce variables in the results. At the very least, more testing will give you a larger data base for more knowledge. Please follow up with an aggressive sampling schedule.
Thank you for your consideration,
Suzanne Dixon
[redacted]
Douglas, MI 49406

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Lynn McIntosh <[redacted]@everyactioncustom.com>
Sent: Friday, January 31, 2020 11:46 AM
To: EGLE-PFAS-RuleMaking
Subject: A good start on MI PFAS standards, adopt them, then improve them quickly (and expand their reach)

Dear Drinking Water and Environmental Health Division Suzann Ruch,

I appreciate that the State of Michigan is one of the few states trying to set stricter standards for the amount of PFAS chemicals in our drinking water. In the absence of the EPA setting federal standards it is imperative that we move to adopt our own state standards.
For this reason, I urge the State to move forward on setting these standards as soon as possible.

However, and this is a major "however," after reading the writings of Linda Birnbaum, PhD, former director of the National Toxicology Program, scientific and public health expert with vast experience, and also reading scientific literature re: Massachusetts's research model for setting standards for PFAS chemicals as a class, there is a strong likelihood that MI's proposed new standards are already outdated.

In fact, in 2018, Massachusetts had adopted an MCL of 70 ppt for a sum of five PFAS chemicals. Within a year, during which the public asked their state to scientifically review again the standards, Massachusetts is in a review process that is proposing 20 ppt for a class of six PFAS chemicals.

This speaks volumes.

The fact that Vermont has set their level to 20 ppt for a sum of 5 PFAS chemicals only underscores the reality that Michigan is not being strict enough.

I am aware that Michigan used a model used by Minnesota. There were good reasons for doing so, but back to my "however." Was equal time given in looking at some of the east coast states' models and their reasons for addressing the additive and synergistic effect of PFAS chemicals as a class?

I remain unconvinced that the model Michigan chose is protective enough.

Three final points:
1)Will an annual review process be included with these standards, given the quickly changing and growing science? This seems imperative.
2)Michigan needs to address community well systems serving 1300 people or less, for example, trailer parks, campgrounds, etc. The current proposed standards will not protect these people.
3)A side issue yet interwoven with this: 25% of Michigan's citizens has private wells. The need for protections for these people cannot be ignored.
Thank you very much for having 3 public hearings so that Michigan citizens could speak with you face to face and voice their concerns. This is a great step and very much appreciated.

Sincerely,
Lynn McIntosh
[redacted] Rockford, MI 49341-1021 [redacted]@gmail.com

Smith, Ian (EGLE)

From: Mary Beth Whitton [redacted]@gmail.com>
Sent: Thursday, January 30, 2020 5:15 PM
To: EGLE-PFAS-RuleMaking
Subject: Input on PFAS in Mi.'s drinking water

I welcome the opportunity to share my concerns on the dire state of these cancer causing chemicals in our water in Michigan.
I recently read a news report that states as the army and our state agencies argue over who is responsible for the clean up of a close base in Eastern mid Mi as the fire fighting chemical leach into a nearby river AND into Lake Huron.
I hope your new proposed rules can address clean up at this sight immediately
Sincerely
Mary Beth Whitton

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Patricia Baldwin <[redacted]@everyactioncustom.com>
Sent: Monday, January 6, 2020 9:16 PM
To: EGLE-PFAS-RuleMaking
Subject: Michigan needs the toughest standards for toxic PFAS chemicals in our water

Categories: Orange Category

Dear Drinking Water and Environmental Health Division Suzann Ruch,

One of my concerns with contaminated communities is that the real estate industry is not involved with the PFAS disclosure process. Mandatory testing of well water for PFAS in contaminated neighborhoods needs to be part of the buy/sell agreements. Realtors should be "mandated reporters" so to speak. If they know of possible contamination, they should be mandated to have that test be part of the buy/sell agreement. Buyers from out of state or even out of the country may not know to test for PFAS. There is negligence in keeping that knowledge from the prospective buyer. To protect everyone, it has to be part of the real estate industry in some fashion.

Sincerely,
Patricia Baldwin
[redacted] Grand Rapids, MI 49546-7270 [redacted]@comcast.net

Smith, Ian (EGLE)

From: Ruth Katsnelson [redacted]@icloud.com>
Sent: Thursday, January 30, 2020 5:11 PM
To: EGLE-PFAS-RuleMaking
Subject: I demand lowest level of PFAS in drinking water.

Any level of PFAS in drinking water is unacceptable for humans in Michigan.

Please do the right thing now

Ruth Katsnelson
West Bloomfield
Mi

Sent from my iPhone

Smith, Ian (EGLE)

From: Ruch, Suzann (EGLE)
Sent: Monday, January 6, 2020 5:07 PM
To: EGLE-PFAS-RuleMaking
Subject: FW: PFAS hearings

Follow Up Flag: Follow up
Flag Status: Completed

Forwarding so it is retained in EGLE-PFAS-RuleMaking mailbox

Suzann J. Ruch
Senior Executive Management Assistant to Eric Oswald
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
P.O. Box 30817
Lansing, Michigan 48909-8311
517-284-6544 | RuchS@Michigan.gov
Follow Us | **Michigan.gov/EGLE**

From: Dave Dempsey <[redacted]@flowforwater.org>
Sent: Monday, January 06, 2020 4:10 PM
To: Oswald, Eric (EGLE) <OswaldE1@michigan.gov>; Philip, Kris (EGLE) <PHILIPK@michigan.gov>
Cc: Ruch, Suzann (EGLE) <RuchS@michigan.gov>
Subject: PFAS hearings

We appreciate the hard work EGLE has put into developing the proposed PFAS MCLs. To better facilitate our efforts to engage Michigan residents in the public comment process, we respectfully request that EGLE livestream the Ann Arbor and Roscommons hearings in addition to the Grand Rapids hearing. Further, we understand you're not providing a two-way stream, but it would be helpful if EGLE staff could take online remote questions during the hearings.

--
Dave Dempsey
Senior Advisor
FLOW (For Love Of Water)
153 1/2 East Front St., Suite 203C
Traverse City, MI 49684
[redacted]@flowforwater.org
[redacted] (o)
[redacted] (c)
flowforwater.org

There is something infinitely healing in the repeated refrains of nature - the assurance that dawn comes after night, and spring after winter. -- Rachel Carson

Smith, Ian (EGLE)

From: Nancee M. <[redacted]@gmail.com>
Sent: Thursday, January 30, 2020 8:25 PM
To: EGLE-PFAS-RuleMaking
Subject: Forever Chemicals

PLEASE clean up our water! We cannot survive, and our planet cannot survive without clean water. PLEASE make this a priority! PLEASE!

Smith, Ian (EGLE)

From: [redacted]@gmail.com
Sent: Thursday, January 30, 2020 8:41 PM
To: EGLE-PFAS-RuleMaking
Subject: Drinking Water Rule Promulgation

I support new and modified state rules/regulations relative to PFOS & PFOA standards and acceptable levels.

Smith, Ian (EGLE)

From: Peter Albertson <[redacted]@icloud.com>
Sent: Thursday, January 30, 2020 5:12 PM
To: EGLE-PFAS-RuleMaking
Subject: Drinking Water Rule Promulgation, Public Comment

January 30, 2020

Reg: Public Hearing Comment: PFAs MI Standards, Public Comment

State of Michigan EGLE:

I am a resident of the of Michigan. My address is: 15736 Robinwood Drive, Northville, Michigan, 48168. We also have property in Lewiston, Michigan. I am requesting your support of the PFAs Standards as recommended by the Michigan Environmental Council:
1. Set a cumulative standard
2. Require a health review in two years
3. Conduct at least three years of quarterly sampling
Your time regarding this very important issues facing all of MIchigan is greatly appreciated.

Sincerely,
Peter J. Albertson
Cell Phone Number: [redacted]

Smith, Ian (EGLE)

From: jairch64 [redacted]@gmail.com>
Sent: Friday, January 31, 2020 3:19 PM
To: EGLE-PFAS-RuleMaking
Subject: My once s regarding PFAS contamination

To whom it may concern,

I am a resident of ALPENA Michigan, and like many other citizens in this county, rely on well water for sustenance. We have been assured that our well and municipal water systems are PFAS free of contaminants, but who really knows this for sure....as other municipalities,I.e. Parchment, Oscoda, and Wolverine were also said to safe, and we know what happened in these communities.

I have been both a private and public advocate for consumer education on this contaminant and, of course cleanup. Please act on behalf of the welfare of our citizens. We cannot, at this time rely on the Federal government. It is up to our Governor, Attorney General, and local representatives to create and pass bills that will lower allowable levels of PFAS in our waters, and pursue Federal cleanup of known sites.
Janet Fairchild
[redacted]
ALPENA, Michigan. 49707

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Sharon Khouri [redacted]@everyactioncustom.com>
Sent: Friday, January 31, 2020 6:00 AM
To: EGLE-PFAS-RuleMaking
Subject: Michigan waterways are critical and under attack. Please protect them.

Dear Drinking Water and Environmental Health Division Suzann Ruch,

Please I'm writing to beg you to take the strongest actions to protect our waters. From pfas of course but in all ways possible. We need to set the highest safety standards to protect waterways. Without clean water what do we have. This is a basic principle that should not even be up for debate. Im writing to urge you to move quickly to set a strong standard for PFAS that is based on the best available science.

PFAS contamination impacts the drinking water of more than 1.9 million Michiganders, and we can't delay action on protecting the health of our communities. We know PFAS causes health impacts, and we know where it is coming from, which is why the state must move swiftly to pass a standard that is protective .

Sincerely,
Sharon Khouri
[redacted] Saint Clair Shores, MI 48081-3847 [redacted]@hotmail.com

Smith, Ian (EGLE)

From: Nora Madden <[redacted]@gmail.com>
Sent: Friday, January 31, 2020 1:47 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS

Dear Suzann Ruch,

I am taking a few minutes on this deadline day to encourage you and your EGLE colleagues to do whatever you can to prohibit further PFAS contamination of our water, and to encourage development of alternatives to their uses and of possible cleanup solutions.

Our State should learn from (and continue to try to remedy!) the shame of the political shenanigans that led to the poisoning of Flint's drinking water. That situation has already cost the State so much in legal fees and will cost so much in long-term health and educational consequences. More than that, of course, is the sickening situation of prioritizng "cost savings" over people.

I am not a scientist; I am not an economist; I am a parent. As such, I beg you to remember that NOTHING is worth more keeping our water clean--and accessible!--and keeping our children healthy. Paying whatever it takes, however we must, right now, is a wise investment.

Thank you for your time and effort,
Nora Madden
Lansing

Smith, Ian (EGLE)

From: Tom Schupbach <[redacted]@yahoo.com>
Sent: Thursday, January 23, 2020 9:53 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS

As the department works on PFAS standards, please consider the following:

1) Setting a cumulative standard.
2) Require a health review in two years.
3)Conducting at least three years of quarterly sampling.

Thank you

Thomas Schupbach
[redacted]
DeWitt MI 48820

[redacted]

Smith, Ian (EGLE)

From: Ann Poznanski <[redacted]@gmail.com>
Sent: Friday, January 17, 2020 12:04 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS

The evidence for the presence of PFAS in our drinking water is alarming. As a resident of Ann Arbor, I urge you to do all that you can to enact the drinking water standards, make polluters pay, and find ways to treat contamination at the source.

Ann Poznanski

Smith, Ian (EGLE)

From: Barbara <[redacted]@yahoo.com>
Sent: Tuesday, January 7, 2020 5:00 PM
To: EGLE-PFAS-RuleMaking
Subject: Our Michigan Waters - The GREATEST IN THE WORLD!!

Categories: Blue Category

Please----you can do better! Strengthen our protection. Any amount of chemicals and poisons in our water is TOO much! Having "acceptable" allowances and no strong oversight for testing is a horrible mistake! It is just a pretense of holding polluters accountable.

We have the Great Lakes surrounding our state. We (Michigan) are central and crucial to protection of these great waters.

Please, do not whore yourselves out to industry.

Barbara

Smith, Ian (EGLE)

From: John Sarver [redacted]@gmail.com>
Sent: Wednesday, January 15, 2020 7:59 AM
To: EGLE-PFAS-RuleMaking
Subject: New PFAS Standards

I commend EGLE for moving ahead on this critical environmental issue. I would recommend that EGLE consider:

Establishing a cumulative standard
Requiring a review in two years
Conducting three years of quarterly sampling

Smith, Ian (EGLE)

From: Barbara Olson [redacted]@yahoo.com>
Sent: Saturday, January 11, 2020 11:12 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS in Michigan

I am not able to attend the public hearings on pfas standards in Michigan but would like to weigh in with my support of the Michigan Environmental Councils policy solutions ensuring the standards fully protect public health and the environment against PFAS. These standards are as following: set a cumulative standard, require a health review in two years, and conduct at least three years of quarterly sampling.

I know there is pushback from industry and industry backers (including in our government body) for what they see as interference with business interests. I am speaking for the millions of people born after 1950 when pfas chemicals were put into production in this country. I was born in 1951. Our generation will not live as long as the previous generation, my parents or grandparents. We celebrated our 60th high school reunion last year. A shocking number of my high schoolmates have died from cancer or disease states before our 70th birthday and many before our 60th. I have 6 family members that were diagnosed with cancer. 2 didn't survive. My twin brother died in 2019 of a stroke before his 68th birthday. I myself am a cancer survivor. I say this not for sympathy or the shock value. I am simply relaying to you what I believe is contributing to the unhealthy state of the population here in the US. Contamination of our water, our soil and our air with chemicals is killing humans and devastating our environment. There has to be a better way to live (and die). Humans can live without the benefit of many of these chemicals and in fact want to live cleaner, safer lives.

Please support the MEC's analysis of the problems concerning PFAS and their solutions for regulation and elimination going forward.

Thank you,
Barbara Olson

Barbara Olson
[redacted]@yahoo.com

A lifetime isn't long enough for the beauty of this world
and the responsibilities of your life.
-Mary Oliver

Smith, Ian (EGLE)

From: Peggy Sooz <[redacted]@aol.com>
Sent: Tuesday, January 7, 2020 12:42 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS in Michigan

Categories: Blue Category

stop letting corporations poison us

- **Take a class-based approach to regulate PFAS in drinking water.** Considering health-based values for the seven individual PFAS chemicals separately does not take into affect how these chemicals interact with each other to cause health impacts.
- **Ensure that the health-based value used to set the PFAS-class drinking water standard protects those most vulnerable to harm.** Children, pregnant women, the elderly, and people suffering from chronic illness are more vulnerable to PFAS health impacts. Fetuses and infants have greater exposure to PFAS via maternal transfer in utero and contaminated breast milk or infant formula, and they are more sensitive to the exposure.
- **Use the most recent science to set a health-based value PFAS-class drinking water standard.** New research shows a relationship between exposure to PFHxS and impaired reproduction issues at 18 parts per trillion (ppt). The health-based value proposed by Michigan for PFHxS is 2.5 times higher or 51 ppt. Given the rapid pace at which new information on the effects of PFAS chemicals on human health at low doses is emerging, Michigan's rules should strive to reflect the very best science in the development of health-based values for PFAS. In addition, Michigan's rules should build in a process for updating the standard as new science emerges.

Sincerely,

Peggy S. Collins
[redacted]
Southfield, MI 48075

Smith, Ian (EGLE)

From: j [redacted]@hotmail.com>
Sent: Thursday, January 30, 2020 5:46 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS in drinking water-public comment

Please make these as low as possible for now. In seven years...when the health effects are better understood, then reevaluate.

Jaclyn Hulst
[redacted]
Zeeland mi 49464

Sent from my iPhone

Smith, Ian (EGLE)

From: Sarah McCallum [redacted]@yahoo.com>
Sent: Saturday, January 11, 2020 7:57 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Drinking Water Standars Comments

TO: EGLE

RE: PFAS DRINKING WATER STANDARDS

Michigan needs to adopt more protective standards when it comes to PFAS. I am requesting that EGLE makes the necessary changes to the standards before they are finalized. We need to set science-based drinking water standards to ensure Michigan's drinking water water and its' citizens fromt these harmful cancer-cuasing chemicals.

- Set a cumulative standard
- Require a health review in two years
- Conduct at least three years of quarterly sampling.

Thank you,

Sarah McCallum
[redacted]
Ann Arbor, MI 48108

Smith, Ian (EGLE)

From: Charity Steere <[redacted]@gmail.com>
Sent: Wednesday, January 29, 2020 1:03 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS drinking water rule

Follow Up Flag: Follow up
Flag Status: Flagged

Regulators,

The proposed Rule Set for PFAS does not go far enough. It needs to contain requirements for:

- Testing *and* Remediation of known PFAS-contaminated sites that threaten drinking water aquifers

- PFOS and PFOA to be considered as a Total PFAS figure

I am a Jackson County resident and 1-year ago it was reported that testing near the Grand River in downtown Jackson showed:

Surface water samples in the vicinity of Michner Plating upstream and downstream of the site sampled at concentrations from 0.9 ppt to 2.0 ppt PFOS (Dec. 20, 2018).
There was groundwater contamination over the Lifetime Health Advisory of 70ppt PFOS +PFOA at all-six monitoring wells (Sept. 24, 2018).

EGLE results from monitoring wells ranged from 483 ppt to 9,479 ppt PFOS+PFOA (9/24/18).
Additional water samples tested corroborated extremely high Total PFAS in Groundwater, Surface water, Basement water, and Indoor Vault water (Jan.18, 2019) related to the Michner site.
Since that time, no plan for removal and remediation has been reported and there has apparently been no follow-up from EGLE. Fish sampling was to be conducted in 2019. Was that sampling conducted and if so, what were the results?

I understand that PFAS can easily move through soil into groundwater aquifers and contaminate drinking water sources. Since PFAS are not known to breakdown in the environment, these “forever chemicals” in an abandoned factory basement, deteriorating by the day, need to be removed to a safer site than near a flowing river in downtown Jackson. Michigan doesn't need another "green ooze" incident. Particularly one so close to the source of drinking water for much of Central and Southwest Michigan.

Respectfully submitted,

Charity W. Steere

[redacted]

Grass Lake, MI 49240

[redacted]

Smith, Ian (EGLE)

From: Grace Donati [redacted]@gmail.com>
Sent: Friday, January 31, 2020 1:57 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS and PFOA Regulation

As a concerned Michigan resident of our Great Lakes state protecting our water quality is of monumental importance to me as it affects all quality of life. I'm asking the department to follow California's regulations to limit PFOA to 5.1ppt and PFAS to 6.5ppt. These are the lowest levels at which these contaminates can be reliably detected.

Thank you for considering my comments and protecting our Pure Michigan!

Grace Donati

Smith, Ian (EGLE)

From: marcia curran <[redacted]@hotmail.com>
Sent: Tuesday, January 14, 2020 9:23 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS compounds

I find the PFAS pollution situation in Michigan totally horrible and inexcusable. Government officials who should be doing their job to protect the public have not been doing that. The EPA is negligent big time when it comes to going after commercial chemical producers. And the state has been apparently reluctant for years to address it.

The State of Michigan should not wait for EPA to act because they will not do so. They do not do science now under the current federal administration. Or if the federal government does set a limit it could easily be much too high. I think often those standards are not set in a way that can give us assurance about public safety.

Too many chemicals are launched into our lives without any proper testing to make sure the public will be protected from hazardous exposure. Companies are not made to protect the public from such exposures. So, naturally now here we are trying to set standards after major public drinking water sources are contaminated by PFASs.

I think we know that there is epidemiological evidence that these substances are very toxic to humans and also to other animals. See the documentaries about their production and application in factories and what that did to the people who worked there.

Now it time to make the water sources in Michigan undergo testing for traces of PFASs and report the results to the public. It is time to make the companies that caused this hazardous pollution pay to clean it up. So that is my recommendation to you.

Thank you,

marcia curran
[redacted]
Frankfort, MI 49635

Smith, Ian (EGLE)

From: Laurie Hoag [redacted]@gmail.com>
Sent: Thursday, January 30, 2020 12:51 PM
To: EGLE-PFAS-RuleMaking
Subject: Pfas

0 contaminates in our drinking water!

Smith, Ian (EGLE)

From: S Donati <[redacted]@gmail.com>
Sent: Friday, January 31, 2020 1:49 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS and PFOA Regulation

As a concerned Michigan resident of our Great Lakes state protecting our water quality is of monumental importance to me as it affects all quality of life. I'm asking the department to follow California's regulations to limit PFOA to 5.1ppt and PFAS to 6.5ppt. These are the lowest levels at which these contaminates can be reliably detected.

Thank you for considering my comments and protecting our Pure Michigan!

Sharon Donati

Smith, Ian (EGLE)

From: Carol Gilchrist <[redacted]@gmail.com>
Sent: Friday, January 31, 2020 8:20 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS

With the Federal government not setting safe standards to regulate PFAS, it is imperative that the states do.. Michigan, with 20% of the world's fresh water, has even more responsibility than most states. We clearly need the toughest standards possible. PFAS are dangerous, "forever chemicals," that essentially don't break down and accumulate in the human body. PFAS chemicals can travel through the air and make their way into our drinking water. They can cause harm to the immune system of adults and especially children. Small doses have been linked to cancer, as well as causing harm to the reproductive and immune systems. And, we cannot count on businesses to self-regulate. DuPont used PFAS in Teflon, and new for decades that it was harmful.to humans, but did nothing to ameliorate the situation. . We need to protect our water as drinking contaminated water is the main way that PFAS individuals are exposed. I personally live in Walled Lake and taught in Wixom, an area affected by PFAS contamination. EGLE has identified 52 such sites throughout our state with possibly up 11,000 still to be identified. We have the ignominious honor of topping the national list for PFAS contamination. We clearly need to act now and establish rigorous and effective regulations that impose deadlines on cleanup and require the polluters to pay the costs of such cleanups. We are, as they say, "behind the eight ball," and need to act now!!!

Carol Gilchrist
[redacted]
Walled Lake, MI. 48390

Smith, Ian (EGLE)

From: Amelia [redacted]@earthlink.net>
Sent: Friday, January 31, 2020 4:07 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Protective Standards

Please give serious consideration to the policy solutions being offered by the Michigan Environmental Council when finalizing protective standards for PFAS and other chemicals. I feel that the addition of a cumulative standard, a bi-annual health review, and three years of quarterly sampling would add more strength to the standards.

Thank you for consideration of my request.

Amelia Lowe
[redacted]
Sylvan Lake, MI 48320

Smith, Ian (EGLE)

From: Michael Kramer <[redacted]@yahoo.com>
Sent: Friday, January 31, 2020 3:50 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Proposed Containment Levels

Please consider two things in approaching this problem.
These contaminants are so toxic they are described in parts per Trillion.This is why they must ***be eliminated*** from our environment to give our children a chance at a healthy life. We must proceed with clean up at the sources of these contaminates NOW.
We live in "Pure Michigan"and we had better start living up to these advertised ideals, or give up our future. The past profits of the companies, and there former owners, that ***knowingly*** polluted our environment, should surely be clawed back to help clean up the problem.
Thank You for the opportunity to register how important this is to me.
Please, consider what is at stake for all our children's health, instead of the financial profit of the irresponsible few.
Michael Kramer
[redacted]
Alpena, MI 49707
586-612-5622

Smith, Ian (EGLE)

From: [redacted]@aol.com
Sent: Tuesday, January 7, 2020 6:06 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS limits

Categories: Blue Category

Since not enough is known about PFAS contaminents, the maximum limits should be set. This is a common sense approach to provide protection to Michiganders state wide. Are there any standards that have been set in other states, or other countries? How does Europe handle this situation? We should be obtaining input from all sources of information on the subject domestic and international.

Joe Jakubowski

Smith, Ian (EGLE)

From: Tesha Galla [redacted]@mail.gvsu.edu>
Sent: Friday, January 24, 2020 6:58 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Levels

Hello,

I am in great support of the PFAS permitted level in water supplies being increased. We need more regulation on this. We are finding this is super toxic and can bioaccumulate in the body.

I feel we should take a very harsh approach and limit the level to 1 ppt as many scientists have suggested due to its highly toxic nature and the fact that it is around forever. We don't yet know enough about the problems this will cause in the future and should take dramatic steps to ensure the health and safety and humans, plants, and animals.

Thank you for your time,

Tesha Galla
Michigan

Smith, Ian (EGLE)

From: Anthony <[redacted]@gmail.com>
Sent: Thursday, January 30, 2020 7:40 PM
To: EGLE-PFAS-RuleMaking
Subject: Pfas rules

THE RULES ARE TOO WEAK. AND SO ARE THE PROPOSED ONES.
STRONGER RULES, PLEASE. THIS IS OUR HEALTH.

--
Anthony Scannell
[redacted]
Detroit MI 48209

Phone: [redacted]
Email: [redacted]@gmail.com

Smith, Ian (EGLE)

From: Val&Paul [redacted]@gmail.com>
Sent: Tuesday, January 14, 2020 12:51 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Rules

Dear Michigan EGLE PFAS Rule making committee,

We have some really bad "stuff" in our water, in our drinking water and more continues to be discovered.

As you establish the rules in allowing PFASs in our/Michigan drinking water please:

Regulate PFAS considering the health impacts of each chemical individually AND how they interact with each other to cause health problems or impacts.

Ensure that the value used to consider the impacts of PFASs protects the most vulnerable including children, pregnant women, the elderly & people suffering from chronic illnesses

Continually use the most recent science in the development of the health based values for PFAS and have a process to updating as new science emerges.

Valerie Deur
[redacted]
Newaygo, MI 49337-9508

[redacted]@gmail.com

Smith, Ian (EGLE)

From: Matt & Laura Hartz [redacted]@att.net>
Sent: Tuesday, January 21, 2020 11:28 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Rule comment

Follow Up Flag: Follow up
Flag Status: Flagged

I would like to comment on the estimate that the state shared regarding the cost of the sample collection and testing. The estimate shared on Jan 8th was $300 for collection and $300 for testing. I am curious as to why a utility has to have a contractor collect samples for $300. It would seem to me that the utility has the ability to collect samples as long as the collector follows the collection instructions provided by the testing laboratory. This was the process that was used during the UCMR3 regulation when collecting samples for Method 537. And both large systems and small systems were able to properly collect samples with minimal issues. Allowing the utilities to collect samples would reduce the overall cost of this Rule by nearly half. Something I would think the state would have great interest in doing.

Thank you,

Matthew Hartz
Niles, MI

Smith, Ian (EGLE)

From: Derrick Golla [redacted]@gmail.com>
Sent: Tuesday, January 7, 2020 2:02 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Rule Comments

Categories: Blue Category

Hello,

I'm writing in support of the newly proposed limits for PFAS in drinking water in Michigan. Creating limits for the seven most commonly found and widely studied compounds is a good start, but the government must continue to research other PFAS chemicals and propose new limits when scientifically feasible.

I understand the municipalities will incur increased costs to account for the newly required PFAS testing, but I strongly urge you to make the test results publicly available immediately. This is a stark contrast to requiring a water supplier to notify the public immediately only if the first sample is more than four times above the proposed PFAS limits. This change will offer the public an opportunity to switch to bottled water more quickly if they don't feel safe drinking tap water containing a certain level of PFAS in it. We as a society currently know very little about PFAS chemicals and their long-term impacts to humans, so increasing the availability of water test information is only natural to allow residents to make better informed decisions, which could ultimately improve public health and reduce costs in the health care sector.

Thank you for your consideration.

Sincerely,
Derrick Golla
Ann Arbor citizen

Smith, Ian (EGLE)

From: Tana Moore [redacted]@apba.org>
Sent: Thursday, January 30, 2020 6:55 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS regulation in Michigan

Since Michigan seems to be among the worst affected states by PFAS in groundwater, the state should step up and strengthen the regulations on the chemicals' use and cleanup.

I urge you to set a combined limit for all toxic contaminants, including PFAS. And that standard should be rigorous and science-based, so as to protect the most vulnerable—rural populations, children, those with chronic illnesses, pregnant women, and the elderly.

The federal government will not help with this issue, which will have negative effects on health for decades. It is up to the state of Michigan.

Remember "Pure Michigan"? The "Water Wonderland"? Haven't heard those terms for awhile, and PFAS contamination is among the reasons why.

Please do your part.

Tana Moore
[redacted]
Southfield MI 48075

Smith, Ian (EGLE)

From: jason davis [redacted]@gmail.com>
Sent: Friday, January 31, 2020 9:54 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Public Comments

Forcing municipalities to pay to remove PFAS from our drinking water is not only ethically wrong, it is likely financially ruinous. Those who created this problem should be the ones paying for it, not small towns & villages that cannot afford the incredibly expensive process of removing PFAS from our drinking water. The state of Michigan needs to make poluters pay ALL COSTS associated with PFAS removal both from the drinking water delivered to customers and more importantly from the public waters that these municipalities are pulling their water from. If we only focus on removing PFAS from the drinking water we will still be in the midst of a public health crisis due to non-potable water used on agricultural crops and the fish that Michigan citizens catch and eat. I am very concerned that by focusing all our attention on water after it has been treated for drinking we are putting ourselves in the position of having to deal with a crisis that has no end in sight. If we want clean drinking water then we need to stop the pollution at its source rather than forcing municipalities to pay to remove it.

Jason Davis

Smith, Ian (EGLE)

From: Sims, Connie L [redacted]@oakgov.com>
Sent: Tuesday, January 14, 2020 1:19 PM
To: EGLE-PFAS-RuleMaking
Cc: Ploof, Amy L
Subject: PFAS Proposed Rule Comment

Hi,
We've reviewed the proposed per- and polyfluoroalkyl (PFAS) rule and have the following comment.

There should be a process for reducing the monitoring from annually if PFAs is not detected. The process can be similar to the reduction to every 3 years as allowed in volatile organics, herbicides and pesticides or metals every 9 years required monitoring.

Please let me know if you have any questions.
Sincerely,
Connie Sims

Connie Sims
Environmental Planner III
Water Systems Engineering
Water Resources Commissioner's Office
[redacted]@oakgov.com

Smith, Ian (EGLE)

From: Laura Rubin [redacted]@nwf.org>
Sent: Tuesday, January 28, 2020 2:55 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS mcl rule-making comments

I would like to submit these comments on the proposed rule-making for PFAS chemicals.

Thank you for proposing these MCL limits for PFAS. This is a great step forward in the absence of federal rule-making. I applaud the EGLE for taking this step. First, I think these standards are a good start and need to be put in place as soon as possible to protect the health of the people and environment of Michigan. While I have some concerns about limiting the number of PFAS chemicals regulated, we need a PFAS drinking water standard immediately. Having been the Executive Director of the HRWC during the PFAS discovery in the Huron River, and now as Director of the Healing Our Waters—Great Lakes Coalition and a staff at the National Wildlife Federation, I know the urgency and need for regulation. I hear daily from citizens, elected officials, and scientists about their concerns on PFAS, the risks they pose to human and environmental health, and the need to act now. We need to enact drinking water standards for PFAS, make the polluters pay, and find ways to treat the contamination at the source. These standards are a good first step.

We applaud Michigan for leading on PFAS identification and prevention. While we strongly support this rulemaking, there is more to be done. There needs to be a total PFAS limit and PFAS should be regulated as a class of chemicals. We need to stop producing, using, and importing these chemicals. And we need to follow up and make the polluters pay rather than Michigan tax payers.

Thank you for the opportunity to comment.
Sincerely,
Laura

Laura Rubin
Director | Healing Our Waters--Great Lakes Coalition
[redacted]

Laura Rubin
National Wildlife Federation
www.nwf.org
Uniting all Americans to ensure wildlife thrive in a rapidly changing world

Smith, Ian (EGLE)

From: Laurie Hoag [redacted]@gmail.com>
Sent: Tuesday, January 28, 2020 6:31 PM
To: EGLE-PFAS-RuleMaking
Subject: Pfas levels

Pfas levels in drinking water should set at less than .01. We should not have any in our drinking water. Need to filter it out! We should not have to pay for contamines in our water!

Smith, Ian (EGLE)

From: Greko <[redacted]@gmail.com>
Sent: Friday, January 31, 2020 3:26 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS levels

Dear EGLE,
I would like to add my concerns and comments about setting the “acceptable” levels of PFAS in Michigan.

First, there is no acceptable level for PFAS. The information that is known about these chemicals at this time is that they are FOREVER chemicals and they are cumulative in our bodies. I have read many, many different accounts of what is considered an acceptable level. The BIG question is: How can you approve this chemical **at all** when there are too many unknowns about them? Since I began reading about this chemical - in the last 3 years - many more warnings and health effects have come to light. What will the next months and years bring?

Certainly the level of 70ppt is way too high. But is 7 or 8 acceptable? Will there still be harmful health effects at this level? It seems that every day more information is disclosed about the effects of these chemicals.

The only “safe” level is 0. The public needs to be made aware of products that contain these chemicals, and companies need to be held accountable to clean up the chemicals that have caused this contamination.

Sincerely,
Michelle Greko
Alpena, Michigan

Sent from my iPad

Smith, Ian (EGLE)

From: Mary Ellen Howard [redacted]@gmail.com>
Sent: Tuesday, January 7, 2020 11:34 AM
To: EGLE-PFAS-RuleMaking
Subject: Proposed Rules Re PFAS

Categories: Blue Category

I am writing regarding the proposed rules that would establish how much of seven PFAS compounds can be in Michigan's drinking water and public notification of contamination.

I am unable to attend the public forums on this topic, so I am submitting my recommendations here. I ask that EGLE:

- **Take a class-based approach to regulate PFAS in drinking water.** Considering health-based values for the seven individual PFAS chemicals separately does not take into affect how these chemicals interact with each other to cause health impacts.
- **Ensure that the health-based value used to set the PFAS-class drinking water standard protects those most vulnerable to harm.** Children, pregnant women, the elderly, and people suffering from chronic illness are more vulnerable to PFAS health impacts. Fetuses and infants have greater exposure to PFAS via maternal transfer in utero and contaminated breast milk or infant formula, and they are more sensitive to the exposure.
- **Use the most recent science to set a health-based value PFAS-class drinking water standard.** New research shows a relationship between exposure to PFHxS and impaired reproduction issues at 18 parts per trillion (ppt). The health-based value proposed by Michigan for PFHxS is 2.5 times higher or 51 ppt. Given the rapid pace at which new information on the effects of PFAS chemicals on human health at low doses is emerging, Michigan's rules should strive to reflect the very best science in the development of health-based values for PFAS. In addition, Michigan's rules should build in a process for updating the standard as new science emerges.

Thank you for your attention to these recommendations. The health and lives of Michiganders depend on your protection of our water and our citizens. Don't fail us!

Mary Ellen Howard, RSM
[redacted]@gmail.com

"They tried to bury us. They didn't know we were seeds." Mexican proverb

Smith, Ian (EGLE)

From: Michelle O'Grady [redacted]@gmail.com>
Sent: Friday, January 31, 2020 12:02 PM
To: EGLE-PFAS-RuleMaking
Cc: State Rep. Yousef Rabhi; [redacted]@a2gov.org
Subject: Proposed rules on PFAS

Hello. I am a resident of Ann Arbor. I am very concerned about the threats posed by groundwater contamination with PFAS substances. As a resident of Ann Arbor, my health is threated by these pollutants. I've also experienced a threat from the Gelman Sciences spill - my neighborhood is on the edge of that area (Evergreen - I live at 455 Evergreen).
I appreciate the progress that's been made in changing rules to more strictly regulate industries and companies that contribute to pollution, and more specifically, groundwater contamination. However, these current & proposed rules don't cover many of the PFAS contaminants. The cost of writing and enforcing these rules may be a consideration in taking action on them, but I firmly believe that it's necessary. Protecting citizen health is one of the fundamental functions of government - and more than compensates for these kinds of costs.
I'm also a maternal health care provider and have a very deep concern for women and children who are exposed to these toxins. Please adhere to the highest standards of government function and role, and put protections in place for the citizens of this area.
Thank you for your attention, and for your action on the behalf of residents here..
Michelle O'Grady, CNM, DNP

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Mike McIntosh [redacted]@everyactioncustom.com>
Sent: Saturday, January 4, 2020 6:04 PM
To: EGLE-PFAS-RuleMaking
Subject: Please strengthen the proposed standards for PFAS for all of Michigan

Categories: Blue Category

Dear Drinking Water and Environmental Health Division Suzann Ruch,

I've been at the epicenter of the heartache and health issues and the slow and inadequate response to the crisis in Northern Kent County. It would be great if you would you set PFAS standards that will really make a difference in protecting Michigan's health and water.

I am very glad you are taking this on. It is good we are setting a standard for GenX (Perfluoro-2-propoxypropanoic acid), which I don't think any other state has set. If the standards are done well, Michigan will continue to be a leader in addressing this issue.

One *key* improvement to the proposed standards is to take a class-based approach that sets a *single standard* for the combined total of the various PFAS chemicals instead of individual limits for each.

Vermont is currently the leader here. That state has a 20ppt standard for 5 related PFAS chemicals.

The standard must also ensure we protect are our vulnerable citizens: pregnant mothers, developing infants and children, and our aging citizens.

In an economic sense, Michigan will pay now or pay later (we are doing a lot of "pay later" in Northern Kent County. Let's *prevent* further health issues and further deaths by addressing this head on.

Sincerely,

Sincerely,
Mike McIntosh
[redacted] Rockford, MI 49341-1021 [redacted]@gmail.com

Smith, Ian (EGLE)

From: Michelle Hamilton <[redacted]@gmail.com>
Sent: Tuesday, January 7, 2020 6:18 PM
To: EGLE-PFAS-RuleMaking
Subject: Please Help Protect Ourselves From These Dangerous Chemicals

Categories: Blue Category

Dear Rule Makers,

Please make rules that will reflect our country's concern for the health of humanity as a whole with farsighted wisdom of thought for the generations to come.

- **Take a class-based approach to regulate PFAS in drinking water.**Considering health-based values for the seven individual PFAS chemicals separately does not take into affect how these chemicals interact with each other to cause health impacts.
- **Ensure that the health-based value used to set the PFAS-class drinking water standard protects those most vulnerable to harm.** Children, pregnant women, the elderly, and people suffering from chronic illness are more vulnerable to PFAS health impacts. Fetuses and infants have greater exposure to PFAS via maternal transfer in utero and contaminated breast milk or infant formula, and they are more sensitive to the exposure.
- **Use the most recent science to set a health-based value PFAS-class drinking water standard.** New research shows a relationship between exposure to PFHxS and impaired reproduction issues at 18 parts per trillion (ppt). The health-based value proposed by Michigan for PFHxS is 2.5 times higher or 51 ppt. Given the rapid pace at which new information on the effects of PFAS chemicals on human health at low doses is emerging, Michigan's rules should strive to reflect the very best science in the development of health-based values for PFAS. In addition, Michigan's rules should build in a process for updating the standard as new science emerges.

Thank you!

Michelle Hamilton

Smith, Ian (EGLE)

From: Chris Reilly [redacted]@chris-reilly.org>
Sent: Thursday, January 30, 2020 6:49 PM
To: EGLE-PFAS-RuleMaking
Subject: Please enact the toughest limits for PFAS chemicals in drinking water

Please enact the toughest limits for PFAS chemicals in drinking water. I want the state to set a combined limit for all toxic contaminants, instead of smaller limits for each. And I want the PFAS standard to be protective of groups most susceptible to the negative health effects of PFAS exposure, such as children, pregnant women, the elderly, and those suffering from chronic illnesses.

PFAS chemicals have been found in the drinking water of communities across the state. With the utter lack of action from the federal level on PFAS and drinking water protections in general, it's really up to the state and at the state level to take action to protect our water. We must do all we can to protect our state's most vulnerable people and natural resources.

--
Chris Reilly
Artist, Teacher, Hacker
[redacted].org

Smith, Ian (EGLE)

From: [redacted]@sbcglobal.net>
Sent: Monday, January 20, 2020 5:50 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAs/microplastics

Follow Up Flag: Follow up
Flag Status: Flagged

To our water protectors,

I have lived in the water wonderland aka Michigan for almost seven decades. The state's aquifers, lakes, rivers, and streams have provided its citizens water for life, recreation, and economic prosperity until industry legally or surreptitiously polluted it until currently it has reached totally unacceptable levels of toxicity. These microplastics and PFAs are infiltrating every facet of our lives.

Please do everything in your power to stop this irresponsible abuse to our water, and immediately begin to reverse the damage already incurred to citizens' health and common good.

Sincerely
Martha Vermeulen

Sent from my Verizon, Samsung Galaxy smartphone

Smith, Ian (EGLE)

From: [redacted]@gmail.com>
Sent: Friday, January 31, 2020 4:42 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Water Rules

As a lifetime resident of Michigan and someone who prides herself on keep8ngmy consumption within the smallest circle possible. PFAS contamination in our watershed, wildlife, woodshed and beyond is of paramount concern to me.

The health on myself, my family and my community is on the line when it comes to l limiting chemicals in our water. I am committed to fighting for a removal of all PFOAS family of chemicals from the drinking water and from the surface and ground water, making those responsible for making and using the chemicals for dumping them responsible for paying to clean them up. Not just from our drinking water, but also from the surface and ground water.

The recent revelation that use of these chemicals in food packaging has caused the compost we use to grow our "organic" garden vegetables is also so contaminated that the leechate in the area is testing high in PFOAS suggests that this is a problem that goes far beyond the scope of SOM EGLE... into SOM DEPT OF AG and to the federal level for further regulation of these chemicals.

Sincerely,
Jennifer Davis

Sent from my Sprint Phone.

Smith, Ian (EGLE)

From: Brad Silvester [redacted]@att.net>
Sent: Monday, January 20, 2020 9:59 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS support

To whom it may concern;

We strongly support legislation and action by the State of Michigan to lower PFAS levels in drinking water to safe levels using current and acceptable science standards. We also support clean up of the unacceptable number of contaminated sites in Michigan and requiring the guilty parties to pay for the clean up costs.

The state of Michigan is so beautiful in part due to all of the rivers, ponds and lakes we have. A significant part of our tourism is due to the water based activities in our state. Protecting these waters for our enjoyment and more importantly for our safety needs to be the highest priority for our state government.

Thanks for your consideration,

Brad and Laurie Silvester
Ann Arbor, MI

Smith, Ian (EGLE)

From: [redacted]@gmail.com
Sent: Tuesday, January 28, 2020 8:02 PM
To: EGLE-PFAS-RuleMaking
Cc: Cris Jones
Subject: PFAS Standards

January 30, 2020

I'm writing on behalf of the Au Sable River Watershed Committee to support the proposed Michigan Safe Drinking Water Act rules that would impose a strong standard to protect the public health from PFAS chemicals in public drinking water supplies.

PFAS contamination affects the drinking water of more than 1.9 million Michiganders, and we can't delay action on protecting the health of our communities. The PFAS standards must be protective of our most vulnerable populations and be based on the best available science.

The PFAS limits proposed by the state are a step in the right direction, but key additions need to be made to ensure those standards protect the health of Michigan communities. These include:

Set a cumulative standard.

In addition to setting numeric standards for individual compounds of PFAS, the state should set a cumulative limit. A cumulative limit would better protect the public against additive or synergistic effects from exposure to multiple PFAS chemicals. It would also create a level of protection for residents exposed to PFAS chemicals that are not included in the seven slated for a drinking water standard.

Require a health review in two years.

The state is moving forward with setting drinking water standards for seven PFAS compounds. That approach leaves thousands of PFAS compounds unregulated. The science on the risk and toxicity of PFAS chemicals is rapidly developing; standards set today could be quickly out of date as new research on toxicity comes in. To ensure Michigan remains ahead of the curve and maintains science-based standards that are protective of public health, the state should conduct a health review two years after the PFAS drinking water standards go into effect. *This requirement should be written into the PFAS drinking water rules*.

Conduct at least three years of quarterly sampling.

We do not know enough about how PFAS moves in the environment or if there are seasonal changes to discharges of PFAS to be able to set reduced sampling frequencies. The current rule requires some quarterly sampling, but also allows water plants to potentially reduce to sampling every six months or only once a year. At a minimum, given the unknowns, all water systems should test quarterly for three years. That will give the state a solid baseline of knowledge to know when PFAS may or may not spike and which supplies are most at risk of exposure. From there the state can better establish a reduced sampling frequency process.

Thank you,
Cris Jones, Chairman
Au Sable River Watershed Committee

Smith, Ian (EGLE)

From: [redacted]@gmail.com
Sent: Friday, January 31, 2020 3:27 PM
To: EGLE-PFAS-RuleMaking
Cc: Charlotte Wilks
Subject: PFAS standards

I am writing to say that PFAS standards should be adopted immediately.

Thank you,
Charlotte Wilks

Sent from my iPhone

Smith, Ian (EGLE)

From: Chuck Kopinski [redacted]@gmail.com>
Sent: Saturday, January 25, 2020 1:52 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Standards Comment

Setting science-based drinking water standards is a critical and necessary step in the right direction. There are also changes to the rules that EGLE should make in order to further strengthen them.

I strongly support the Michigan Environmental Council recommendations to ensure the standards fully protect human health and the environment against PFAS detailed as follows:

- Set a cumulative standard. In addition to setting numeric standards for individual compounds of PFAS, the state should set a cumulative limit. A cumulative limit would better protect the public against additive or synergistic effects from exposure to multiple PFAS chemicals. It would also create a level of protection for residents exposed to PFAS chemicals that are not included in the seven slated for a drinking water standard.

- Require a health review in two years. The state is moving forward with setting drinking water standards for seven PFAS compounds. While a step in the right direction, that approach leaves thousands of PFAS compounds unregulated. The science on the risk and toxicity of PFAS chemicals is rapidly developing; standards set today could be quickly out of date as new research on toxicity comes in. To ensure Michigan remains ahead of the curve and maintains science-based standards that are protective of public health, the state should conduct a health review two years after the PFAS drinking water standards go into effect. This requirement should be written into the PFAS drinking water rules.

- Conduct at least three years of quarterly sampling. We do not know enough about how PFAS moves in the environment or if there are seasonal changes to discharges of PFAS to be able to set reduced sampling frequencies. The current rule requires some quarterly sampling, but also allows water plants to potentially reduce to sampling every six months or only once a year. At a minimum, given the unknowns, all water systems should test quarterly for three years. That will give the state a solid baseline of knowledge to know when PFAS may or may not spike and which supplies are most at risk of exposure. From there the state can better establish a reduced sampling frequency process.

Thank-you for consideration of these comments.

Charles Kopinski
[redacted]
Ludington, MI 49431

[redacted]@gmail.com

Smith, Ian (EGLE)

From: Mark Blazejewski [redacted]@gmail.com>
Sent: Wednesday, January 22, 2020 7:40 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS standards

Follow Up Flag: Follow up
Flag Status: Completed

I cannot attention your meeting unfortunately. The standards need to be at 0. The state and federal government allowed this cancer causing chemical into our bodies. Zero is the only acceptable limit. If you actually care you will respond.

Mark Blazejewski

Smith, Ian (EGLE)

From: Gary Gritter [redacted]@comcast.net>
Sent: Thursday, January 9, 2020 5:17 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Rules Proposal

Follow Up Flag: Follow up
Flag Status: Completed

Dear Rule Makers,

Three matters of great importance.

Take a class-based approach to regulate PFAS in drinking water.

Ensure that the health-based value used to set the PFAS-class drinking water standard protects those most vulnerable to harm.

Use the most recent science to set a health-based PFAS-class drinking water standard.

Thank you for your consideration.

Thank you.

Gary Gritter

Smith, Ian (EGLE)

From: Georgia Griffin <[redacted]@gmail.com>
Sent: Monday, January 20, 2020 7:16 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS standards

To whom it may concern,

I am writing to urge changes to Michigan's PFAS standards before they are finalized.

I strongly urge that a cumulative standard be established, that a two-year health review be required, and that a minimum of three years of quarterly sampling be conducted.

Thank you for considering my comments.

Georgia Griffin, D.O.
Chesterfield Township, MI

Smith, Ian (EGLE)

From: Michael Lambrix <[redacted]@gmail.com>
Sent: Friday, January 31, 2020 8:01 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Rules Comment

To Whom It May Concern,

Michigan needs to be the front runner in protecting our natural beauty and safety for humans and animals. Our residents depend on our ground water, our economy is intertwined with our natural environment and our citizen's health is at risk.

Therefore, PFAS and other "Forever Chemicals" need to be regulated to the toughest limits by our State. The federal government's lack of action is both astounding and distressing.

We cannot reverse time to stop the PFAS and companies using the chemicals from getting into our water and environment. But we can implement the strictest standards to date and be the leader in environmental protection.

As a 25 year old male raised in Ludington, went to college in Kalamazoo, and living in Grand Rapids, I have been a Michigan resident my entire life. I intend to raise a family here in the mitten state. But I cannot fathom our state not protecting our natural beauty and the largest resource of freshwater in the world.

We are at a turning point to decide how healthy we want our Great Lakes, environment, and children to be. An older and well-known quote is fitting to this situation.

"*The best time to plant a tree was 20 years ago. The second best time is now.*"

Regulate PFAS and the other "Forever Chemicals" to the toughest standards. Current and future generations, along with the nation, will see the Michigan government fighting for the greater good for decades to come.

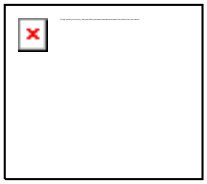
Thank you for your time.

Sincerely,

Michael Lambrix

Smith, Ian (EGLE)

From: Micaela Preskill-E2 <[redacted]@e2.org>
Sent: Friday, January 31, 2020 3:21 PM
To: EGLE-PFAS-RuleMaking
Subject: Public Comment on PFAS Rulemaking



Good for the Economy.
Good for the Environment.

1/31/2020

Dear Governor Whitmer and the Michigan Department of Environment, Great Lakes, and Energy (EGLE),

As business leaders and members of E2 (Environmental Entrepreneurs) we write in strong support of further strengthening Michigan Department of Environment, Great Lakes and Energy (EGLE) draft regulations for seven PFAS chemicals.

E2 is a national, nonpartisan group of business leaders who advocate for smart policies that are good for our economy and good for our environment. Our members have founded or funded more than 2,500 companies, created more than 600,000 jobs, and manage more than $100 billion in venture and private equity capital.

One of the most pressing and potentially costly pollutants in Michigan's waters are chemical compounds called per- and polyfluoroalkyl substances, or PFAS, which don't break down in the environment and can bioaccumulate over time in plants, animals and humans. As of November 2019, there were 68 known PFAS contamination sites across Michigan. The Detroit Free Press estimates that PFAS could negatively impact Michigan's hunting and fishing industry, property values, local business development and employment at facilities such as airports.

Businesses in Michigan need the promise of safe, reliable and affordable drinking water in order to locate and thrive in our state. Michigan industries depend on clean water. Examples include:

- Commercial fishing generates $50 million in annual revenues
- Craft brewing employs more than 5,000 Michiganders who take home more than $150 million in annual wages
- Auto manufacturing takes up to 40,000 gallons of water to manufacture a single car

According to E2's recent report, *How Investing in Michigan's Water Infrastructure Protects our Economy, Creates Jobs and Drives Growth*, closing Michigan's water infrastructure gap will not only protect our most precious resource and bring nearly 90,000 direct job-years to local communities, but investment would also propel Michigan businesses to become

national leaders in developing and commercializing new water technologies, just as early-mover states like California have become national leaders in clean tech.

While the Whitmer Administration has moved quickly to draft regulations to address the dangers posed by PFAS in Michigan's drinking water, we believe these proposed standards do not go far enough. **Therefore, we urge EGLE to adopt the recommendations included herein to strengthen the health protections embedded within Michigan's enforceable drinking water standards.**

I. Take a class-based approach to regulating PFAS in drinking water.

In order for Michigan to lead the way on this issue, we must regulate PFAS as a class or subclasses as opposed to individual chemicals. The proposed rule sets maximum contamination levels for only seven (of nearly 5,000) specific chemicals in the PFAS category, and this is simply not enough.

To protect Michiganders from the health risks posed by the PFAS class of chemicals EGLE should set a treatment technique that is most effective at cleaning up all known PFAS from drinking water. If not immediately possible, at the very least, EGLE should set a cumulative limit on the PFAS chemicals it has proposed to regulate.

By setting limits for individual PFAS without a limit on the cumulative presence of PFAS chemicals, the proposed standards do not effectively keep our water safe. When people are exposed to multiple chemicals at a time, the chemicals can interact and produce greater effects than anticipated for individual exposures. This is especially true for chemicals that share similar chemical properties. Michigan water testing confirms that PFAS-contaminated water often contains multiple PFAS chemicals, thus exposing persons drinking the water to a mixture of PFAS. Vermont and Massachusetts have already set or proposed a combined standard for 5 or 6 PFAS, respectively.

II: The Proposed Individual Maximum Contamination Levels are Too High

The new maximum contamination levels must be low enough to account for the effects of exposure from multiple PFAS chemicals over a lifetime and to protect those most vulnerable to the effects of PFAS.

The Natural Resources Defense Council (NRDC) released a study earlier this year which establishes science-based recommendations for maximum PFAS levels that are lower than what's currently proposed. NRDC proposed Michigan immediately set a health-based goal of zero for all PFAS chemicals in drinking water and a combined maximum contaminant level of 2 ppt for the following specific PFAS chemicals: PFOA, PFOS, PFHxS, and PFNA, and 5 ppt for a GenX. NRDC also recommended the State, within two years, determine a treatment technique based on the most effective treatment to remove the full class of thousands of PFAS chemicals in water.

Conclusion

As business leaders representing broadly diverse industries in Michigan, we urge you to do what's best for Michigan's economy and adopt stronger standards to regulate PFAS chemicals. Strong standards will help businesses in the state's water services industry become national leaders in developing and commercializing new water technologies and

ensure that all Michigan industries are in the best position possible for decades of ongoing growth.

For more information, please contact E2 Midwest Advocate Micaela Preskill at [redacted]@e2.org.

Richard Allison
CEO, Domino's Pizza
Amjad Aman
Battery Modeling Engineer, Ford Motor Company
Dayne Bartscht
Managing Partner, Eastern Market Brewing Co
Monique Becker
Partner, Mona Lisa Development
Kurtis Cook
AquaPure Water Conditioning
Sarah Craft
Director of Detroit, Venture For America
Ben Dueweke
Director of Community Development, Walker Miller Energy Services
Brittany Eshelman
Media Planner, The Outloud Group
Jake Graham
Energy Project Engineer, Energy Science
Ryan Greenwalt
CEO, Alta Equipment
Brad Hinkley
Operations Manager, Westside Solutions
Emma Johnson
Freelance Writer, Great Lakes Bay Magazine
Greg Mangan
Real Estate Advocate, Southwest Detroit Business Association
Malcolm Miller
Director of Business Development, Walker Miller Energy Services
Roslyn Ogburn
Membership Engagement Coordinator, Good Jobs Now
Darren Riley
Manager, Endeavor Detroit
Brock Rodgers
Director of Sustainability, Foresight
Vito Rosolino
Project Manager of Sustainability and Service, Ferndale Electric
Jim Saber
CEO, NextEnergy
Justin Schott
Executive Director, EcoWorks
Mark Stenftenagel
CEO and Principal, Whitney Inc.
Ian Tran
Principal Strategist/Advocacy Chair, ISMOTION / USGBC MI

Smith, Ian (EGLE)

From: Acer Home <[redacted]@sbcglobal.net>
Sent: Tuesday, January 14, 2020 9:54 AM
To: EGLE-PFAS-RuleMaking
Subject: Public Comment Rule Set 2019-35 EG

Follow Up Flag: Follow up
Flag Status: Flagged

Public Comment 1/14/2020
Administrative Rules for Supplying Water to the Public
Rule Set 2019-35 EG

The proposed Rule Set does not go far enough. It needs to contain requirements for:

- Testing *and* Remediation of known PFAS-contaminated sites that threaten drinking water aquifirs
- PFOS and PFOA to be considered as a Total PFAS figure

I'm a Jackson County resident and 1-year ago EGLE made a presentation to the Upper Grand River Watershed Alliance. Testing by EGLE proved that on the very banks of the Grand River in downtown Jackson, we have a basement-full of high-level PFAS in the abandoned chrome-plating Michner Industries. EGLE reported to us:

- Groundwater contamination over the Lifetime Health Advisory of 70ppt PFOS +PFOA at all-six monitoring wells (Sept. 24, 2018)
- EGLE results from monitoring wells ranged from 483 ppt to 9,479 ppt PFOS+PFOA (9/24/18)
- Surface water samples in the vicinity of Michner Plating upstream and downstream of the site were concentrations from 0.9 ppt to 2.0 PFOS (Dec. 20, 2018)
- EGLE met with contractor, "Wood", on behalf of Remediation and Redevelopment Division
- Additional 12 water samples were then tested and those results corroborated extremely high Total PFAS in Groundwater, Surface water, Basement water, and Indoor Vault water (Jan.18, 2019)
- No plan for removal and remediation has been put forth and we've had no follow-up from EGLE after 1-year
- Fish sampling was to be conducted in 2019

I understand that PFAS can easily move through soil into groundwater aquifers and contaminate drinking water sources. Since PFAS are not known to breakdown in the environment, these "forever chemicals" in an abandoned factory basement deteriorating by the day need to be removed to a safer site than a flowing river in downtown Jackson.
Respectfully submitted,
Marguerite Clevenger
Jackson County, MI

Smith, Ian (EGLE)

From: Andrea Wotan [redacted]@gmail.com>
Sent: Saturday, January 25, 2020 2:33 PM
To: EGLE-PFAS-RuleMaking
Subject: Public Comment on PFAS Drinking Water Rule

Dear EGLE Team,

I ask you to enact these rules ASAP to immediately begin protecting our drinking water. HOWEVER, I ask that you make a public announcement that the PFAS limits will be lowered shortly to the following level:

Limits shall be lowered for each of the seven PFAS compounds to the lowest detectable quantity of each.

Also, I ask you to specify a cap on total PFAS compounds detected in our water, as a class, to protect against high levels of additional PFAS compounds not included in the ruling.

Going forward, I urge EGLE and Governor Whitmer to adopt a ZERO TOLERANCE POLICY for any and all contaminants in our water, including drinking water, other surface waters (rivers, lakes, streams) and ground water. What this would mean practically would be that any and all contaminants, including PFAS, would be limited to the lowest levels detectable by current technology. As technology becomes more precise, we should continue to lower those limits to get as close to Zero as possible.

I also urge EGLE and Governor Whitmer to launch any and all investigations required to identify polluters and force them to immediately cease production until they can prove that they no longer emit PFAS of any kind AND pay a huge fine AND pay the cost to clean up drinking water for the public AND pay the cost of ongoing monitoring of public drinking water to determine that it is meeting limitations.

Thank you,

Andrea Wotan, Ann Arbor Resident

Smith, Ian (EGLE)

From: renae mata [redacted]@gmail.com>
Sent: Thursday, January 30, 2020 7:01 PM
To: EGLE-PFAS-RuleMaking
Subject: Rule Set #2019-35 EG comments

Good afternoon,
Regarding proposed changes to the rules titled "Supplying Water to the Public", I would like to make the following comments for the public record:

1. Thank you for proposing to establish drinking water MCL's for the 7 PFAS for community water supplies and non-community ones like schools. It is a good start but why couldn't all levels be the same, like zero ideally, or at least 6 ppt, the lowest level (PFNA). Since their additive effect can make them more toxic,we should take our cue from other states and evaluate them as a Class of chemicals, max 20 ppt for the total group of PFAS. I'm sure PFAS have their uses but we lived w/o them before the 1930's, so why not just ban the production and use and import of them immediately!?! I would do w/o their convenience for the sake of health and lives. And this includes supposedly safer (not harmless) chemicals, like GenX, which breaks down more easily into shorter chains, but they are still fluorocarbons! And Michigan needs to set a schedule for reviewing MCL's so they can be revised/lowered to coincide with new science.

2. Ban them and be as restrictive as possible on the amounts allowed in drinking water because the high risks associated with them far outweigh the benefits. We are all familiar with the costs of cancer (I work at a local hospital cancer pavilion) - thyroid cancer is a telltale one for effects of contamination, and now kidney cancer (which my mother-in-law has) and testicular cancer that affects too many young men/teenagers - I hope not (and pray for) my two young sons, ages 12 & 16, who drank Plainfield Twp municipal water since before birth, breastfeeding (for a very short time since I couldn't produce much - another effect of PFAS I'm told), formula bottles, and right from the tap since we were told how wonderful & award-winning our water was (our family toured the Twp water treatment center). I worry most about unborn children who ingest even "low" amounts of PFAS that are then incorporated into their very growing & multiplying cells. Could this be to blame in part for the increase in immunological and neurological/behavioral issues such as ADHD and autism spectrum disabilities, and childhood cancers like leukemia? A friend's daughter was diagnosed with a cancerous tumor in utero, which she fought from birth for 8 short years - their only child since they never want to go through that horror ever again.

3. Ban/severely restrict them b/c there are too many other non-cancer risks, like fertility and pregnancy issues - our nation's birth rate has already dropped for various reasons, why make it any worse. And long-term digestive diseases that make people's lives miserable, like ulcerative colitis and fatty liver disease. And more insidious and prevalent issues such as high cholesterol, like my husband has, which will potentially decrease his heart health/life span.

4. I realize private wells, used by ~25% of MI citizens, are regulated by the local health department, but I believe that the MCL's allowed for private consumption should mirror the state's MCL's. The state needs to work together with local units of government to make this happen, since well owners very often are taking their water from the exact same aquifer that community water supplies are taking theirs from, especially if it's an unconfined aquifer.

5. Knowing how contamination plumes migrate, community source water should be sampled regularly to maintain wellhead protection. And potential sources of pollution need to be pinpointed, especially if there are high-risk industries in the area - they should be monitored as a matter of course. It was an embarrassment, more than that: a travesty, that the State accepted Wolverine's statement that there was "no known contamination" on their tannery property - it was a Tannery for goodness sake! That's like saying a pig farm doesn't stink.

Thank you for taking public comments into account when formulating new rules - I hope they will be truly analyzed and put into action! Michigan should be courageously leading the country on setting the toughest standards for toxic PFAS chemicals in our water.
Sincerely,
Ms. Renae L. Mata
Plainfield Twp/Comstock Park

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Nova Lawrence [redacted]@everyactioncustom.com>
Sent: Tuesday, January 14, 2020 5:52 PM
To: EGLE-PFAS-RuleMaking
Subject: Rise to the Responsibility for Public Fear of Catastrophe around PFAS

Dear Drinking Water and Environmental Health Division Suzann Ruch,

PFAS are forever chemicals and the makings of a public health emergency. As their effects in our community unfold in the years to come, we will understand how only a ruling to heighten these standards will have been situated on the right side of history. I'm sure there will be the lives and livelihoods (and perhaps the lawsuits, too) of many Michiganders -- 1.9 million of whom have their drinking water supply already contaminated by PFAS -- resting on your collective conscious in the future.

In the present, my friends, family, colleagues, and I are all scared for our community's health, and what the risks could come to without appropriate action. Both those who, like me, are scientists by training, and those who are completely unfamiliar with the chemicals and regulations therein feel our health is threatened by environmental oversight in our state, and are starting to consider relocating to cities and regions with a more responsible command over and care for their communities than that of SE Michigan.

On top of this, marginalized, working class, and poorer communities will be categorically hit the hardest by any and all failures to protect the people's health, environmental needs, and access to resources like clean water that are human rights. We must not only provide protections to those who voice their concerns in these comments, but also those who cannot speak or have not spoken, as they will face the deadliest consequences of a perilous series of environmental events and catastrophes in the coming years and decades.

The goings on of my industry and yours may not appear at the surface to corroborate any such tale of deep change, but as the arc of history turns and empowers its citizens, so rages the people's demands for accountability from our public officials and the industries they regulate. We will notice failure, and we plead that you come out on the right side of our collective environmental history.

Some demands toward achieving the minimum in equitable and healthy regulations and procedures include:

-Taking a class-based approach that sets a standard for the combined total of the various PFAS chemicals instead of individual limits for each.
-Ensuring the standards are protective of our most vulnerable populations, like developing infants and children.
-Basing the standards on the best and most recent science.
-Regularly consulting with experts of all kinds, and effectively encouraging and marketing the opportunities for such engagement. These include scientists, environmental groups, researchers, advocates, and frontline communities.

Sincerely,

Sincerely,
Nova Lawrence
[redacted] Ann Arbor, MI 48104-1303 [redacted]@gmail.com

Smith, Ian (EGLE)

From: Angie Johnson [redacted]@yahoo.com>
Sent: Friday, January 17, 2020 3:44 PM
To: EGLE-PFAS-RuleMaking
Subject: Re: PFAS MCL Public Hearing (January 14) -- Thank you for attending

After listening to the presentation
At the public hearing I have 3 major concerns:
1-ALL PFAS need to be monitored and banned IMO, as was the opinion of several of the audience. The Wixom company just switches over to a different unmonitored PFAS to avoid problems...NOT ACCEPTABLE.
2-companies, like the one in Wixom and the Wolverine business NEED TO NOT ONLY BE CAREFULLY MONITORED...BUT NEED TO BE FINED. There should be a SIGNIFICANT MONETARY FINE FOR POISONING...if it was a dose of cyanide there would be long jail time so why is this any different?
3-government cleanup needs to be a HUGE priority at the military sites and at business sites. Hire more inspectors or whatever...BUT GET IT DONE QUICKLY!!!
4-it's imperative that studies linking skin absorption of PFAS be done with test results published so that recreation activities can either be curtailed or continued without considerable worry. HURRY!
5-all this work is all good and well, but time is of the essence. Putting this on a speed timetable needs to be done. PLEASE, HURRY, the future depends on this!

Thank you for the chance to air my thoughts. I'm watching this closely since we live in Belleville Lake.
Thanks,
Angela M. Garcia-Johnson

Sent from my iPhone

On Jan 17, 2020, at 1:28 PM, EGLE-PFAS-RuleMaking <EGLE-PFAS-RuleMaking@michigan.gov> wrote:

> Good Afternoon:
> Thank you for taking the time to attend the January 14th Information Session and Public Hearing regarding the Proposed Administrative Rule Revisions to Rule Set #2019 - 35 EG: PFAS Amendment to Supplying Water to the Public Rule. The purpose of the Information Session and Public Hearing was to provide a way for the public to ask questions and get information about the rule revisions.
> At the Public Hearing, we provided copies of the Agenda and Issue Summary, which may be viewed on the EGLE Drinking Water Rule Promulgation webpage at Michigan.gov/CommunityWater. Scroll down to Laws and Rules and click on "Drinking Water Rule Promulgation." The Information Session presentation is available from this site, as well as the Livestream recording of the Information Session and Public Hearing. You may also view the proposed rules from this webpage, and information about the rulemaking process.
> As we move forward, we will post information on this webpage, and update you directly via e-mail. We appreciate your interest in the proposed rule revisions and want to continue to provide you information on what the state agencies involved are doing.
> Thank you again for taking time out of your busy schedule to attend the January 14th Information Session and Public Hearing and provide your input.

Sincerely,
Eric Oswald, Director
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
<image001.jpg>
Follow Us | **Michigan.gov/EGLE**

Smith, Ian (EGLE)

From: Crystal Cunningham <[redacted]@dwellingplacegr.org>
Sent: Monday, January 13, 2020 2:23 PM
To: EGLE-PFAS-RuleMaking
Subject: Re: PFAS MCL Public Hearing (January 8) -- Thank you for attending

Follow Up Flag: Follow up
Flag Status: Flagged

I am so very relieved, delighted to know you have taken on this very serious health needs. Thank you for your action, your time ,your energy and your comprehension of this as a "Health need" Thank for wanting to insure there are measures taken to insure the health and safety of our water here in Michigan. I am so angered by this whole issue, and the frustration sometimes takes up my energy so I try to refocus on actually being involved in the "DO SOMETHING" and not waste energy on just being angry. Its difficult when people insult these real crisis by calling it **Emerging** when it i**s a well known fact**

On Mon, Jan 13, 2020 at 2:16 PM EGLE-PFAS-RuleMaking <EGLE-PFAS-RuleMaking@michigan.gov> wrote:

> Good Afternoon:
>
> Thank you for taking the time to attend the January 8th Information Session and Public Hearing regarding the Proposed Administrative Rule Revisions to Rule Set #2019 - 35 EG: PFAS Amendment to Supplying Water to the Public Rule. The purpose of the Information Session and Public Hearing was to provide a way for the public to ask questions and get information about the rule revisions.
>
> On Wednesday evening, we provided copies of the Agenda and Issue Summary, which may be viewed on the EGLE Drinking Water Rule Promulgation webpage at Michigan.gov/CommunityWater. Scroll down to Laws and Rules and click on “Drinking Water Rule Promulgation.” The Information Session presentation is available from this site, as well as the Livestream recording of the Information Session and Public Hearing. You may also view the proposed rules from this webpage, and information about the rulemaking process.
>
> As we move forward, we will post information on this webpage, and update you directly via e-mail. We appreciate your interest in the proposed rule revisions and want to continue to provide you information on what the state agencies involved are doing.
>
> Thank you again for taking time out of your busy schedule to attend the January 8th Information Session and Public Hearing and provide your input.
>
> Sincerely,
>
> Eric Oswald, Director
>
> Drinking Water and Environmental Health Division
>
> Michigan Department of Environment, Great Lakes, and Energy

Follow Us | **Michigan.gov/EGLE**

--
Crystal Cunningham
Resident Services Coordinator
[redacted] or
[redacted]@dwellingplacegr.org

Smith, Ian (EGLE)

From: Mark Blazejewski [redacted]@gmail.com>
Sent: Saturday, January 11, 2020 12:31 PM
To: EGLE-PFAS-RuleMaking
Subject: Public input

I am writing about the meetings discussing PFAS standards. I wish I could attend. As a tax paying citizen I demand the standard for PFAS, raw sewage, the various chemical spills and all contaminated drinking water be set at ZERO. There is nothing to discuss. The state and federal government allowed this to happen. They approved products that had these chemicals and did so for profit. Now because the public is aware you want to do something. The same foolish people that researched and approved this to begin with are now going to set standards?? I don't think so. I also expect this to be publicly addressed and I will spread word like wildfire to get this to happen. Lastly I don't want to hear about money being an issue. We all know you have plenty of money. Maybe you should stop portraying us as Pure Michigan and actually make it PURE.

Mark Blazejewski

Smith, Ian (EGLE)

From: JENNIFER MASTERSON <[redacted]@comcast.net>
Sent: Friday, January 31, 2020 8:42 AM
To: EGLE-PFAS-RuleMaking
Subject: Public comments

Dear Ms. Ruch:

I am a resident of Ann Arbor. I drink and bathe in city water. I have seen with my own eyes the white fluffy foam on the top of the river banks that make it look like snow in the winter.

I have my Bachelor's degree Biochemistry. I trained in Molecular Biology. I have worked temporarily at drinking and wastewater treatment plant. I currently work as Microbiologist.

I am a Mother and hopefully someday Grandmother.

I am a concerned citizen of my community and my world.

I attended PFAS meeting 1/14/2020 at Washtenaw Community College and want my opinion to be heard and taken into consideration.

1. We must regulate PFAS and GenX compounds as a class.

By regulating only a few of the PFAS's

a. Companies will simply select a different compound that is not listed and escape costly regulations. There are more than 4700 to choose from.

b. When companies switch to other not tested PFAS compounds, this will cost the State and taxpayers more because we will be testing for something that is not being used.

c. When the State tests for PFAS compounds that are not being used, this will give the community the false sense of security that everything is very low and safe when it isn't.

d. When companies are allowed to use any of the other PFAS compounds that are not regulated they will pollute our water and send the waste downstream for some other community to bear the burden of the contamination and costly cleanup. This is not fair.

e. The legislation will be too narrow to stop polluters. We must develop legislation similar to that developed for the Cannabinoids when Spice and K2 came out. Legislators would declare a compound banned because of its harmful effects. The chemist over in China would then add an atom somewhere making the compound a "new" compound. Because the compound had changed it became a new compound even if it had the same effects. Legislators would then need to develop legislation against the "new" compound. It became a game of cat and mouse and there was no way the legislation could keep up. Newer legislation identified them as a class of harmful compounds making it easier to ban.

2. Because new discoveries are made daily in science, annual review of literature must be performed so that the law can be dynamic and incorporate these discoveries.

3. The lifetime exposures period must be extended to 72 years of age because of the risk of bioaccumulation.

4. If corporations take water from the cleaner headwaters of the Huron River (or anywhere else) they must be responsible to replace that water as clean or cleaner than what they took out.I rely on the City of Ann Arbor to provide my drinking and wastewater services. When I use water, a majority of it comes from the Huron River. I pay my community to remove the water and clean it, then I also pay to have it cleaned before I send it back to the river. Corporations must act responsibly.

5. These are “forever” chemicals. We must act cautiously. These chemicals bioaccumulate. Each successive generation will ingest more and more of these compounds. According to the EPA website, “studies indicate that PFOA and PFOS can cause reproductive and developmental, liver and kidney, and immunological effects in laboratory animals. Both chemicals have caused tumors in animals. The most consistent findings are increased cholesterol levels among exposed populations, with more limited findings related to:

- low infant birth weights,
- effects on the immune system,
- cancer (for PFOA), and
- thyroid hormone disruption (for PFOS).”

Our future deserves to be treated better.

Thank you for your consideration.

Jennifer A. Masterson
[redacted]
Ann Arbor, MI 48104
[redacted]@comcast.net
[redacted]

Smith, Ian (EGLE)

From: Sharon McGladdery <[redacted]@gmail.com>
Sent: Friday, January 3, 2020 10:28 PM
To: EGLE-PFAS-RuleMaking
Subject: Stop PFAS Contamination Now

Categories: Blue Category

We agree with this info from Freshwater Future.

Per- and polyfluoroalkyl substances (PFAS) compounds are man-made chemicals found in nonstick cookware, flame- and water-resistant clothing, food wrappers, plumber's tape, stain prevention products, and even coatings on wires. Unfortunately, now **we know PFAS are toxic, harmful to human health, and extremely persistent in the environment.**

The Michigan Department of Environment, Great Lakes, and Energy (EGLE) Drinking Water and Environmental Health Division are holding **three public hearings on the proposed rules that would establish how much of seven PFAS compounds:**

- Can be in your drinking water,
- How water utilities should sample for these compounds,
- Certification criteria for labs sampling water potentially contaminated with PFAS, and
- How the public should be made aware of contamination.

Smith, Ian (EGLE)

From: Nonie Muller [redacted]@yahoo.com>
Sent: Friday, January 31, 2020 4:38 PM
To: EGLE-PFAS-RuleMaking
Subject: Setting PFAS standards

Why isn't it a singular priority to have safe, clean water today? Allowing our beautiful lakes to be ruined for a profit is ridiculous! We MUST have safe water to drink.

To debate safe levels only feeds the addiction of the wealthy for more and more money $$$ and PROFITS!! Just like King Midas, more is never enough. Putting Billion dollar profits over OUR water is insane! That water belongs to all of us.

I am writing to say NO LEVELS ARE SAFE! Stopping the source of these "forever toxic chemicals" and removing the rest from our land, lakes and streams is the only option. "Oops, a spill, we're sorry." "Oh, that's not much, only a 'few' points over the limit". ALL of these toxins must be removed from our environment and futher manufacturing of them stopped.

Consider what PFAS also means:

P=POISONOUS
F=FUTURE
A=and
S=Sickness

Respectfully submitted,
Nonie Muller, retired RN, MSN
Sent from Yahoo Mail on Android

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Susan Popma [redacted]@everyactioncustom.com>
Sent: Tuesday, January 28, 2020 9:10 PM
To: EGLE-PFAS-RuleMaking
Subject: strong standards for MI AND yearly reviews to make adjustments

Dear Drinking Water and Environmental Health Division Suzann Ruch,

Please make strong standard for the Forever Chemicals, PFAS etc.
People a dying because they are drinking poison.
Keep out water clean so we don't lose any more MI residents.

ALSO, please review the standards EVERY YEAR.
Don't let corporations encourage you to take the easy road so their life will be easier but ours will not be easier.
Please.

Sincerely,
Sue Popma
[redacted]
Rockford MI 49341

Sincerely,
Susan Popma
[redacted] Rockford, MI 49341-1543 [redacted]@yahoo.com

Smith, Ian (EGLE)

From: Angela Mann [redacted]@gmail.com>
Sent: Tuesday, January 14, 2020 9:50 AM
To: EGLE-PFAS-RuleMaking
Subject: Stronger PFAS Drinking Water Limits

Please implement and enforce stronger limits on PFAS. Michigan, as the Great Lakes State, should be a leader in strong standards for safe drinking water. Please protect our citizens.

Thank you

Angela Mann

Smith, Ian (EGLE)

From: Virginia DeHaan [redacted]@yahoo.com>
Sent: Saturday, January 18, 2020 8:53 AM
To: EGLE-PFAS-RuleMaking
Subject: Safety for Citizens First

Hello, I am a resident of Grand Rapids. I encourage the State of Michigan to go the rout of setting tougher standards for PFAs allowable limits in drinking water. I am aware that recently the US House recommended that higher standards be put into effect in the nation, but that the Senate is bound to take the opposite approach, claiming that doing so would be too hard on the business community. Ridiculous! We elect people to be in government to serve THE PEOPLE, not profits. I'm proud that in my state, the proposals are leaning towards the tougher end, and seeking to hold business accountable. While I tend to vote Democratic, it seems to me that Republicans are more interested in protecting business interests, not actual living, breathing people/citizens. I dearly hope that in my state, Republicans care more about citizens than business profits in the current debate about standards. After all, Republicans are living, breathing citizens who need safe water too. Thank you. Sincerely, Virginia L DeHaan

[redacted]
Grand Rapids, MI 49506

Smith, Ian (EGLE)

From: Mark Blazejewski [redacted]@gmail.com>
Sent: Tuesday, January 14, 2020 6:56 PM
To: EGLE-PFAS-RuleMaking
Subject: Safe standards

I'm tired along with a great many of all the chemicals in our water. There is no safe standard besides zero. The state allowed it, they can clean it. I want it at the level it was before it was allowed.

Mark Blazejewski

Smith, Ian (EGLE)

From: Sue Popma <[redacted]@yahoo.com>
Sent: Thursday, January 30, 2020 6:35 PM
To: EGLE-PFAS-RuleMaking
Subject: We have ingested enough Forever Chemicals. Please stop them from poisoning us even more.

The Forever Chemicals are in our carpets, Scotchguard clothing, just to name 2 sources of the poisoning.
PLEASE stop chemical companies and other companies from making a profit and refusing to clean up their mess.
Thank You.
Take Care,
Susan Popma
[redacted]
Rockford MI 49341
[redacted]

Smith, Ian (EGLE)

From: Cheryl Darnton <[redacted]@dexterschools.org>
Sent: Friday, January 31, 2020 7:16 AM
To: EGLE-PFAS-RuleMaking
Subject: Zero PFAS is the only acceptable level in drinking water

Dear EGLE,

As a resident of Michigan, and a public school teacher, I would like to express my concern over PFAS in drinking water. Zero is the only appropriate goal.

Children's health is at risk. A lifetime of PFAS exposure is dangerous. We do not fully understand the effects of the chemical group. Cancer and reproductive problems are clearly at issue, and it may be that the chemicals will also limit intellectual skills and other abilities of Michigan children. We cannot condemn our children to a lifetime of compromised health. Money should not be a consideration in this case. There is no more important outcome than the health of generations going forward.

Respectfully,
Cheryl Darnton
[redacted]
Ann Arbor MI 48103

Sent from my iPhone

Smith, Ian (EGLE)

From: Susan <[redacted]@aol.com>
Sent: Thursday, January 30, 2020 5:21 PM
To: EGLE-PFAS-RuleMaking
Subject: Water Quality

To whom it may concern,

We are fortunate to live and work in Michigan. Few states in America can claim access to fresh water like we can. That being said I would like to add my voice to the many who are demanding fresh drinking water and strict guidelines on what is considered “safe”.

While I understand there is a cost to increased monitoring we really don’t have a choice. We can’t live without clean water or air. To choose otherwise would be catastrophic to our health and well being.

I know of not one reasonable person who would willingly say they would take money over their health. If such a person exists they certainly should not be in the agency that monitors our water.

Thank you
Susan Payne
Sent from my iPhone

Smith, Ian (EGLE)

From: Cynthia Kamp [redacted]@gmail.com>
Sent: Saturday, January 18, 2020 7:57 AM
To: EGLE-PFAS-RuleMaking
Subject: Water Quality and PFAS

January 18, 2020

To Whom It May Concern,

I am writing as a new resident of the state of Michigan. having moved here from Chicago in part for the beautiful lakes and rivers here.

Clean water is one of the most important things for human life, as well as for that of all other creatures. Please work to reverse the damage done by PFAS and prevent any future damage.

Here are some specific measures that should be taken:

- Set a cumulative standard.
- Require a health review in 2 years.
- Conduct at least 3 years of quarterly sampling.

I feel incredibly fortunate to live in such a beautiful part of the world rich in natural resources such as water, and I believe it is our responsibility to preserve it for our children and generations to come.

Sincerely,

Cindy Kamp
[redacted]
Ada, MI 49301

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Smith, Ian (EGLE)

From: Larry Scheer [redacted]@gmail.com>
Sent: Tuesday, January 28, 2020 9:36 AM
To: EGLE-PFAS-RuleMaking
Subject: Upcoming PFAS Limits

1. MCLs for PFAS should be based on scientific evidence to protect human health and the environment. They should not be relaxed based on economic, commercial or industrial concerns.

2. The health-based values don't include a total PFAS contamination level similar to the cumulative level that EPA recommends. EGLE needs to put a combined MCL in place for total PFAS.

3. PFAS should be regulated as a class of chemicals. There are over 5000 of them, and placing regulations on some may simply make polluters use other PFAS compounds. Class regulations, or regulations on subclasses would prevent users from making specific compound switches to avoid restrictions.

4. The Health-based values from MPART are an improvement from EPA guidelines, but new information coming from New Hampshire and North Carolina suggests that some of the Michigan HBVs are still way too high for specific chemicals. (Gen X, PFHxS, PFHxSA)

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Mark Weaver [redacted]@everyactioncustom.com>
Sent: Sunday, January 26, 2020 9:01 AM
To: EGLE-PFAS-RuleMaking
Subject: Tough standards for PFAS?

Dear Drinking Water and Environmental Health Division Suzann Ruch,

I grew up in Oscoda and lived on the AuSable River. This is personal.

You know the math. You know the environmental impact. Don't work to establish tough standards. Ban PFAS completely. Standards are compromises, simply resulting in less danger. Unacceptable.

Michigan is an environmental jewel. Let's keep it that way.

Sincerely,
Mark Weaver
[redacted] Dr Lowell, MI 49331-9698
[redacted]@comcast.net

Smith, Ian (EGLE)

From: Mark Swan, OD, MEd [redacted]@me.com>
Sent: Friday, January 31, 2020 6:04 AM
To: EGLE-PFAS-RuleMaking
Subject: Support for new PFAS rules

I live in Belmont MI with my wife and four year old. We support these changes to the rules that will improve the protection of water supplies for all MI residents.

Mark Swan

Sent from my iPhone

Paul Kolber

Dresher, PA 19025

PFAS (including PFOS, PFOA and GenX) NEVER break down once they're in the environment. They will continue to persist in our food supply, and in human (and animal) tissue. Exposure has been linked to reproductive and developmental harm as well as liver and kidney damage and cancer. They is your opportunity to fix a problem that otherwise will permanently poison the earth. How many animals and people need to die before you wake up? Please pass the strongest possible protections to reduce PFAS exposure. Thank you.

Crystal Thrall

Saline, MI 48176

Dear Michigan Department of Environment, Great Lakes, and Energy:

Cc: Governor Gretchen Whitmer

Michigan residents are slowly being poisoned by our state's most precious natural resource. While I feel devastated that our water has been abused and neglected, there is hope that our government will finally mandate improvements to our water quality for the benefit of all life. As a message to those that might pollute our waters in the future, those parties responsible for our current condition must be held accountable and assume full responsibility for remediation. For the future, policies should be put in place to protect our water from further pollution.

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Janis Bobrin [redacted]@everyactioncustom.com>
Sent: Wednesday, January 29, 2020 5:01 PM
To: EGLE-PFAS-RuleMaking
Subject: Comments on Proposed PFAS MCL's

Dear Drinking Water and Environmental Health Division Suzann Ruch,

To the Drinking Water and Environmental Health Division:

Thank you for this opportunity to comment on the proposed Maximum Contaminant Levels for seven PFAS compounds, and for your work to put protective standards into place to address these "forever chemicals." As a long-time environmental professional and activist in Michigan, I have worked with water quality protection issues and contamination cleanup. In my 40+ years, never once have I seen a chemical to be determined LESS of an environmental and public health threat than originally judged, but always as of greater concern.

Right now, there are close to 2 million people in Michigan who cannot trust their drinking water. As the stewards of the single greatest source of fresh water in the United States, it is incumbent on us to be both cautious and proactive in setting our standards. Finalizing MCL's for PFAS compounds must proceed without delay. My specific comments on that MCLs as proposed very much echo those provided to you by the Huron River Watershed Council, of which I am a Board and Executive Committee member:

1. While the proposed MCL's are an improvement over those contained in EPA guidance, new information from around the country suggests that some of the levels are not adequately protective. Please examine these levels in light of the most current information and set levels that are most protective of public health.

2. Michigan's Maximum Contaminant levels must consider cumulative impacts and provide a combined MCL for total PFAS.

3. PFAS is a family of over 5,000 chemicals and should be regulated as such. Industry is substituting similar but slightly modified chemicals in manufacturing processes, the safely of which are not fully known. This is not acceptable.

4. Protection of public health and the environment must be the driving considerations in setting contaminant limits.

Right now, Michigan is dealing with hundreds of contamination sites, and untold millions of dollars in cleanup costs, for both the public and the private sectors (if and when a responsible and financially viable party can be found). Source control through appropriately protective standards is paramount.

Again, thank you for your work on this critical issue, and for the opportunity to comment.

Sincerely,

Janis Bobrin
[redacted]
Ann Arbor, MI 48105

Sincerely,
Janis Bobrin
[redacted] Ann Arbor, MI 48105-2544 [redacted]@comcast.net

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Elizabeth Pepper <[redacted]@everyactioncustom.com>
Sent: Friday, January 31, 2020 4:44 PM
To: EGLE-PFAS-RuleMaking
Subject: Standards for toxic PFAS chemicals in our water

Dear Drinking Water and Environmental Health Division Suzann Ruch,

I'm writing to urge you to move quickly to set a strong standard for PFAS that is based on the best available science and is protective of public health.

PFAS contamination impacts the drinking water of more than 1.9 million Michiganders, and we can't delay action on protecting the health of our communities. We know PFAS causes health impacts, and we know where it is coming from, which is why the state must move swiftly to pass a standard that is protective of public health.

Michigan should be a leader on addressing the PFAS contamination crisis, and that starts with strong standards for these toxic chemicals.

Key changes need to be made to ensure the PFAS limits protect the health of Michigan communities.

Those include:

-Taking a class-based approach that sets a standard for the combined total of the various PFAS chemicals instead of individual limits for each.

-Ensuring the standards are protective of our most vulnerable populations, like developing infants and children.

-Basing the standards on the best and most recent science.

Michigan should be leading the country on setting the toughest standards for toxic PFAS chemicals in our water. Just because we're in Michigan doesn't mean we should be satisfied with sub-standard requirements for our water.

Sincerely,

Sincerely,
Elizabeth Pepper
[redacted] Ann Arbor, MI 48103-3903 [redacted]@gmail.com

Smith, Ian (EGLE)

From: Cheryl Gambaro <[redacted]@gmail.com>
Sent: Tuesday, January 14, 2020 5:44 PM
To: EGLE-PFAS-RuleMaking
Subject: Protect Michiganders from PFAS

Dear Lawmaker,

When creating legislation with regards to protecting your constituents exposure to PFAS in Michigan, please consider the following:

- Set a cumulative standard. In addition to setting numeric standards for individual compounds of PFAS, the state should set a cumulative limit. A cumulative limit would better protect the public against additive or synergistic effects from exposure to multiple PFAS chemicals. It would also create a level of protection for residents exposed to PFAS chemicals that are not included in the seven slated for a drinking water standard.

- Require a health review in two years. The state is moving forward with setting drinking water standards for seven PFAS compounds. While a step in the right direction, that approach leaves thousands of PFAS compounds unregulated. The science on the risk and toxicity of PFAS chemicals is rapidly developing; standards set today could be quickly out of date as new research on toxicity comes in. To ensure Michigan remains ahead of the curve and maintains science-based standards that are protective of public health, the state should conduct a health review two years after the PFAS drinking water standards go into effect. This requirement should be written into the PFAS drinking water rules.

- Conduct at least three years of quarterly sampling. We do not know enough about how PFAS moves in the environment or if there are seasonal changes to discharges of PFAS to be able to set reduced sampling frequencies. The current rule requires some quarterly sampling, but also allows water plants to potentially reduce to sampling every six months or only once a year. At a minimum, given the unknowns, all water systems should test quarterly for three years. That will give the state a solid baseline of knowledge to know when PFAS may or may not spike and which supplies are most at risk of exposure. From there the state can better establish a reduced sampling frequency process.

Sincerely,

Cheryl Gambaro
Oakland County resident

Smith, Ian (EGLE)

From: Rep. Rachel Hood (District 76) <RachelHood@house.mi.gov>
Sent: Friday, January 31, 2020 3:08 PM
To: EGLE-PFAS-RuleMaking
Cc: Curtis Audette
Subject: Proposed PFAS Drinking Water Standards

Dear Ms. Ruch,

Below you will find my commentary pertaining to the proposed PFAS drinking water standards. My office has also sent a letter via ID mail to your office as well.

Thank you,
Rachel Hood
State Representative
Michigan's 76th House District

January 31, 2020
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311
RE: Comment to the State of Michigan's Department of Environment Great Lakes and Energy regarding proposed PFAS MCL standards to be
Dear Ms. Ruch,
On behalf of the constituents of Michigan's 76th House District, I am writing to provide comments regarding the recommended PFAS maximum contaminant levels (MCL) standards to be established under Michigan's regulatory drinking water standards. After study and reviewing comments from a variety of stakeholders, it is clear that the levels recommended by the Science Advisory Workgroup, are not fully protective of human health, particularly vulnerable populations including pregnant mothers, infants, and children.
Workgroup recommendations for seven PFAS: PFNA (6ppt), PFOA (8ppt), PFOS (16ppt), PFHxS (51ppt), GenX (370ppt), PFBS (420ppt), PFHxA (400,000ppt), many of which are well beyond the most stringent levels recommended to be protective of public health, below 1ppt. Knowing that science is rapidly evolving around full understanding of these contaminants, taking a more conservative approach to MCLs is highly recommended.
Further, the MCLs recommended don't address the presence of two or more PFAS in a given area. Other US states have established a combined MCL of 20ppt to guide action when multiple PFAS are present.

Finally, the state must continue to establish treatment techniques for drinking water, such as reverse osmosis. Continued investments in education and public health information are necessary.
Thank you for receiving my comments and for all the work you to do to protect human and ecosystem health in Michigan.
Sincerely,
Rachel Hood

State Representative
Serving Michigan's 76th House District

Smith, Ian (EGLE)

From: Andrea Hill <[redacted]@umich.edu>
Sent: Thursday, January 30, 2020 2:12 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS regulation

Hello,

I am writing to lend support to these comments made by Yousef Rabhi:

I am glad to see our regulators proposing standards to protect the people of Michigan from toxic PFAS, which build up in the environment and our bodies. But these draft rules do not go far enough to protect human health.

For too long we have given polluters the benefit of the doubt, allowing them to put millions of tons of chemicals out into our environment without any safety testing. Only once entire communities had already been poisoned did regulators propose drinking water limits and cleanup rules. Due to the negligence of polluters, the inaction of previous administrations and the willful dismantling of environmental protection by lawmakers, communities like Ann Arbor have been left on the hook for costly water service improvements.

That's obviously the wrong way around. The proposed rule would set MCLs for seven PFAS compounds. But there are an estimated 4,700 PFAS compounds. How long would it take to do testing and administrative rulemaking on each one? Longer than the lifetimes of the people whose health will be ruined, though unfortunately probably not longer than these compounds will persist in our soil, streams and rivers. We must regulate PFAS as a class now to prevent this entirely predictable environmental and public health catastrophe.

These proposed MCLs are a step in the right direction but we can do much better than that for the people of our state.

Please pass standards that actually protect us and our children.

Thank you,

Andrea Hill

--
Andrea Hill, LLMSW
Student Navigator and Climate Enhancer
Pronouns: She/Her/Hers
Phone: [redacted]

Biostatistics Department
M4317A SPH2 | 1415 Washington Heights | Ann Arbor, MI 48109-2029

Smith, Ian (EGLE)

From: Julie Spahn [redacted]@yahoo.com>
Sent: Tuesday, January 7, 2020 10:00 AM
To: EGLE-PFAS-RuleMaking
Cc: MarkHuizenga@house.mi.gov
Subject: PFAS in drinking water

Categories: Blue Category

Science Advisory Workgroup
Michigan PFAS Action Response Team's (MPART) The Michigan Department of Environment, Great Lakes and Energy

To Whom it May Concern,

I am writing in regards to the proposed new limits for PFAS in drinking water.

I have seen and heard about the effects of PFAS in the water (drinking water and water used for recreation and other purposes), and I have very strong concerns about the current laws in Michigan that require the state to match limits set by the EPA.

I happen to live in the first house downstream (property-owning) from the Wolverine Worldwide tannery in Rockford, Michigan. When the community first learned of the pollution and the PFAS class of chemicals, I immediately began to research the health effects that these chemicals could produce.

I saw photos of Bucky Bailey, and I cried at the pain that he has had (and continues) to endure.

I joined my neighborhood response groups, and I learned about the health challenges that my neighbors face and have faced. They drank contaminated water for decades.

The story that broke my heart was one of two elementary-aged children, next-door neighbors, who developed cancer and died within months of each other. Those kids lived on Cahill Street, others lived and died on East Main—I read about multiple children dying from cancer, and I knew that it was more than coincidence that caused those illnesses.

We must do better.

I have three children myself. My kids grew up playing and swimming in the PFAS-filled Rogue River that borders our backyard. I have photos of them innocently smiling, waist-deep in PFAS-filled muck and tannery sludge. We were told that the area had been cleaned. City leaders lied to us. Business owners had lied to them. We must do better.

Please allow independent scientists to guide your work. I've heard from the Wolverine-paid team of "researchers" who told a gym filled with concerned citizens that we are not at risk. They said current guidelines were "conservative." Esteemed Harvard scientists say otherwise, and you know that to be true.

Please protect my children. Please protect ALL children and citizens of Michigan. I ask that you prohibit ALL detectable amounts of PFAS in our drinking water. That is the only way to know that we are all safe.

Sincerely,

Julie Spahn

[redacted]
Rockford, MI 49341

Smith, Ian (EGLE)

From: Smith, Margo [redacted]@msu.edu>
Sent: Tuesday, January 21, 2020 5:12 PM
To: EGLE-PFAS-RuleMaking
Subject: Comments on PFAS Rules

Hi: I wish to comment on rules for PFAS.
1- Set cumulative limit or standard to account for the seven or more PFAS chemicals.
2- have three years of quarterly testing of waters.
3- provide for health review in 2 years.

Thank you.
Margo K. Smith
[redacted]
East Lansing, MI 48823

[redacted]@msu.edu

Sent from my iPhone

Smith, Ian (EGLE)

From: Cecilia Trudeau <[redacted]@comcast.net>
Sent: Friday, January 17, 2020 6:48 AM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Concerns

Thank you for giving us the opportunity to express our concerns regarding PFAS standards for our state. As are many citizens across the state and country, I am appalled at the presence of PFAS chemicals in our water and in our bodies. As a nurse and Ecology Center Health Fellow, I am well aware of the potentially life-changing, damaging effects of these substances for human beings and for all living beings. Because of the tenacious nature of PFAS substances, we can ill-afford to continue to contaminate our environment with these substances. Thus, I urge you to adopt strict and effective standards for levels of total PFAS chemicals and to hold accountable organizations that continue to add them to the environment and neglect their moral responsibilities to remedy this serious threat to our well-being.

Sent from my iPad

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of William and Carol Parker <[redacted]@everyactioncustom.com>
Sent: Tuesday, January 7, 2020 11:25 AM
To: EGLE-PFAS-RuleMaking
Subject: Michigan needs the toughest standards for toxic PFAS chemicals in our water

Categories: Orange Category

Dear Drinking Water and Environmental Health Division Suzann Ruch,

For too long we have been allowing a quasi-science to direct our country. We have toxins sprayed on our food. We have GMO products introduiced as "wonderful". We get flouride in our water, a neurotoxin, and we get bromide in our bread, another neurotoxin. Our skies are loaded with aluminum nanoparticles for controlling the weather. Now we have stain repellant, water repellant, or skillets that won't stick, courtesy of PFAS.

The question is, "Do we care?" The answer is "Yes, I do care."

At some point don't we have to start pushing back against the rain of pollution that is constantly dropping on our heads? -Bill and Carol Parker

Sincerely,
William and Carol Parker
[redacted] Rockford, MI 49341-1133 [redacted]@gmail.com

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Susan Popma <[redacted]@everyactioncustom.com>
Sent: Wednesday, January 15, 2020 12:30 PM
To: EGLE-PFAS-RuleMaking
Subject: Michigan needs the toughest standards for toxic PFAS chemicals in our water

Dear Drinking Water and Environmental Health Division Suzann Ruch,

The proposed State standards are certainly much better than the Federal guideline level of 70 parts per trillion (ppt).

And the state of Vermont has even tighter guidelines than what proposed for MI.

However, MI need to be the leader in setting the tightest standard NOW.

We don't need a standard that is "a good start" at stopping the chemicals damaging Michigan.

We need to be the leader.

These chemicals are "forever" chemicals which are also damaging other states.

We pay taxes to the government to keep us safe & healthy and make good decisions for us.

We are depending on you to keep us safe and healthy.

Please be the leader and setting the thightest standard.

The companies that are polluting our drinking water will not always be in business to assist with the cleanup.
We need EGLE to keep MI residents healthy & safe from bad chemicals, so we can work and pay our taxes so you will be there to keep and eye out for us.

Thank you. Susan Popma, [redacted] Rockford MI 49341-1543
[redacted]@yahoo.com[redacted]

Sincerely,
Susan Popma
[redacted] Rockford, MI 49341-1543 [redacted]@yahoo.com

Smith, Ian (EGLE)

From: Stacy Mates <[redacted]@gmail.com>
Sent: Thursday, January 16, 2020 11:41 AM
To: EGLE-PFAS-RuleMaking
Subject: We need stricter, class-based standards for PFAS

To the members of EGLE,
As a resident of one of many communities that is dealing with PFAS contamination in our drinking water source, I applaud that you are taking some strides to regulate PFAS and urge you to act quickly. However, I'm also deeply concerned that the proposed standards are not strict enough to protect our health, because they address individual PFAS chemicals rather than the combined total, and do not address the effects on vulnerable populations like children and the elderly.

Please help MI be a leader by enacting standards that set a limit on combined total PFAS contaminants, and that establish standards based on impact on vulnerable populations rather than healthy adults.

Thank you,
Stacy Mates
Ann Arbor, MI

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Wesley Dick [redacted]@everyactioncustom.com>
Sent: Thursday, January 30, 2020 9:45 PM
To: EGLE-PFAS-RuleMaking
Subject: Michigan needs the toughest standards for toxic PFAS chemicals in our water

Dear Drinking Water and Environmental Health Division Suzann Ruch,

Michigan has been a national leader in environmental initiatives and environmental clean up. Enacting the strongest standards for regulating PFAS chemicals in Michigan water will be in the state's best tradition regarding conservation and place Michigan on the right side of history.

Dr. Wesley Arden Dick
Albion, Michigan

Sincerely,
Wesley Dick
[redacted] Albion, MI 49224-1851 [redacted]@albion.edu

Smith, Ian (EGLE)

From: Charlotte Jameson <[redacted]@environmentalcouncil.org>
Sent: Friday, January 31, 2020 5:04 PM
To: EGLE-PFAS-RuleMaking
Subject: Re: Comments Michigan PFAS MCL (2019-35-EG)
Attachments: PFAS MCL Comments (2019-35-EG).pdf

My apologies. Please use the attached version of the comments.
Best,
Charlotte

On Fri, Jan 31, 2020 at 4:55 PM Charlotte Jameson [redacted]@environmentalcouncil.org> wrote:

> Ms. Rush-
> Please accept the attached comments on the proposed Michigan PFAS MCL (2019-35-EG). The comments are submitted on behalf of Ecology Center, FLOW, Freshwater Future, Huron River Watershed Council, Michigan Environmental Council, Sierra Club, and Tip of the Mitt Watershed Council.
>
> Please contact me if you have any questions or concerns.
> Charlotte
>
> --
> Charlotte Jameson
> Program Director Legislative Affairs, Energy, and Drinking Water Policy
> Michigan Environmental Council
> [redacted]@environmentalcouncil.org
> (c) [redacted]; (o) [redacted]
>
> environmentalcouncil.org
> twitter.com/MichEnvCouncil
> facebook.com/MichiganEnvironmentalCouncil
>
> Join Us!

--
Charlotte Jameson
Program Director Legislative Affairs, Energy, and Drinking Water Policy
Michigan Environmental Council
[redacted]@environmentalcouncil.org
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Join Us!

January 31, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: Suzann Ruch
PO Box 30817
Lansing, Michigan 48909-8311

EGLE-PFAS-RuleMaking@Michigan.gov

Re: Comments on Proposed Administrative Rules Establishing Michigan PFAS Drinking Water Standards (2019-35 EG)

Dear Ms. Ruch:

We the undersigned appreciate the opportunity to submit comments on the proposed rules establishing drinking water standards for PFAS in Michigan. Drinking water is one of the primary exposure routes for toxic PFAS chemicals and getting the PFAS out of our public water systems is vital to protect public health. Manufacturers of PFAS chemicals have known about the dangers that the compounds pose to human health for decades, but continued to incorporate these toxins into industrial and everyday products. More recently, publicly available toxicological research has increased decision-makers' and the public's understanding of the harms these toxins pose to the public and in particular to the most vulnerable among us. It is clearly time to put into place drinking water standards to reduce exposure to these toxins in our public water supply systems.

The approach set forth in this proposed rule package is designed to both protect public health, but do it in a way which attempts to mimic existing regulatory structures to facilitate compliance by water suppliers. To that end, the package gives public water supply systems a clear process to undertake to protect public health. As communities begin to sample regularly for PFAS compounds and install better treatment technology and as new science emerges on the toxicity of PFAS, EGLE should revisit these drinking water standards via a health-based review. This will ensure that Michigan continues to optimize our standards based on the best science and data available.

The undersigned strongly support Michigan moving ahead with establishing drinking water standards in the absence of federal action. We know enough about the science of PFAS to act swiftly to put in place these critical protections.

The following sections detail areas where the undersigned believe EGLE must strengthen and improve the Michigan PFAS drinking water standards to improve public health protections for all Michiganders.

Take a Class-Based Approach

Regulating individual compounds of PFAS when thousands are known to exist is not a comprehensive method for protecting public health. A class-based approach would better protect the public against additive or synergistic effects from exposure to multiple PFAS chemicals. We know from water samples and other exposure data that Michigan residents are currently being exposed to multiple compounds of PFAS simultaneously. Our drinking water standard should reflect that reality and protect public health from these cumulative impacts.

Other states are moving forward with setting class-based standards in spite of claims from industry and others that there is not sufficient evidence. Michigan should maintain its leadership in protecting public health from PFAS; not lag behind the protections put in place in other states.

Set an MCL for Additional Long-Chain PFAS Included in US EPA Method 537.1

While the undersigned still strongly prefer and urge the department to adopt a class-based approach to regulating PFAS compounds in drinking water, at a minimum we believe the department erred in not including a MCL for the additional long-chain PFAS that are detected through EPA 537.1. In their report titled "Health-Based Drinking Water Value Recommendation for PFAS in Michigan," the Michigan Science Advisory Workgroup recognized that the additional long-chain PFAS compounds not given a Health Based Value "are expected to produce similar health effects" to the long-chain PFAS compounds proposed for regulation.[1] The workgroup recommended setting 6 ng/L as a "a screening level for all other long-chain PFAS included on the USEPA Method 537.1 analyte list for which the Workgroup did not develop an individual HBV. Those other long-chain PFAS included in USEPA Method 537.1 are: NEtFOSAA (CASRN: 2991-50-6); NMeFOSAA (CASRN: 2355-31-9); PFDA (CASRN: 335-76-2); PFDoA (CASRN: 307-55-1); PFTA (CASRN: 376-06-7); PFTrDA (CASRN: 72629-94-8); and PFUnA (CASRN: 2058-94-8)." The undersigned concur with the workgroup that given the similarity in chemistry between long-chain PFAS compounds, these compounds will cause similar health effects. The department should not wait on additional research to show what we already know -- compounds of very similar chemistry have similar impacts on public health. We ask the department to adopt a 6 ng/L MCL for these additional seven compounds, so that requirements around monitoring, public notification, and best available treatment technology apply to all long-chain PFAS compounds identified through USEPA method 537.1.

By not adopting an MCL for these additional long-chain compounds people will continue to potentially be exposed to unsafe levels of compounds that look and act very similarly to PFNA -- a compound proposed for regulation under these rules.

Three Years of Quarterly Sampling

The rules should be amended to require all suppliers to conduct at least three years of quarterly sampling before they are eligible for a reduced frequency in sampling. We do not know enough about how PFAS moves in the environment or if there are seasonal changes to discharges of PFAS to be able to set reduced sampling frequencies. The current rule requires some quarterly sampling, but also allows water suppliers to potentially reduce to sampling every six months or only once a year. Amending the rules to require at least three years of quarterly sampling will give the state a solid baseline of knowledge to know when PFAS may or may not spike and which supplies are most at risk of exposure. From there the state can better establish a reduced sampling frequency process.

List Failure to Monitor as a Tier 2 Violation

The failure to monitor for PFAS should be a tier 2 violation. Currently in the rules, failure to monitor is listed as a tier 3 violation. We can only protect public health when we know what is in the water. By not monitoring, suppliers deprive their customers and state regulators of critical

[1] Health-Based Drinking Water Value Recommendation for PFAS in Michigan, page 3 https://www.michigan.gov/documents/pfasresponse/Health-Based_Drinking_Water_Value_Recommendations_for_PFAS_in_Michigan_Report_659258_7.pdf

information. The entirety of an effective drinking water protection program rests on sound and consistent monitoring. Therefore, not monitoring should be an elevated violation to better match its potential impact on public health.

In its audit of the EGLE drinking water division in the wake of the Flint water crisis, the USEPA specifically pointed out the serious concern raised by the lack of tier 3 public notice for failure to monitor and the practice of late reporting.[2] The majority of the discrepancies found in the file review were monitoring and reporting violations. Furthermore, the audit revealed that the non-community program does not tract tier 3 public notice violations, but does track tier 1 and 2 notice violations. Across the board, failure to sample or failure to sample on time is a common approach to avoid detecting contaminants in drinking water and therefore, it delays or circumvents an appropriate public health response. In Flint these delays and lack of information translated into very serious public health consequences.

The department should take this lesson learned from Flint and the USEPA audit and use the PFAS MCL as a means to begin to correct it. It should treat failure to monitor and failure to report with the risk they pose to public health. Both of those goals can and should be accomplished by making failure to monitor and failure to report tier 2 violations.

Require a Health Review in Two Years

Moving forward with setting PFAS drinking water standards for a subset of PFAS compounds is a step in the right direction, but that approach leaves thousands of PFAS compounds unregulated. The science on the risk and toxicity of PFAS chemicals is rapidly developing; standards set today will be quickly out of date as new research on toxicity comes in. We should continue to move forward with setting drinking water standards despite the evolving science. However, to ensure Michigan remains ahead of the curve and maintains science-based standards that are protective of public health, the state should conduct a health review two years after the PFAS drinking water standards go into effect. The health based review should be written into the PFAS drinking water rules as a requirement for the department.

Require Sampling, Lab Analysis, and Reporting for all Analytes Included in US EPA Methods 537.1 and 533

In December of 2019 the US EPA released a new method for validation of PFAS in drinking water -- method 533.[3] Method 533 is to serve as a compliment to method 537.1 and focuses on short-chain PFAS identification. Method 533 measures up to 29 PFAS compounds.

We urge the department to ensure that laboratories certified under the rule collect and analyze samples according to both US EPA method 537.1 and 533. Additionally, we ask the department to ensure that all water samples collected by suppliers under the rule are analyzed for all analytes

[2] US Environmental Protection Agency Public Water System Supervision Program, Program Review of the Michigan Department of Environmental Quality Water Bureau https://www.epa.gov/sites/production/files/2015-11/documents/program-review-mdeq-water-bureau-20100830-76pp_0.pdf

[3] US Environmental Protection Agency, Method 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry https://www.epa.gov/dwanalyticalmethods/method-533-determination-and-polyfluoroalkyl-substances-drinking-water-isotope

measured using both 537.1 and 533 and that all results for any PFAS analyte identified under both of those methods are reported to the department.

While the department is not proposing to regulate short-chain PFAS nor many of the long-chain PFAS that can be measured under 537.1, it remains critically important that suppliers, the department, and the public have the data necessary to understand what PFAS compounds are in their water and to what extent regardless of the establishment of an MCL. We can not act to protect public health when we lack reliable information on the presence of these compounds in our drinking water.

Conclusion

In addition to these summary comments we have included a red-lined edit of the rule package with specific recommendations on language changes. These red-lined edits reflect the recommendations outlined above and present a suggested pathway for incorporating them into the rules.

We appreciate the opportunity to comment and commend Governor Whitmer and EGLE for moving swiftly to put in place critical public health and environmental protections from toxic PFAS. However, we urge EGLE to adopt the recommendations we have laid out here to ensure that those protections are comprehensive, based on the most up to date science, and implemented in an effective manner.

Sincerely,

Ecology Center
FLOW
Freshwater Future
Huron River Watershed Council
Michigan Environmental Council
Sierra Club
Tip of the Mitt Watershed Council

DEPARTMENT OF ~~ENVIRONMENTAL QUALITY~~ **ENVIRONMENT, GREAT LAKES, AND ENERGY**

DRINKING WATER AND ~~MUNICIPAL ASSISTANCE~~ **ENVIRONMENTAL HEALTH** DIVISION

SUPPLYING WATER TO THE PUBLIC

Filed with the secretary of state on

These rules take effect 7 days after filing with the secretary of state.

(By authority conferred on the department of environmen~~tal~~**, Great Lakes, and energy** ~~quality~~ by section 5 of **the safe drinking water act,** 1976 PA 399, MCL 325.1005)

R 325.10107, R 325.10116, R 325.10308b, R 325.10313, R 325.10401a, R 325.10405, and R 325.12701 of the Michigan Administrative Code are amended, and R 325.10604g, R 325.10717d, R 325.12708, and R 325.12710 are added, as follows:

PART 1. GENERAL PROVISIONS

R 325.10107 Definitions; P, R.

Rule 107. As used in these rules:

(a) "Permit" means a public water supply construction permit that is issued to a supplier of water by the department under section 4 of the act**, MCL 325.1004**.

(b) "Person" means an individual, partnership, copartnership, cooperative, firm, company, public or private association or corporation, political subdivision, agency of the state, agency of the federal government, trust, estate, joint structure company, or any other legal entity, or their legal representative, agent, or assignee.

(c) "PFAS" means per- and polyfluoroalkyl substances.

~~(c)~~ **(d)** "Pitless adapter" means a device or assembly of parts ~~which~~ **that** permits water to pass through the wall of a well casing or extension of a well casing and ~~which~~ **that** provides access to the well and to the parts of the system within the well in a manner that prevents the entrance of contaminants into the well and the water produced.

~~(d)~~ **(e)** "Plans and specifications" means drawings, data, and a true description or representation of an entire waterworks system or parts of the system as it exists or is to be constructed, and a statement of how a waterworks system ~~shall~~ **must** be operated.

~~(e)~~ **(f)** "Plant intake" means the works or structures at the head of a conduit through which water is diverted from a source, for example, river or lake, into the treatment plant.

~~(f)~~ **(g)** "Point-of-entry treatment device (POE)" means a treatment device applied to the drinking water entering a house or building for the purpose of reducing contaminants in the drinking water distributed throughout the house or building.

~~(g)~~ **(h)** "Point-of-use treatment devise (POU)" means a treatment device applied to a single tap used for the purpose of reducing contaminants in drinking water at that 1 tap.

~~(h)~~ **(i)** "Political subdivision" means a city, village, township, charter township, county, district, authority, or portion or combination of any of the entities specified in this subdivision.

~~(i)~~ **(j)** "PQL" means the practical quantitation levels. The PQL is the lowest concentration that can be reliably achieved by well-operated laboratories within specified limits of precision and accuracy during routine laboratory operating conditions.

~~(j)~~ **(k)** "Presedimentation" means a preliminary treatment process used to remove gravel, sand, and other particulate material from the source water through settling before the water enters the primary clarification and filtration processes in a treatment plant.

~~(k)~~ **(l)** "Production well" means a well that has been approved for use for a public water supply ~~in accordance with the provisions of~~ **pursuant to** part 8 of these rules.

~~(l)~~ **(m)** "Public hearing" means a hearing ~~which~~ **that** is conducted by the director of the department on matters relating to the functions and responsibilities of the division and ~~which~~ **that** seeks public input relevant to such functions and responsibilities.

~~(m)~~ **(n)** "Public water supply" or "public water system" means a waterworks system that provides water for drinking or household purposes to persons other than the supplier of the water, and does not include either of the following:

(i) A waterworks system that supplies water to only 1 living unit.

(ii) A waterworks system that consists solely of customer site piping.

~~(n)~~ **(o)** "Pumping water level" means the distance measured from an established datum at or above ground level to the water surface in a well being pumped at a known rate for a known period of time.

~~(o)~~ **(p)** "Rated treatment capacity" means 1 or any combination of the following capacities when water treatment is practiced:

(i) Rated capacity from an approved surface water supply, ground water supply under the direct influence of surface water, or complete treatment system as contained in R 325.11006.

(ii) Firm capacity from an approved ground water supply where firm capacity means the production capability of each respective component of the waterworks system with the largest well, pump, or treatment unit out of service.

(iii) Available capacity obtained under contract and capable of delivery from another approved public water supply.

~~(p)~~ **(q)** "Raw water" means water that is obtained from a source by a public water supply before the public water supply provides any treatment or distributes the water to its customers.

~~(q)~~ **(r)** "Regional administrator" means the EPA region V administrator.

~~(r)~~ **(s)** "Regulated VOCs" means a group of volatile organic chemicals for which state drinking water standards have been promulgated but does not include total trihalomethanes.

~~(s)~~ **(t)** "Removed from service" means physically disconnected from the waterworks system in a manner that would prevent the inadvertent use of the well and would require specific authorization from the public water supply to reconnect.

~~(t)~~ **(u)** "Repeat sample" means a sample that is collected and analyzed in response to a previous coliform-positive sample.

~~(u)~~ **(v)** "Resident" means an individual who owns or occupies a living unit.

~~(v)~~ **(w)** "Routine sample" means a water sample that is collected and analyzed to meet the monitoring requirements for total coliform, as outlined in the written sampling plan.

R 325.10116 Addresses.

Rule 116. The following are addresses and contact information of the department and other organizations referred to in these rules:

(a) Department of ~~Environmental Quality~~ **Environment, Great Lakes, and Energy**, ~~Office of~~ Drinking Water and ~~Municipal Assistance~~ **Environmental Health Division**, 525 West Allegan Street, Post Office Box 30~~241~~**817**, Lansing, MI 48909-~~7741~~**8311**, Telephone 800-662-9278. Internet address: http://www.michigan.gov/~~deq~~**egle**.

(b) National Council ~~O~~**o**n Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 400, Bethesda, Maryland 20814-3095, Telephone 301-657-2652. Internet address: http://www.ncrponline.org/.

(c) NSF International, P.O Box 130140, 789 North Dixboro Road, Ann Arbor, Michigan 48105, ~~t~~**T**elephone 734-769-8010 or 800-673-6275, email info@nsf.org, Internet address http://www.nsf.org.

(d) Superintendent of Documents, ~~United States Government Printing~~ **U.S. Government Publishing** Office, ~~Post Office~~ **P.O.** Box 979050, St. Louis, MO 63197-9000, Telephone 202-512-1800. Internet address ~~to download documents is http://www.gpoaccess.gov/index.html or~~ to purchase documents online is http://bookstore.gpo.gov.

PART 3. VARIANCES, EXEMPTIONS, AND TREATMENT TECHNOLOGIES

R 325.10308b Best available technology.

Rule 308b. (1) The department identifies the following as the best technology, treatment technique, or other means generally available for achieving compliance with the MCL:

(a) For organic contaminants in R 325.10604b ~~and~~**,** R325.10604d**, and R 325.10604g** the best available technologies, treatment techniques, or other means available for achieving compliance with the MCLs are granular activated carbon (GAC), packed tower aeration (PTA), or oxidation (OX), as listed in table 1 of this rule.

Table 1 Best available technologies for organic contaminants

Contaminant	GAC	PTA	OX
Alachlor	x		
Aldicarb	x		
Aldicarb sulfone	x		
Aldicarb sulfoxide	x		
Atrazine	x		
Benzene	x	x	
Benzo(a)pyrene	x		
Carbofuran	x		
Carbon tetrachloride	x	x	
Chlordane	x		
Dalapon	x		
2,4 D	x		

Contaminant	GAC	PTA	OX
Di (2 ethylhexyl)adipate	x	x	
Di (2 ethylhexyl)phthalate	x		
Dibromochloropropane (DBCP)	x	x	
o Dichlorobenzene	x	x	
para Dichlorobenzene	x	x	
1,2 Dichloroethane	x	x	
1,1 Dichloroethylene	x	x	
cis 1,2 Dichloroethylene	x	x	
trans 1,2 Dichloroethylene	x	x	
Dichloromethane		x	
1,2 Dichloropropane	x	x	
Dinoseb	x		
Diquat	x		
Endothall	x		
Endrin	x		
Ethylbenzene	x	x	
Ethylene Dibromide (EDB)	x	x	
Glyphosate			x
Heptachlor	x		
Heptachlor epoxide	x		
Hexachlorobenzene	x		
Hexachlorocyclopentadiene	x	x	
Hexafluoropropylene oxide dimer acid (HFPO-DA)	**x[1]**		
Lindane	x		
Methoxychlor	x		
Monochlorobenzene	x	x	
Oxamyl (Vydate)	x		
Pentachlorophenol	x		
N-ethyl perfluorooctanesulfonamidoacetic acid (NEtFOSAA)	**x[1]**		
N-methyl perfluorooctanesulfonamidoacetic acid (NMeFOSAA)	**x[1]**		
Perfluorobutanesulfonic acid (PFBS)	**x[1]**		
Perfluorohexanesulfonic acid (PFHxS)	**x[1]**		
Perfluorohexanoic acid (PFHxA)	**x[1]**		
Perfluorononanoic acid (PFNA)	**x[1]**		
Perfluorooctanesulfonic acid (PFOS)	**x[1]**		
Perfluorooctanoic acid (PFOA)	**x[1]**		
Perfluorodecanoic acid (PFDA)	**x[1]**		
Perfluorododecanoic acid (PFDoA)	**x[1]**		
Perfluorotetradecanoic acid (PFTA)	**x[1]**		
Perfluorotridecanoic acid (PFTrDA)	**x[1]**		
Perfluoroundecanoic acid (PFUnA)	**x[1]**		

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Contaminant	GAC	PTA	OX
Picloram	x		
Polychlorinated biphenyls(PCB)	x		
Simazine~~Picloram~~	x~~x~~		
Styrene~~Polychlorinated biphenyls(PCB)~~	x~~x~~	x	
2,3,7,8 TCDD (Dioxin)~~Simazine~~	x~~x~~		
Tetrachloroethylene~~Styrene~~	x~~x~~	x~~x~~	
Toluene~~2,3,7,8 TCDD (Dioxin)~~	x~~x~~	x	
Toxaphene~~Tetrachloroethylene~~	x~~x~~	~~x~~	
2,4,5 TP (Silvex)~~Toluene~~	x~~x~~	~~x~~	
1,2,4 Trichlorobenzene~~Toxaphene~~	x~~x~~	x	
1,1,1 Trichloroethane~~2,4,5 TP (Silvex)~~	x~~x~~	x	
1,1,2 Trichloroethane~~1,2,4 Trichlorobenzene~~	x~~x~~	x~~x~~	
Trichloroethylene~~1,1,1 Trichloroethane~~	x~~x~~	x~~x~~	
Vinyl chloride~~1,1,2 Trichloroethane~~	~~x~~	x~~x~~	
Xylene~~Trichloroethylene~~	x~~x~~	x~~x~~	
~~Vinyl chloride~~		~~x~~	
~~Xylene~~	~~x~~	~~x~~	

[1]Best available technology is GAC or an equally efficient technology.

(b) For inorganic contaminants in R 325.10604c, the best available technologies, treatment techniques, or other means available for achieving compliance with the MCLs are listed in table 2 of this rule. The affordable technology, treatment technique, or other means available to supplies serving 10,000 or fewer people for achieving compliance with the maximum contaminant level for arsenic are listed in table 3 of this rule.

Table 2 Best available technologies for inorganic contaminants

Chemical name	Best available technologies
Antimony	2,7
Arsenic[4]	1,2, 5,6,7,9,11[5]
Asbestos	2,3,8
Barium	5,6,7,9
Beryllium	1,2,5,6,7
Cadmium	2,5,6,7
Chromium	2,5,6[2],7
Cyanide	5,7,10
Mercury	2[1],4,6[1],7 [1]
Nickel	5,6,7
Nitrate	5,7,9
Nitrite	5,7
Selenium	1,2[3],6,7,9
Thallium	1,5

[1]Best available technology only if influent Hg concentrations are 10 µg/l or less.
[2]Best available technology for chromium III only.
[3]Best available technology for selenium IV only.

[4]BATs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.

[5]To obtain high removals, iron to arsenic ratio ~~shall~~ **must** be at least 20:1.

Key to best available technologies in table:
1 = activated alumina
2 = coagulation/filtration (not BAT for supplies with fewer than 500 service connections)
3 = direct and diatomite filtration
4 = granular activated carbon
5 = ion exchange
6 = lime softening (not BAT for supplies than 500 service connections)
7 = reverse osmosis
8 = corrosion control
9 = electrodialysis
10 = alkaline chlorination (pH greater than or equal to 8.5)
11 = oxidation/filtration

Table 3 Small supplies compliance technologies (SSCTs) for arsenic[1]

Small supply compliance technology	Affordable for listed small supply categories.[2]
Activated alumina (centralized)	All size categories.
Activated alumina (point-of-use)[3]	All size categories.
Coagulation/filtration	501-3,300, 3,301-10,000.
Coagulation-assisted microfiltration	501-3,300, 3,301-10,000.
Electrodialysis reversal	501-3,300, 3,301-10,000.
Enhanced coagulation/filtration	All size categories.
Enhanced lime softening (pH more than 10.5)	All size categories.
Ion exchange	All size categories.
Lime softening	501-3,300, 3,301-10,000.
Oxidation/filtration[4]	All size categories.
Reverse osmosis (centralized)	501-3,300, 3,301-10,000.
Reverse osmosis (point-of-use)[3]	All size categories.

[1] SSCTs for Arsenic V. Pre-oxidation may be required to convert Arsenic III to Arsenic V.

[2]Three categories of small supplies are: (i) those serving 25 or more, but fewer than 501, (ii) those serving more than 500, but fewer than 3,301, and (iii) those serving more than 3,300, but fewer than 10,001.

[3]POU ~~shall~~ **must** not be used to obtain a variance.

[4]To obtain high removals, iron to arsenic ratio ~~shall~~ **must** be at least 20:1.

(c) For radionuclide contaminants in R 325.10603, the best available technologies, treatment techniques, or other means available for achieving compliance with the MCLs are listed in table 4 for all size supplies. The affordable technology, treatment technique,

or other means available for achieving compliance with the maximum contaminant level are listed in table 5 for supplies serving 10,000 or fewer people as categorized in table 6.

Table 4 Best available technologies for radionuclide contaminants

Contaminant	Best available technologies.
Combined radium 226 and radium 228	Ion exchange, reverse osmosis, lime softening.
Uranium	Ion exchange, reverse osmosis, lime softening, coagulation/filtration.
Gross alpha particle activity (excluding radon and uranium)	Reverse osmosis.
Beta particle and proton radioactivity	Ion exchange, reverse osmosis.

Table 5 List of small supplies compliance technologies for radionuclides and limitations to use

Unit Technologies	Limitations (see footnotes)	Operator skill level required *	Raw water quality range and considerations.
1. Ion exchange	(a)	Intermediate	All ground waters.
2. Reverse osmosis (RO)	(b)	Advanced	Surface waters usually require pre-filtration.
3. Lime softening	(c)	Advanced	All waters.
4. Green sand filtration	(d)	Basic	
5. Co-precipitation and Barium sulfate	(e)	Intermediate to Advanced	Ground waters with suitable water quality.
6. Electrodialysis/ electrodialysis reversal	Not applicable	Basic to intermediate	All ground waters.
7. Pre-formed hydrous Manganese oxide filtration.	(f)	Intermediate	All ground waters.
8. Activated alumina	(a), (g)	Advanced	All ground waters; competing anion concentrations may affect regeneration frequency.
9. Enhanced coagulation/ filtration	(h)	Advanced	Can treat a wide range of water qualities.

* An operator with a basic skill level has minimal experience in the water treatment field and can perform the necessary system operation and monitoring if provided with

proper instruction. The operator is capable of reading and following explicit directions. An operator with an intermediate skill level understands the principles of water treatment and has a knowledge of the regulatory framework. The operator is capable of making system changes in response to source water fluctuations. An operator with an advanced skill level possesses a thorough understanding of the principles of system operation. The operator is knowledgeable in water treatment and regulatory requirements. The operator may, however, have advanced knowledge of only the particular treatment technology. The operator seeks information, remains informed, and reliably interprets and responds to water fluctuations and system intricacies.

Limitations Footnotes: Technologies for Radionuclides:

a. The regeneration solution contains high concentrations of the contaminant ions. Disposal options ~~shall~~ **must** be carefully considered before choosing this technology.

b. Reject water disposal options ~~shall~~ **must** be carefully considered before choosing this technology.

c. The combination of variable source water quality and the complexity of the water chemistry involved may make this technology too complex for small surface water systems.

d. Removal efficiencies may vary depending on water quality.

e. This technology may be very limited in application to small systems. Since the process requires static mixing, detention basins, and filtration, it is most applicable to systems with sufficiently high sulfate levels that already have a suitable filtration treatment train in place.

f. This technology is most applicable to small systems that already have filtration in place.

g. Handling of chemicals required during regeneration and pH adjustment may be too difficult for small systems without an adequately trained operator.

h. Assumes modification to a coagulation/filtration process already in place.

Table 6 Compliance technologies by supply size category for radionuclide Requirements

Contaminant	Compliance technologies* for supply size categories (population served)		
	25-500	501-3,300	3,301 – 10,000
1. Combined radium 226 and radium 228	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7	1, 2, 3, 4, 5, 6, 7
2. Gross alpha particle activity	2	2	2
3. Beta particle activity and photon activity	1, 2	1, 2	1, 2
4. Uranium	1, 8, 9	1, 2, 3, 8, 9	1, 2, 3, 8, 9

* Numbers correspond to those technologies listed in Table 5 of this rule.

(2) The department shall require community water supplies and nontransient, noncommunity water supplies to employ a treatment method identified in subrule (1) of this rule as a condition for granting a variance, except as provided in subrule (3) of this rule. If, after the treatment method is installed in the system, the supply cannot meet the MCL, then the supply ~~shall be~~ **is** eligible for a variance under this part and section 20 of the act**, MCL 325.1020**.

(3) If a supply demonstrates through comprehensive engineering assessments, which may include pilot plant studies, that the treatment methods identified in subrule (1) of this rule may only achieve a de minimis reduction in contaminants, then the department may issue a schedule of compliance that requires the supply being granted the variance to examine other treatment methods as a condition of obtaining the variance.

(4) If the department determines that a treatment method identified in subrule (3) of this rule is technically feasible, then the department may require the supply to use that treatment method in connection with a compliance schedule issued under section 20 of the act**, MCL 325.1020**. The department's determination **must** ~~shall~~ be based on studies by the supply and other relevant information.

(5) The department may require a community or noncommunity supply to use point-of-use devices, point-of-entry devices, or other means as a condition of granting a variance or an exemption from the requirements of R 325.10603, R 325.10604b, R 325.10604c, ~~or~~ R 325.10604d, **or R325.10604g** to avoid an unreasonable risk to health. The department may require a public water supply to use point-of-use devices or other means, but not point-of-entry devices, as a condition for granting an exemption from corrosion control treatment requirements for lead and copper in R 325.10604f(2) and (3) to avoid an unreasonable risk to health. The department may require a public water supply to use point-of-entry devices as a condition for granting an exemption from the source water and lead service line replacement requirements for lead and copper under R 325.10604f(4) and (5) to avoid an unreasonable risk to health, provided the supply demonstrates that the device will not cause an increased corrosion of lead and copper bearing materials located between the device and the tap that may increase contaminant levels at the tap.

(6) Community or noncommunity water supplies that use point-of-use or point-of-entry devices under this rule shall meet the conditions in R 325.10313.

R 325.10313 Criteria for water supplies using POE, or POU, or both.

Rule 313. (1) Community and noncommunity water supplies shall not use point-of-use devices (POU) or point-of-entry devices (POE) except as required by the department under R 325.10308b or under all of the following provisions with department approval:

(a) Community water supplies may use POE to comply with the maximum contaminant level or treatment technique for organic, inorganic, and radiological contaminants.

(b) Noncommunity water supplies may use POU, or POE, or both, to comply with maximum contaminant levels or treatment techniques for organic and inorganic contaminants.

(c) An alternative source of water that meets state drinking water standards is not available.

(2) Supplies that use POU or POE, or both, shall meet all of the following requirements:

(a) The supply shall operate and maintain the POU, or POE, or both.

(b) Before POU, or POE, or both, are installed, the supply shall obtain department approval of a monitoring plan that ensures that the devices provide health protection equivalent to that provided by central water treatment. If the POU, or POE, or both, are being used to comply with maximum contaminant levels or treatment techniques, then "equivalent" means that the water ~~shall~~ **must** meet all state drinking water standards and ~~shall~~ **must** be of acceptable quality similar to water distributed by a well-operated central treatment plant. At a minimum, the monitoring plan ~~shall~~ **must** include all of the following:

(i) Contaminants and parameters to be analyzed.

(ii) Physical measurements and observations, such as total flow treated and mechanical condition of the treatment equipment.

(iii) Location of sampling sites.

(iv) Frequency of sampling. Approximately 10% of the treatment units ~~shall~~ **must** be sampled at regular intervals so that all the POE or POU are monitored at least as frequently as required in part 7 for a particular contaminant. For example, for a contaminant that is required to be sampled every 3 years, 10% of the POE or POU ~~shall~~ **must** be monitored quarterly so that in 3 years time all of the POE or POU have been monitored. The department may approve an alternate frequency that better represents the rate of degradation of the POE or POU.

(c) Before POU, or POE, or both, are installed, the supply shall obtain department approval of a technology plan that ensures that effective technology is applied and that the microbiological safety of the water is maintained at all times. At a minimum, the technology plan ~~shall~~ **must** include all of the following:

(i) The POU, or POE, or both, ~~shall~~ **must** be equipped with mechanical warnings to ensure that customers are automatically notified of operational problems.

(ii) If a specific type of POU or POE has been independently certified to comply with the maximum contaminant level or treatment technique in accordance with the American ~~n~~**N**ational ~~s~~**S**tandards ~~i~~**I**nstitute/~~n~~**N**ational ~~s~~**S**anitation ~~f~~**F**oundation standards 44, 53, 58, or 62, as adopted by reference in R 325.10112, then individual units of that type ~~shall~~ **must** be used to comply with the maximum contaminant level or treatment technique. A supply may use an alternate type of POU or POE if the supply demonstrates to the department, using pilot plant studies or other means, that the alternative POU or POE consistently complies with the maximum contaminant level or treatment technique and the department approves the use of the POU or POE.

(iii) The design and application of the POU, or POE, or both, ~~shall~~ **must** consider the potential for increasing concentrations of heterotrophic bacteria in water treated with activated carbon. Frequent backwashing, post-contactor disinfection, and heterotrophic plate count monitoring may ensure that the microbiological safety of the water is not compromised.

(d) The supply shall demonstrate that buildings connected to the system have sufficient POU, or POE, or both, that are properly installed, maintained, and monitored such that all ~~of~~ customers ~~shall be~~ **are** protected.

(e) If the POU, or POE, or both, are used to meet an MCL or treatment technique, then the supply shall replace or repair the POU or POE when the contaminant for which the device is intended to control is above the maximum contaminant level in a confirmed sample.

(3) Compliance with the maximum contaminant level ~~shall~~ **must** be determined based on the analytical results obtained at each POU or POE, also known as **the** "sampling point". **The** ~~C~~**c**ompliance determination ~~shall~~ **must** be made under R 325.10604b(2) for volatile organic contaminants, R 325.10604c(2) for inorganic contaminants, ~~or~~ R 325.10604d(2) for synthetic organic chemicals**, or R 325.10604g(2) for per- and polyfluoroalkyl substances**.

(4) Supplies that violate the MCL shall notify the department under part 7 of these rules and shall notify the public under part 4 of these rules. The supply may limit the distribution of the public notice to only persons served by the POU or POE that is out of compliance.

PART 4. PUBLIC NOTIFICATION AND PUBLIC EDUCATION

R 325.10401a General public notification requirements.

Rule 401a. (1) Each community water supply, nontransient noncommunity water supply, or transient noncommunity water supply shall give notice for violations of the maximum contaminant level (MCL), maximum residual disinfection level (MRDL), treatment technique (TT), monitoring requirements, testing procedures in these rules, and for other situations, as listed in the following provisions:

(a) Violations and other situations requiring public notice, including all of the following:

(i) Failure to comply with an applicable maximum contaminant level (MCL) or maximum residual disinfectant level (MRDL).

(ii) Failure to comply with a prescribed treatment technique (TT).

(iii) Failure to perform water quality monitoring, as required by part 7 of these rules.

(iv) Failure to comply with testing procedures as prescribed by part 6 of these rules.

(b) Variance**s** and exemptions under part 3 of these rules, including both of the following:

(i) Operation under a variance or an exemption.

(ii) Failure to comply with the requirements of a schedule that has been set under a variance or exemption.

(c) Special public notices, including all of the following:

(i) Occurrence of a waterborne disease outbreak or other waterborne emergency.

(ii) Exceedance of the nitrate MCL by noncommunity water supplies, where granted permission by the department.

(iii) Fluoride level above 2.0 mg/l as specified in R 325.10408a.

(iv) Availability of unregulated contaminant monitoring data.

(v) Other violations and situations ~~which~~ **that** are determined by the department to require a public notice under this part and ~~which~~ **that** are not already listed in table 1 of this rule. The tier assignment for each specific violation or situation requiring a public notice is identified in table 1 of this rule. Community and noncommunity water supplies are also considered "water supplies" or "supplies" in this rule, R 325.10402 to R 325.10407, and R 325.10408a to R 325.10409.

(2) Public notice requirements are divided into 3 tiers to take into account the seriousness of the violation or situation and of the potential adverse health effects that may be involved. The public notice requirements for each violation or situation listed in

subrule (1) of this rule are determined by the tier to which the violation or situation is assigned. The definition of each tier is provided in the following provisions:

(a) Tier 1 public notice is required for violations and situations that have significant potential to have serious adverse effects on human health as a result of short term exposure.

(b) Tier 2 public notice is required for all other violations and situations that have potential to have serious adverse effects on human health.

(c) Tier 3 public notice is required for all other violations and situations not included in tier 1 and tier 2. The tier assignment for each specific violation or situation is identified in table 1 of this rule.

(3) Supplies shall provide public notice to the following:

(a) Each supply shall provide public notice to persons served by the supply as specified in this part. Supplies that sell or otherwise provide drinking water to other public water supplies, such as to consecutive supplies, shall give public notice to the consecutive supply. The consecutive supply shall provide public notice to the persons it serves.

(b) If a public water supply has a violation in a portion of the distribution system that is physically or hydraulically isolated from other parts of the distribution system, then the department may grant permission, which ~~shall~~ **must** be in writing, to the supply to limit distribution of the public notice to only persons served by that portion of the system ~~which~~ **that** is out of compliance. To be **considered** physically ~~separated~~ **isolated**, the supply shall show that the affected portion of the distribution system is separated from other parts of the distribution system with no interconnections. To be considered hydraulically ~~separated~~ **isolated**, the supply shall show that the design of the distribution system or the system operation, or both, created a situation where water in the affected portion is effectively isolated from the water in all other parts of the distribution system because of projected water flow patterns and water pressure zones.

(4) The supply, within 10 days of completing the public notification requirements under this part for the initial public notice and applicable repeat notices, shall submit to the department a certification that it fully complied with the public notification regulations. The supply shall include with this certification a representative copy of each type of notice distributed, published, posted, and made available to the persons served by the supply and to the media.

Table 1 Violations and other situations requiring public notice

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
I. Violations of MCL, MRDL, treatment technique, monitoring and reporting, and testing procedure requirements:				
A. Microbiological contaminants				
Total coliform until March 31, 2016	2	R 325.10602**(1)**(a) and (b)	3	R 325.10704 to R 325.10707a R 325.10702(2) R 325.10707b(4)

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Total coliform (TT violations resulting from failure to perform assessments or corrective actions, monitoring violations, and reporting violations) beginning April 1, 2016	2	R 325.10704j(2)(a)	3	R 325.10704j(3) R 325.10704j(4)(a)
Seasonal supply failure to follow department-approved start-up plan before serving water to the public or failure to provide certification to the department beginning April 1, 2016	2	R 325.10704j(2)(b)	3	R 325.10704j(4)(c)
Fecal coliform/E. coli until March 31, 2016	1	R 325.10602**(1)**(c)	1, 3 [2]	R 325.10704(3) R 325.10707b(4)
E. coli (MCL, monitoring, and reporting violations) beginning April 1, 2016	1	R 325.10704j(1)	3	R 325.10704j(3)(b) R 325.10704j(4)(a) R 325.10704j(4)(b)
E. coli (TT violations resulting from failure to perform level 2 assessments or corrective action) beginning April 1, 2016	2	R 325.10704j(2)(a)	n/a	n/a
Turbidity (for TT violations resulting from a single exceedance of maximum allowable turbidity level)	2, 1 [3]	R 325.10611b	3	R 325.10605 R 325.10720(2)(a) and (b)
Violations, other than violations resulting from single exceedance of max. allowable turbidity level (TT)	2	R 325.10611, R 325.10611a, and R 325.10611b	3	R 325.10605 R 325.10720(2)(c) and (d)
Violations of disinfection profiling and benchmarking	N/A	N/A	3	R 325.10722
Violations of filter backwash recycling provisions	2	R 325.10611c	3	R 325.1**1**507

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Violations of enhanced treatment for cryptosporidium	2	R 325.10611e to R 325.10611m	2, 3	40 CFR ~~§~~141.701 to §141.705, as adopted by reference in R 325.10720b, R 325.10720c and R 325.10720d. Failure to collect 3 or more samples for Cryptosporidium analysis is a ~~T~~tier 2 violation requiring special notice as required in R 325.10408d. All other monitoring and testing procedure violations are ~~T~~tier 3.
Violations of rules for ground water supplies subject to R 325.10612	2	R 325.10612b	3	R 325.10739(7) R 325.10739a(5)
B. Inorganic chemicals (IOC)				
Antimony	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Arsenic	2	R 325.10604c(1)	3	R 325.10710(4) and (5) R 325.10605
Asbestos (fibers longer than 10 μm)	2	R 325.10604c(1)	3	R 325.10710(4), (6)
Barium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Beryllium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Cadmium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Chromium (total)	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Cyanide (free)	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Fluoride	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Mercury (inorganic)	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Nitrate (as nitrogen)	1	R 325.10604c(1)	1, 3 [4]	R 325.10710(3), (4), (7), and (9)(b)
Nitrite (as nitrogen)	1	R 325.10604c(1)	1, 3 [4]	R 325.10710(3), (4), (8), and (9)(b)

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Total nitrate and nitrite (as nitrogen)	1	R 325.10604c(1)	3	R 325.10710(4)
Selenium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
Thallium	2	R 325.10604c(1)	3	R 325.10710(4) and (5)
C. Lead and copper (action level for lead is 0.015 mg/l through December 31, 2024 and 0.012 mg/l beginning January 1, 2025; action level for copper is 1.3 mg/l)				
Lead and copper rule (TT)	2	R 325.10604f(1) – (5) R 325.10410(2) and (3)	3	R 325.10710a to R 325.10710c and R 325.10605
D. Synthetic organic chemicals (SOC)				
2,4-D	2	R 325.10604d(1)	3	R 325.10717
2,4,5-TP (silvex)	2	R 325.10604d(1)	3	R 325.10717
Alachlor	2	R 325.10604d(1)	3	R 325.10717
Atrazine	2	R 325.10604d(1)	3	R 325.10717
Benzo(a)pyrene (PAHs)	2	R 325.10604d(1)	3	R 325.10717
Carbofuran	2	R 325.10604d(1)	3	R 325.10717
Chlordane	2	R 325.10604d(1)	3	R 325.10717
Dalapon	2	R 325.10604d(1)	3	R 325.10717
Di (2-ethylhexyl) adipate	2	R 325.10604d(1)	3	R 325.10717
Di (2-ethylhexyl) phthalate	2	R 325.10604d(1)	3	R 325.10717
Dibromochloropropane	2	R 325.10604d(1)	3	R 325.10717
Dinoseb	2	R 325.10604d(1)	3	R 325.10717
Dioxin (2,3,7,8-TCDD)	2	R 325.10604d(1)	3	R 325.10717
Diquat	2	R 325.10604d(1)	3	R 325.10717
Endothall	2	R 325.10604d(1)	3	R 325.10717
Endrin	2	R 325.10604d(1)	3	R 325.10717
Ethylene dibromide	2	R 325.10604d(1)	3	R 325.10717
Glyphosate	2	R 325.10604d(1)	3	R 325.10717
Heptachlor	2	R 325.10604d(1)	3	R 325.10717
Heptachlor epoxide	2	R 325.10604d(1)	3	R 325.10717
Hexachlorobenzene	2	R 325.10604d(1)	3	R 325.10717
Hexachlorocyclo-pentadiene	2	R 325.10604d(1)	3	R 325.10717
Lindane	2	R 325.10604d(1)	3	R 325.10717
Methoxychlor	2	R 325.10604d(1)	3	R 325.10717
Oxamyl (vydate)	2	R 325.10604d(1)	3	R 325.10717
Pentachlorophenol	2	R 325.10604d(1)	3	R 325.10717
Picloram	2	R 325.10604d(1)	3	R 325.10717
Polychlorinated biphenyls [PCBs]	2	R 325.10604d(1)	3	R 325.10717
Simazine	2	R 325.10604d(1)	3	R 325.10717
Toxaphene	2	R 325.10604d(1)	3	R 325.10717
E. Volatile organic chemicals (VOC)				
Benzene	2	R 325.10604b(1)	3	R 325.10716
Carbon tetrachloride	2	R 325.10604b(1)	3	R 325.10716
Chlorobenzene (monochloro-benzene)	2	R 325.10604b(1)	3	R 325.10716

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
O-dichlorobenzene	2	R 325.10604b(1)	3	R 325.10716
P-dichlorobenzene	2	R 325.10604b(1)	3	R 325.10716
1,2-dichloroethane	2	R 325.10604b(1)	3	R 325.10716
1,1-dichloroethylene	2	R 325.10604b(1)	3	R 325.10716
Cis-1,2-dichloroethylene	2	R 325.10604b(1)	3	R 325.10716
Trans-1,2-dichloroethylene	2	R 325.10604b(1)	3	R 325.10716
Dichloromethane	2	R 325.10604b(1)	3	R 325.10716
1,2-dichloropropane	2	R 325.10604b(1)	3	R 325.10716
Ethylbenzene	2	R 325.10604b(1)	3	R 325.10716
Styrene	2	R 325.10604b(1)	3	R 325.10716
Tetrachloro-ethylene	2	R 325.10604b(1)	3	R 325.10716
Toluene	2	R 325.10604b(1)	3	R 325.10716
1,2,4-trichlorobenzene	2	R 325.10604b(1)	3	R 325.10716
1,1,1-trichloroethane	2	R 325.10604b(1)	3	R 325.10716
1,1,2-trichloroethane	2	R 325.10604b(1)	3	R 325.10716
Trichloroethylene	2	R 325.10604b(1)	3	R 325.10716
Vinyl chloride	2	R 325.10604b(1)	3	R 325.10716
Xylenes (total)	2	R 325.10604b(1)	3	R 325.10716
F. per- and polyfluoroalkyl substances (PFAS)				
Hexafluoropropylene oxide dimer acid (HFPO-DA)	**12**	**R 325.10604g(1)**	**3**	**R 325.10717d**
Perfluorobutane sulfonic acid (PFBS)	**12**	**R 325.10604g(1)**	**3**	**R 325.10717d**
Perfluorohexane sulfonic acid (PFHxS)	**12**	**R 325.10604g(1)**	**3**	**R 325.10717d**
Perfluorohexanoic acid (PFHxA)	**2**	**R 325.10604g(1)**	**2[6], 3**	**R 325.10717d**
Perfluorononanoic acid (PFNA)	**2**	**R 325.10604g(1)**	**2[6], 3**	**R 325.10717d**
Perfluorooctane sulfonic acid (PFOS)	**2**	**R 325.10604g(1)**	**2[6], 3**	**R 325.10717d**
Perfluorooctanoic acid (PFOA)	**2**	**R 325.10604g(1)**	**2[6], 3**	**R 325.10717d**
N-ethyl perfluorooctanesulfonamidoacetic acid (NEtFOSAA)	2	R 325.10604g(1)	2[6], 3	R 325.10717d
N-methyl perfluorooctanesulfonamidoacetic acid (NMeFOSAA)	2	R 325.10604g(1)	2[6], 3	R 325.10717d
Perfluorodecanoic acid (PFDA)	2	R 325.10604g(1)	2[6], 3	R 325.10717d
Perfluorododecanoic acid (PFDoA)	2	R 325.10604g(1)	2[6], 3	R 325.10717d

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Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Perfluorotetradecanoic acid (PFTA)	2	R 325.10604g(1)	2[6], 3	R 325.10717d
Perfluorotridecanoic acid (PFTrDA)	2	R 325.10604g(1)	2[6], 3	R 325.10717d
Perfluoroundecanoic acid (PFUnA)	2	R 325.10604g(1)	2[6], 3	R 325.10717d
~~F~~ **G**. Radioactive contaminants				
Beta/photon emitters	2	R 325.10603(2)(c)	3	R 325.10605 R 325.10725 R 325.10730
Alpha emitters (gross alpha)	2	R 325.10603(2)(b)	3	R 325.10605 R 325.10725 R 325.10726 R 325.10728 R 325.10729
Combined radium (226 & 228)	2	R 325.10603(2)(a)	3	R 325.10605 R 325.10725 R 325.10726 R 325.10728 R 325.10729
Uranium (pCi/L)	2	R 325.10603(2)(d)	3	R 325.10605 R 325.10725 R 325.10726 R 325.10728 R 325.10729
~~G~~ **H**. Disinfection byproducts (DBP), byproduct precursors, disinfectant residuals. Where disinfection is used in the treatment of drinking water, disinfectants combine with organic and inorganic matter present in water to form chemicals called disinfection byproducts (DBP). The department sets standards for controlling the levels of disinfectants and DBPs in drinking water, including trihalomethanes (THM) and haloacetic acids (HAA). See R 325.10610 to R 325.10610d, and R 325.10719e to R 325.10719n for disinfection byproduct MCLs, disinfectant MRDLs, and related monitoring requirements.				
Total trihalomethanes (TTHM)	2	R 325.10610(2) R 325.10610b(2)(a)	3	R 325.10610d, R 325.10719e(1) and (2)(a), and R 325.10719h to R 325.10719n
Haloacetic acids (HAA)	2	R 325.10610(2) R 325.10610b(2)(a)	3	R 325.10610d, R 325.10719e(1) and (2)(a), and R 325.10719h to R 325.10719n
Bromate	2	R 325.10610 R 325.10610b(2)(b)	3	R 325.10719e(1) and (2)(c)
Chloramine (MRDL)	2	R 325.10610a R 325.10610b(3)(a)	3	R 325.10719e(1) and (3)
Chlorine (MRDL)	2	R 325.10610a R 325.10610b(3)(a)	3	R 325.10719e(1) and (3)

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Chlorite	2	R 325.10610 R 325.10610b(2)(c)	3	R 325.10719e(1) and (2)(b)
Chlorine dioxide (MRDL), where any 2 consecutive daily samples at entrance to distribution system only are above MRDL	2	R 325.10610a R 325.10610b(3)(b)(ii)	2 *, 3	R 325.10719e(1), (3)(b)(i) and (iii)
	* Failure to monitor for chlorine dioxide at the entrance to the distribution system the day after exceeding the MRDL at the entrance to the distribution system is a tier 2 violation.			
Chlorine dioxide (MRDL), where sample(s) in distribution system the next day are also above MRDL	1 *	R 325.10610a R 325.10610b(3)(b)(i)	1	R 325.10719e(1), (3)(b)(ii) and (iii)
	* If any daily sample taken at the entrance to the distribution system exceeds the MRDL for chlorine dioxide and 1 or more samples taken in the distribution system the next day exceed the MRDL, tier 1 notification is required. Failure to take the required samples in the distribution system after the MRDL is exceeded at the entry point also triggers tier 1 notification.			
Control of DBP precursors—TOC (TT)	2	R 325.10610b(4) R 325.10610c	3	R 325.10719e(1) and (4)
Bench marking and disinfection profiling	N/A	N/A	3	R 325.10722
Development of monitoring plan	N/A	N/A	3	R 325.10719e(5)
~~H~~ **I**. Other treatment techniques				
Acrylamide (TT)	2	R 325.10604e	N/A	N/A
Epichlorohydrin (TT)	2	R 325.10604e	N/A	N/A
II. Other monitoring:				
Unregulated contaminants	N/A	N/A	3	40 CFR §141.40 [5]
Nickel	N/A	N/A	3	R 325.10710(4), (5), and (9)
III. Public notification for variances and exemptions:				
Operation under a variance or exemption	2~~3~~	R 325.10302	N/A	N/A
Violation of conditions of a variance or exemption	2	R 325.10312	N/A	N/A
IV. Other situations requiring public notification:				
Fluoride level above 2.0 mg/l	3	R 325.10408a(1)	N/A	N/A
Exceedance of nitrate MCL for noncommunity supplies, as allowed by the department	1	R 325.10604c(3)	N/A	N/A
Availability of unregulated contaminant monitoring data	3	R 325.10407	N/A	N/A
Waterborne disease outbreak	1	R 325.10734(4)	N/A	N/A
Source water sample positive for ~~F~~fecal ~~I~~indicator: E.coli, enterococci, or coliphage	1	R 325.10739(6)	N/A	N/A
	1 or 2 or 3 *	N/A	N/A	N/A

Contaminant	MCL/MRDL/TT violations [1]		Monitoring, testing, & reporting procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
Other waterborne emergencies and other situations as determined by the department	* Waterborne emergencies require a tier 1 public notice. The department may place other situations in any tier it determines appropriate, based on threat to public health.			

[1]MCL - Maximum contaminant level, MRDL - maximum residual disinfectant level, TT - treatment technique.

[2]Failure to test for fecal coliform or E. coli is a tier 1 violation if testing is not done after any repeat sample tests positive for coliform. All other total coliform monitoring and testing procedure violations are tier 3.

[3]Supplies with treatment technique violations involving a single exceedance of a maximum turbidity limit under R 325.10611b(1) are required to initiate consultation with the department within 24 hours after learning of the violation. Based on this consultation, the department may subsequently decide to elevate the violation to tier 1. If a supply is unable to make contact with the department in the 24-hour period, the violation is automatically elevated to tier 1.

[4]Failure to take a confirmation sample within 24 hours for nitrate or nitrite after an initial sample exceeds the MCL is a tier 1 violation. Other monitoring violations for nitrate are tier 3.

[5]~~Title 40 CFR part 141 Section 40, being~~ 40 CFR §141.40,~~(2014),~~ which pertains to unregulated contaminant monitoring, is contained in Title 40 CFR parts 136 to 149 and is available for purchase for $67.00 from the superintendent of documents at the address in R 325.10116. The material is available for inspection from the offices of the department at the address in R 325.10116(a) or available on the ~~I~~**i**nternet at http://www.ecfr.gov/.

[6]Failure to monitor for PFAS analytes identified in US EPA method 537.1 and 533 and failure to report monitoring results are tier 2 violations .

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R 325.10405 Content of public notice.

Rule 405. (1) If a community or noncommunity water supply that is subject to R 325.10401a has a violation or situation requiring public notification, then each public notice ~~shall~~ **must** include all of the following elements:

(a) A description of the violation or situation, including the contaminant or contaminants of concern, and, as applicable, the contaminant level or levels.

(b) When the violation or situation occurred.

(c) The potential adverse health effects from the violation or situation, including the standard language under subrule (4)(a) or (b) of this rule, whichever is applicable.

(d) The population at risk, including subpopulations particularly vulnerable if exposed to the contaminant in their drinking water.

(e) If alternative water supplies should be used.

(f) What actions consumers should take, including when they should seek medical help, if known.

(g) What the supply is doing to correct the violation or situation.

(h) When the supply expects to return to compliance or resolve the situation.

(i) The name, business address, and phone number of the supply or designee of the supply as a source of additional information concerning the notice.

(j) A statement to encourage the notice recipient to distribute the public notice to other persons served, using the standard language under subrule (4)(c) of this rule, where applicable.

(2) All of the following elements ~~shall~~ **must** be included in the public notice for public water supplies operating under a variance or exemption:

(a) If a public water supply has been granted a variance or an exemption, then the public notice ~~shall~~ **must** contain all of the following elements:

(i) An explanation of the reasons for the variance or exemption.

(ii) The date on which the variance or exemption was issued.

(iii) A brief status report on the steps the supply is taking to install treatment, find alternative sources of water, or otherwise comply with the terms and schedules of the variance or exemption.

(iv) A notice of opportunities for public input in the review of the variance or exemption.

(b) If a public water supply violates the conditions of a variance or exemption, then the public notice ~~shall~~ **must** contain the 10 elements listed in subrule (1) of this rule.

(3) The public notice ~~shall~~ **must** be presented in the following manner:

(a) Each public notice required by this part ~~shall~~ **must** meet all of the following criteria:

(i) ~~Shall~~ **Must** be displayed in a conspicuous way when printed or posted.

(ii) ~~Shall~~ **Must** not contain overly technical language or very small print.

(iii) ~~Shall~~ **Must** not be formatted in a way that defeats the purpose of the notice.

(iv) ~~Shall~~ **Must** not contain language ~~which~~ **that** nullifies the purpose of the notice.

(b) In communities where more than 10% of the consumers are non-English speaking consumers, the public notice ~~shall~~ **must** contain information in the appropriate language or languages regarding the importance of the notice or contain a telephone number or address where persons served may contact the supply to obtain a translated copy of the notice or to request assistance in the appropriate language.

(4) The supply shall include the following standard language in the public notice:

(a) The supply shall include in each public notice the health effects language specified in table 1 of this rule corresponding to each MCL, MRDL, and treatment technique violation listed in table 1 of R 325.10401a, and for each violation of a condition of a variance or exemption.

(b) The supply shall include the following language in the notice, including the language necessary to fill in the blanks, for all monitoring and testing procedure violations listed in table 1 of R 325.10401a: "We are required to monitor your drinking water for specific contaminants on a regular basis. Results of regular monitoring are an

indicator of whether or not your drinking water meets health standards. During [compliance period], we 'did not monitor or test' or 'did not complete all monitoring or testing' for [contaminant or contaminants], and therefore cannot be sure of the quality of your drinking water during that time."

(c) The supply shall include in the notice the following language, where applicable, to encourage the distribution of the public notice to all persons served: "Please share this information with all the other people who drink this water, especially those who may not have received this notice directly (for example, people in apartments, nursing homes, schools, and businesses). You can do this by posting this notice in a public place or distributing copies by hand or mail."

Table 1 Regulated contaminants

Key

AL=Action level
MCL=Maximum contaminant level
MCLG=Maximum contaminant level goal
mfl=Million fibers per liter
MRDL=Maximum residual disinfectant level
MRDLG=Maximum residual disinfectant level goal
mrem/year=Millirems per year (a measure of radiation absorbed by the body)
N/A=Not applicable
NTU=Nephelometric turbidity units (a measure of water clarity)
pci/l=Picocuries per liter (a measure of radioactivity)
ppm=Parts per million, or milligrams per liter (mg/l)
ppb=Parts per billion, or micrograms per liter (µg/l)
ppt=Parts per trillion, or nanograms per liter
ppq=Parts per quadrillion, or picograms per liter
TT=Treatment technique

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Microbiological contaminants						
Total coliform bacteria until March 31, 2016	MCL: For water supplies analyzing 40 or more samples per month, not more than 5.0% of the monthly samples may be positive for total coliform. For supplies analyzing fewer than 40 samples per month, not more than 1 sample per month may be positive for total coliform.			zero	Naturally present in the environment	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, bacteria may be present. Coliforms were found in more samples than allowed and this was a warning of potential problems.
Total coliform bacteria beginning April 1, 2016. This row applies to Consumer Confidence Reporting.	TT	No conversion necessary	TT	N/A	Naturally present in the environment	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system.
Fecal coliform and E. coli until March 31, 2016	zero	No conversion necessary	zero	zero	Human and animal fecal waste	Fecal coliforms and E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
E. coli beginning April 1, 2016	MCL: Routine and repeat samples are total coliform-positive and either is E. coli-positive or supply fails to take all required repeat samples following E. coli-positive routine sample or supply fails to analyze total coliform-positive repeat sample for E. coli			zero	Human and animal fecal waste	E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely-compromised immune systems.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Coliform Assessment ~~and/~~or Corrective Action Violations**, or both,** beginning April 1, 2016. This row applies to public notification. For Consumer Confidence Reporting, see R 325.10413(12)(g)(i).	N/A	No conversion necessary	TT	N/A	N/A	Coliforms are bacteria that are naturally present in the environment and are used as an indicator that other, potentially harmful, waterborne pathogens may be present or that a potential pathway exists through which contamination may enter the drinking water distribution system. We found coliforms indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct assessments to identify problems and to correct any problems that are found. [THE SUPPLY MUST USE 1 OF THE FOLLOWING APPLICABLE SENTENCES:] We failed to conduct the required assessment. We failed to correct all identified sanitary defects that were found during the assessment(s).
E. coli Assessment ~~and/~~or Corrective Action Violations**, or both,** beginning April 1, 2106. This row applies to public notification. For Consumer Confidence Reporting, see R 325.10413(12)(g)(ii).	N/A	No conversion necessary	TT	N/A	N/A	E. coli are bacteria whose presence indicates that the water may be contaminated with human or animal wastes. Human pathogens in these wastes can cause short-term effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a greater health risk for infants, young children, the elderly, and people with severely compromised immune systems. We violated the standard for E. coli, indicating the need to look for potential problems in water treatment or distribution. When this occurs, we are required to conduct a detailed assessment to identify problems and to correct any problems that are found. [THE SUPPLY MUST USE 1 OF THE FOLLOWING APPLICABLE SENTENCES:] We failed to conduct the required assessment. We failed to correct all identified sanitary defects that were found during the assessment that we conducted.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Seasonal Supply Treatment Technique Violations of the Total Coliform Rule beginning April 1, 2016.	N/A	No conversion necessary	TT	N/A	N/A	When this violation includes the failure to monitor for total coliforms or E. coli prior to serving water to the public, the mandatory language found at R 325.10405(4)(b) ~~shall~~ **must** be used. When this violation includes failure to complete other actions, the appropriate public notice elements found in R 325.10405(1) ~~shall~~ **must** be used.
Fecal indicator under groundwater requirements in R 325.10612 et. al: - E.coli - enterococci or - coliphage)	TT	No conversion necessary	TT	E.coli: zero Others: N/A	Human and animal fecal waste	Fecal indicators are microbes whose presence indicates that the water may be contaminated with human or animal wastes. Microbes in these wastes can cause short-term health effects, such as diarrhea, cramps, nausea, headaches, or other symptoms. They may pose a special health risk for infants, young children, some of the elderly, and people with severely compromised immune systems.
Violations of rules for ground water supplies subject to R 325.10612	TT	No conversion necessary	TT	N/A	N/A	Inadequately treated or inadequately protected water may contain disease-causing organisms. These organisms can cause symptoms such as diarrhea, nausea, cramps, and associated headaches.
Turbidity (ntu)	TT	No conversion necessary	TT	N/A	Soil runoff	Turbidity has no health effects. However, turbidity can interfere with disinfection and provide a medium for microbial growth. Turbidity may indicate the presence of disease-causing organisms. These organisms include bacteria, viruses, and parasites that can cause symptoms such as nausea, cramps, diarrhea, and associated headaches.
Other microbiological contaminants						
Giardia lamblia, viruses, heterotrophic plate count (HPC) bacteria, legionella, cryptosporidium	TT*	No conversion necessary	TT*	zero	Naturally present in the environment	Inadequately treated water may contain disease-causing organisms. These organisms include bacteria, viruses, and parasites which can cause symptoms such as nausea, cramps, diarrhea, and associated headaches.
	* The treatment technique violations that involve turbidity exceedances may use health effects language for turbidity instead.					
Inorganic contaminants						

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Antimony (ppb)	0.006	1000	6	6	Discharge from petroleum refineries; fire retardants; ceramics; electronics; solder	Some people who drink water containing antimony well in excess of the MCL over many years could experience increases in blood cholesterol and decreases in blood sugar.
Arsenic (ppb)	0.010	1000	10	0	Erosion of natural deposits; runoff from orchards; runoff from glass and electronics production wastes	Some people who drink water containing arsenic in excess of the MCL over many years could experience skin damage or problems with their circulatory system, and may have an increased risk of getting cancer.
Asbestos [fibers longer than 10 µm] (mfl)	7 mfl	No conversion necessary	7	7	Decay of asbestos cement water mains; erosion of natural deposits	Some people who drink water containing asbestos in excess of the MCL over many years may have an increased risk of developing benign intestinal polyps.
Barium (ppm)	2	No conversion necessary	2	2	Discharge of drilling wastes; discharge from metal refineries; erosion of natural deposits	Some people who drink water containing barium in excess of the MCL over many years could experience an increase in their blood pressure.
Beryllium (ppb)	0.004	1000	4	4	Discharge from metal refineries and coal-burning factories; discharge from electrical, aerospace, and defense industries	Some people who drink water containing beryllium well in excess of the MCL over many years could develop intestinal lesions.
Cadmium (ppb)	0.005	1000	5	5	Corrosion of galvanized pipes; erosion of natural deposits; discharge from metal refineries; runoff from waste batteries and paints	Some people who drink water containing cadmium in excess of the MCL over many years could experience kidney damage.
Chromium [total] (ppb)	0.1	1000	100	100	Discharge from steel and pulp mills; erosion of natural deposits	Some people who use water containing chromium well in excess of the MCL over many years could experience allergic dermatitis.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Cyanide [free] (ppb)	0.2	1000	200	200	Discharge from steel/metal factories; discharge from plastic and fertilizer factories	Some people who drink water containing cyanide well in excess of the MCL over many years could experience nerve damage or problems with their thyroid.
Fluoride (ppm)	4.0	No conversion necessary	4.0	4.0	Erosion of natural deposits; water additive that promotes strong teeth; discharge from fertilizer and aluminum factories	Some people who drink water containing fluoride in excess of the MCL over many years could get bone disease, including pain and tenderness of the bones. Fluoride in drinking water at half the MCL or more may cause mottling of children's teeth, usually in children less than 9 years old. Mottling, also known as dental fluorosis, may include brown staining ~~and/~~or pitting of the teeth, **or both,** and occurs only in developing teeth before they erupt from the gums.
Mercury [inorganic] (ppb)	0.002	1000	2	2	Erosion of natural deposits; discharge from refineries and factories; runoff from landfills; runoff from cropland	Some people who drink water containing inorganic mercury well in excess of the MCL over many years could experience kidney damage.
Nitrate [as nitrogen] (ppm)	10	No conversion necessary	10	10	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	Infants below the age of 6 months who drink water containing nitrate in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.
Nitrite [as nitrogen] (ppm)	1	No conversion necessary	1	1	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	Infants below the age of 6 months who drink water containing nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.
Total nitrate and nitrite [as nitrogen] (ppm)	10	No conversion necessary	10	10	Runoff from fertilizer use; leaching from septic tanks, sewage; erosion of natural deposits	Infants below the age of 6 months who drink water containing nitrate and nitrite in excess of the MCL could become seriously ill and, if untreated, may die. Symptoms include shortness of breath and blue baby syndrome.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Selenium (ppb)	0.05	1000	50	50	Discharge from petroleum and metal refineries; erosion of natural deposits; discharge from mines	Selenium is an essential nutrient. However, some people who drink water containing selenium in excess of the MCL over many years could experience hair or fingernail losses, numbness in fingers or toes, or problems with their circulation.
Thallium (ppb)	0.002	1000	2	0.5	Leaching from ore-processing sites; discharge from electronics, glass, and drug factories	Some people who drink water containing thallium in excess of the MCL over many years could experience hair loss, changes in their blood, or problems with their kidneys, intestines, or liver.
Lead and copper						
Lead (ppb)	AL=0.015 through December 31, 2024; AL= 0.012 beginning January 1, 2025.	1000	AL=15 through December 31, 2024; AL=12 beginning January 1, 2025. (TT)	zero	Lead services lines, corrosion of household plumbing including fittings and fixtures; erosion of natural deposits	Infants and children who drink water containing lead could experience delays in their physical or mental development. Children could show slight deficits in attention span and learning abilities. Adults who drink this water over many years could develop kidney problems or high blood pressure.
Copper (ppm)	AL=1.3	No conversion necessary	AL=1.3 (TT)	1.3	Corrosion of household plumbing systems; erosion of natural deposits	Copper is an essential nutrient, but some people who drink water containing copper in excess of the action level over a relatively short amount of time could experience gastrointestinal distress. Some people who drink water containing copper in excess of the action level over many years could suffer liver or kidney damage. People with Wilson's disease should consult their personal doctor.
Synthetic organic contaminants including pesticides and herbicides						
2,4-D (ppb)	0.07	1000	70	70	Runoff from herbicide used on row crops	Some people who drink water containing the weed killer 2,4-d well in excess of the MCL over many years could experience problems with their kidneys, liver, or adrenal glands.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
2,4,5-TP [silvex] (ppb)	0.05	1000	50	50	Residue of banned herbicide	Some people who drink water containing silvex in excess of the MCL over many years could experience liver problems.
Alachlor (ppb)	0.002	1000	2	zero	Runoff from herbicide used on row crops	Some people who drink water containing alachlor in excess of the MCL over many years could have problems with their eyes, liver, kidneys, or spleen, or experience anemia, and may have an increased risk of getting cancer.
Atrazine (ppb)	0.003	1000	3	3	Runoff from herbicide used on row crops	Some people who drink water containing atrazine well in excess of the MCL over many years could experience problems with their cardiovascular system or reproductive difficulties.
Benzo(a)pyrene [PAHs] (ppt)	0.0002	1,000,000	200	zero	Leaching from linings of water storage tanks and distribution lines	Some people who drink water containing benzo(a)pyrene in excess of the MCL over many years may experience reproductive difficulties and may have an increased risk of getting cancer.
Carbofuran (ppb)	0.04	1000	40	40	Leaching of soil fumigant used on rice and alfalfa	Some people who drink water containing carbofuran in excess of the MCL over many years could experience problems with their blood or nervous or reproductive systems.
Chlordane (ppb)	0.002	1000	2	zero	Residue of banned termiticide	Some people who drink water containing chlordane in excess of the ~~mcl~~ **MCL** over many years could experience problems with their liver or nervous system, and may have an increased risk of getting cancer.
Dalapon (ppb)	0.2	1000	200	200	Runoff from herbicide used on rights of way	Some people who drink water containing dalapon well in excess of the MCL over many years could experience minor kidney changes.
Di(2-ethylhexyl) adipate (ppb)	0.4	1000	400	400	Discharge from chemical factories	Some people who drink water containing di (2-ethylhexyl) adipate well in excess of the MCL over many years could experience toxic effects such as weight loss, liver enlargement, or possible reproductive difficulties.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Di(2-ethylhexyl) phthalate (ppb)	0.006	1000	6	zero	Discharge from rubber and chemical factories	Some people who drink water containing di (2-ethylhexyl) phthalate well in excess of the MCL over many years may have problems with their liver, or experience reproductive difficulties, and may have an increased risk of getting cancer.
Dibromochloropropane [DBCP] (ppt)	0.0002	1,000,000	200	zero	Runoff/leaching from soil fumigant used on soybeans, cotton, pineapples, and orchards	Some people who drink water containing DBCP in excess of the MCL over many years could experience reproductive difficulties and may have an increased risk of getting cancer.
Dinoseb (ppb)	0.007	1000	7	7	Runoff from herbicide used on soybeans and vegetables	Some people who drink water containing dinoseb well in excess of the MCL over many years could experience reproductive difficulties.
Dioxin [2,3,7,8-TCDD] (ppq)	0.00000003	1,000,000,000	30	zero	Emissions from waste incineration and other combustion; discharge from chemical factories	Some people who drink water containing dioxin in excess of the MCL over many years could experience reproductive difficulties and may have an increased risk of getting cancer.
Diquat (ppb)	0.02	1000	20	20	Runoff from herbicide use	Some people who drink water containing diquat in excess of the MCL over many years could get cataracts.
Endothall (ppb)	0.1	1000	100	100	Runoff from herbicide use	Some people who drink water containing endothall in excess of the MCL over many years could experience problems with their stomach or intestines.
Endrin (ppb)	0.002	1000	2	2	Residue of banned insecticide	Some people who drink water containing endrin in excess of the MCL over many years could experience liver problems.
Ethylene dibromide (ppt)	0.00005	1,000,000	50	zero	Discharge from petroleum refineries	Some people who drink water containing ethylene dibromide in excess of the MCL over many years could experience problems with their liver, stomach, reproductive system, or kidneys, and may have an increased risk of getting cancer.
Glyphosate (ppb)	0.7	1000	700	700	Runoff from herbicide use	Some people who drink water containing glyphosate in excess of the MCL over many years could experience problems with their kidneys or reproductive difficulties.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Heptachlor (ppt)	0.0004	1,000,000	400	zero	Residue of banned pesticide	Some people who drink water containing heptachlor in excess of the MCL over many years could experience liver damage and may have an increased risk of getting cancer.
Heptachlor epoxide (ppt)	0.0002	1,000,000	200	zero	Breakdown of heptachlor	Some people who drink water containing heptachlor epoxide in excess of the MCL over many years could experience liver damage, and may have an increased risk of getting cancer.
Hexachlorobenzene (ppb)	0.001	1000	1	zero	Discharge from metal refineries and agricultural chemical factories	Some people who drink water containing hexachlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys, or adverse reproductive effects, and may have an increased risk of getting cancer.
Hexachlorocyclopentadiene (ppb)	0.05	1000	50	50	Discharge from chemical factories	Some people who drink water containing hexachlorocyclopentadiene well in excess of the MCL over many years could experience problems with their kidneys or stomach.
L~~l~~indane (ppt)	0.0002	1,000,000	200	200	Runoff/leaching from insecticide used on cattle, lumber, gardens	Some people who drink water containing lindane in excess of the MCL over many years could experience problems with their kidneys or liver.
Methoxychlor (ppb)	0.04	1000	40	40	Runoff/leaching from insecticide used on fruits, vegetables, alfalfa, livestock	Some people who drink water containing methoxychlor in excess of the MCL over many years could experience reproductive difficulties.
Oxamyl [vydate] (ppb)	0.2	1000	200	200	Runoff/leaching from insecticide used on apples, potatoes, and tomatoes	Some people who drink water containing oxamyl in excess of the MCL over many years could experience slight nervous system effects.
Pentachlorophenol (ppb)	0.001	1000	1	zero	Discharge from wood preserving factories	Some people who drink water containing pentachlorophenol in excess of the MCL over many years could experience problems with their liver or kidneys, and may have an increased risk of getting cancer.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Picloram (ppb)	0.5	1000	500	500	Herbicide runoff	Some people who drink water containing picloram in excess of the MCL over many years could experience problems with their liver.
Polychlorinated biphenyls [PCBs] (ppt)	0.0005	1,000,000	500	zero	Runoff from landfills; discharge of waste chemicals	Some people who drink water containing PCBs in excess of the MCL over many years could experience changes in their skin, problems with their thymus gland, immune deficiencies, or reproductive or nervous system difficulties, and may have an increased risk of getting cancer.
Simazine (ppb)	0.004	1000	4	4	Herbicide runoff	Some people who drink water containing simazine in excess of the MCL over many years could experience problems with their blood.
Toxaphene (ppb)	0.003	1000	3	zero	Runoff/leaching from insecticide used on cotton and cattle	Some people who drink water containing toxaphene in excess of the MCL over many years could have problems with their kidneys, liver, or thyroid, and may have an increased risk of getting cancer.
Per- and polyfluoroalkyl substances (PFAS)						
Hexafluoropropylene oxide dimer acid (HFPO-DA) (ppt)	**370 ppt (ng/l)**	**No conversion necessary**	**370**	**N/A**	**Discharge and waste from industrial facilities utilizing the Gen X chemical process**	**Some people who drink water containing HFPO-DA in excess of the MCL could experience problems with their liver. Some fetuses of pregnant women and infants born to mothers who drink water containing HFPO-DA in excess of the MCL may experience developmental effects.**
Perfluorobutane sulfonic acid (PFBS) (ppt)	**420 ppt (ng/l)**	**No conversion necessary**	**420**	**N/A**	**Discharge and waste from industrial facilities; stain-resistant treatments**	**Some infants born to mothers who drink water containing PFBS in excess of the MCL may experience decreased thyroid hormone levels.**
Perfluorohexane sulfonic acid (PFHxS) (ppt)	**51 ppt (ng/l)**	**No conversion necessary**	**51**	**N/A**	**Firefighting foam; discharge and waste from industrial facilities**	**Some people who drink water containing PFHxS in excess of the MCL could experience problems with their thyroid, liver, and cholesterol levels.**

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Perfluorohexanoic acid (PFHxA) (ppt)	**400,000 ppt (ng/l)**	**No conversion necessary**	**400,000**	**N/A**	**Firefighting foam; discharge and waste from industrial facilities**	**Some people who drink water containing PFHxA in excess of the MCL could experience problems with their liver and kidneys.**
Perfluorononanoic acid (PFNA) (ppt)	**6 ppt (ng/l)**	**No conversion necessary**	**6**	**N/A**	**Discharge and waste from industrial facilities; breakdown of precursor compounds**	**Some fetuses of pregnant women and infants born to mothers who drink water containing PFNA in excess of the MCL may experience developmental delays and decreased body weight gain.**
Perfluorooctane sulfonic acid (PFOS) (ppt)	**16 ppt (ng/l)**	**No conversion necessary**	**16**	**N/A**	**Firefighting foam; discharge from electroplating facilities; discharge and waste from industrial facilities**	**Some fetuses of pregnant women and infants born to mothers who drink water containing PFOS in excess of the MCL may experience developmental delays and decreased body weight gain.**
Perfluorooctanoic acid (PFOA) (ppt)	**8 ppt (ng/l)**	**No conversion necessary**	**8**	**N/A**	**Discharge and waste from industrial facilities; stain-resistant treatments**	**Some fetuses of pregnant women and infants born to mothers who drink water containing PFOA in excess of the MCL may experience neurodevelopmental effects and skeletal effects.**
N-ethyl perfluorooctanesulfonamidoacetic acid (NEtFOSAA)	6	No conversion necessary	6	N/A		Some fetuses of pregnant women and infants born to mothers who drink water containing PFNA in excess of the MCL may experience developmental delays and decreased body weight gain.
N-methyl perfluorooctanesulfonamidoacetic acid (NMeFOSAA)	6	No conversion necessary	6	N/A		Some fetuses of pregnant women and infants born to mothers who drink water containing PFNA in excess of the MCL may experience developmental delays and decreased body weight gain.
Perfluorodecanoic acid (PFDA)	6	No conversion necessary	6	N/A		Some fetuses of pregnant women and infants born to mothers who drink water containing PFNA in excess of the MCL may experience developmental delays and decreased body weight gain.

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Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Perfluorododecanoic acid (PFDoA)	6	No conversion necessary	6	N/A		Some fetuses of pregnant women and infants born to mothers who drink water containing PFNA in excess of the MCL may experience developmental delays and decreased body weight gain.
Perfluorotetradecanoic acid (PFTA)	6	No conversion necessary	6	N/A		Some fetuses of pregnant women and infants born to mothers who drink water containing PFNA in excess of the MCL may experience developmental delays and decreased body weight gain.
Perfluorotridecanoic acid (PFTrDA)	6	No conversion necessary	6	N/A		Some fetuses of pregnant women and infants born to mothers who drink water containing PFNA in excess of the MCL may experience developmental delays and decreased body weight gain.
Perfluoroundecanoic acid (PFUnA)	6	No conversion necessary	6	N/A		Some fetuses of pregnant women and infants born to mothers who drink water containing PFNA in excess of the MCL may experience developmental delays and decreased body weight gain.
Volatile organic contaminants						
Benzene (ppb)	0.005	1000	5	zero	Discharge from factories; leaching from gas storage tanks and landfills	Some people who drink water containing benzene in excess of the MCL over many years could experience anemia or a decrease in blood platelets, and may have an increased risk of getting cancer.
Carbon tetrachloride (ppb)	0.005	1000	5	zero	Discharge from chemical plants and other industrial activities	Some people who drink water containing carbon tetrachloride in excess of the MCL over many years could experience problems with their liver and may have an increased risk of getting cancer.
Chlorobenzene (ppb)	0.1	1000	100	100	Discharge from chemical and agricultural chemical factories	Some people who drink water containing chlorobenzene in excess of the MCL over many years could experience problems with their liver or kidneys.
O-dichlorobenzene (ppb)	0.6	1000	600	600	Discharge from industrial chemical factories	Some people who drink water containing o-dichlorobenzene well in excess of the MCL over many years could experience problems with their liver, kidneys, or circulatory systems.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
P-dichlorobenzene (ppb)	0.075	1000	75	75	Discharge from industrial chemical factories	Some people who drink water containing p-dichlorobenzene in excess of the MCL over many years could experience anemia, damage to their liver, kidneys, or spleen, or changes in their blood.
1,2-dichloroethane (ppb)	0.005	1000	5	zero	Discharge from industrial chemical factories	Some people who drink water containing 1,2-dichloroethane in excess of the MCL over many years may have an increased risk of getting cancer.
1,1-dichloroethylene (ppb)	0.007	1000	7	7	Discharge from industrial chemical factories	Some people who drink water containing 1,1-dichloroethylene in excess of the MCL over many years could experience problems with their liver.
Cis-1,2-dichloroethylene (ppb)	0.07	1000	70	70	Discharge from industrial chemical factories	Some people who drink water containing cis-1,2-dichloroethylene in excess of the MCL over many years could experience problems with their liver.
Trans-1,2-dichloroethylene (ppb)	0.1	1000	100	100	Discharge from industrial chemical factories	Some people who drink water containing trans-1,2-dichloroethylene well in excess of the MCL over many years could experience problems with their liver.
Dichloromethane (ppb)	0.005	1000	5	zero	Discharge from pharmaceutical and chemical factories	Some people who drink water containing dichloromethane in excess of the MCL over many years could have liver problems and may have an increased risk of getting cancer.
1,2-dichloropropane (ppb)	0.005	1000	5	zero	Discharge from industrial chemical factories	Some people who drink water containing 1,2-dichloropropane in excess of the MCL over many years may have an increased risk of getting cancer.
Ethylbenzene (ppb)	0.7	1000	700	700	Discharge from petroleum refineries	Some people who drink water containing ethylbenzene well in excess of the MCL over many years could experience problems with their liver or kidneys.
Styrene (ppb)	0.1	1000	100	100	Discharge from rubber and plastic factories; leaching from landfills	Some people who drink water containing styrene well in excess of the MCL over many years could have problems with their liver, kidneys, or circulatory system.
Tetrachloro-ethylene (ppb)	0.005	1000	5	~~Z~~zero	Discharge from factories and dry cleaners	Some people who drink water containing tetrachloroethylene in excess of the MCL over many years could have problems with their liver, and may have an increased risk of getting cancer.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Toluene (ppm)	1	No conversion necessary	1	1	Discharge from petroleum factories	Some people who drink water containing toluene well in excess of the MCL over many years could have problems with their nervous system, kidneys, or liver.
1,2,4-trichlorobenzene (ppb)	0.07	1000	70	70	Discharge from textile-finishing factories	Some people who drink water containing 1,2,4-trichlorobenzene well in excess of the MCL over many years could experience changes in their adrenal glands.
1,1,1-trichloroethane (ppb)	0.2	1000	200	200	Discharge from metal degreasing sites and other factories	Some people who drink water containing 1,1,1-trichloroethane in excess of the MCL over many years could experience problems with their liver, nervous system, or circulatory system.
1,1,2-trichloroethane (ppb)	0.005	1000	5	3	Discharge from industrial chemical factories	Some people who drink water containing 1,1,2-trichloroethane well in excess of the MCL over many years could have problems with their liver, kidneys, or immune systems.
Trichloroethylene (ppb)	0.005	1000	5	zero	Discharge from metal degreasing sites and other factories	Some people who drink water containing trichloroethylene in excess of the MCL over many years could experience problems with their liver and may have an increased risk of getting cancer.
Vinyl chloride (ppb)	0.002	1000	2	zero	Leaching from PVC piping; discharge from plastics factories	Some people who drink water containing vinyl chloride in excess of the MCL over many years may have an increased risk of getting cancer.
Xylenes [total] (ppm)	10	No conversion necessary	10	10	Discharge from petroleum factories; discharge from chemical factories	Some people who drink water containing xylenes in excess of the MCL over many years could experience damage to their nervous system.
Radioactive contaminants						
Beta/photon emitters (mrem/yr)	4 mrem/yr	No conversion necessary	4	zero	Decay of natural and man-made deposits	Certain minerals are radioactive and may emit forms of radiation known as photons and beta radiation. Some people who drink water containing beta particle and photon radioactivity in excess of the MCL over many years may have an increased risk of getting cancer.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Alpha emitters [gross alpha] (pci/l)	15 pCi/L	No conversion necessary	15	zero	Erosion of natural deposits	Certain minerals are radioactive and may emit a form of radiation known as alpha radiation. Some people who drink water containing alpha emitters in excess of the MCL over many years may have an increased risk of getting cancer.
Combined radium [226 & 228] (pci/l)	5 pCi/L	No conversion necessary	5	zero	Erosion of natural deposits	Some people who drink water containing radium 226 or 228 in excess of the MCL over many years may have an increased risk of getting cancer.
Uranium (pCi/L)	30 ug/L	No conversion necessary	30	~~Z~~zero	Erosion of natural deposits	Some people who drink water containing uranium in excess of the MCL over many years may have an increased risk of getting cancer and kidney toxicity.
Disinfection byproducts (DBP), byproduct precursors, and disinfectant residuals: where disinfection is used in the treatment of drinking water, disinfectants combine with organic and inorganic matter present in water to form chemicals called disinfection byproducts (DBP). The department sets standards for controlling the levels of disinfectants and DBP in drinking water, including trihalomethanes (THM) and haloacetic acids (HAA). See R 325.10610 to R 325.10610d and R 325.10719e to R 325.10719n for disinfection byproduct MCLs, disinfectant MRDLs, and related monitoring requirements.						
Total trihalomethanes [TTHM] (ppb)	0.080*	1000	80*	N/A	By-product of drinking water disinfection	Some people who drink water containing trihalomethanes in excess of the MCL over many years may experience problems with their liver, kidneys, or central nervous system, and may have an increased risk of getting cancer.
	* The MCL for total trihalomethanes is the sum of the concentrations of the individual trihalomethanes.					
Haloacetic acids (HAAs) (ppb)	0.060*	1000	60*	N/A	By-product of drinking water disinfection	Some people who drink water containing haloacetic acids in excess of the MCL over many years may have an increased risk of getting cancer.
	* The MCL for haloacetic acids is the sum of the concentrations of the individual haloacetic acids.					
Bromate (ppb)	0.010	1000	10	zero	By-product of drinking water disinfection	Some people who drink water containing bromate in excess of the MCL over many years may have an increased risk of getting cancer.
Chloramines (ppm)	MRDL = 4	No conversion necessary	MRDL = 4	MRDLG = 4	Water additive used to control microbes	Some people who use water containing chloramines well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chloramines well in excess of the MRDL could experience stomach discomfort or anemia.

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Chlorine (ppm)	MRDL = 4	No conversion necessary	MRDL = 4	MRDLG = 4	Water additive used to control microbes	Some people who use water containing chlorine well in excess of the MRDL could experience irritating effects to their eyes and nose. Some people who drink water containing chlorine well in excess of the MRDL could experience stomach discomfort.
Chlorite (ppm)	1	No conversion necessary	1	0.8	By-product of drinking water disinfection	Some infants and young children who drink water containing chlorite in excess of the MCL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorite in excess of the MCL. Some people may experience anemia.
Chlorine dioxide (ppb)	MRDL = 0.8	1000	MRDL = 800	MRDLG = 800	Water additive used to control microbes	Some infants and young children who drink water containing chlorine dioxide in excess of the MRDL could experience nervous system effects. Similar effects may occur in fetuses of pregnant women who drink water containing chlorine dioxide in excess of the MRDL. Some people may experience anemia.
	Add the following only to public notification where any 2 consecutive daily samples taken at the entrance to the distribution system are above the MRDL: "The chlorine dioxide violations reported today are the result of exceedances at the treatment facility only, not within the distribution system which delivers water to consumers. Continued compliance with chlorine dioxide levels within the distribution system minimizes the potential risk of these violations to consumers." Add the following only to public notification where 1 or more distribution system samples are above the MRDL: "The chlorine dioxide violations reported today include exceedances of the drinking water standard within the distribution system which delivers water to consumers. Violations of the chlorine dioxide standard within the distribution system may harm human health based on short-term exposures. Certain groups, including fetuses, infants, and young children, may be especially susceptible to nervous system effects from excessive chlorine dioxide exposure."					

Contaminant in CCR units	Traditional MCL in mg/l, except where noted	To convert for CCR, multiply by	MCL in CCR units	MCLG in CCR units	Major sources in drinking water	Health effects language
Total organic carbon [TOC - control of DBP precursors] (ppm)	TT	No conversion necessary	TT	None	Naturally present in the environment	Total organic carbon (TOC) has no health effects. However, total organic carbon provides a medium for the formation of disinfection byproducts. These byproducts include trihalomethanes (THM) and haloacetic acids (HAA). Drinking water containing these byproducts in excess of the MCL may lead to adverse health effects, liver or kidney problems, or nervous system effects, and may lead to an increased risk of getting cancer.
Other treatment techniques						
Acrylamide	TT	No conversion necessary	TT	zero	Added to water during sewage/ wastewater treatment	Some people who drink water containing high levels of acrylamide over a long period of time could have problems with their nervous system or blood, and may have an increased risk of getting cancer.
Epichlorohydrin	TT	No conversion necessary	TT	zero	Discharge from industrial chemical factories; an impurity of some water treatment chemicals	Some people who drink water containing high levels of epichlorohydrin over a long period of time could experience stomach problems, and may have an increased risk of getting cancer.

PART 6. STATE DRINKING WATER STANDARDS AND ANALYTICAL METHODS

R 325.10604g MCLs for per- and polyfluoroalkyl substances.

Rule 604g. (1) The maximum contaminant levels and effective dates for per- and polyfluoroalkyl substances in table 1 of this rule apply to community and nontransient noncommunity water supplies.

Table 1 MCLs for per and polyfluoroalkyl substances

Contaminant	Maximum Contaminant Level in ng/l	Effective Date
Hexafluoropropylene oxide dimer acid (HFPO-DA)	**370**	**[effective date of this rule]**
Perfluorobutane sulfonic acid (PFBS)	**420**	**[effective date of this rule]**
Perfluorohexane sulfonic acid (PFHxS)	**51**	**[effective date of this rule]**
Perfluorohexanoic acid (PFHxA)	**400,000**	**[effective date of this rule]**
Perfluorononanoic acid (PFNA)	**6**	**[effective date of this rule]**
Perfluorooctane sulfonic acid (PFOS)	**16**	**[effective date of this rule]**
Perfluorooctanoic acid (PFOA)	**8**	**[effective date of this rule]**
N-ethyl perfluorooctanesulfonamidoacetic acid (NEtFOSAA)	**6**	**[effective date of this rule]**
N-methyl perfluorooctanesulfonamidoacetic acid (NMeFOSAA)	**6**	**[effective date of this rule]**
Perfluorodecanoic acid (PFDA)	**6**	**[effective date of this rule]**
Perfluorododecanoic acid (PFDoA)	**6**	**[effective date of this rule]**
Perfluorotetradecanoic acid (PFTA)	**6**	**[effective date of this rule]**
Perfluorotridecanoic acid (PFTrDA)	**6**	**[effective date of this rule]**
Perfluoroundecanoic acid (PFUnA)	**6**	**[effective date of this rule]**

(2) Compliance with the MCLs in table 1 of this rule must be determined based on the analytical results obtained at each sampling point. If 1 sampling point is in violation of an MCL, then the supply is in violation of the MCL. All of the following provisions apply:

(a) For supplies monitoring more than once per year, compliance with the MCL is determined by a running annual average at each sampling point.

(b) Supplies monitoring annually whose sample result exceeds an MCL in table 1 of this rule shall begin quarterly sampling. Compliance with the MCL must be based on the running annual average. For the purpose of calculating the running annual average, the initial exceedance must be the result for the first quarter. If the department requires a confirmation sample under R 325.10717d(12), then the average of the initial exceedance and the confirmation sample must be the result for the first quarter, unless the department determines a sample should be excluded per R

325.10717d(12). The supply shall not be in violation of the MCL until it has completed 1 year of quarterly sampling.

(c) If any sample result causes the running annual average to exceed the MCL at any sampling point, then the supply is out of compliance with the MCL immediately.

(d) If a supply fails to collect the required number of samples, then compliance must be based on the total number of samples collected.

(e) If a sample result is less than the reporting limit, then zero must be used to calculate the annual average.

(3) Two years following the effective date of R 325.10604g the deparment shall:

(a) For the PFAS listed in USEPA Method 537.1 and USEPA method 533 re-review all existing and proposed national and state-derived PFAS drinking water standards and review any new toxicity data on the health impacts of PFAS. Then identify the most scientifically defensible non-cancer or cancer-based public health toxicity values available for each individual PFAS chemical family member, or combination thereof. Provide written justification that shall include, but not be limited to, the basis for the selection of the primary study, critical effect identification, point of departure determination, evaluation of all uncertainty and/or modification factors applied, and the non-cancer or cancer-based toxicity value derivation.

(b) Review all existing and proposed national- and state-derived PFAS drinking water standards and identify exposure assessment and risk evaluation methodology for each individual PFAS chemical family member, or combination thereof. Provide written justification that shall include, but not be limited to, selection of the most appropriate receptor(s) and identification of all appropriate exposure assumptions for the receptor(s).

PART 7. SURVEILLANCE, INSPECTION, AND MONITORING

R 325.10717d Collection and analysis of samples for per- and polyfluoroalkyl substances.

Rule 717d. (1) Suppliers of community and nontransient noncommunity water supplies shall collect samples and cause analyses to be made under this rule for all analytes of per- and polyfluoroalkyl substances included in USEPA method 537.1 and 533 to determine compliance with this rule. ~~e state drinking water standards in R 325.10604g.~~ Each supplier shall monitor at the time designated by the department.

(2) For transient noncommunity and type III public water supplies, the department may require samples to be collected and analyzed at prescribed frequencies for per- and polyfluoroalkyl substances.

(3) A groundwater supplier shall take at least 1 sample at every entry point to the distribution system that is representative of each well after treatment, also known as sampling point. Each sample must be taken at the same sampling point unless conditions make another sampling point more representative of each source or treatment plant.

(4) A surface water supplier, or combined surface water and ground water, shall take at least 1 sample at points in the distribution system that are representative of each source or at each entry point to the distribution system after treatment, also known as sampling point. Each sample must be taken at the same sampling point unless

conditions make another sampling point more representative of each source or treatment plant.

(5) If a system draws water from more than 1 source and the sources are combined before distribution, then the supplier shall sample at an entry point to the distribution system during periods of normal operating conditions when water that is representative of all sources is being used.

(6) An existing supplier with one or more samples taken at each sampling point described in subrules (3), (4), or (5) of this rule as part of the State of Michigan's 2018/2019 Statewide PFAS Survey shall conduct initial sampling as follows:

(a) A supplier with one or more sample results greater than 50% of the MCL for a contaminant listed in rule 10604g shall collect samples from each sampling point beginning the first full quarter following the effective date of this rule.

(b) A supplier with no detection or a detection less than or equal to 50% of the MCL for a contaminant listed in rule 10604g shall collect at least 1 sample from each sampling point within 6 months of the effective date of this rule.

(7) An existing supplier without sampling conducted under subrule (6) of this rule, shall collect samples beginning the first full quarter following the effective date of this rule.

(8) A new community or nontransient noncommunity water supply shall collect samples beginning the first full quarter following the initiation of operations.

(9) A supplier shall collect samples quarterly for the first three years after the effective date of this rule or after the first three years of initiation of operations.

(9) If, after three years of quarterly sampling, the results of samples collected under subrules (6), (7), or (8) of this rule are below the reporting limits specified in R 325.12708, the department may allow the water supply to monitor annually.

(10) If a contaminant in R 325.10604g is detected above the reporting limit in any sample, then all of the following provisions apply:

(a) Each supply shall monitor quarterly at each sampling point that resulted in a detection. ~~The department may decrease the quarterly monitoring requirement specified in this subrule if it has determined that the supply is reliably and consistently below the MCL.~~ A groundwater supplier shall take not fewer than 2 quarterly samples and a surface water supplier shall take not fewer than 4 quarterly samples before this determination.

(b) After the department determines that the supply is reliably and consistently below the MCL, the department may allow the supply to monitor annually.

(11) A supplier that violates R 325.10604g shall monitor quarterly. If not fewer than 4 quarterly samples show that the supply is in compliance and the department determines the supply is reliably and consistently below the MCL, then the department may allow the supply to monitor annually.

(12) The department may require confirmation sampling for positive or negative results. If confirmation sampling is required, then the results must be averaged with the first sampling result and the average must be used for the compliance determination. The department may exclude results of obvious sampling errors from this calculation.

(13) The department may increase the required monitoring to detect variations within the system.

(14) All new supplies or supplies that use a new source of water shall demonstrate compliance with the MCLs before serving water to the public. The supply shall also comply with the initial sampling frequencies specified by the department.

PART 27. LABORATORY CERTIFICATION

R 325.12701 Purpose.

Rule 2701. An analytical result that is used to determine compliance with a state drinking water standard established in part 6 **must** ~~shall~~ be the result of an analysis performed by a department or EPA certified laboratory, except that measurements for alkalinity, bromide, calcium, daily chlorite samples at the entrance to the distribution system, conductivity, magnesium, orthophosphate, pH, residual disinfectant concentration, silica, specific ultraviolet absorbance, temperature, **chloride, sulfate,** and turbidity may be performed by personnel acceptable to the department. This part sets forth requirements established by the federal act for laboratory certification.

R 325.12708 Certification for PFAS analyses.

Rule 2708. To qualify for certification to conduct analyses for the PFASs in table 1 of R 325.10604g, a laboratory must be in compliance with the following provisions:

(a) Samples must be collected and analyzed in accordance with EPA method 537.1 and EPA method 533. ~~**or other methods as approved by the department**~~**.**

(b) The minimum reporting limit must be 2 ng/l.

(c) Analytical results must be reported to the nearest ng/l.

(d) The laboratory must analyze performance evaluation samples that include the PFASs in table 1 of this rule and are acquired from a third party proficiency test provider approved by the department at least once per year.

(e) For each regulated PFAS contaminant included in the performance evaluation sample, the laboratory must achieve quantitative results on the analyses that are within the acceptance limits listed in table 1 of this rule.

Table 1 Acceptance limits

Contaminant	Chemical Abstract Services Registry Number	Acceptance Limits (percent)
Hexafluoropropylene oxide dimer acid (HFPO-DA)	13252-13-6	± 30% (GV) [1]
Perfluorobutane sulfonic acid (PFBS)	373-73-5	± 30% (GV) [1]
Perfluorohexane sulfonic acid (PFHxS)	335-46-4	± 30% (GV) [1]
Perfluorohexanoic acid (PFHxA)	307-24-4	± 30% (GV) [1]
Perfluorononanoic acid (PFNA)	375-95-1	± 30% (GV)[1]
Perfluorooctane sulfonic acid (PFOS)	1763-23-1	± 30% (GV) [1]
Perfluorooctanoic acid (PFOA)	335-67-1	± 30% (GV) [1]

[1]Gravimetric value

R 325.12710 Suspension or revocation of certification.

Rule 2710. (1) If the department determines that a laboratory certified under the act and these rules is not operating in an approved manner, is reporting results that do not meet state laboratory certification requirements, or is operating in a manner that may cause a hazard to the public health, the department may move to suspend or revoke the certification of the laboratory pursuant to the administrative procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

(2) Reasons for suspension of a laboratory's certification, in part or whole, or the denial of an initial certification request include, but are not limited to the following:

(a) Failure to pay certification fees.

(b) Failure to pass a laboratory inspection.

(c) Failure to meet proficiency test requirements.

(d) Failure to respond to a laboratory inspection report within the allotted timeframe.

(e) Persistent failure to report compliance data to the public water system or the state drinking water program in a timely manner, thereby preventing timely compliance determination with federal or state regulations and endangering public health.

(f) Failure to correct deficiencies noted in an on-site inspection report.

(g) Refusal to participate in an on-site inspection conducted by the certifying agency.

(h) Failure to make records pertaining to the analysis of regulated drinking water contaminants available for review or copying by the laboratory certification program.

(3) Suspension of a laboratory's certification remains in effect until the laboratory provides documentation that the reason or reasons for the suspension have been corrected.

(4) Reasons for revocation of a laboratory's certification include but are not limited to:

(a) Falsification of the certification application or certification renewal application.

(b) Fraud or other criminal activity.

(c) Falsification of records or analytical results.

(d) Reporting results not meeting the federal act, the act and administrative rules promulgated thereunder, or method requirements.

(e) Reporting proficiency test data from another laboratory as its own.

(f) Using analytical methodology not listed on the laboratory's certification letter for reporting regulated drinking water contaminants.

(g) A written notification from the laboratory that it is voluntarily relinquishing certification.

Smith, Ian (EGLE)

From: Roper, Cyndi <[redacted]@nrdc.org>
Sent: Friday, January 31, 2020 2:54 PM
To: EGLE-PFAS-RuleMaking
Cc: Ruch, Suzann (EGLE); Reade, Anna
Subject: Re: NRDC's comments on proposed PFAS MCLs: PRS# - 2019-35 EG
Attachments: NRDC PFAS MCL Comments 1.31.20.docx; NRDC Assessment for Addressing PFAS Chemicals in Michigan Drinking Water.pdf

Hi Suzann,

I'm reattaching our comments along with the scientific report referenced in the comments. EGLE has previously received this report, but we want to be sure to resubmit it along with our comments.

Thank you!
Cyndi

From: Roper, Cyndi
Sent: Friday, January 31, 2020 2:27 PM
To: EGLE-PFAS-RuleMaking <EGLE-PFAS-RuleMaking@michigan.gov>
Cc: Ruch, Suzann (EGLE) <RuchS@michigan.gov>; Reade, Anna <[redacted]@nrdc.org>
Subject: NRDC's comments on proposed PFAS MCLs: PRS# - 2019-35 EG
Hi Suzann,

NRDC's comments on the proposed PFAS MCL are attached to this message.

Would you mind confirm receipt of this message?

Thank you!
Cyndi

Cyndi Roper
Michigan Senior Policy Advocate
Healthy People & Thriving Communities Program -
Safe Water Initiative
Climate & Clean Energy Program

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Comments of the Natural Resources Defense Council on the Michigan Department of Environment, Great Lakes, and Energy's Proposed PFAS MCLs Pending Rule Set: 2019-35-EG

January 31, 2020

On behalf of our more than 3 million members and online activists, including 69,000 members in Michigan, the Natural Resources Defense Council (NRDC) appreciates the opportunity to comment on the Michigan Department of Environment, Great Lakes, and Energy (EGLE) proposed Maximum Contaminant Levels (MCLs) for perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), perfluorobutane sulfonic acic (PFBS), perfluorohexane sulfonic acid (PFHxS), perfluorohexanoic acid (PFHxA), and hexafluoropropylene oxide dimer acid (GenX).

We laud the Whitmer Administration for its leadership in advancing drinking water standards to protect Michiganders instead of waiting for the U.S. Environmental Protection Agency (EPA) to take action. However, NRDC has serious concerns about the proposed MCLs, which we raised with the Michigan PFAS Action Response Team (MPART) after its Science Advisory Workgroup (SAW) released the Health-Based Values (HBVs) upon which Michigan's proposed MCL are based.

NRDC's comments focus on following two major shortcomings with the proposed rules:

1) Absence of class-based regulations; and
2) Inadequate consideration of science for individual PFAS MCLs, including new science and state action since the development of the HBVs.

Given what's at stake with PFAS in Michigan's drinking water and the resulting health risks posed to communities throughout the state, we believe the agency must be much more proactive in developing protections for this pathway of exposure.

I. ABSENCE OF CLASS-BASED REGULATION

The SAW recommended HBVs for seven individual PFAS chemicals, and a screening level for all other long-chain PFAS detected with Method 537.1, based on their strictest HBV of 6 ppt for

PFNA. As the SAW noted, "these compounds are expected to produce similar health effects." We agree with this approach for screening levels for poorly studied chemicals.

However, the HBVs and proposed MCLs for individual PFAS chemicals alone are not protective against the likelihood of additive or synergistic effects from exposure to multiple PFAS.

Michigan water testing confirms that when water is contaminated with PFAS, people are nearly always ingesting multiple chemicals. Furthermore, a recent Harvard Nurses Study publication that used a novel method known as extractable organofluorine (EOF) to measure total organic fluorine in drinking water in five Northeast cities.[1] The authors report that the total "unknown" fluorochemicals dwarfed the amount of identifiable per- and poly-fluorinated carboxylates and sulfonates in treated drinking water. The amount of total organic fluorine also increased dramatically in each of the water systems between 1990 and 2016.

Biomonitoring studies also demonstrate that Americans have chronic exposure to multiple PFAS chemicals throughout their lifetimes. CDC's national biomonitoring studies, NHANES, reveal that nearly every American has PFOS, PFOA, PFHxS and PFNA detected in their blood stream, including young children.[2] At least eight other PFAS are detected in blood serum by NHANES studies: MeFOSAA, PFDeA, PFUA, PFHpA, PFBS, FOSA, EtFOSAA, PFDoA, and PFHpA. Most other PFAS chemicals are not routinely included in biomonitoring studies. Similar to total organic fluorine measurements in drinking water, alternative methods for detecting PFAS in blood serum are showing an increasing trend of unidentified organofluorine in blood serum samples, which also suggest that people are being exposed to new and unidentified PFAS.[3,4]

The ATSDR toxicity profile on 14 PFAS[5] and the EPA's toxicity assessments of various PFAS suggest that PFAS chemicals, including newer generation PFAS, such as PFBS[6] and GenX,[7] share many of the same toxicity endpoints, including harm to the liver, thyroid, kidney, immune system, development and reproduction. In addition to shared toxicity endpoints, there are a few recent studies of the effects associated with exposure to mixtures of PFAS or mixtures of PFAS and other toxicants. For example, a study of PFOA, PFOS, and PFNA found that toxicity in a human macrophage cell line and acute toxicity in zebrafish were greater for mixtures than individual compounds.[8] An in vitro study of amphibian fibroblast cells showed that the cytotoxic effects of mixtures of PFAS were additive, except with PFOS and PFOA, which were slightly synergistic.[9] Zebrafish embryos exposed to either PFHxA and PCB126 or PFHxA, PFOS, and PCB126 showed lower oxidative stress response, an effect not seen for the individual chemicals or a mixture of PFOS and PCB126, which suggests PFHxA plays a synergistic role in inducing this effect.[10]

Not only do the proposed rules fail to address the risk of exposure to multiple known PFAS, they fall short of providing the co-benefits of a treatment-based water standard for public water systems with detectable PFAS. Although it was within MPART's authority to investigate the ability of different water treatment technologies to reduce concentrations of a range of PFAS chemicals in water, its SAW focused on quantitative limits for individual chemicals. A focus on treatments that are effective for broad numbers of PFAS chemicals will have significant co-benefits of reducing the bulk of unclassified PFAS chemicals, which include

perfluoroalkyl acids (PFAA) precursors which can transform over time into the very PFAS EGLE is proposing to regulate, and other water contaminants.

Other states, like Vermont and Massachusetts, have taken a more class-based approach to setting water standards for PFAS, setting a combined standard for 5 or 6 PFAS, respectively. Vermont updated its drinking water health advisory level, originally for PFOA and PFOS only, to include PFHxS, PFHpA, and PFNA based on class similarity.[11] Vermont also passed legislation last year directing the state to consider regulating PFAS as a class or subclasses.[12] Recent published research and various assessments by federal and state agencies led Massachusetts to announce, in January 2019, its initiation of the process of developing a combined MCL for 6 PFAS at 20 ppt: PFOA, PFOS, PFNA, PFHxS, PFHpA, and PFDA.[13] Similarly, Massachusetts stated that the "additional PFAS were included because they share very similar chemical structures and the available data indicates they are likely to exhibit similar toxicities." Even the EPA's health advisory is a combined level for PFOA and PFOS due to,

> "Adverse effects observed following exposures to PFOA and PFOS are the same or similar and include effects in humans on serum lipids, birth weight, and serum antibodies. Some of the animal studies show common effects on the liver, neonate development, and responses to immunological challenges. Both compounds were also associated with tumors in long-term animal studies. The RfDs for both PFOA and PFOS are based on similar developmental effects and are numerically identical; when these two chemicals co-occur at the same time and location in a drinking water source, a conservative and health-protective approach that EPA recommends would be to compare the sum of the concentrations ([PFOA] + [PFOS]) to the HA (0.07 μg/L)."[14]

Finally, in December 2019, the European Commission proposed setting a drinking water standard for the entire class.[15] In addition, Sweden, the Netherlands, Germany, and Denmark have proposed a plan to the European Commission to phase out most uses of PFAS compounds by 2030.[16]

Michigan has led the nation on PFAS action so far. However, not considering the structural similarities of PFAS and the potential harm the entire class poses does not follow this trend. It puts Michiganders at increased, unnecessary risk. We recommend the following (please see attached NRDC report for further details):

1) **Set a Maximum Contaminant Level Goal (MCLG) of Zero for Total PFAS**

   PFAS share similar structure and properties, including extreme persistence and high mobility in the environment. Many PFAS are also associated with similar health endpoints, some at extremely low levels of exposure. There is additionally potential for additive or synergistic toxicity among PFAS. Given the similarity among chemicals of the PFAS class and the known risk of the well-studied PFAS, there is reason to believe that other members of the PFAS class pose similar risk. Therefore, health-protective standards for PFAS should be based on the known adverse effects of the well-studied members of the PFAS class.

   First, there is sufficient evidence to classify PFOA as a known or probable carcinogen.

Therefore, a MCLG of zero should be promulgated for PFOA, consistent with EPA's approach to regulating known or probable carcinogens. Both IARC's and EPA's findings on PFOA's carcinogenic potential are based heavily on the C8 study, whose Science Panel determined that PFOA is a probable carcinogen. There is also significant additional animal and human evidence for an association between PFOA exposure and cancer, particularly kidney and testicular cancer, and more recently for pancreatic cancer.

In addition to being a carcinogen, PFOA causes adverse non-cancer health effects at exceedingly low doses. A MCLG based on altered mammary gland development would be well below 1 ppt for PFOA, further supporting our recommendation of zero for a MCLG. Although the evidence of carcinogenic potential for other PFAS is not as well established as PFOA, given the similarities in structure and toxicity to PFOA, their potential for carcinogenicity cannot be ruled out. We therefore recommend a MCLG of zero for other PFAS as well.

In support, other shared health effects amongst PFAS occur at extremely low levels, such as immunotoxicity, developmental harm, and liver damage. For example, evidence indicates that PFOS causes adverse cancer and non-cancer health effects at exceedingly low doses. A MCLG based on immunotoxicity or pancreatic cancer (see Section II.3 below) would be well below 1 ppt for PFOS, further supporting our recommendation of zero for a MCLG. A MCLG for PFNA based on developmental toxicity is below 1 ppt, approximately 2 ppt for PFHxS based on thyroid toxicity, and below 1 ppt for GenX based on liver toxicity (see attached NRDC report for calculations); and as low as the single digit to teens ppt for PFBS and PFHxA (see Section II.6 and II.7 below). The health harms associated with these PFAS, combined with their co-occurrence in our environment, must be considered in setting a health protective MCLG for these PFAS.

The structure of the fluorine-carbon bond and the impacts documented on the studied PFAS already available support concern over the health impacts of the entire class. This is supported by the constant exposure to short-chain chemicals, even if they have a relatively short presence in the body, as well as the fact that in many cases the use of these chemicals may be much higher than their long-chain cousins. Furthermore, many PFAS can convert into PFAAs (a PFAS subgroup, which includes PFOA and PFOS, that is linked to many adverse health effects) or PFAAs are used in their manufacture and can be contaminants in their final product.

Setting a MCLG of zero for the class is needed to provide an adequate margin of safety to protect public health from a class of chemicals that is characterized by extreme persistence, high mobility, and is associated with a multitude of different types of toxicity at very low levels of exposure.

2) Set a Combined Standard for the PFAS Michigan is Proposing to Regulate

As discussed in the previous section and in the attached report, NRDC's review of the toxicity data on PFAS finds evidence that they are linked to cancer and other serious adverse health effects. Following conventional risk assessment protocols, we determine that the goal for PFAS should be zero exposure to these chemicals in drinking water.

As technologies for detection and water treatment do not currently allow for the complete removal of PFAS from drinking water, a MCL for any PFAS should be based on the best detection and treatment technologies available. **Our review of current technology suggests a combined MCL of 2 ppt is feasible for PFOA, PFOS, PFNA, PFHxS, PFHxA, and PFBS, with a separate MCL of 5 ppt for GenX.**

Laboratory methods support a reporting limit of 2 ppt with EPA Method 537.1 (5 ppt for GenX), and therefore all water testing should be required to achieve this limit for the PFAS chemicals detectable with this method. Further, the removal of all of these PFAS has been demonstrated to be effective with technologies such as GAC and RO to below detection levels, supporting our determination that the MCL meets technological feasibility.

3) Develop a Treatment Standard for Total PFAS within Two Years

In the absence of a reliable method that is economically and technically feasible to measure a contaminant at concentrations to indicate there is not a public health concern, the state should establish a treatment technique. **A treatment technique is a minimum treatment requirement or a necessary methodology or technology that a public water supply must follow to ensure control of a contaminant.**

At present, there is no single methodology for isolating, identifying, and quantifying all PFAS in drinking water. We recommend that Michian explore an analytical method, or combination of methods, that can be used as a surrogate for total PFAS. In particular, we recommend that Michigan evaluate alternative detection methodologies, such as the total oxidizable precursor or extractable organofluorine assays, to measure the concentration of non-discrete and difficult to measure PFAS compounds that are not determined by conventional analytical methods.

Furthermore, we recommend reverse osmosis, or other treatment method that has been demonstrated to be at least as effective as reverse osmosis for removing all identified PFAS chemicals, as the treatment technique for public water supplies. Reverse osmosis is currently the preferred treatment technology for the following reasons:

- Reverse osmosis has been demonstrated to effectively remove a broad range of PFAS compounds.**Error! Bookmark not defined.**
- Reverse osmosis is the most robust technology for protecting against unidentified contaminants.**Error! Bookmark not defined.**
- Reverse osmosis would likely result in lower finished water concentrations of GenX and other PFAS compounds such as PFMOAA and PFO2HxA.**Error! Bookmark not defined.**
- Reverse osmosis does not require frequent change out of treatment media and does not release elevated concentrations after granular activated carbon bed life is spent or ion exchange feed concentration drops.**Error! Bookmark not defined.**

Reverse osmosis requires considerations for the safe disposal of high-strength waste streams and spent/used membranes. **We also recommend Michigan evaluate the safest disposal method for contaminated waste, and that disposal require full destruction of PFAS compounds before entering the environment.**

II. INADEQUATE CONSIDERATION OF SCIENCE FOR INDIVIDUAL PFAS MCLS

In order to fully protect public health, the MCLs adopted by EGLE should rely on current science, properly account for scientific uncertainties, and strive to be protective of the likely additive effects of exposure to multiple PFAS chemicals over a lifetime of exposure. NRDC's comments underscore multiple opportunities for EGLE to strengthen the protection of human health, especially for those most vulnerable to PFAS exposure, developing fetuses, infants, and children.

1. **Protecting fetuses, infants and children.**

   We support the SAW's use of the Minnesota transgenerational toxicokinetic model[17] to estimate drinking water exposures over a person's lifetime (and the use of infant exposure assumptions when there was not enough data to use the model) for PFOA, PFOS, PFNA, PFHxS, and PFBS. **We take exception to the SAW's decisions for GenX and PFHxA, where adult exposure assumptions were used.**

   Fetuses and infants have greater exposure to PFAS than adults, and are also more sensitive to the effects of these contaminants.[18] Almost all fetuses and infants will have some degree of exposure, including exposure as fetuses during pregnancy through placental transfer.[19] For infants, exposure may be further elevated due to ingestion of contaminated breastmilk (a result of the mothers' ingestion of contaminated water and other sources) or infant formula prepared with contaminated drinking water.[20] Levels of PFOA and other PFAS in breastmilk are much higher than what is typically found in drinking water, as PFOA and other PFAS bioaccumulate in the body and are then transferred into the breastmilk.[21] Moreover, since infants consume approximately five times more water per body weight than adults,[22] their exposure is likely higher than adults regardless of whether they are breastfeed or are fed infant formula prepared with PFAS-contaminated drinking water. Infant blood serum levels of PFAS are often the highest of any age group in studies that compare people in multiple stages of life.[23] Compounding the issue of increased exposure, fetuses, infants, and children are also more vulnerable to exposure-related health effects than adults. The young may be more sensitive to the effects of PFAS due to their immature, developing biological systems (such as the immune system), and rapid body growth during development.[24] For example, exposure to PFAS before birth and/or in early childhood may result in decreased birthweight, decreased immune responses, and hormonal effects later in life.[25]

Decisions made when developing a health benchmark, such as evaluation of data gaps, the selection of uncertainty factors, and choice of exposure parameters to use, should be made to be protective of the most vulnerable populations, particularly developing fetuses, infants, and children. In fact, **the National Academy of Sciences (NAS) has recommended the use of an additional uncertainty factor of 10 to ensure protection of fetuses, infants and children who often are not sufficiently protected from toxic chemicals such as pesticides by the traditional intraspecies (human variability) uncertainty factor**.[26] Congress adopted this requirement in the Food Quality Protection Act for pesticides in foods.[27] Considering the many health effects linked to PFAS that affect this vulnerable population and the substantial data gaps on exposure and toxicity of these compounds in complex mixtures, **we recommend the use of this uncertainty factor when deriving health-protective benchmarks for PFAS.**

2. **The HBV for GenX does not fully acknowledge the uncertainty in the risk assessment process and is not protective of fetuses, infants and children, the most vulnerable populations to PFAS exposure.**

    a. Derivation of human equivalent oral exposures.

Like the EPA, the SAW used the Body Weight$^{3/4}$ allometric scaling approach to calculate a human equivalent dose from an animal-based point of departure. The Body Weight$^{3/4}$ allometric scaling approach is based on body surface area and basal metabolic rate in adults.[28] While the liver effects in the critical study for GenX occurred in adult mice, developmental effects also occur at low doses, and infants and children may be a more vulnerable population. The EPA states that this approach is not suitable for estimating an equivalent dose in infants and children. Therefore, it is unclear how the human equivalent dose based on liver effects in adults would compare to the human equivalent dose based on developmental effects in infants and children. **This uncertainty should be acknowledged in an additional uncertainty factor to protect fetuses, infants and children.**[29]

Furthermore, this approach does not account for differences in toxicokinetics between animals and humans, which for PFAS are often vastly different.[30] Even within animal models, data suggest a potentially complex toxicokinetic profile for GenX when dosing occurs over multiple days.[31] When male mice received doses of 1, 10 and 100 mg/kg/day for 28 days, their serum levels did not reach a steady state. This indicates possible changes in toxicokinetics after repeated dosing, which is relevant when considering safety levels in a public drinking water supply.

Depending on the specific PFAS, human clearance time can be an order of magnitude, or more, higher than in animal models. Therefore, the Netherland's National Institute for Public Health and the Environment (RIVM) determined that although the elimination rates for GenX are faster than PFOA in animal models, without data in humans, it is not possible to make assumptions on the human toxicokinetics of GenX chemicals.[32] Due to the uncertainty from lack of human toxicokinetic data on GenX chemicals, RIVM calculated and applied an additional uncertainty factor to account for the potential kinetic

difference between animals and humans. RIVM postulated that the vast differences in clearance rates between animals and humans may be due to species differences between organic anion transporters (OATs). Differences in OATs could result in stronger reabsorption of anions, like the anion forms of PFOA and HFPO dimer acid (GenX), from the lumen of the kidney back into the blood in humans.[33]

It is possible that the shorter half-live of GenX in animal models is due to little to no reabsorption by OATs in these species. However, RIVM reasoned that it could not be assumed this would be the same for humans, due to the genetic differences of the OATs between animal models and humans.[34] RIVM states, "contrary to other perfluorinated compounds, no data are available for FRD-902 [GenX chemical] to confirm whether the fast elimination and absence of accumulation as seen in several animal species also applies to humans. In view of the above, an additional toxicokinetic assessment factor is applied to take into account the uncertainty in the human elimination rate of FRD-902." This additional toxicokinetic factor used by RIVM is based on the difference in half-lives between cynomolgus monkeys and humans for PFOA. A half-life ratio was calculated using a half-life of 1378 days in humans[35] and of 20.9 days in male cynomolgus monkeys[36] resulting in an additional toxicokinetic factor of 66 (1378 / 20.9). **This additional uncertainty factor to account for the potential kinetic difference between animals and humans is an example of an alternative approach to extrapolating animal doses to human doses for PFAS that do not yet have human toxicokinetic data. At the very least an uncertainty factor of 10, not 3, should be used for animal to human differences.**

b. Database uncertainty.

There are significant database limitations for GenX. **A factor of 3 is insufficient to cover this level of uncertainty in the database.** In contrast, the Agency for Toxic Substance and Disease Registry (ATSDR) used a database uncertainty factor of 10 for PFNA and PFHxS (two PFAS with far more data than GenX) due to lack of, or limited testing of developmental and immunological effects, which ATSDR identified as two of the most sensitive PFAS endpoints.[37] Uncertainties in the database on GenX include:

- No human data.

  Human data has significantly improved our understanding of the toxicological profile of many PFAS.[38] Human data is especially important considering the difference in elimination rates for PFAS between animal models and humans. A lack of human data to complement and compare to animal toxicological data is a critical data gap.

- No chronic studies in mice.

  The single chronic study was performed in rats, which are less sensitive than mice to GenX chemicals. An additional limitation of this study is that there were higher than normal early deaths across all study groups.[39]

- Limited data on developmental toxicity and immunotoxicity.

Developmental toxicity and immunotoxicity are common health effects associated with PFAS exposure, both of which can occur at extremely low levels of exposure.[40] Two developmental toxicity studies, only one of which was in mice, and a single study that specifically assesses immune effects is a serious database limitation. One critical data gap is the lack of a full 2-generation toxicity study evaluating exposures during early organogenesis. Additionally, there are many developmental and immune effects that have yet to be assessed, including reproductive system development (i.e. mammary gland development and function), neurodevelopment, autoimmunity, infectious disease resistance, and immune hypersensitivity (i.e. asthma and allergies).

- Limited peer-reviewed, independently funded studies for GenX.

Of the studies that assess health effects of GenX, only three were peer-reviewed. Of these three, one was independently funded,[41] one was funded by DuPont,[42] and one was independently funded but excluded from the EPA assessment,[43] on which the SAW's assessment is based.

- Lack of toxicity data from inhalation and dermal exposure routes.

GenX can be transported through air.[44] Inhalation could be a significant exposure route, especially in areas where GenX processing or use occurs. In 2017 the North Carolina Division of Air Quality estimated that despite some cutback in emissions, the Chemours Fayetteville Works plant emitted approximately 2,700 pounds of GenX chemicals per year[45] and GenX chemicals have been found in rainwater up to 7 miles from the Chemours Fayetteville Works plant.[46] Minimal dermal absorption of GenX has also been demonstrated,[47] however, there is a lack of information on the dermal absorption potential or toxicity of GenX.

- New toxicity data on GenX chemicals not considered

SAW relied on EPA's draft toxicity assessment of GenX, released in November of 2018. New toxicity data on GenX chemicals has been published since this time.[48] At the time of EPA's assessment, very few peer-reviewed studies were available, as noted above. Therefore, it is especially important for Michigan to consider any new peer-reviewed studies on GenX toxicity.

c. Overall uncertainty not addressed.

The total uncertainty factor used by North Carolina's Department of Environmental Quality was 1000.[49] The total uncertainty factor used by the RIVM was 1088. Both North Carolina and RIVM concluded that the current overall uncertainty in assessing the toxicity of GenX is at least three times greater than what the SAW is acknowledging through its application of a total uncertainty factor of 300.

d. Use of adult drinking water exposure assumptions

The SAW applied drinking water exposure parameters for adults, which does not account for the most vulnerable populations to PFAS exposure in drinking water. Sensitive members of the population, such as fetuses, infants, children, pregnant women, nursing mothers, and those with certain pre-existing conditions, face particular risk from chemicals of such persistence, and which demonstrate clear adverse effects at very low levels of exposure. Michigan should develop a health benchmark protective of the of the most vulnerable populations, particularly developing fetuses, infants, and children, by accounting for these sensitive subgroups in the choice of exposure parameters to use.[50] The SAW states that it used adult drinking water exposure assumptions because the critical effect (liver damage) they selected occurred in adults and at a lower dose than the developmental effects seen. However, as discussed in Section III.2.b, there is limited data on developmental toxicity for GenX. There is not enough data to confidently determine how fetuses, infants and children are affected by GenX, in their livers and in general. Until there is more confidence that development is not being affected at lower levels than liver effects in adults, infant exposure assumptions should be applied. As explained above in Section III.1, infants are more likely to have higher exposure than adults to these contaminants because they ingest more water per kilogram of body weight than adults. **Accounting for the unique exposure situation of infants would significantly reduce the health-based value for GenX to approximately 109 ppt. The health-based value would be lowered to approximately 11 ppt if full uncertainty factors for database limitations and animal to human differences, discussed above, were applied, and to 1 ppt with an additional uncertainty factor to ensure adequate protection of fetuses, infants and children,** as recommended by the National Academy of Sciences and as required in the Food Quality Protection Act.[51]

3. The HBV for PFOA does not incorporate the most recent science on PFOA associated health effects and therefore is not protective of cancer or altered mammary gland development, the most sensitive health endpoints associated with PFOA exposure.

The SAW did not select the most sensitive health effects associated with PFOA exposure, cancer and altered mammary gland development. For the later, it states, "mammary gland effects may represent a delay that may not be considered adverse."

However, in a 2009 a workshop of experts in mammary gland biology and risk assessment came to the consensus that changes in mammary gland growth and differentiation, including changes in developmental timing, are a health concern.[52] Altered mammary gland development may lead to difficulty in breastfeeding and/or an increase in susceptibility to breast cancer later in life.[53]

Only one animal study has assessed the effects of PFOA exposure on mammary gland growth and differentiation for multiple generations.[54] The authors saw striking morphological abnormalities in the lactating glands of dams (mothers) chronically

exposed to environmentally relevant levels of PFOA; however, no effects on body weight of their pups were seen. It is possible that compensatory behavior, such as increased number of nursing events per day or longer nursing duration per event masked a decreased potential in milk production by the dams, however the authors did not evaluate these endpoints in the study. It is also possible that PFOA exposure could increase time to peak milk output through the reduction in number and density of alveoli available to produce milk.

For human mothers, low-level functional effects on lactation that cause even a short delay in substantial milk output might result in cessation in breastfeeding before the recommended time-frame. This is supported by three human studies which have reported that maternal PFOA exposure is associated with decreased duration of breastfeeding.[55]

Early life exposures to factors that disrupt development may influence susceptibility to carcinogens later in life. For example, hormone disruption is an important determinant of breast cancer susceptibility in humans and rodents.[56] Proliferating and undifferentiated structures, such as terminal end buds, display elevated DNA synthesis compared to other mammary gland structures; which is why terminal end buds are considered the most vulnerable mammary gland target structure of carcinogen exposure.[57] Delays in mammary gland development would result in a prolonged window of increased vulnerability to carcinogens. In humans, perturbations to the timing of menarche is linked to breast cancer.[58] This further raises the concern that changes in patterns of breast development in U.S. girls could be contributing to an increased risk of breast cancer or other adult diseases later in life.[59] However, an increase in susceptibility to breast cancer later in life was not explored in the multigeneration mammary gland development study.

In general, as the 2018 Michigan Science Advisory Panel states, "developmental delay can reflect an overall detrimental effect of chemical exposure that lead to growth and developmental deficit in the offspring."[60]

While the SAW applied an extra uncertainty factor of 3 to protect against the possibility of endocrine effects (related to mammary gland development) occurring at lower levels than the health effect they chose, this is not sufficient to protect against mammary gland effects. **Indeed, New Jersey has calculated a reference dose for mammary gland development, and if this had been used, the HBV for PFOA would be less than 1 ppt.[61]**

Furthermore, in August of 2019, California's Office of Environmental Health Hazard Assessment developed reference levels PFOA and PFOS in drinking water for both cancer and non-cancer effects.[62] The cancer effect reference level is based on the concentration of the chemical in drinking water that would not pose more than a one in one million cancer risk over a lifetime. **For PFOA, OEHHA derived a reference level of <u>0.1 ppt</u> based on pancreatic and liver tumors found in male rats in a new National Toxicology Program study.[63] We urge Michigan to examine OEHHA's risk assessment on PFOA as it is significantly stricter than what was proposed by SAW, which developed its HBV recommendations before August 2019.**

4. **The HBV for PFOS does not incorporate the most recent science on PFOS associated health effects.**

   As explained above, OEHHA recently developed reference levels PFOA and PFOS in drinking water for both cancer and non-cancer effects.[64] **For PFOS, OEHHA derived a reference level of <u>0.4 ppt</u> based on liver tumors in male rats and the structural and biological similarity of PFOS to PFOA. Again, we urge Michigan to examine OEHHA's risk assessment on PFOS as it is significantly stricter than what was proposed by SAW.**

5. **The HBV for PFHxS does not incorporate the most recent science on PFHxS associated health effects.**

   As noted by the SAW's use of an uncertainty factor of 10 for database deficiencies (lack of a two-generational study and limited understanding of immunotoxicity and early life sensitivity), the science on possible health effects associated with exposure to PFHxS is still developing. In fact, **a new derivation of a chronic reference dose for PFHxS based on a different study (Chang et al., 2018[65]) and health endpoint (impaired reproduction – reduced litter size) was just published**.[66] This approach was originally **used by New Hampshire to set a MCL of 18 ppt for PFHxS** in July 2019, and then published in September 2019. Considering the significantly stricter level that results from use of this new information it is imperative that Michigan consider this recent publication to ensure it sets a health-protective MCL for PFHxS.

   In short, the new study reviewed available toxicity studies using a weight-of-evidence approach, which led them to choose a 42-day reproductive study in mice (Chang, 2018). They performed benchmark dose modeling to derive a point of departure (13,000 ng/ml PFHxS in serum) for reduced litter size. The authors then used a similar dosimetric adjustment factor and the same total uncertainty factor as SAW to arrive at a chronic reference dose of 4 ng/kg/day, approximately 2.5 times lower than SAW's reference dose. Like SAW, New Hampshire used the Minnesota transgenerational toxicokinetic model to generate a drinking water limit from its reference dose.

   The SAW does state that its point of departure was comparable to the NOAEL of the Chang, 2018 study, however it also states that in general a benchmark dose modeling-based point of departure is preferred to a NOAEL. A benchmark dose level (BMDL) for the Chang, 2018 study was not available to the SAW at the time to compare its point of departure to (based on thyroid effects). However, now that New Hampshire has derived a BMDL-based point of departure for the Chang, 2018 study, we can see that the two points of departure are not comparable and that the point of departure for the Chang, 2018 study is significantly lower.

   The SAW stated that the health outcome (reduced litter size) in Chang, 2018 was a marginal effect. However, it was statistically significant and more than a 10% decrease in

litter size in the study. **Given the enormous personal and societal impact of infertility and pregnancy complications in a human population, the SAW should not dismiss these important indicators of harm in animal models.**

6. **The HBV for PFHxA does not fully acknowledge the uncertainty in the risk assessment process and is not protective of fetuses, infants and children, the most vulnerable populations to PFAS exposure.**

    a. Derivation of human equivalent oral exposures.

Due to limited data on PFHxA, the SAW used the Body Weight$^{3/4}$ allometric scaling approach to calculate a human equivalent dose from an animal-based point of departure. The Body Weight$^{3/4}$ allometric scaling approach is based on body surface area and basal metabolic rate in adults.[67] This approach resulted in a dose adjustment factor of approximately 3. The EPA states that this approach is not suitable for estimating an equivalent dose in infants and children. Therefore, it is unclear how the human equivalent dose based on kidney effects in adults would compare to the human equivalent dose based on developmental effects in infants and children. **This uncertainty should be acknowledged in an additional uncertainty factor to protect fetuses, infants and children.[68] And, due to the limited data on how humans process PFHxA, an uncertainty factor of 10, not 3, should be used to account for animal to human differences.**

Furthermore, this approach does not account for differences in toxicokinetics between animals and humans, which for PFAS are often vastly different.[69] Depending on the specific PFAS, human clearance time can be an order of magnitude, or more, higher than in animal models. PFBS is also a short-chain PFAS, with shorter half-life than long-chain PFAS, such as PFOA and PFAS. However, the dose adjustment factor the SAW used for PFBS was based on the ratio of human to animal half-lives for PFBS, not the Body Weight$^{3/4}$ allometric scaling approach. The SAW states,

> "As that [half-life-based dose adjustment factor] allowed conversion of the point of departure to a human equivalent dose using chemical-specific information, the SAW selected this approach over the allometric scaling used in the draft USEPA (2018) PFBS toxicity assessment."

Although the half-life of PFBS and PFHxA is significantly shorter than long-chain PFAS (665 hours vs. 1241 days for PFOS), the half-life in humans is still much longer than in animals (665 hours in humans vs 2.1 hours mice) for PFBS. The dose adjustment factor for PFBS was 316.

This is similar to PFHxA, the human half-life for PFHxA is estimated to be 32 days, or 768 hours (geomean), 1 hour for mice, between 0.4 and 9.8 hours for rats, and from 2 to 5 hours for monkeys, resulting in dose adjustment factors ranging from 78 to 1920, depending on the mammalian species used.[70] As the critical study occurred in rats, the dose adjustment factor for calculating a human equivalent dose from the rat dose would

be based on the human to rat half-life ratio. The most health-protective choice would be to use the half-life estimate of 0.4 hours for rats, resulting in a dose adjustment factor of 1920. In comparison, the dose adjustment factor based on Body Weight$^{3/4}$ allometric scaling is 3.65 for PFHxA, suggesting that the Body Weight$^{3/4}$ allometric scaling approach for PFAS, even short-chain PFAS, is not an appropriate approach to convert animal dose to human equivalent doses and that the human equivalent dose (and thus the health-based value) for PFHxA could be off by at least a couple orders of magnitude. Although the same level of information is available for PFBS and PFHxA, the SAW does not clearly explain why it chooses a different approach for the two chemicals. The PFBS approach to extrapolating from animal to human doses is more relevant to the unique properties of PFAS and would result in a point of departure for PFHxA ranging from 0.0471 to 1.15 mg/kg/day, depending on the dose adjustment factor used. **Application of full uncertainty factors for human variation, animal to human differences, database deficiencies, and to protect fetuses, infants and children would then result in a toxicity value ranging between 4.7 to 115 ng/kg/day.**

b. Use of adult drinking water exposure assumptions

The SAW states that it used adult drinking water exposure assumptions because the critical effect (kidney effects) they selected occurred in adults. However, there is limited data on developmental toxicity for PFHxA. There is not enough data to confidently determine how fetuses, infants and children are affected by PFHxA, in their kidneys and in general. Until there is more confidence that development is not being affected at lower levels than kidney effects in adults, infant exposure assumptions should be applied. As explained above in Section III.1, infants are more likely to have higher exposure than adults to these contaminants because they ingest more water per kilogram of body weight than adults. **The health-based value would be between 7 to 162 ppt if the SAW's infant exposure assumptions (0.142 L/kg/day, 20% relative source contribution) were applied to the toxicity values listed above.**

7. PFBS and PFNA

We support the SAW's use of a half-life-based dose adjustment factor over the BodyWeight ¾ allometric scaling method for generating a human equivalent dose from an animal point of departure for PFBS. We also support the use of drinking water exposure assumptions based on infants, in order to better protect this vulnerable population. However, we suggest Michigan consider applying a full uncertainty factor for animal to human variability, as there is a lack of toxicological information on PFBS, and the SAW's preferred models were not able to be used for deriving the HBV.

We also generally support the SAW's choices in developing a HBV PFNA, however, would **urge Michigan to consider (for all the PFAS analyzed) NAS' recommendation to apply an additional uncertainty factor of 10 to ensure protection of fetuses, infants and children** who often are not sufficiently protected from toxic chemicals by the traditional human variability uncertainty factor.

CONCLUSION

The Whitmer Administration has moved quickly to address the dangers posed by PFAS in Michigan's drinking water. MPART's SAW was charged with reviewing PFAS scientific data, and their recommendations became the basis for EGLE's proposed enforceable drinking water protections. However, more studies and analysis have been performed since SAW's review and our scientific review identified significant shortcomings in the recommendations adopted by MPART in June. As tends to be the trend with PFAS, further study of the health harms associated with PFAS exposure suggest the need for stricter health protections from this very concerning class of chemicals. We urge EGLE to adopt the recommendations laid out in these comments that reflect the current state of science and actions needed to protect public health.

Respectfully submitted,

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Michigan PFAS 2019

Scientific and Policy Assessment for Addressing Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water

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EXECUTIVE SUMMARY

Over the past few decades per- and poly-fluoroalkyl substances (PFAS) contamination has grown into a serious global health threat. PFAS are a large class of several thousand chemically-related synthetic chemicals that are widely used for their water- and oil-repellant properties in a variety of industrial processes and consumer goods. A defining feature of PFAS is their carbon-fluorine bonds, which impart high thermal stability and resistance to degradation. PFAS are also highly mobile in the environment and many have been found to bioaccumulate, or build up, in humans and animals. People are concurrently exposed to dozens of PFAS chemicals daily through their drinking water, food, air, indoor dust, carpets, furniture, personal care products, and clothing. As a result, PFAS are now present throughout our environment and in the bodies of virtually all Americans.

PFAS are associated with many serious health effects such as cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity - some of which occur at extremely low levels of exposure. Additionally, because PFAS are chemically related, they may have additive or synergistic effects on target biological systems within our bodies.

Despite the known health impacts and known contamination in people's homes and in the environment, no enforceable national drinking water standards have been set. The few, mostly non-enforceable, advisories or guidelines that do exist at the federal and state levels are mainly for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS). PFOA and PFOS are the most extensively studied PFAS to-date and, as such, their toxicity has been well characterized in humans and animal models. Although the database for other PFAS is not as robust as for PFOA and PFOS, evidence is growing quickly that indicates they collectively pose similar threats to human health and the environment, often at exceedingly low doses. These toxicity data, combined with concerns over their similar environmental mobility and persistence and widespread human and environmental exposure, have led independent scientists and other health professionals from around the globe to express concern about the continued and increasing production and release of PFAS.

Michigan is currently facing a PFAS contamination crisis. In response to growing concern over PFAS contamination in the state, Michigan has performed extensive testing for certain PFAS. The data show that PFAS have been detected in more than 100 public water systems. As of February 26, 2019, at least 162 unique samples from water systems tested positive for at least one tested PFAS contaminant, with concentrations ranging from 2 to 1,828 parts per trillion (ppt). However, small private water systems and private wells not serving schools are not tested under the state's program. Therefore, the full extent of Michigan's PFAS contamination crisis is still unclear.

The purpose of this report is to provide relevant scientific information which will help Michigan make informed decisions about how to protect its citizens. This report discusses the most critical health effects known to be associated with PFAS, the risk of additive/synergistic effects from concurrent exposure to multiple PFAS, existing or proposed standards and advisories, and

detection and treatment technologies available. Special attention has been given to comparing and analyzing existing or proposed standards and advisories, from which our recommendations arise. For this analysis, we focused on PFOA and PFOS, and two additional PFAS, perfluorononanoic acid (PNFA), and perfluorohexane sulfonic acid (PFHxS), because the Agency for Toxic Substances and Disease Registry has generated minimal risk levels for all four. GenX chemicals, used as a replacement for PFOA, were also analyzed in this report, as their toxicity was recently assessed by the US Environmental Protection Agency (EPA).

Our analysis of current literature and standards/advisories for PFOA, PFOS, PFNA, PFHxS, and GenX show that existing standards and advisories are not health protective. Importantly, Michigan's PFAS Science Advisory Panel also concludes that, "*the research supports the potential for health effects resulting from long term exposure to drinking water with concentrations below 70 ppt*" (the EPA's lifetime health advisory for PFOA and PFOS). If toxicity assessments were based on the most sensitive health effect, protective of the most vulnerable population, and fully acknowledged uncertainties in the toxicity assessment process, maximum contaminant level goals (MCLGs)[a], which are to be set at a level fully protective of human health, would range from 0 to 2 ppt for drinking water. As technology for detection and water treatment do not currently allow for the complete removal of PFAS from drinking water, maximum contaminant levels (MCLs)[b] for PFOA, PFOS, PFNA, PFHxS, and GenX should be based on the best detection and treatment technologies available. Our review of detection and treatment capabilities suggests, a combined MCL of 2 ppt is feasible for PFOA, PFOS, PFNA, and PFHxS, with a separate MCL of 5 ppt for GenX.

However, we conclude that setting a MCLG of zero for the class is needed to provide an adequate margin of safety to protect public health from a class of chemicals that is characterized by extreme persistence, high mobility, and is associated with a multitude of different types of toxicity at very low levels of exposure. If only a handful of PFAS are regulated, there will be swift regrettable substitution with other, similarly toxic PFAS - creating an ongoing problem where addressing one chemical at a time incentivizes the use of other toxic chemicals and we fail to establish effective safeguards to limit this growing class of dangerous chemicals.

The problems with PFAS as a class are highlighted by the fact that many complex PFAS have the potential to break down into less complex perfluoroalkyl acids (PFAAs), a subgroup of PFAS that includes PFOA and PFOS, for which there are substantial known health risks. These problems are compounded by the fact that the production of certain PFAS, such as fluoropolymers, requires the use of PFAAs in their manufacture. This use increases total PFAA

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[a] An MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. MCLGs are non-enforceable health goals and consider only public health and not the limits of detection and treatment technology effectiveness.
[b] An MCL is the legal threshold of the amount of a chemical that is allowed in public water systems under the Safe Drinking Water Act. An MCL is based on the concentration established by its corresponding MCLG, but may be adjusted up for feasibility reasons, reflecting difficulties in measuring small quantities of a contaminant, or a lack of available, adequate treatment technologies.

contamination and exposure through industrial discharge, as was seen with the production of Teflon®, as well as through impurities in PFAS-containing products.

At present, there is no single methodology for isolating, identifying, and quantifying all PFAS compounds in drinking water. We recommend that the state explore an analytical method, such as total oxidizable precursor assay (TOPA)[c], or combination of methods, that can be used as a surrogate for total PFAS. Until a comprehensive analytical method has been approved to quantify PFAS compounds as a class, we recommend reverse osmosis, or other treatment method at least as effective as reverse osmosis, as a treatment technique – an enforceable treatment procedure to ensure contamination control - for public water supplies. Reverse osmosis is the preferred treatment technology because it has been demonstrated to effectively remove a broad range of PFAS compounds, it is the most robust technology for protecting against unidentified contaminants, and it does not require frequent change out of treatment media or release elevated concentrations of pollutants after media is spent. We recommend Michigan evaluate the safest disposal method for high-strength waste streams and spent/used membranes, and that disposal require full destruction of PFAS compounds before entering the environment.

In summary, this report finds that the current available scientific evidence supports the need for:

1) comprehensive testing of drinking water;

2) a maximum contaminant level goal of zero for total PFAS;

3) a combined maximum contaminant level of 2 parts per trillion (ppt) for PFOA, PFOS, PFNA, and PFHxS, and a maximum contaminant level of 5 ppt for GenX; and

4) the setting of a Treatment Technique – an enforceable treatment procedure to ensure contamination control – for the PFAS class based on the best available detection and treatment technologies.

[c] TOPA estimates the full array of potential polyfluoroalkyl acid (PFAA) precursors in a sample. TOPA replicates what micro-organisms in the environment would achieve after many years by rapidly converting precursors into PFAAs such as PFOA, using a hydroxyl radical-based chemical oxidation method.

INTRODUCTION

Per- and poly-fluoroalkyl substances (PFAS) are synthetic chemicals that are widely used in a variety of industrial processes and consumer goods. The carbon-fluorine bonds in PFAS impart high thermal stability and resistance to degradation. While useful chemicals, PFAS are highly resistant to environmental degradation and persist in the environment. As a result, PFAS are now present throughout our environment and in the bodies of virtually all people.

PFAS have been associated with a wide variety of adverse health effects including cancer, hormone disruption, liver damage, developmental harm, and immune system toxicity - some of which occur at extremely low levels of exposure. PFAS are widely prevalent in drinking water sources across the country, including in Michigan. Consequently, there is an urgent need to take action to address this growing health threat. Yet, there are still no enforceable regulations for PFAS in drinking water at the federal level, and very few regulations addressing PFAS in drinking water at the state level.

In response to Michigan's PFAS contamination crisis in its drinking water, this report provides a summary of relevant scientific information on PFAS, including information on PFAS exposure, their effects on human health, and how existing or proposed standards and advisories have been developed. Based on this information, we make recommendations on how Michigan can protect the health of its citizens by addressing PFAS contamination in its drinking water.

This report is organized into six parts: Part I is an introduction to the PFAS class of chemicals. Part II provides an overview of the widespread presence of PFAS in drinking water and in people. Part III discusses the health risks associated with PFAS exposure. Part IV compares and analyzes existing health thresholds set or recommended for levels of certain PFAS (PFOA, PFOS, PFNA, PFHxS and GenX chemicals[d]). Part V provides an overview of detection/analytical methods and treatment technologies for PFAS removal from water. Part VI offers conclusions and recommendations on how Michigan can address PFAS contamination in its drinking water.

PART I: WHAT ARE PFAS

PFAS are a large class of synthetic fluorochemicals that are widely used for their water- and oil-repellant properties. PFAS can be found in consumer products such as non-stick cookware, clothing, leather, upholstery, and carpets; in paints, adhesives, waxes and polishes; in aqueous

[d] As explained by the U.S. Environmental Protection Agency, "GenX is a trade name for a processing aid technology developed by DuPont (now Chemours). In 2008, EPA received new chemical notices under the Toxic Substance Control Act from DuPont (which is now Chemours) for two chemical substances that are part of the GenX process (Hexafluoropropylene oxide (HFPO) dimer acid and the ammonium salt of HFPO dimer acid)." See EPA, GenX Chemicals Studies, available online at https://www.epa.gov/pfas/genx-chemicals-studies, visited December 4, 2018.

fire-fighting foams; and industrially as surfactants, emulsifiers, wetting agents, additives and coatings.[1,2,3]

A defining feature of PFAS are their carbon-fluorine bonds, which impart high thermal stability and resistance to degradation.[4,5] As a result, PFAS are highly resistant to environmental degradation and persist in the environment. They are relatively water-soluble and have been detected in drinking water sources and in finished (treated) drinking water. Due to their water solubility, after exposure by any route, these chemicals are found in human blood serum rather than in body fat where fat-soluble persistent organic pollutants such as PCBs reside. With half-lives of years, PFAS persist in humans and are found in the blood serum of almost all US residents and populations worldwide.[2,6] PFAS are commonly found together in samples from contaminated water[7] and are identified as co-contaminants in blood serum.[6]

The two most well-known PFAS, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), were manufactured between the 1940s and mid-2010 when they were voluntarily phased out from U.S. manufacturing due to health concerns.[8] However, PFOA and PFOS are still manufactured and used internationally and may enter the U.S. through imported goods.[9] There is widespread contamination of PFOA and PFOS in the environment and their toxicity has been well characterized in humans and animal models.[5] PFOA and PFOS are the most extensively studied PFAS to-date, and as such, they are often the only PFAS chemicals with exposure guidelines in drinking water or other environmental media.

However, issues related to the entire PFAS class, which has now grown to an estimated 4,700 chemicals, have been of increasing concern for researchers and health authorities.[10,11,12] Although there is not a robust toxicity database for the suite of PFAS, it is generally recognized that these chemicals are structurally similar, and it is reported that the health risks associated with one PFAS are expected for other PFAS as well.[2,10,13,14] Moreover, as discussed below, many PFAS have the potential to convert into perfluoroalkyl acids (PFAAs), a subgroup of PFAS that includes PFOA and PFOS, for which there are substantial known health risks. Health risks of PFAS include cancer, immune system disfunction, liver damage, hormone disruption, low birth weight and other developmental effects, changes in serum lipid levels, and reproductive harm.[5] While some scientific uncertainties exist, the weight of scientific evidence is substantial: in experimental animals, in exposed residential populations drinking contaminated water, and in occupational studies, PFOA, PFOS, and related PFAS cause adverse health effects, particularly on the young, and increase cancer risks[15] in exposed populations (discussed further in Part III).

PFAS Classification

PFAS can be classified into various subgroups (see Figure 1 below for a simplified classification diagram).[10] The PFAS subgroup with the most toxicological information is perfluoroalkyl acids (PFAAs), which includes PFOA and PFOS.[5] Another PFAS subgroup is PFAA precursors, which consists of PFAS that can be converted into PFAAs.[16,17] PFAA precursors include fluorotelomer-based substances and PASF (perfluoroalkane sulfonyl fluoride)-based substances.

In a recent review of the global distribution of PFAS, authors concluded that PFAA precursors should be given attention in addition to PFOA, PFOS and other PFAAs.[18] For example, one PFAA precursor subgroup, polyfluorinated phosphate esters (PAPs), are not routinely measured or widely investigated, however recent studies show that they are present in house dust, sometimes at extremely high levels that exceed other PFAS subgroups.[19] Additionally, PAPs were found to be incorporated into produce, such as pumpkin, grown on contaminated soils.[20] PFAA precursors can pose health risks associated with their precursor form and when broken down into PFAAs. Germany and Sweden have proposed a restriction under REACH (a 2006 European regulation that addresses the registration and production of chemical substances) to cover six PFAS and any substance that can degrade into one of the six. The Swedish Chemicals Agency estimates that the restriction will cover a group of about 200 PFAS.[21]

Figure 1: Simplified Classification of PFAS Class

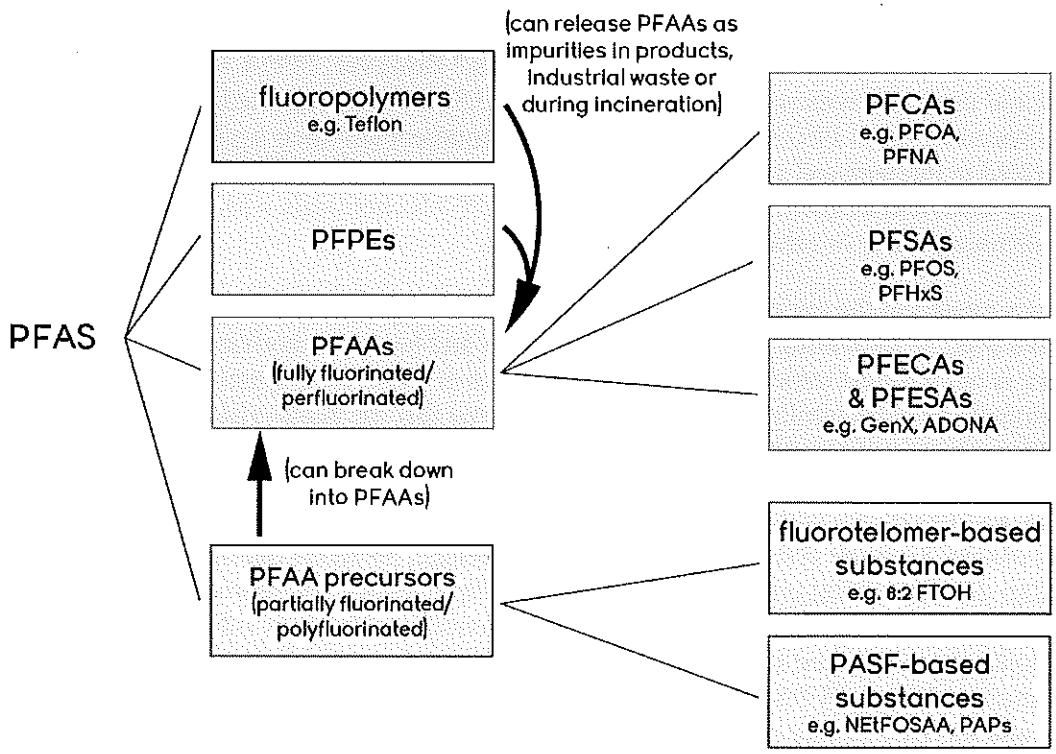

Figure 1 shows the relationship between various subgroups within the PFAS class. This classification scheme is not inclusive of all PFAS subgroups. PFAS (per- and polyfluoroalkyl substances), PFPEs (perfluoropolyethers), PFAAs (perfluoroalkyl acids), PFCAs (perfluoroalkyl carboxylic acids), PFSAs (perfluoroalkyl sulfonic acids), PFECAs (perfluoroether carboxylic acids), PFESAs (perfluoroether sulfonic acids), PASF (perfluoroalkane sulfonyl fluoride).

Perfluoropolyethers (PFPEs) are large molecular sized PFAS with ether linkages and fluoropolymers are composed of multiple repeating units of PFAS.[10,17] While neither are known to actively degrade into PFAAs, they are highly persistent and PFAAs are used in their manufacture, can occur as impurities in the final product, and can be formed when the polymers are heated or incinerated. A well-known fluoropolymer is polytetrafluoroethylene, also known as Teflon. The use of PFAAs such as PFOA and GenX chemicals in the manufacture of perfluoropolyethers and fluoropolymers has resulted in severe environmental contamination around manufacturing and processing plants.[22]

There is concern that simply substituting one PFAS that has been shown to be toxic for another, often less studied PFAS, will result in a regrettable substitution that is not protective of public health. Regrettable substitutions of certain PFAS compounds with others demonstrating similar toxicological characteristics have already occurred. For example, GenX is a replacement technology for PFOA and perfluorobutane sulfonic acid (PFBS) is a replacement for PFOS. The US Environmental Protection Agency (EPA) released draft toxicity assessments in November of 2018 on two GenX chemicals (hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt) and PFBS confirming that GenX chemicals are associated with liver and pancreatic cancers and adverse effects on the kidneys, blood, liver, immune system, and development.[23] In addition, PFBS is associated with thyroid and kidney effects and reproductive and developmental toxicity.[24]

Table 1: Replacements for PFOA and PFOS are Associated with Similar Health Effects

	Cancer	Immune	Liver or Kidney	Developmental & Reproductive	Endocrine
PFOA	●	●	●	●	●
GenX	●	●	●	●	
PFOS	●	●	●	●	●
PFBS		○	●	●	●

Table 1 compares several health effects associated with exposure to PFOA and its replacement GenX, and PFOS and its replacement PFBS. Based on human and animal evidence (not inclusive of all associated health effects).[e,f,g]

Indeed the EPA, in an evaluation of alternative PFAS to PFOA and PFOS, stated that there is, *"concern that these ... substances will persist in the environment, could bioaccumulate, and be toxic ("PBT") to people, wild mammals, and birds."*[25] Of particular relevance to this report, the

[e] ATSDR, 2018. Agency for Toxic Substances and Disease Registry. Toxicological Profile for Perfluoroalkyls. Draft for Public Comment, June 2018.

[f] U.S. Environmental Protection Agency, 2018. Toxicity Assessment: Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3). November 2018. EPA 823-P-18-001.

[g] U.S. Environmental Protection Agency, 2018. Toxicity Assessment: Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3). November 2018. EPA 823-R-18-0307.

Michigan PFAS Science Advisory Panel has recommended that, although there is limited data on PFAS other than PFOA and PFOS, Michigan should "consider setting advisory limits for these additional PFAS in light of their similar chemical structures and toxicity."[26] Furthermore, the 2014 Helsingør[11] and 2015 Madrid Statements,[12] founded on extensive reviews of the scientific literature, provide consensus from more than 200 scientists on the potential for harm associated with the entire class of PFAS.

PART II: HOW ARE PEOPLE EXPOSED TO PFAS

Almost all Americans tested have one or more PFAS in their bodies.[6,27] Widespread use of PFAS has resulted in the ubiquitous presence of these chemicals in the environment including in rivers, soil, air, house dust, food and drinking water from surface water and groundwater sources. We are exposed to PFAS by inhaling house dust contaminated with PFAS due to their use in consumer products, such as treated upholstery and carpet, and from ingesting small amounts in drinking water, food and food packaging.

PFAS in People

Persistent, bioaccumulative chemicals such as those in the PFAS family are characterized by long periods during which the body retains these chemicals after exposure ceases.[3,5,28] PFOA, PFOS, PFNA, PFHxS, and related PFAS are known to bioaccumulate in the bodies of people of all ages, even before birth. Government agencies estimate the human adult half-life (the time it takes to reduce the concentration of a chemical by half) of various PFAS to be on the order of years. Half-life estimates for the PFAS discussed in this report are: 2.3 to 3.8 years for PFOA; 5.4 years for PFOS, 8.5 years for PFHxS, and 2.5 to 4.3 years for PFNA.

The use of PFOA and PFOS in manufacturing has been phased out in the United States, and levels in blood serum have started to decrease as reported in national surveys.[6] However, PFOA and PFOS bioaccumulate and do not degrade in the environment, therefore they will persist in the environment and continue to be a source of exposure for many years in the future.

Blood serum can be used as a long-term measure of exposure for some PFAS and can indicate an increase in risk of disease at the population level. Blood serum concentrations of several PFAS have been evaluated in a large representative sample of the US populations age 12 and older by the National Health and Nutrition Examination Survey (NHANES).[6] The table below (Table 2) summarizes the geometric mean blood serum concentration in ng/L, or parts per trillion (ppt), of different PFAS measured by NHANES since 1999. Note that blood serum concentration is usually expressed in ppb (ug/L or ng/mL) but was converted to ppt in this report to facilitate comparisons to drinking water levels, usually reported in ppt for PFAS.

Table 2: Results of NHANES Biomonitoring Data

Survey Year	PFBS	PFDA	PFDoA	PFHpA	PFHxS	PFNA
1999-2000	NA	*	*	*	2130	551
2003-04	*	*	*	*	1930	966
2005-06	*	355	*	*	1670	1090
2007-08	*	286	*	*	1950	1220
2009-10	*	279	*	*	1660	1260
2011-12	*	199	*	*	1280	881
2013-14	*	185	*	*	1350	675
Survey Year	**PFOA**	**PFOS**	**PFOSA**	**EtFOSAA**	**MeFOSAA**	**PFUA**
1999-2000	5210	30400	355	642	846	*
2003-04	3950	20700	*	*	*	*
2005-06	3920	17100	*	*	410	*
2007-08	4120	13200	*	*	303	*
2009-10	3070	9320	*	*	198	172
2011-12	2080	6310	*	*	*	*
2013-14	1940	4990	NA	NA	*	*

Table 2 shows the geometric mean levels in blood serum in ng/L (ppt) from NHANES biomonitoring data. "" indicates mean was not calculated, proportion of results below limit of detection was too high to provide a valid result. "NA" indicates the PFAS was not measured in that round of NHANES.*

State and regional biomonitoring trends, as well as trends among different age groups and sexes can differ from the national trends represented in NHANES. For example, one study found that children 2 to 5 years old and adults over 60 had a higher blood serum PFOA (median 600 ppb) in the Little Hocking Water Association district compared with residents in all other age groups (median 321 ppb).[29] The authors note that infants and children proportionally drink more water per unit of body weight than adults, and children and the elderly tend to spend more time at home with exclusive use of residential water than other age groups. Additionally, NHANES biomonitoring measures a limited number of PFAS and is likely not reflective of current exposures to PFAS. Alternative methods for detecting PFAS in blood serum are showing an increasing trend of unidentified organofluorine in blood serum samples, which suggest that people are being exposed to new and unidentified PFAS.[30,31]

Fetal and Infant Exposure to PFAS

Fetuses, infants and children are particularly susceptible to the impacts of exposure to toxic chemicals due to their rapidly growing and developing bodies. As such, they are at increased risk of harmful health effects due to PFAS exposure (discussed in further detail in Part II of this

report). Almost all fetuses and infants will have some degree of exposure to PFAS, including fetal exposure during pregnancy through placental transfer.[2,5] For infants, PFAS exposure may be further elevated due to ingestion of contaminated breast milk (a result of the mother's ingestion of contaminated water, and other sources) or infant formula contaminated by PFAS-containing food packaging and/or prepared with contaminated drinking water.[32,33] Fetuses and nursing infants' exposures are influenced by the mother's past exposures or "body burden," as measured by blood serum concentrations.

PFAS have been detected in virtually all umbilical cord blood tested, indicating that PFAS can cross the placental barrier, exposing fetuses *in utero*.[5] Researchers have studied the transfer of PFAS during pregnancy and found a positive correlation between maternal plasma and serum with cord serum levels, concluding that either maternal plasma or serum could be used to estimate fetal exposure to PFAS.[34]

Infant formula can be contaminated with PFAS through the use of PFAS-contaminated water when reconstituting powdered formula. PFAS has also been detected in infant formula itself. For example, one study detected PFAS in all infant milk formulas and baby cereals tested, with the highest levels coming from PFOA, PFOS, PFNA, and PFDA.[33] Contamination of infant formula and cereal could be due to migration from food packaging and/or from containers during production.[35]

ATSDR summarizes reports on breast milk concentrations of PFAS found in the general population.[5] Numerous PFAS, including PFOS, PFOA, PFBS, PFHxS, PFNA, perfluorodecanoic acid (PFDeA), perfluorododecanoic acid (PFDoA), perfluoroundecanoic acid (PFUA), and perfluorooctanesulfonamide (PFOSA), have been detected in breast milk samples in women in China, Korea, Japan, Malaysia, Cambodia, India, Korea, Vietnam, Indonesia, Norway, Philippines, Sweden, and the United States.

PFAS levels in breast milk are higher than what is typically found in drinking water, due to the mothers' past accumulated exposures and transfer to breast milk. For example, in biomonitoring studies average concentrations of PFOA in breast milk range from 2.5%[36] to 9%[37] of the concentration of PFOA in mothers' blood serum. Therefore, breast milk concentrations can be up to an order of magnitude higher than drinking water concentrations because PFOA maternal blood serum levels are approximately 100 times greater than the drinking water she ingested over time.

PFAS in Drinking Water

Drinking water is the dominant source of exposure to PFAS for people living in communities with drinking water highly contaminated with these chemicals, far exceeding exposure from other sources.[38] Even relatively low PFAS concentrations in drinking water can be associated with substantial increases in blood serum levels. For example, since the clearance of PFOA is slow and because it accumulates in blood, after a long period of exposure, a person's blood

serum PFOA level will be about 100 times greater than the PFOA concentration ingested via drinking water.[2]

In 2009, researchers evaluated the contribution of water, diet, air and other sources for various exposure scenarios to PFOA.[38] They found that when drinking water concentrations of PFOA are low, dietary exposure is the dominant source of exposure. However, as drinking water concentrations increase, the ingestion of contaminated water becomes the predominant source of exposure. Drinking water concentrations of 100 ppt and 400 ppt are predicted to contribute 71% and 91%, respectively, of total exposure; and are estimated to increase blood serum levels, on average, by 250% and 1000%, respectively.[2]

Analysis of EPA's Unregulated Contaminant Monitoring Rule (UCMR3) data shows that about 4% of tested public water supplies in the U.S. (about 200 of 5,000 public water supplies studied), serving 16.5 million Americans in 33 states, 3 territories and an American Indian community, have levels of PFAS above the EPA-specified reporting limits[h] for UCMR3.[7] Sixty-six tested public water supplies, serving six million Americans, had at least one sample above EPA's 2016 PFOA and PFOS non-enforceable lifetime health advisory of 70 ppt.[3,28] PFOA was the most frequently detected PFAS in drinking water, followed by PFOS. Exceedances of the EPA's health advisory have been detected in California, New Jersey, North Carolina, Alabama, Florida, Pennsylvania, Ohio, New York, Georgia, Minnesota, Arizona, Massachusetts and Illinois. High levels of PFAS in drinking water were strongly associated with proximity to major PFAS industrial sites, civilian airports, and military fire training areas.

As concerning as the UCMR3 data are, they significantly underestimate how many drinking water sources are contaminated by PFAS. This is in part because the lowest levels of PFAS that are required to be reported to EPA, sometimes referred to as the "Minimum Reporting Levels" or "Method Reporting Levels" under the UCMR3 were very high, meaning that even if PFAS were detected at levels below these cutoffs, they are not required to be reported to EPA. Indeed, these cutoffs are significantly higher than the limit of quantitation reported in most published studies and by a prominent laboratory using the same method, which completed about one-third of the PFAS monitoring under the UCMR3.[39] The UCMR3's overall limitations have been well described:

> *"The [Minimum Reporting Levels] (10–90 ng/L) in the UCMR3 database are up to 2 orders of magnitude higher than the limit of quantitation in most published studies, and more than 10 times higher than the drinking water limit (1 ng/L) suggested by human and animal studies. Because PFASs are detectable in virtually all parts of the environment, we infer that the large fraction of samples below reporting limits is driven in part by high [Minimum Reporting Levels]."* [7]

Moreover, the UCMR3 only required testing for 6 PFAS out of the several thousand PFAS that have been cleared for use in the United States.[40] The UCMR3 data are further limited by the

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[h] Reporting limits for UCMR3 were: PFOA - 20 ppt, PFOS - 40 ppt, PFHxS - 30 ppt, PFNA - 20 ppt, perfluorohepatanoic acid (PFHpA) - 10 ppt, and perfluorobutane sulfonic acid (PFBS) - 90 ppt

inclusion of only 0.5 % of the nation's small public water supplies and no testing results for private wells.

Exposure to PFAS in Michigan Locations

Evaluation of Local Sites in Michigan

Prior to launching a more comprehensive drinking water testing program, the Michigan Department of Environmental Quality (MDEQ) had evaluated more than 30 groundwater, surface water and drinking water sites throughout the state for PFOA, PFOS, and at some of the sites, other PFAS contaminants. These local sites include industrial facilities, military bases, and landfills known to have used or disposed of PFAS-containing materials. Some of the testing data and other information can be found at: https://www.michigan.gov/pfasresponse/0,9038,7-365-86511_82704---,00.html. Multiple sites tested positive for PFAS, sometimes exceeding 70 ppt for one of the compounds or combined levels of the compounds. However, these data are not the result of comprehensive sampling and therefore may understate the contamination problem. Reports indicate that MDEQ has suggested that statewide, more than 11,300 total sites may be contaminated with PFAS.[41] MDEQ continues to investigate PFAS contamination sites and as of February 13, 2019 the current number of sites under investigation is 43.

Public Water Supplies

Commendably, MDEQ has performed testing of certain PFAS at public water systems (PWS) throughout the state. MDEQ currently provides testing data from raw and treated water for 1,114 PWS within the state that have been sampled for PFOA, PFOS, and certain other PFAS. Under the program, MDEQ analyzed 14 PFAS in drinking water using EPA Method 537.[42] According to the agency, MDEQ is also using an isotope dilution method for community water systems with surface water intakes that analyzes 24 compounds including compounds included in the EPA Method 537 testing. Notably, reporting limits for PFAS testing by MDEQ are substantially lower than those used in UCMR3 (as low as 2 ppt). The PWS sampling data are reported at: https://www.michigan.gov/pfasresponse/0,9038,7-365-86510_87918-474941--,00.html and show the presence of PFOA, PFOS and other tested PFAS in more than 100 PWS. As of February 26, 2019, at least 78 unique samples from PWS tested positive for PFOA and PFOS, with concentrations ranging from 2 to 1,520 ppt, and at least 162 unique samples from PWS tested positive for total PFAS (of the PFAS contaminants tested), with concentrations ranging from 2 to 1,828 ppt. MDEQ plans to continue periodic monitoring of its PWS.

Figure 2: PFAS Contaminated Public Water Supplies and Sites in Michigan

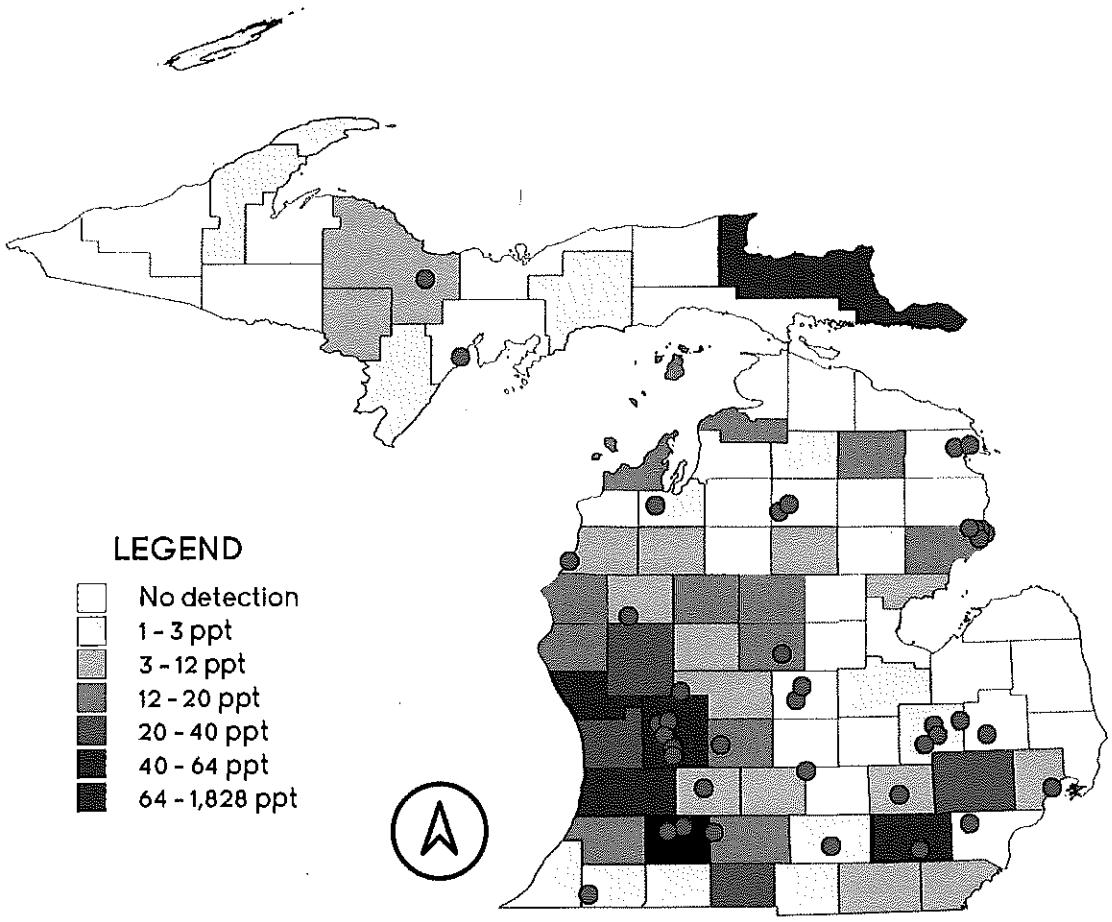

Figure 2 shows the highest total PFAS concentration that was sampled in a public water system in that county.[i] Green dots represent PFAS contamination sites currently under investigation by MDEQ.[j]

Well Water Testing for Schools in Michigan

In addition to PWS sampling described above, MDEQ began a statewide sampling program for PFAS in drinking water from all schools that use well water. The data are available at: https://data.michigan.gov/Environment/PFAS-Results-Schools/e22v-q344 and show the presence of PFOA, PFOS and certain other PFAS at numerous schools. Raw and/or treated water have

[i] MDEQ, 2019. PFAS Response - Statewide Sampling Initiative for Public Water Supplies. https://www.michigan.gov/pfasresponse/0,9038,7-365-86510_87918-474941--,00.html

[j] MDEQ, 2019. Michigan PFAS Sites. https://www.michigan.gov/pfasresponse/0,9038,7-365-86511---,00.html

been sampled for PFOA, PFOS and certain PFAS at 461 schools and 150 childcare centers/Head Start programs. As of February 26, 2019, at least 28 schools tested positive for PFOA and PFOS in drinking water, with concentrations ranging from 2 ppt to 119 ppt, and 60 schools tested positive for total PFAS (of the PFAS contaminants tested), with concentrations ranging from 2 to 182 ppt. These results are of particular concern, as schools serve drinking water to the most vulnerable populations – children and women who are pregnant or of child-bearing age.

The above data show that there is a serious PFAS contamination crisis affecting Michigan. However, gaps in our knowledge remain. Private water systems serving no more than 25 people, and having no more than 15 service connections, and most private wells, are not tested under the state's program. Site investigations performed by MDEQ show significant contamination not always reflected by PWS data. For example, although here are there are two contamination sites in Alpena county, no detections were reported for PWS within the county. Furthermore, in Iosco county there was one detection at 14 ppt for total PFAS, however there are 7 contamination sites within the Oscoda community in Iosco county. For groundwater in Oscoda, 51% (373/736) of samples had combined levels of PFOA and PFOS between detection levels and EPA's health advisory level of 70 ppt and 36% (268/736) of samples tested above 70 ppt. Further rounds of testing should be performed to account for testing variability and to ensure no additional discharges of PFAS are occurring. Additionally, the state should offer drinking water testing of private water systems and private wells in or proximate to areas where elevated PFAS levels have been identified, in addition to the school wells already tested under the program. Furthermore, at present, the state only publicly reports concentrations for PFOA and PFOS combined and for total PFAS detected in drinking water systems; MDEQ should publicly report unique values for detected levels of all tested PFAS.

Biomonitoring in Michigan

Although drinking contaminated water has been found to result in elevated blood serum concentrations, blood serum monitoring results are not available which relate Michigan drinking water levels of PFAS with blood serum levels in people. A newly planned study may provide information to help fill this need. In November 2018, the Michigan Department of Health and Human Services and the Kent County Health Department announced it would be conducting blood testing for up to 800 people in the Kent County area where many drinking water sources are contaminated.[43] The sampling effort will evaluate drinking water sources and participant blood samples for suite of 24 PFAS. These results will be compared to blood serum concentration averages in people not exposed to these sources. Invited study participants began providing blood samples beginning in December 2018. A report of the results will not be available until roughly a year from now, although some sampling results will be available in two to four months. A similar study is being considered for the Parchment, MI area.

There have been some isolated reports of PFAS in the blood of people in Michigan. Wood TV reported that exceptionally high blood serum concentrations were found in several individuals in areas where drinking water is known to be contaminated.[44] For example, a child was reported to

have a blood serum level of 484,000 ppt PFAS, and a woman was reported to have 5 million ppt.[44] The specific PFAS identified were not provided. Both live near Wolverine's former tannery site in Rockford, MI.

PART III: HEALTH RISKS ASSOCIATED WITH EXPOSURE TO PFAS

There is a sufficiently robust body of scientific research to evaluate the adverse health effects of several PFAS, with the most highly studied being PFOA, PFOS, PFNA and PFHxS. Both human studies and animal studies should be used to evaluate adverse effects of chemical exposures (see Box 8 for further discussion). Animal and human studies show similar adverse effects and cancer risks.

Due to the structural similarity and the co-occurrence of PFOA and PFOS in the environment and in people, public health protection and guidance usually address both PFOA and PFOS. In June 2018, minimal risk levels were also generated by the Agency for Toxic Substances and Disease Registry (ATSDR) for PFNA and PFHxS, which are chemically related and often co-occur with PFOA and PFOS.[5] In November of 2018, the EPA released human health toxicity values (reference doses) for PFBS and hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt, also known as GenX chemicals.[23,24] PFBS is a replacement chemical for PFOS and GenX is a replacement technology for PFOA, and both were found to be associated with a variety of adverse health effects. Considerably less information is available for the larger group of PFAS, however, as stated above, due to the structural similarity of these contaminants, it is expected that many PFAS will have similar health effects. [2,13,14]

Several reviews of the scientific literature on the health effects associated with PFAS exposure have recently been published.[1,2,5,14,15,45,46,47] ATSDR has performed the most recent and comprehensive review. This review is summarized below, as an overview of health effects associated with PFAS exposure. This summary is followed by sections that discuss in further detail cancer risk and two of the most common and sensitive health effects for PFAS, development harm and immunotoxicity. Understanding these health effects is particularly important to determining how to best protect the public from PFAS contamination.

ATSDR Draft Toxicological Profile for Perfluoroalkyls

ATSDR performs risk assessment and evaluation of chemicals as part of the U.S. Centers for Disease Control and Prevention (CDC). ATSDR released a draft Toxicological Profile for Perfluoroalkyls in June 2018.[5] The toxicological profile on perfluoroalkyl compounds included the suite of chemicals in that group that have been measured in the blood serum collected as part of the NHANES 2003-2004 survey, and other monitoring studies. The 14 perfluoroalkyl compounds included in the toxicological profile are:

Perfluorobutyric acid (PFBA, CAS 375-22-4)

Perfluorohexanoic acid (PFHxA, CAS 307-24-4)
Perfluoroheptanoic acid (PFHpA, CAS 375-85-9)
Perfluorooctanoic acid (PFOA, CAS 335-67-1)
Perfluorononanoic acid (PFNA, CAS 375-95-1)
Perfluorodecanoic acid (PFDeA, CAS 335-76-2)
Perfluoroundecanoic acid (PFUA, CAS 2058-94-8)
Perfluorododecanoic acid (PFDoA, CAS 307-55-1)
Perfluorobutane sulfonic acid (PFBS, CAS 375-73-5)
Perfluorohexane sulfonic acid (PFHxS, CAS 355-46-4)
Perfluorooctane sulfonic acid (PFOS, CAS 1763-23-1)
Perfluorooctane sulfonamide (PFOSA, CAS 754-91-6)
2-(N-Methyl-perfluorooctane sulfonamide) acetic acid (Me-PFOSA-AcOH, CAS 2355-31)
2-(N-Ethyl-perfluorooctane sulfonamide) acetic acid (Et-PFOSA-AcOH, CAS 2991-50-6)

ATSDR provided an exhaustive assessment of these 14 PFAS in their Toxicological Profile for Perfluoroalkyls. Their assessment found that there is consistent association between PFAS exposure and several health outcomes. The table (Table 3) below summarizes health effects ATSDR found linked to the 14 PFAS reviewed in the profile.

Table 3: Summary of ATSDR's Findings on Health Effects from PFAS Exposure

	Immune e.g. decreased antibody response, decreased response to vaccines, increased risk of asthma diagnosis	**Developmental & Reproductive** e.g. pregnancy-induced hypertension/pre-eclampsia, decreased fertility, small decreases in birth weight, developmental toxicity	**Lipids** e.g. increases in serum lipids, particularly total cholesterol and low-density lipoprotein	**Liver** e.g. increases in serum enzymes and decreases in serum bilirubin levels	**Endocrine** e.g. increased risk of thyroid disease, endocrine disruption	**Body Weight** e.g. decreased body weight	**Blood** e.g. decreased red blood cell count, decreased hemoglobin and hematocrit levels
PFOA	✖	✖	✖	✖	✖	✖	✖
PFOS	✖	✖	✖	✖	✖	✖	✖
PFHxS	✖			✖			✖
PFNA	✖		✖			✖	
PFDeA	✖	✖	✖	✖	✖	✖	
PFDoA	✖	✖				✖	
PFUA	✖	✖				✖	✖
PFHxA		✖					✖
PFBA		✖		✖	✖		✖
PFBS				✖			✖

Table 3 summarizes ATSDR's findings on the associations between PFAS exposure and health outcomes in human and animal studies (not an exhaustive list of health outcomes).

ATSDR determined that there was sufficient data to support generating minimal risk levels for PFOA, PFOS, PFNA, and PFHxS. Our maximum contaminant level recommendations are, in part, based on these minimal risk levels, which is discussed in Part III of this report.

Caucer Risks from PFOA, PFOS, PFNA, PFHxS, and GenX Exposure

Chemical exposures that contribute to an increase in cancer risk have a significant impact on public health. As the National Cancer Institute states, "*the years of life lost due to premature deaths, the economic burden due to lost productivity and the costs associated with illness and therapy, and the long-term effects of cancer and its treatment on the quality of life of survivors take a toll at a population level.*"[48]

Toxicological studies in humans and animals have found associations between increased cancer risk and PFOA and PFOS exposure, and several authoritative bodies have made findings on their carcinogenic potential. PFNA, PFHxS, and GenX are less well studied, however, their chemical similarity to PFOA and PFOS and the data that is available suggests that there is reason to be concerned about increased cancer risk.

PFOA and PFOS

Carcinogens are chemicals that cause cancer. The C8 Science Panel[k] has identified PFOA as a probable carcinogen[15], and the International Agency for Research on Cancer (IARC) has classified PFOA as a possible[49] carcinogen. The EPA Science Advisory Board and the EPA Office of Water have concluded that PFOA and PFOS demonstrate likely[50] or suggestive[3] evidence of carcinogenic potential, respectively.

From 2005-2013 the C8 Science Panel determined blood levels and collected health information from communities in the Mid-Ohio Valley that had been potentially affected by the release of PFOA emitted from a DuPont plant since the 1950s.[15,51,52] They then assessed the links between PFOA exposure and a number of diseases. Based on epidemiologic and other data available to the C8 Science Panel, they concluded that there is a probable link between exposure to PFOA and testicular and kidney cancer (as well as high cholesterol, ulcerative colitis, thyroid disease and pregnancy-induced hypertension). Because these studies relied largely on a survivor cohort, results regarding associations with PFOA may be biased toward the null (i.e. a greater chance of failing to identify an association) for highly aggressive cancers like pancreatic, lung and kidney cancers, which should not be ruled out based on this study. These studies also found weak associations between Non-Hodgkin lymphoma and ovarian and prostate cancers.

[k] The C8 Science Panel was established as a result of a class action lawsuit against DuPont and charged with assessing probable links between PFOA (also called C8) exposure and disease in communities near the DuPont Washington Works plant in Parkersburg, West Virginia.

IARC, the specialized cancer agency of the World Health Organization, has classified PFOA as "possibly carcinogenic to humans" (Group 2B) based on limited evidence that PFOA causes testicular and renal cancer, and limited evidence in experimental animals."[49] IARC considers human, animal, and mechanistic data in making its determinations of evidence for cancer risk to humans. The human data considered by IARC in making this determination included increases in cancer among highly exposed members of the C8 Health Project study population[51,52] discussed above, and among workers in the DuPont Washington Work plant in Parkersburg, WV.[53] Researchers studied the mortality of 5,791 workers at the DuPont chemical plant in Parkersburg, West Virginia from 1952-2008. The authors found exposure-response relationships with PFOA for chronic renal disease, both malignant and non-malignant.[53]

The EPA Office of Water concluded that there is suggestive evidence of carcinogenic potential of PFOA in humans.[3] This conclusion was based on Leydig cell testicular tumors in rats, and the reported probable link to testicular and renal tumors among the members of the C8 Health Project. EPA also concluded that there is suggestive evidence of carcinogenic potential of PFOS in humans based on liver and thyroid adenomas observed in a chronic rat bioassay.[28,54]

Cancers other than kidney and testicular cancer have also shown positive associations in studies of occupational exposure, though they have not reached statistical significance. One study reported a non-significant positive association between PFOA and prostate cancer in employees of DuPont in West Virginia.[55] Another study reported modestly elevated risk of prostate and bladder cancer in employees of 3M in Minnesota.[56]

Two small studies of the Inuit population in Greenland found significantly increased risk of breast cancer associated with certain PFAS, including PFOA and PFOS,[57] and a greater elevated odds ratio for breast cancer in women with both high PFAS levels and specific genetic variations that affect levels of hormones such as estrogens.[58] A later, larger study evaluated the association between PFAS serum levels in pregnant Danish women and the risk of premenopausal breast cancer.[59] This study did not find convincing evidence establishing a causal link between PFAS exposures and increased risk of breast cancer 10 to 15 years later. These data suggest the need for further research on this topic, especially considering the effects PFAS exposure can have on mammary gland development (see Box 6).

While there have been some studies that do not support a relationship between PFAS exposure and cancer, those studies have notable limitations. For example, New York State Department of Health (NYSDOH) conducted an evaluation of cancer occurrence in the Hoosick Falls population where residents' blood serum median levels were 23,500 ppt.[60] In that study, no relationship was found between PFOA exposure and testicular, kidney, prostate or bladder cancer. However, studies of community exposures have inherent limitations and are difficult to evaluate in low number populations. As noted by NYSDOH, limitations of this study include small population and incomplete inclusion of the potentially exposed populations.

PFNA, PFHxS, and GenX

PFNA and PFHxS have been studied to a lesser degree than PFOA and PFOS. One study reported a significantly higher risk for prostate cancer among subjects with a hereditary risk and blood serum PFHxS levels above the median, finding a significant odds ratio of 4.4 (1.7-12).[61] An increased, though non-significant, odds ratio of 2.1 (1.2-6.0) was also reported among subjects with a hereditary risk for prostate cancer and blood serum PFNA levels above the median.

Researchers evaluated participants in the C8 Health studies for associations between PFNA and PFHxS and elevated serum levels of prostate-specific antigen, a biomarker that can be used to screen for prostate cancer.[62,63] Their findings were non-significant, however, one limitation with this study is that changes in prostate-specific antigen levels are not exclusively due to cancer but can also be attributed to other factors such as prostate inflammation, urinary retention, local trauma and increase in age.

In EPA's draft toxicity assessment of GenX, the EPA determined that "*there is Suggestive Evidence of Carcinogenic Potential of oral exposure to GenX chemicals in humans, based on the female hepatocellular adenomas and hepatocellular carcinomas and male combined pancreatic acinar adenomas and carcinomas [in rats].*"[23] The EPA also notes that evidence suggest that mice are more sensitive to the effects of GenX than rats, and that a lack of data evaluating cancer in mice is a database deficiency. There are currently no studies evaluating cancer risk from GenX exposure in humans.

Further research is needed to understand the relationship between PFOA and PFOS exposure and various cancers other than kidney and testicular cancer, such as prostate, bladder, ovarian and breast cancer, which have limited, but suggestive evidence for association with PFAS exposure. Additionally, more research is needed to understand the carcinogenic potential of other PFAS, which, due to similar chemical characteristics to PFOA and PFOS, are likely to also increase the risk for certain cancers.

Risks to Fetal Development and the Young

Developing infants and children are particularly susceptible to the impacts of exposure to toxic chemicals. The impacts of PFAS exposure on fetal development and the young have been studied in both humans and animals. These studies find similar and profound adverse health effects.

Since infants and children consume more water per body weight than adults, their exposures may be higher than adults in communities with PFAS in drinking water. In addition, the young may also be more sensitive to the effects of PFAS due to their immature developing immune system, and rapid body growth during development.[1,5,64,65,66] Exposure to PFAS before birth or in early childhood may result in decreased birth weight, decreased immune responses, and hormonal effects later in life.

Recent literature has identified developmental effects of significance from exposure to PFAS. For a review of effects on children from PFAS exposure, sixty-four studies were evaluated for six categories of health outcome: immunity, infection, asthma, cardio-metabolic, neurodevelopmental/attention, thyroid, renal, and puberty onset.[66] The review found evidence of later age at menarche (menstruation), effects on renal function and lipid serum levels, and immunotoxicity (asthma and altered vaccine response).

A particularly significant developmental effect linked to PFAS exposure is alterations to mammary gland development. Prenatal exposure of mice to PFOA results in delays in mammary gland development in offspring of treated females, including reduced ductal elongation and branching, delays in timing and density of terminal end buds (developmental structures important for forming proper mammary gland ductal structure), and decreases in mammary epithelial growth.[67,68,69] These studies found that PFOA-induced effects on mammary tissue occur at extremely low doses - much lower than effects on liver weight. Due to the low-dose sensitivity of mammary glands to PFOA in mice, a no-observable adverse effect level for mammary gland developmental delays could not be determined. In other words, the studies found that all dose levels were associated with effects on mammary gland development. (see Box 6 for a discussion on the biological relevance of altered mammary gland development)

Risk to Immune System Function

Evidence from both animal and human studies suggest that the immune system is also highly sensitive to PFAS exposure. For instance, immunotoxicity is currently the most sensitive health endpoint identified for PFOS exposure and occurs at doses at least an order of magnitude less than other health endpoints. As documented in the ATSDR profile, both animal and epidemiology studies provide strong evidence linking PFAS exposure to immunotoxic effects.[5]

The strongest evidence of the PFAS-associated immunotoxicity in humans comes from epidemiology studies finding associations evaluating the antibody response to vaccines.[5] Associations have been found for PFOA, PFOS, PFHxS, and PFDeA; with limited evidence for PFNA, PFUA, and PFDoA. Increases in asthma diagnosis and effects on autoimmunity, specifically ulcerative colitis, have also been linked to PFAS exposure. Animal studies suggest the immune system is a highly sensitive target of PFAS-induced toxicity; observed effects include impaired responses to T-cell dependent antigens, impaired response to infectious disease, decreases in spleen and thymus weights, and in the number of thymic and splenic lymphocytes.[5,23]

The immunotoxic effects of PFAS could have significant detrimental impacts on public health. For example, PFAS is associated with reduced antibody titer rise in response to vaccines,[5,70] resulting in increased risk of not attaining the antibody level needed to provide long-term protection from serious diseases such as measles, mumps, rubella, tetanus and diphtheria. PFAS can also be transferred to fetuses *in utero*, and to infants via breast milk[71] or PFAS-contaminated infant formula, which presents a particular hazard to the adaptive immune system during this critical window of development. As noted by the Michigan PFAS Science Advisory Panel, "*the developing immune system is especially sensitive to environmental stressors... Disruption of immune development is likely to have broader impacts than the antibody changes that are directly measured in these studies and may have long lasting consequences.*"[26]

Box 1: Immunotoxicity of PFOA, PFOS

In 2016, the National Toxicology Program conducted a systematic review to evaluate immunotoxicity data on PFOA and PFOS. It concluded that both are presumed to constitute immune hazards to humans based on a high level of evidence that they suppress antibody response in animal studies and a moderate level of evidence from studies in humans. They also identified additional evidence linking PFOA exposure to reduced infectious disease resistance, increased hypersensitivity-related outcomes, and increased autoimmune disease incidence (human studies), and PFOS exposure to suppressed disease resistance and lowered immune cell activity (animal studies).[70]

In 2018, the Michigan PFAS Science Advisory Panel recommended adding immunologic effects to the list of health conditions of concern, "*particularly those that arise during prenatal exposure and childhood... based on strong toxicologic findings and supporting epidemiologic evidence.*"[26]

Short-chain PFAS

Short-chain PFAS (less than six or seven carbons, depending on the PFAS subclass) have been introduced as 'safer' alternatives due to their supposed shorter half-lives in humans, but little research is publicly available on the toxic effects related to exposure, retention, and persistence. The evidence that does exist suggests short-chain PFAS are associated with similar adverse health effects as the long-chain, legacy PFAS that they have replaced.[72,73] Importantly, short-chain PFAS are still highly persistent and are even more mobile in the environment than long-chain PFAS.[74]

Some short-chain PFAS are not detected frequently or detected at low levels in human blood; therefore, some industry groups have claimed that short-chain PFAS are readily eliminated from the body. However, recent research does not support this conclusion. Short-chain PFAS are found to accumulate in

interior organs, some at concentrations that are higher than long-chain PFAS, such as PFOA and PFOS.[81] As Dr. Philippe Grandjean pointed out in his testimony to the Michigan State Legislature, "*Given the inability to assess organ concentrations in clinical studies, our understanding of the health risks associated with the short-chained compounds is extremely limited.*" Biomonitoring programs are currently exploring other forms of media, such as urine, as more appropriate measures of short-chain PFAS exposure and retention.

Additionally, developing science on short-chain PFAS metabolism indicates, "*that some fluorinated alternatives have similar or higher toxic potency than their predecessors when correcting for differences in toxicokinetics* [rate a chemical enters the body, is metabolized, and excreted]".[73] The rate a chemical will enter the body and the process of excretion and metabolism in the body may in fact be an inadequate measure of health threats to humans from chemicals with chronic exposure. The widespread use of short-chain PFAS in commerce and their persistence in the environment could lead to chronic exposures in people. Researchers find:

> "*Considering that the exposure to short-chain PFAAs is unlikely to be stopped shortly, there will be increasing continuous and poorly reversible environmental background concentrations of short-chain PFAAs. Consequently, organisms and humans will be permanently exposed to short-chain PFAAs, resulting in continuous and poorly reversible internal concentrations. The poorly reversible internal concentrations in organisms are caused by the persistence of short-chain PFAAs and their continuous presence in the environment. Therefore, the organismal elimination efficiencies are of secondary relevance.*"[72]

Finally, it is important to acknowledge that exposure to short-chain and other replacement PFAS, is happening on top of a pre-existing health burden from historically used, long-chain PFAS, as discussed further in the following section.

Box 2: Persistence, Mobility, and Toxicity

The German Environment Agency has shifted the classification of emissions, registered under REACH, to specific intrinsic properties that indicate a hazard to sources of drinking water.[75] These properties include persistence (P) in the environment, mobility (M) in the aquatic environment, and toxicity (T) (PMT). Substances that are considered very persistent in the environment (vP) and very mobile in the aquatic environment (vM), regardless of their toxicity, must also be considered, due to their increased probability of reaching and accumulating in sources of drinking water.[76] Because very short chain PFAS are volatile and can be dispersed far from areas of direct exposure,[77,78] recent efforts have shifted the focus toward mobility as a key chemical parameter of concern, moving from the established criteria persistent (P), bioaccumulative (B), and toxic (T) (PBT) toward PMT.[75,79] This new criteria has prompted the designation of PFAS substances as posing an "equivalent level of concern" under REACH, thereby prompting the need for a new paradigm for chemical assessment and authorization.[80]

Additive and Synergistic Effects of Exposure to Multiple PFAS

Importantly, exposures to PFAS do no occur in isolation. Biomonitoring studies demonstrate that Americans have chronic exposure to multiple PFAS chemicals throughout their lifetimes. CDC's national biomonitoring studies, NHANES, reveal that nearly every American has PFOS, PFOA, PFHxS and PFNA detected in their blood stream, including young children.[6] At least eight other PFAS are detected in blood serum by NHANES studies: MeFOSAA, PFDeA, PFUA, PFHpA, PFBS, FOSA, EtFOSAA, PFDoA, and PFHpA.[6] Most other PFAS chemicals are not routinely included in biomonitoring studies. As mentioned previously, alternative methods in biomonitoring suggest that humans are being exposed to new and unidentified PFAS.[30,31]

Multiple PFAS are found in drinking water, food, dust, personal care products and a variety of different environmental media. In drinking water PFOA, PFOS, PFNA, PFHxS, PFBS, PFHpA (measured in UCMR3), and other PFAS are often found in conjunction.[7] Food contact materials and packaging in the United States has shown detectable levels of PFOA, PFHxS, PFDA, PFHpA, PFDoA, PFHxA, PFBA, PFPeA, PFUA, PFOS and 8:2 FTOH,[82] and likely contain other unknown PFAS. A single consumer product such as carpet, clothing, outdoor gear, or dental floss can contain up to nine different identifiable PFAS compounds[83] along with other undetermined PFAS. Samples of dust collected throughout homes and offices have shown high concentrations of 8:2 FTOH, PFDA, PFHpA, PFNA, 10:2 FTOH, PFDoA and PFTeDA with detection frequencies over 70%.[84]

Figure 3: Possible Sources of PFAS Exposure

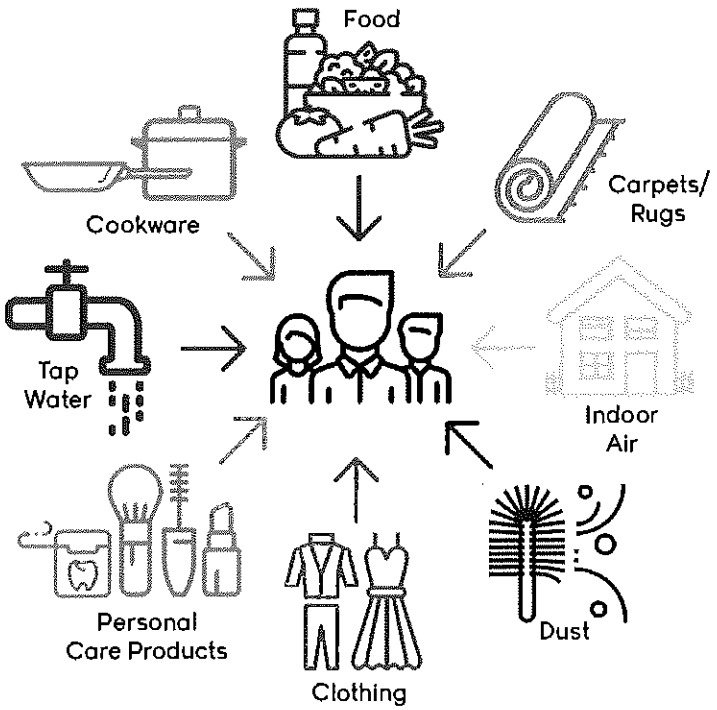

Figure 3 shows the most common pathways of PFAS exposure for humans. PFAS can be found in people's bodies as a result of exposure from multiple environmental sources. [l,m]

Therefore, risk and safety assessments cannot assume that exposures occur in isolation. A person is concurrently exposed to dozens of PFAS chemicals daily, and their exposures extend throughout their lifetimes. Health evaluations should consider the impacts of multiple PFAS chemicals that target the same body systems regardless of detailed knowledge of the underlying mechanism of action. Because PFAS are chemically related, they may have additive or synergistic effects on target systems. An additive effect is when the combined effect of multiple chemicals is the sum of each of the chemicals' effects alone. A synergistic effect is caused when concurrent exposure to multiple chemicals results in effects that are greater than the sum of each of the chemicals' effects alone. For example, many PFAS have been associated with immunological effects. Exposure to a mixture of PFAS could result in adverse effects on the immune system that represents the total dose of all PFAS in the mixture or even greater adverse effects than predicted by summing the dose of all PFAS in the mixture.

PART IV: COMPARISON AND ANALYSIS OF EXISTING HEALTH THRESHOLDS

A number of regulatory and non-regulatory health-based thresholds have been developed for PFAS (mainly PFOA and PFOS) by both federal and state agencies. The data used, and decisions made by these agencies are discussed in this section.

Health advisories issued by the EPA are non-enforceable and non-regulatory. Health advisories provide technical information to state agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination.

Guidance values are state-specific values – used, for example, by the Minnesota Department of Health to evaluate potential human health risks from exposures to chemicals in groundwater – that are non-enforceable goals, benchmarks, or indicators of potential concern. There are three types of guidance values used by Minnesota, health risk limits which are guidance values that have been adopted, and health-based values and risk assessment advice which provide technical guidance but have not yet been formally adopted. In Minnesota, the state develops guidance values by considering health impacts to the most sensitive and most exposed populations across all stages of human development.

Notification levels are state-specific values. California's Division of Drinking Water, for example, has established advisory levels for chemicals in drinking water that lack maximum

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[l] ATSDR, 2018. Agency for Toxic Substances and Disease Registry. Toxicological Profile for Perfluoroalkyls. Draft for Public Comment, June 2018.

[m] Guo, Z, et al., 2009. Perfluorocarboxylic acid content in 116 articles of commerce. *Research Triangle Park, NC: US Environmental Protection Agency*

contaminant levels (MCLs, see below). When these chemicals are detected at concentrations greater than their notification levels, state actions include consumer notification and, for larger exceedances, removal of the source water from the drinking water supply.

EPA defines a **Reference dose (RfD)** as "*an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is generally expressed in units of milligrams per kilogram of bodyweight per day (mg/kg/day).*"[85]

A **minimal risk level (MRL)** is an estimate made by ATSDR of the daily human total exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified route, including routes other than drinking water exposure, and a specified duration of exposure. MRLs serve as screening tools to help public officials decide where to look more closely and identify contaminants of concern at hazardous waste sites. Like EPA's health advisories, MRLs do not carry regulatory weight by requiring agency-initiated cleanup or setting of action or maximum contaminant levels. MRLs are based on noncancer effects only. These MRLs can be used, similar to reference doses, to generate maximum contaminant level goals for drinking water.

A **maximum contaminant level goal (MCLG)** is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, allowing an adequate margin of safety. When determining a MCLG under the federal Safe Drinking Water Act, the EPA considers adverse health risk to sensitive subpopulations, such as infants, children, the elderly, those with compromised immune systems and chronic diseases. MCLGs are non-enforceable health goals and consider only public health and not the limits of detection and treatment technology effectiveness. Therefore, they sometimes are set at levels which water systems cannot meet because of technological limitations.

A **maximum contaminant level (MCL)** is the legal threshold of the amount of a chemical that is allowed in public water systems under the federal Safe Drinking Water Act. A MCL is based on the concentration established by its corresponding MCLG but may be adjusted for feasibility reasons, reflecting difficulties in measuring small quantities of a contaminant, or a lack of available, adequate treatment technologies. The MCL is an enforceable standard and exceedance of the MCL requires water systems to take certain steps, including providing public education, notifying consumers, and adjusting treatment or making structural changes or repairs to come into compliance with the standard for public health protection.

Current or proposed state and federal health thresholds for PFOA and PFOS in drinking water range from 10 ppt to 70 ppt and higher. Although the health thresholds for PFOA and PFOS in drinking water vary, the thresholds cluster at low ppt levels, orders of magnitude lower than thresholds set for many other environmental contaminants. The thresholds are based on adverse health effects, such as developmental effects and cancer risks, and health authorities uniformly acknowledge the serious concerns related to exposure from consuming PFOA and/or PFOS contaminated drinking water. The selection of critical endpoints to use, uncertainty factors to

apply, and estimates of exposure parameters are the major determinants for the variation in the concentrations developed as thresholds. However, none of the federal and state assessments dispute that very serious adverse health effects are associated with exposure to PFOA and PFOS at very low levels of exposure.

The generation of health thresholds by various agencies for PFOA, PFOS, PFNA, PFHxS, and GenX chemicals are **summarized and compared in Tables 4-7** and described in further detail below. Notably, advisories have become more stringent over time as more information becomes available on the exposure to and toxicity of these chemicals.

Table 4: Selected Thresholds for Drinking Water and/or Groundwater- PFOA

Author	Threshold type	Threshold (ppt)	Critical Dose includes UFs (mg/kg/day)	Total UFs	Study Endpoint 2	Drinking water exposure assumptions	Notes
				PFOA			
USEPA	health advisory	70	2×10^{-5}	300	Developmental effects on bone growth and male puberty (Lau, 2006)	0.054 L/kg/day, 90th percentile for lactating women, RSC = 20%	combined with PFOS
Minnesota	guidance value	35	2×10^{-5}	300	Developmental effects on bone growth and male puberty, increased liver weights (Lau, 2006)	modeled for breast- or formula-fed infants, including fetal exposure, RSC = 50%	adopted guidance value - health risk limit - for groundwater
Vermont	health advisory	20	2×10^{-5}	n/a	based on EPA	0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%	combined with PFOS, PFNA, PFHxS, PFHpA (also a ground water enforcement standard); to be adopted as a combined MCL
New Jersey	MCL	14	2×10^{-6}	300	Increased liver weights (Loveless, 2006) + UF for mammary gland effects	0.029 L/kg/day, default adult assumptions, RSC = 20%	proposed; groundwater criteria also proposed at 10 ppt
California	notification level	14	n/a	n/a	Developmental, immunotoxicity, liver toxicity, and cancer	n/a	interim notification levels based on NJ & ATSDR values
ATSDR	environmental media evaluation guide	21	3×10^{-6}	300	Developmental: altered activity, skeletal alterations (Onishchenko, 2011; Koskela, 2016)	0.143 L/kg/day for a infant, RSC = 100%	minimal details provided on calculation of drinking water concentrations from MRL
ATSDR - more protective	estimated MCL	3*	3×10^{-6}	300	Developmental: altered activity, skeletal alterations (Onishchenko, 2011; Koskela, 2016)	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	*threshold for water based on ATSDR's minimal risk level (for total exposure)
NJ - more protective	estimated MCL	0.1	1×10^{-7}	30	**altered mammary gland development**	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	using RfD calculated by New Jersey
Protective choices combined	**MCLG (goal)**	0.01	1×10^{-8}	300**	**altered mammary gland development**	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	****an additional UF of 10, to protect fetuses, infants, children added**

**An additional uncertainty factor of 10 to protect fetuses, infants and children is recommended by the National Academy of Sciences (NAS 1993) for pesticides and as required in the Food Quality Protection Act. 21 U.S.C. §346a(b)(2)(C)(ii)(II).

More protective choices highlighted in bold

Table 5: Selected Thresholds for Drinking Water and/or Groundwater - PFOS

Author	Threshold type	Threshold (ppt)	Critical Dose includes UFs (mg/kg/day)	Total UFs	Study Endpoint 2	Drinking water exposure assumptions	Notes
USEPA	health advisory	70	2×10^{-5}	30	Developmental: decreased pup weight (Leubker, 2005)	0.054 L/kg/day, 90th percentile for lactating women, RSC = 20%	combined with PFOA
Minnesota	guidance value	27	5×10^{-6}	100	Developmental: decreased pup weight (Leubker, 2005)	modeled for breast- or formula-fed infants, including fetal exposure, RSC = 50%	health-based value, provides technical guidance for groundwater
Vermont	health advisory	20	2×10^{-5}	n/a	based on EPA	0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%	combined with PFOS, PFNA, PFHxS, PFHpA (also a ground water enforcement standard); to be adopted as a combined MCL
New Jersey	MCL	13	2×10^{-6}	30	Immunotoxicity: decreased plaque forming response (Dong, 2009)	0.029 L/kg/day, default adult assumptions, RSC = 20%	proposed; groundwater criteria also proposed at 10 ppt
California	notification level	13	n/a	n/a	Developmental, immunotoxicity, liver toxicity, and cancer	n/a	interim notification levels based on NJ & ATSDR values
ATSDR	environmental media evaluation guide	14	2×10^{-6}	300	Developmental: delayed eye opening, decreased pup weight (Leubker, 2005) + UF for immunotoxicity	0.143 L/kg/day for a infant, RSC = 100%	minimal details provided on calculation of drinking water concentrations from MRL
ATSDR - more protective	estimated MCL	2*	2×10^{-6}	30	Developmental: delayed eye opening, decreased pup weight (Leubker, 2005) + UF for immunotoxicity	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	*threshold for water based on ATSDR's minimal risk level (for total exposure)
NJ - more protective	estimated MCL	2	2×10^{-6}	30	Immunotoxicity (Dong, 2009)	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	
ATSDR - more protective	estimated MCL	0.02	2×10^{-8}***	30	**Immunotoxicity (Peden-Adams, 2008)**	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	***critical dose estimated by ATSDR's MRL method
Protective choices combined	**MCLG (goal)**	0.002	2×10^{-9}	300**	**Immunotoxicity**	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	**an additional UF of 10, to protect fetuses, infants, children added**

**An additional uncertainty factor of 10 to protect fetuses, infants and children is recommended by the National Academy of Sciences (NAS 1993) for pesticides and as required in the Food Quality Protection Act. 21 U.S.C. §346a(b)(2)(C)(ii)(II).

More protective choices highlighted in bold

Table 6: Selected Thresholds for Drinking Water and/or Groundwater - PFNA

Author	Threshold type	Threshold (ppt)	Critical Dose includes UFs (mg/kg/day)	Total UFs	Study Endpoint 2	Drinking water exposure assumptions	Notes
Vermont	health advisory	20	n/a	n/a	based on class similarity to PFOA/PFOS, added to original PFOA/PFOS combined MCL	n/a	combined with PFOS, PFNA, PFHxS, PFHpA (also a ground water enforcement standard); to be adopted as a combined MCL
New Jersey	maximum contaminant level (MCL)	13	5 ng/mL ^	1000	Increased liver weights (Das, 2015)	RSC of 50% for 95th percentile general population	adopted; ^ internal serum level, not external dose
ATSDR	environmental media evaluation guide	21	3×10^{-6}	300	Developmental delays, decreased body weight (Das, 2015)	0.143 L/kg/day for a infant, RSC = 100%	minimal details provided on calculation of drinking water concentrations from MRL
ATSDR - more protective	estimated MCL	3*	3×10^{-6}	300	Developmental delays, decreased body weight (Das, 2015)	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	*threshold for water based on ATSDR's minimal risk level (for total exposure)
ATSDR - more protective	estimated MCL	2*	2×10^{-6} #	300	Developmental delays, decreased body weight (Das, 2015)	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	**# Using longer, more representative (men and older women) half-life estimate than ATSDR used (young women)**
Protective choices combined	**MCLG (goal)**	0.2	2×10^{-7}	3000**	Develomental toxicity	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	****an additional UF of 10, to protect fetuses, infants, children added**
**An additional uncertainty factor of 10 to protect fetuses, infants and children is recommended by the National Academy of Sciences (NAS 1993) for pesticides and as required in the Food Quality Protection Act. 21 U.S.C. §346a(b)(2)(C)(ii)(II).							

More protective choices highlighted in bold

Table 7: Selected Thresholds for Drinking Water and/or Groundwater - PFHxS

Author	Threshold type	Threshold (ppt)	Critical Dose includes UFs (mg/kg/day)	Total UFs	Study Endpoint 2	Drinking water exposure assumptions	Notes
ATSDR	environmental media evaluation guide	140	2×10^{-5}	300	Thyroid follicular cell damage (Butenhoff, 2009; Hoberman & York, 2003)	0.143 L/kg/day for a infant, RSC = 100%	minimal details provided on calculation of drinking water concentrations from MRL
Minnesota	guidance value	27	n/a	n/a	based on class similarity to PFOS	n/a	risk assessment advice - for ground water; use PFOS as surrogate for PFHxS until more data is available
ATSDR - more protective	estimated MCL	23*	2×10^{-5}	300	Thyroid follicular cell damage (Butenhoff, 2009; Hoberman & York, 2003)	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	*threshold for water based on ATSDR's minimal risk level (for total exposure)
Vermont	health advisory	20	n/a	n/a	based on class similarity to PFOA/PFOS, added to original PFOA/PFOS combined MCL	n/a	combined with PFOS, PFNA, PFHxS, PFHpA (also a ground water enforcement standard); to be adopted as a combined MCL
Protective choices combined	**MCLG (goal)**	2	2×10^{-6}	3000**	developmental and thyroid toxicity	**0.175 L/kg/day for a infants less than 1 year of age, RSC = 20%**	****an additional UF of 10, to protect fetuses, infants, children added**
**An additional uncertainty factor of 10 to protect fetuses, infants and children is recommended by the National Academy of Sciences (NAS 1993) for pesticides and as required in the Food Quality Protection Act. 21 U.S.C. §346a(b)(2)(C)(ii)(II).							

More protective choices highlighted in bold

PFOA

Comparison

In May 2016, the EPA issued a drinking water health advisory for PFOA of 70 ppt.[3] In the case of co-occurrence of PFOA and PFOS, the sum of the concentrations is not to exceed 70 ppt. The EPA applied a combined uncertainty factor of 300 (10 for human variability, 3 for animal to human toxicodynamic differences, 10 for use of a lowest-observed-adverse-effect-level (LOAEL) instead of a no-observed-adverse-effect-level (NOAEL)) on a LOAEL for decreased bone development in the fore and hind limbs, in pup mice (both sexes) and accelerated puberty in male mice[89] to generate a reference dose of 2×10^{-5} mg/kg/day.

The EPA used drinking water intake and body weight parameters for lactating women in the calculation of their lifetime health advisory due to the potential increased susceptibility during this time window. EPA assumed a drinking water ingestion rate of 0.054 L/kg-day, which represents the 90th percentile water ingestion estimate for a lactating woman, based on direct and indirect water intake of community water supply consumers.[90] The EPA also concluded that there are significant sources of PFOA and PFOS exposure other than drinking water ingestion. As information is not available to quantitatively characterize exposure from all of these different sources, the EPA used a default relative source contribution (RSC, discussed in Box 3) of 20% of daily exposure coming from drinking water and 80% from other sources.

Box 3: Uncertainty Factors

The use of uncertainty factors (UFs) has a long history in developing regulatory standards and guidance for chemicals. Uncertainty refers to our inability to know all the adverse effects related to a chemical, often due to incomplete data. When assessing the potential for risks to people, toxicology studies often involve exposing test animals (generally rats and mice) which are used as a surrogate for humans.[86] A thorough review of the development and use of science-based uncertainty factors is provided by the EPA and National Academy of Sciences.[86,87,88]

Risk assessment for public health protection must account not only for what is known about a chemical's adverse effects, but also what is not known about differences between toxic effects in animals compared to humans; children compared to adults; differences in absorption, metabolism and excretion; and other unknown factors. The selection of uncertainty factors is designed to account for the incomplete understanding or availability of studies upon which toxicity is appraised.

The EPA typically uses factors of 1, 3 (an approximation of $\sqrt{10}$), or 10, depending on the level of uncertainty for each factor.

In June 2016, Vermont published a health advisory for combined exposure to PFOA and PFOS not to exceed 20 ppt based on EPA's selected developmental effects.[91] It also applied combined uncertainty factors of 300 using EPA's rationale, however generated a lower health advisory due to selection of drinking water exposure parameters for a breastfeeding or formula-fed infant. Breastfeeding and formula-fed infants is a population that drinks the largest volume per body

weight and is the most vulnerable to the toxic effects of exposure to PFAS. The 95th percentile Body Weight Adjusted Water Intake Rate for the first year of life based on combined direct and indirect water intake from community water supplies for consumers only is 0.175 L/kg-day.[90,93] Vermont also used a relative source contribution from drinking water of 20%.

In August 2018, Minnesota adopted a guidance value (health risk limit) of 35 ppt for PFOA in groundwater based the same critical endpoint as the EPA.[94] Minnesota applied a combined uncertainty factor of 300 including: 10 for human variability, 3 for animal to human toxicodynamic differences, 3 for use of a LOAEL instead of a NOAEL, and 3 for database uncertainty. Like Vermont, Minnesota's more protective guidance values are due to the use of drinking water exposure estimates based on infants, but also the accounting of a pre-existing body burden through placental transfer (Minnesota calculated a placental transfer factor of 87% based on average cord to maternal serum concentration ratios). Minnesota estimated breastmilk concentrations by applying a breast milk transfer factor of 5.2%, which is an estimate of the amount of PFOA that is transferred from a mother's serum to her breastmilk. As serum levels for PFOA are approximately 100 times the concentration in a person's drinking water, a breast milk transfer factor of 5.2% would result in breast milk concentrations approximately 5 times higher than in the drinking water. However, Minnesota also used a less conservative relative source contribution of 50%, resulting in drinking water values approximately half of EPA's.

Box 4: Relative Source Contribution

One important factor that should be considered when generating a health-protective drinking water limit for a contaminant is the percentage of the total allowable dose (RfD or MRL) that comes from water, versus other exposure routes. The portion of a total daily dose that comes from a specific exposure route (such as drinking water) is represented by a relative source contribution (RSC).

EPA suggest RSC's for drinking water range from 0.2 to 0.8 (20% to 80% coming from drinking water). In the absence of complete data, the EPA's default RSC value is 0.2.

- Studies demonstrate that there are many other sources of PFAS exposure, including food and consumer products, though the relative contribution from each source is still poorly understood.
- For children, researchers estimated exposure to PFOA and PFOS from hand-to-mouth transfer from treated carpets to be 40–60% of the total uptake in infants, toddlers, and children.[92]
- Therefore, the RSC from drinking water for this vulnerable population should not exceed 0.4 (40%). Importantly, as we do not understand all the exposure sources for this population, the default value of 0.2 is the most protective and recommended.

In March 2017, New Jersey derived a recommended MCL in water for PFOA of 14 ppt based on increased liver weight in rodent studies.[95] Previously in 2007, New Jersey issued a preliminary drinking water guidance level for PFOA of 40 ppt, which was revised in 2016 to a more stringent level of 14 ppt based on chronic exposure from drinking water for cancer and non-cancer

endpoints. Non-cancer endpoints were derived based on increased liver weight with applied uncertainty factors of 300 (10 for human variability, 3 for animal to human toxicodynamic differences, and 10 to protect against more sensitive toxicological effects). The more protective health threshold is mainly due to the use of an additional uncertainty factor of 10 to protect against more sensitive toxicological effects (delayed mammary gland development), which is explained by New Jersey in the following excerpt:

> *"Delayed mammary gland development from perinatal exposure is the most sensitive systemic endpoint for PFOA with data appropriate for dose-response modeling. It is a well-established toxicological effect of PFOA that is considered to be adverse and relevant to humans for the purposes of risk assessment.*
>
> *To the knowledge of the Health Effects Subcommittee, an RfD for delayed mammary gland development has not previously been used as the primary basis for health-based drinking water concentrations or other human health criteria for environmental contaminants. Because the use of this endpoint as the basis for human health criteria is a currently developing topic, the Health Effects Subcommittee decided not to recommend a Health-based MCL with the RfD for delayed mammary gland development as its primary basis. However, the occurrence of this and other effects at doses far below those that cause increased relative liver weight (the endpoint used as the primary basis for the recommended Health-based MCL) clearly requires application of an uncertainty factor to protect for these more sensitive effects."*[95]

The MCL based on cancer endpoints was derived from testicular tumor data from chronic dietary exposure in rats and also resulted in a MCL of 14 ppt. New Jersey used values for adult drinking water exposure (0.029 L/kg-day) and a relative source contribution of 20%. In January 2019, New Jersey announced a proposed specific ground water quality criteria based on the same reasoning for its proposed MCL, however, since interim ground water criteria are rounded to one significant figure in New Jersey, the proposed criteria for PFOA is 10 ppt (0.01 µg/L).[96]

In June 2018, ATSDR generated a MRL for PFOA.[5] A MRL exposure scenario of 3×10^{-6} mg/kg/day was based on a LOAEL of 0.000821 mg/kg/day for neurodevelopmental and skeletal effects in mice[97,98] with an uncertainty factor of 300 (10 for use of a LOAEL instead of a NOAEL, 3 for extrapolation from animals to humans with dosimetry adjustments, and 10 for human variability). A MCLG based on ATSDR's MRL for PFOA would be 11 ppt, using the same assumptions and parameters the EPA used for calculating their health advisory (based on lactating mothers), or 3 ppt, using drinking water exposure assumptions based on breastfeeding and formula-fed infants (see Appendix C for MCLG calculations).

Box 5: ATSDR's Environmental Media Evaluation Guides

In November 2018 ATSDR posted on its website a webpage entitled "ATSDR's Minimal Risk Levels (MRLs) and Environmental Media Evaluation Guides (EMEGs) for PFAS."[99] ATSDR provides the body weights and drinking water intake rates it would use for an average adult or child (under one year) and lists what the corresponding drinking water

concentrations would be if converted from ATSDR's proposed MRLs: for an adult 78 ppt for PFOA, 52 ppt for PFOS, 517 ppt for PFHxS, and 78 ppt for PFNA; and for a child, 21 ppt for PFOA, 14 ppt for PFOS, 140 ppt for PFHxS, and 21 ppt for PFNA. ATSDR does not provide any details as to how it derived the values presented on the webpage. However, based on the information ATSDR did provide, drinking water values, body weight and intake rates, we were able to calculate the relative source contribution used by ATSDR. According to our calculations, ATSDR used a relative source contribution of 1, which assumes that 100% of a person's exposure comes from drinking water, not 20% or 50%, as all other agencies have adopted (see Appendix E for calculations).

Studies demonstrate that there are many other sources of PFAS exposure, including food and consumer products. For example, NHANES demonstrates that greater than 95 percent of Americans have detectable PFAS in their bodies, however many of these Americans do not have detectable PFAS in their drinking water. Therefore, the assumption that a person would be only exposed to PFAS from drinking water is not supported by the scientific literature.

In June 2018, at the request of the California State Water Resources Control Board, the California Office of Environmental Health Hazard Assessment (OEHHA) recommended an interim notification level of 14 ppt for PFOA in drinking water.[100] The notification level is based on developmental toxicity, immunotoxicity, liver toxicity, and cancer. OEHHA reviewed currently available health-based advisory levels and standards, including the documents and process used by New Jersey to derive its water advisory levels. OEHHA found New Jersey's process to be both rigorous and sufficient for establishing an interim notification level for PFOA. They note that this level is similar to that derived by ATSDR, whose minimal risk level equates to a drinking water advisory level of 13 ppt for PFOA, as calculated by OEHHA. OEHHA is currently completing its own derivation of a recommended drinking water notification level for PFOA.

In December 2018, the New York Drinking Water Quality Council recommended that the New York Department of Health adopt MCLs of 10 ppt each for PFOA and PFOS.[101] Although no supporting documentation is currently available in relation to this recommendation, the council notes that these levels "take into consideration the national adult population's "body burden," or the fact that all adults already have some level of exposure to these and other related chemicals."

Analysis

Although altered mammary gland development is the most sensitive endpoint for PFOA exposure,[67,68,69] both the EPA and ATSDR did not consider altered mammary gland development as the critical effect in their toxicity assessment of PFOA.

The EPA excluded the results of the mammary gland findings based on the agency's view that the effects were of "unknown biological significance," concern for variability in the sensitivity for these effects amongst mice strains,[69] the fact that the mode of action for these effects are

unknown, and that mammary gland effects had not been previously used for risk assessment.[3] Similarly, ATSDR classified altered mammary gland development as not adverse due to uncertainty around the effect's biological significance.

However, experts in the field have concluded that changes in mammary gland growth and differentiation, including changes in developmental timing, are a health concern.[102] Studies have shown a relationship between altered breast development, lactational deficits and breast cancer (discussed further in Box 6). Therefore, unless it can be shown that this relationship does not exist for PFOA, altered mammary gland growth and differentiation should be considered an adverse health effect of PFOA exposure and the critical endpoint for PFOA.

Box 6: "Is altered mammary development an adverse effect?"

Both the EPA and ATSDR did not consider altered mammary gland development as the critical effect in their toxicity assessment of PFOA. However, in a 2009 a workshop of experts in mammary gland biology and risk assessment came to the consensus that changes in mammary gland growth and differentiation, including changes in developmental timing, are a health concern.[102] Altered mammary gland development may lead to difficulty in breastfeeding and/or an increase in susceptibility to breast cancer later in life.[103]

Only one animal study has assessed the effects of PFOA exposure on mammary gland growth and differentiation for multiple generations.[68] The authors saw striking morphological abnormalities in the lactating glands of dams (mothers) chronically exposed to environmentally relevant levels of PFOA; however, no effects on body weight of their pups were seen. It is possible that compensatory behavior, such as increased number of nursing events per day or longer nursing duration per event masked a decreased potential in milk production by the dams, however the authors did not evaluate these endpoints in the study. It is also possible that PFOA exposure could increase time to peak milk output through the reduction in number and density of alveoli available to produce milk.

For human mothers, low-level functional effects on lactation that cause even a short delay in substantial milk output might result in cessation in breastfeeding before the recommended time-frame. This is supported by a cohort study that found an inverse correlation between levels of maternal serum PFOA and duration of breastfeeding.[104]

Early life exposures to factors that disrupt development may influence susceptibility to carcinogens later in life. For example, hormone disruption is an important determinant of breast cancer susceptibility in humans and rodents.[105] Proliferating and undifferentiated structures, such as terminal end buds, display elevated DNA synthesis compared to other mammary gland structures; which is why terminal end buds are considered the most vulnerable mammary gland target structure of carcinogen exposure.[106] Delays in mammary gland development would result in a prolonged window of increased vulnerability to carcinogens. In humans, perturbations to the timing of menarche is linked to breast cancer.[107] This further raises the concern that changes in patterns of breast development in U.S. girls could be contributing to an increased risk of breast cancer or other adult diseases later in

life.[108] However, an increase in susceptibility to breast cancer later in life was not explored in the multigeneration mammary gland development study.[68]

In general, "*developmental delay can reflect an overall detrimental effect of chemical exposure that lead to growth and developmental deficit in the offspring*," as the Michigan PFAS Science Advisory Panel states in its discussion of EPA's choice of reduced bone ossification as a critical endpoint.[26]

New Jersey did classify delayed mammary gland development as adverse, though, it stopped short of using it to generate their MCL for PFOA. However, New Jersey did calculate a reference dose, 1.1×10^{-7} mg/kg/day, based on delayed mammary gland development. If this more protective reference dose were used, the MCLG for PFOA would be less than 1 ppt, regardless of which population the drinking water parameters are based on (see Appendix D for calculation). The MCLG would be lowered even further below 1 ppt if an additional uncertainty factor of 10 was applied to ensure adequate protection of fetuses, infants and children, as recommended by the National Academy of Sciences and as required in the Food Quality Protection Act (see Box 7).

PFOS

Comparison

In May 2016, the EPA issued a drinking water health advisory for PFOS of 70 ppt,[28] with the sum of PFOA and PFOS concentrations not to exceed 70 ppt. The EPA applied combined uncertainty factors of 30 (10 for human variability, 3 for animal to human toxicodynamic differences) on a NOAEL of decreased pup weight in a two-generation rat study.[109] As with PFOA, the EPA used drinking water intake and body weight parameters for lactating women and a relative source contribution of 20%.

As mentioned above, in June 2016 Vermont published a health advisory for total concentrations of PFOA and PFOS in drinking water at 20 ppt based on EPA's selected developmental effects and drinking water exposure parameters for breastfeeding or formula-fed infants.[91]

In May 2017, Minnesota proposed a groundwater guidance value (health-based value) of 27 ppt for PFOS based the same critical endpoints as the EPA.[110] However, Minnesota applied a larger combined uncertainty factor than the EPA. Minnesota applied a total uncertainty factor of 100 including: 3 for animal to human toxicodynamic differences, 10 for human variability and an additional 3 for database uncertainty (based on the need for additional immunotoxicity data). Minnesota accounted for a pre-existing body burden through a placental transfer factor of 46%, used drinking water exposure estimates based on infants with an estimated breast milk transfer factor of 1.3%, and used a relative source contribution of 50%.

In June 2018, New Jersey derived a recommended MCL in water for PFOS of 13 ppt for chronic exposure from drinking water based on immune suppression in mice,[112] an endpoint that is significantly more sensitive than the endpoint used by EPA.[113] New Jersey applied a combined uncertainty factor of 30 (10 for human variability and 3 for animal to human toxicodynamic differences) to an internal NOAEL of 674 ng/ml of PFOS in animal serum to generate an human serum target level. This target level was then multiplied by a clearance factor to arrive at a reference dose of 1.8×10^{-6} mg/kg/day. New Jersey used values for adult drinking water exposure and a relative source contribution of 20%. Like for PFOA, in January 2019, New Jersey announced a proposed specific ground water quality criteria based on the same reasoning for its proposed MCL, however, since interim ground water criteria are rounded to one significant figure in New Jersey, the proposed criteria for PFOS is 10 ppt (0.01 µg/L).[114]

Box 7: Additional Protection for Fetuses, Infants, and Children

The National Academy of Sciences has recommended the use of an additional uncertainty factor of 10 to ensure protection of fetuses, infants and children who often are not sufficiently protected from toxic chemicals such as pesticides by the traditional intraspecies (human variability) uncertainty factor.[111] Congress adopted this requirement in the Food Quality Protection Act for pesticides in foods. 21 U.S.C. 346a(b)(2)(C)(ii)(II)

Considering the many health effects linked to PFAS that affect this vulnerable population and the substantial data gaps on exposure and toxicity of these compounds in complex mixtures, we recommend the use of this uncertainty factor when deriving health-protective thresholds for PFAS.

In June 2018, ATSDR generated a MRL for PFOS based on delayed eye opening and decreased pup weight[109] in rats.[5] A MRL exposure scenario of 2×10^{-6} mg/kg/day was based on a NOAEL of 0.000515 mg/kg/day using an uncertainty factor of 300 (10 for concern that immunotoxicity may be a more sensitive endpoint than developmental toxicity, 3 for extrapolation from animals to humans with dosimetry adjustments, and 10 for human variability). A MCLG based on ATSDR's MRL for PFOS would be 7 ppt, using EPA's drinking water exposure assumptions, or 2 ppt, using drinking water exposure assumptions based on breastfeeding and formula-fed infants (see Appendix C for MCLG calculations).

In June 2018, at the request of the California State Water Resources Control Board, OEHHA recommended an interim notification level of 13 ppt for PFOS in drinking water.[100] The notification level is based on the same analysis performed for PFOA, described above. OEHHA notes that this level is similar to that derived by ATSDR, whose minimal risk level equates to a drinking water advisory level of 9 ppt for PFOS, as calculated by OEHHA. OEHHA is currently completing its own derivation of recommended drinking water notification levels for PFOS.

As noted above, a MCL of 10 ppt each for PFOA and PFOS were recommended by the New York Drinking Water Quality Council.[101]

Analysis

Immunotoxicity is currently the most sensitive health endpoint known for PFOS exposure. As documented in the ATSDR's profile, both animal and epidemiology studies provide strong evidence linking PFOS exposure to immunotoxic effects (decreased antibody response to vaccines in humans, decreased host resistance to viruses, and suppressed immune response to antigens in animals). The National Toxicology Program also reviewed the immunotoxicity data on PFOA and PFOS in 2016 and concluded that both are presumed to constitute immune hazards to humans[70] (discussed further in Box 1).

Again, although immunotoxicity is the most sensitive endpoint for PFOS exposure, the EPA excluded immune system effects based on uncertainties related to mode of action, variation in dose effects between studies, differences in sensitivity between males and females, and lack of a *"demonstrated clinically recognizable increased risk of infectious diseases as a consequence of a diminished vaccine response."*[28]

ATSDR states concern that immunotoxicity is a more sensitive endpoint than developmental toxicity; however, it stops short of deriving a MRL from this endpoint. Instead, ATSDR posits that an additional modifying, or uncertainty factor of 10 is sufficient to address the doses where immunotoxic effects have been observed. However, this value is only consistent with the immunotoxicity study with the highest LOAEL.[115] The other immunotoxicity studies all result in MRLs approximately 2.5-100 times lower than those currently calculated (see Appendix A for MRL derivations). If a MCLG were generated from the most sensitive health endpoint (immunotoxicity) and from the study with the lowest LOAEL, as is normally done by ATSDR, it would be less than 1 ppt (see Appendix C for MCLG calculations). The MCLG would be lowered even further below 1 ppt if an additional uncertainty factor of 10 was applied to ensure adequate protection of fetuses, infants and children, as recommended by the National Academy of Sciences and as required in the Food Quality Protection Act. Additionally, a MCLG based on benchmark dose calculations for immunotoxicity in children would also be approximately 1 ppt.[116]

New Jersey did select immunotoxicity as its critical health effect, resulting in the lowest generated reference dose for PFOS. However, the use of adult drinking water assumptions results in a higher proposed MCL than what we have calculated using estimated MRLs based on immunotoxicity (see Appendix A and C).[n]

PFNA

Comparison

[n] Additionally, there are a couple of differences between New Jersey's and ATSDR's approach to generating a RfD/MRL, including the use of slightly different clearance factors and ATSDR's use of the trapezoid rule to estimate a time weighted average serum concentration for the animal point of departure.

In July 2015, New Jersey proposed a MCL for PFNA of 13 ppt for chronic exposure from drinking water based on increased liver weight in rodents[117] with a total uncertainty factor of 1000 (10 for human variability and 3 for animal to human toxicodynamic differences, 10 for less than chronic exposure duration, and 3 for database uncertainty).[118] Extrapolation from animal to human dose levels were made on the basis of internal serum levels rather than administered dose and were based on an estimated 200:1 ratio between PFNA serum levels and drinking water concentration in humans. A chemical-specific relative source contribution of 50% was developed using the "subtraction" approach. A subtraction approach is used when other sources of exposure (air, food, consumer product, etc.) can be considered background, and can thus be subtracted from the total dose to arrive at the allowable limit or dose from drinking water.[119] New Jersey based their calculations on the 2011-12 NHANES biomonitoring data for the 95th percentile PFNA serum level in the U.S. general population. This MCL was adopted into law in September 2018.[120] As of January 2019, this is the only finalized, enforceable drinking water limit for a PFAS chemical. New Jersey also has a specific ground water quality criteria for PFNA set at 13 ppt, based on its MCL for PFNA.

In July 2018, Vermont updated its drinking water health advisory level to include (based on class similarity) PFOA, PFOS, PFHxS, PFHpA, and PFNA for a combined total not to exceed 20 ppt.[121] Based on its health advisory, Vermont updated its enforceable groundwater standard to include all 5 PFAS at a combined 20 ppt.[122] In January 2019, Vermont announced it will initiate the process of adopting its health advisory for these five PFAS as an enforceable MCL.[123]

For PFNA, ATSDR based its assessment on decreased body weight and developmental delays in mice pups.[5,117] A MRL exposure scenario of 3×10^{-6} mg/kg/day was based on a NOAEL of 0.001 mg/kg/day using an uncertainty factor of 300 (10 for database limitations, 3 for extrapolation from animals to humans with dosimetry adjustments, and 10 for human variability).[5] A MCLG based on ATSDR's MRL for PFNA would be 11 ppt, using EPA's drinking water exposure assumptions for PFOA and PFOS, or 3 ppt, using drinking water exposure assumptions based on breastfeeding and formula-fed infants (see Appendix C for MCLG calculations).

Analysis

Importantly, ATSDR underestimated the half-life of PFNA in humans. In the paper used to estimate the half-life of PFNA,[124] two different half-life values were derived: one of 900 days for young women and one of 1,570 days for everyone else. Younger women of childbearing age have additional excretion pathways for PFAS than other populations, including through breastmilk and menstruation. ATSDR provided no rationale for why the shorter half-life was selected. The longer half-life represents a larger population with minimal excretion pathways for PFNA and would result in a more protective MRL value. Importantly, New Jersey's 200:1 estimated ratio between PFNA serum levels and drinking water concentration in humans is based on the longer, more representative half-life of 1,570 days.[118] When the longer half-life is used, the resulting MRL is 2×10^{-6} mg/kg/day (see Appendix B for MRL calculations). A MCLG based on this more protective MRL for PFNA would be 7 ppt, using EPA's drinking water

exposure assumptions for PFOA and PFOS, or 2 ppt, using drinking water exposure assumptions based on breastfeeding and formula-fed infants (see Appendix C for MCLG calculations). The MCLG would be below 1 ppt if an additional uncertainty factor of 10 was applied to ensure adequate protection of fetuses, infants and children, as recommended by the National Academy of Sciences and as required in the Food Quality Protection Act.

PFHxS

Comparison

As mentioned above, Vermont's drinking water health advisory and its groundwater standard now includes PFOA, PFOS, PFHxS, PFHpA, and PFNA for a combined total not to exceed 20 ppt and Vermont is now in the process of adopting the advisory as a MCL. [121,123]

Minnesota recently recommended using PFOS as surrogate for PFHxS until more data is available, setting a guidance value (risk assessment advice) of 27 ppt for PFHxS.[125]

For PFHxS, ATSDR based its assessment on thyroid follicular cell damage in rats.[126,127] A MRL exposure scenario of 2×10^{-5} mg/kg/day was based on a NOAEL of 0.0047 mg/kg/day using an uncertainty factor of 300 (10 for database limitations, 3 for extrapolation from animals to humans with dosimetry adjustments, and 10 for human variability).[5] A MCLG based on ATSDR's MRL for PFHxS would be 74 ppt, using EPA's drinking water exposure assumptions for PFOA and PFOS, or 23 ppt, using drinking water exposure assumptions based on breastfeeding and formula-fed infants (see Appendix C for MCLG calculations). The MCLG would be lowered to 2 ppt if an additional uncertainty factor of 10 was applied to ensure adequate protection of fetuses, infants and children, as recommended by the National Academy of Sciences and as required in the Food Quality Protection Act.

GenX

Comparison

In 2017, North Carolina set a non-enforceable health goal for the GenX chemical, HFPO dimer acid, to 140 ppt in drinking water.[128] The health goal was based on a reference dose of 1×10^{-4} mg/kg/day, generated from a NOAEL for liver toxicity in mice (single-cell necrosis in hepatocytes and correlative increases in liver enzymes) with combined uncertainty factor of 1000 (10 for human variability, 10 for animal to human toxicodynamic differences, 10 for extrapolating from subchronic to chronic exposure duration). According to North Carolina Department of Human Health Services, their health goal for GenX is for "the most vulnerable population – i.e. bottle-fed infants, the population that drinks the largest volume of water per body weight."[128] The state used drinking water exposure assumptions based on bottle-fed infants (0.141 L/kg/day) and a relative source contribution of 20%.

In November 2018, the EPA proposed a chronic reference dose of 8 x 10^{-5} mg/kg/day for two GenX chemicals, HFPO dimer acid and its ammonium salt.[23] The EPA applied a combined uncertainty factor of 300 (10 for human variability, 3 for animal to human toxicodynamic differences, 3 for database limitations, and 3 for extrapolation from subchronic to chronic exposure duration) on a NOAEL for single-cell necrosis in livers of male mice from a DuPont study.[129] The EPA did not provide drinking water values in their toxicity assessment of GenX chemicals, however, using EPA's drinking water exposure assumptions for PFOA and PFOS, a MCLG would be 296 ppt, or 91 ppt using drinking water exposure assumptions based on breastfeeding and formula-fed infants (see Appendix F for calculations).

Analysis

The EPA notes that there are the following database deficiencies for GenX chemicals: no human data from epidemiological studies, limited testing for developmental toxicity and immunological responses, lack of a full two-generational reproductive toxicity study, and lack of a chronic study in mice (which appear to be more sensitive to GenX than rats). Additionally, of the studies considered for the development of the reference dose, only two were published in a peer-reviewed journal. These are significant limitations in the toxicity data available for GenX, and as such, an uncertainty factor of 3 is unlikely to be sufficient. Importantly, North Carolina does not apply an uncertainty factor for database limitations at all. In comparison, ATSDR used an uncertainty factor of 10 for database limitations for PFNA and PFHxS due to a lack of or limited testing of developmental and immunological effects, which ATSDR states are two of the most sensitive PFAS endpoints.[5]

To extrapolate from animal to human dose, the EPA used the Body Weight$^{3/4}$ allometric scaling approach, which is based on body surface area and basal metabolic rate in adults. This approach does not account for differences in toxicokinetics between animals and humans, which for PFAS are often vastly different. The Netherland's National Institute for Public Health and the Environment (RIVM) determined that although the elimination rates for GenX are faster than PFOA in animal models, without data in humans, it is not possible to make assumptions on the toxicokinetics of GenX chemicals in humans.[130] Due to the uncertainty from lack of human toxicokinetic data on GenX chemicals, RIVM calculated and applied an additional uncertainty factor to account for the potential kinetic difference between animals and humans.
This additional toxicokinetic factor used by RIVM is based on the difference in half-lives between cynomolgus monkeys and humans for PFOA. A half-life ratio was calculated using a half-life of 1378 days in humans[131] and of 20.9 days in male cynomolgus monkeys[132] resulting in an additional toxicokinetic factor of 66 (1378 / 20.9). This additional uncertainty factor to account for the potential kinetic difference between animals and humans is an example of an alternative approach to extrapolating animal doses to human doses for PFAS like GenX that do not yet have human toxicokinetic data. Considering the limitations of EPA's scaling approach, an uncertainty factor of 3 to account for interspecies toxicokinetic differences is likely to be insufficient.

Finally, North Carolina used an uncertainty factor of 10 to extrapolate from subchronic to chronic exposure duration, compared to the EPA's use of an uncertainty factor of 3. The EPA

states that effects for the subchronic study it selected (performed in mice) are consistent with effects seen for the single chronic study available. However, the chronic study is in rats, a species that the EPA acknowledges is much less sensitive to the effects of GenX than mice. Therefore, this logic is not supported by the EPA's own findings.

If uncertainty factors that properly reflected the deficiencies in toxicity data (database, sub-chronic to chronic, children's vulnerability, human variability, animal to human differences) were used, the combined uncertainty factor could be as high as 100,000, which would result in a MCLG of less than 1 ppt for GenX chemicals (see Appendix F for calculations). This highlights the current considerable level of uncertainty in determining a safe level of exposure for GenX chemicals.

Box 8: Epidemiological Data in Risk Assessment

To generate accurate and relevant health thresholds, all toxicological information available should be evaluated. Epidemiological studies provide direct information on effects of chemical exposures in people. However, epidemiological data from human health studies are not always utilized. Human studies should be used in conjunction with animal studies to best inform risk assessment.

Use of epidemiology data in risk assessment is not a new approach, for example, epidemiological data was used quantitatively in an EPA evaluation of risk for methylmercury, as recommended by the National Academy of Sciences.[133] The EPA based the oral reference dose on lasting neurological effects in children exposed during early life.[134] In 2018, the European Food Safety Authority (EFSA) derived health-based guidance values for PFOA and PFOS based on epidemiological studies.[135] EFSA used benchmark modelling of serum levels to generate daily tolerable intakes (similar to a reference dose, a daily or weekly tolerable intake is an estimate of the amount of a substance in food or drinking water which can be consumed over a lifetime without presenting an appreciable risk to health) of 0.8 ng/kg/bw for PFOA based on increased serum cholesterol in adults and 1.8 ng/kg/bw for PFOS based on increased serum cholesterol in adults and decrease in antibody response at vaccination in children. These values are approximately 10-20 times stricter than the reference dose generated by the EPA, 20 ng/kg/bw.

Another powerful way of using epidemiological data is demonstrated by the Michigan PFAS Science Advisory Panel's use of epidemiology data to evaluate the EPA's health advisory level of 70 ppt for PFOA and PFOS.[26] The Panel estimated that drinking water with 70 ppt of PFOA over several years would result in serum concentrations around 10,000 ppt in adults and 16,500 ppt among those with higher consumption (such as nursing mother and infants). For adults, the Panel used a model[136] to estimate that 8,000 ppt would result from drinking water that contained 70 ppt PFOA, which is in addition to 2,000 ppt from background exposures (as estimated from NHANES national biomonitoring data).

A PFOA serum concentration of 10,000 ppt would represent the first quartile in the C8 study (contaminated community) and the top bracket in epidemiology studies of the general population. Many health effects have been seen in epidemiology studies at these blood serum concentrations. The Panel concludes, ***"...this evaluation places those with chronic exposure to 70 ppt or higher levels of PFOA in their drinking water well within the range at which credible associations with health effects were found by the C8 Science Panel studies."***[26] In other words, human data shows that the EPA's health advisory for PFOA and PFOS is not health protective.

Conclusions

Differences in the selection of critical endpoints and the application of uncertainty factors have led to the generation of different health thresholds for PFOA, PFOS, PFNA, PFHxS and GenX chemicals. Another source of variation in health thresholds comes from differences in exposure assumptions, such as drinking water intake rate, body weight and relative source contribution from drinking water. For example, the exposure levels of an average male adult versus a lactating mother versus a breastfeeding or formula-fed infant vary greatly. For an in-depth discussion of the main sources of variation in current health thresholds for PFOA and PFOS, including "*managing scientific uncertainty, technical decisions and capacity, and social, political, and economic influences from involved stakeholders*," see recently published article by researchers from Whitman College, Silent Spring Institute, and Northeastern University.[137]

Evidence shows that PFAS exposure poses a high risk to fetuses, infants, children and pregnant women. There is particular risk for sensitive members of the population from chemicals of such persistence and clear adverse effects at very low levels of exposure. Decisions made when developing a health threshold, such as evaluation of data gaps, the selection of uncertainty factors, and the choice of exposure parameters to use, should be made to be protective of the most vulnerable populations, particularly developing fetuses, infants, and children.[138]

Taking into consideration the above information, for risk assessment we recommend: 1) the use of the most sensitive health endpoint, regardless of whether the endpoint has been used in a risk assessment previously; 2) the use of drinking water exposure parameters that protect vulnerable populations, particularly breastfeeding or formula-fed infants; 3) the use of an additional uncertainty factor of 10 to protect fetuses, infants and children as recommended by the National Academy of Sciences[111] and as required in the Food Quality Protection Act (see Box 7); 4) the use of both human and animal data when assessing the toxicity of a chemical, or group of

Box 9: Real-World Exposures

Fundamentally, exposures to PFAS occur as mixtures. With individual PFAS targeting many of the same biological systems, concurrent exposures to multiple PFAS likely have additive or synergistic effects. Therefore, traditional toxicity assessments that assume exposures to a chemical occur in isolation could be significantly underestimating the real-world effects of PFAS.

chemicals (see Box 8); and 5) the examination of possible additive or synergistic effects from exposure to mixtures of similar chemicals that target the same biological systems (see Box 9).

PART V: DETECTION/ANALYTICAL METHODS AND TREATMENT TECHNOLOGIES

As discussed in this section, PFOA, PFOS, PFNA, PFHxS, and GenX chemicals can be reliably quantified and treated to low levels, therefore, it is feasible for the state to establish strict MCLs for such PFAS. At present, there is no single methodology for isolating, identifying, and quantifying all PFAS in drinking water. Until total PFAS can be reliably quantified, the state should establish a treatment technique for the class of PFAS chemicals.

Analytical Methods for Detecting and Measuring Concentrations of PFAS

When a laboratory measures an chemical, the laboratory often reports the method detection limit (MDL) and the method reporting limit (also sometimes called the minimum reporting limit or limit of quantification).[42] The MDL is the minimum concentration of a substance that can be measured and reported with 99% confidence that the chemical is present in a concentration greater than zero; any concentration measured below the minimum detection limit is considered non-detect. The method reporting limit is the lowest chemical concentration that meets data quality objectives that are developed based on the intended use of this method; concentrations above this limit are considered quantified with statistical rigor. A laboratory may also report the single laboratory lowest concentration minimum reporting limit (LCMRL), a value between the method detection and reporting limits, which is the "lowest true concentration for which the future recovery is predicted to fall, with high confidence (99%), between 50 and 150% recovery."[42] Action levels, such as a MCL, should be set at or above the method reporting limit.

Figure 4: Detection, Quantification and Reporting Limits

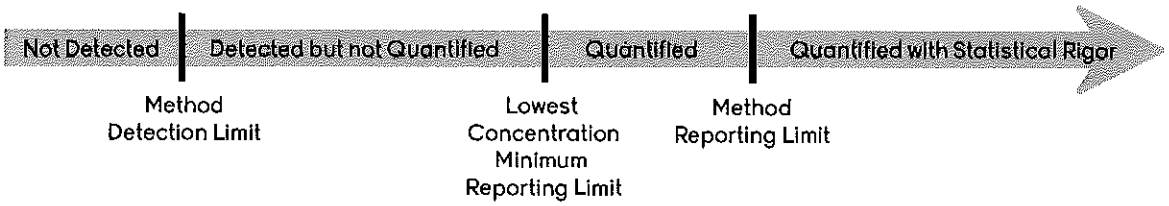

Figure 4 shows the relationship between the types of detection and quantification limits for laboratory testing. The method detection limit (MDL) is the lowest concentration that can be detected. The lowest concentration minimum reporting limit (LCMRL) is the lowest concentration that can be quantified and the method reporting limit, also known as the limit of

quantification (LOQ), is the lowest concentration that can be reliably quantified and meets data quality objectives.[o]

The detection sensitivity of PFAS varies depending on the method of analysis used to quantify the results and the laboratory conducting the analysis. Historically, laboratories have used a liquid chromatography-tandem mass spectrometry method such as EPA Method 537, or a modified version,[139] with quantified reporting limits in the low single-digit ppt range. EPA Method 537, updated in November 2018 and referred to as Method 537.1, now includes detection limits ranging from 0.53 to 2.8 ppt for the 18 PFAS compounds included in the updated testing method.[140] In studies where an alternative method is used, researchers were able to achieve reporting limits below 1 ppt for PFOS, PFNA, and PFHxS. In Europe and Australia, reporting limits of less than 1 ppt for PFOA have been achieved.[141] Prominent laboratories that provide analytical detection services for PFAS, including at least one used by the state of Michigan, have already established reporting limits of 2 ppt for at least 17 PFAS compounds including PFOA, PFOS, PFNA, and PFHxS, and a reporting limit of 5 ppt for GenX, using EPA Method 537 or Method 537.1; and one company confirms a 2 ppt reporting limit for the additional PFAS compounds in the updated EPA Method 537.1 will be achievable, except for GenX, which would typically be reported at 5 ppt, but can be lowered to a 2 ppt with an alternative analytical method.[142]

EPA Method 537.1

EPA Method 537.1 is a solid phase extraction (SPE) liquid chromatography/tandem mass spectrometry (LC/MS/MS) method for the determination of selected PFAS in drinking water.[140] This method can be used to quantify 18 PFAS compounds including PFOA, PFOS, PFNA, PFHxS, and a GenX chemical, HFPO dimer acid. The EPA states that detection limits range from 0.53 to 1.9 ppt and single laboratory LCMRLs range from 0.53 – 2.7 ppt for PFOA, PFOS, PFNA, PFHxS, and HFPO-DA. We recommend that, at minimum, the state require the use EPA Method 537.1 with method reporting limits of 2 ppt, 5 ppt for GenX, when testing for PFAS in drinking water.

Table 8: Method Reporting Limits from three sources that use EPA Method 537 and/or 537.1

Contaminant	CAS Registry Number	Method Reporting Limits (ppt)			
		EPA 537.1[p]	UCMR3[q]	Eaton Analytics[r]	Vista Analytical[s]
PFOS	1763-23-1	2.7	40	2	2
PFOA	335-67-1	0.82	20	2	2

[o] Adapted from https://acwi.gov/monitoring/webinars/mpsl_qa_services_intro_rls_012517.pdf

[p] LCMR from https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=537290&Lab=NERL

[q] https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule

[r] http://greensciencepolicy.org/wp-content/uploads/2017/12/Andy_Eaton_UCMR3_PFAS_data.pdf

[s] http://www.vista-analytical.com/documents/Vista-PFAS-rev3.pdf

PFNA	375-95-1	0.83	20	2	2
PFHxS	355-46-4	2.4	30	2	2
HFPO-DA	13252-13-6	4.3	Not available	5	Not available

Table 8 shows the method reporting limits documented for the new EPA Method 537.1, the method reporting limits under the unregulated contaminant monitoring rule 3 (UCMR3) for EPA Method 537, and the method reporting limits reported by two laboratories that conduct testing of PFAS compounds, Eaton Analytical and Vista Analytical.

Alternative Analytical Methods

A Water Research Foundation report published in 2016[143] evaluated the ability of a wide spectrum of full-scale water treatment techniques to remove PFASs from contaminated raw water or potable reuse sources. One of the studies in the report was conducted at Southern Nevada Water Authority's Research and Development laboratory where researchers used a methodology that was able to achieve reporting limits below 1 ppt for several PFAS compounds, including PFOS, PFNA and PFHxS. The method used by researchers in this study is described as "*an analysis... via liquid-chromatography tandem mass-spectrometry (LC-MS/MS) using a previously reported method,[144] adapted and expanded to include all analytes of interest*". This method achieved minimum reporting limits below 1 ppt for PFOS, PFNA, and PFHxS.

Table 9: Minimum Reporting Levels Using Southern Nevada Water Authority Method

Contaminant	CAS Registry Number	Minimum Reporting Level (ppt)
PFOS	1763-23-1	0.25
PFOA	335-67-1	5
PFNA	375-95-1	0.5
PFHxS	355-46-4	0.25

Table 9 shows the minimum reporting levels achieved by the Southern Nevada Water Authority's analytical method for detecting selected PFAS.[t]

International Analytical Methods

A study conducted in Catalonia, Spain analyzed the concentrations of 13 perfluorinated compounds (PFBS, PFHxS, PFOS, THPFOS, PFHxA, PFHpA, PFOA, PFNA, PFDA, PFUA, PFDoA, PFTeA, and PFOSA) in municipal drinking water samples collected at 40 different locations.[141] Detection limits ranged between 0.02 ppt (PFHxS) and 0.85 ppt (PFOA). Analysis was performed "*using an Acquity UPLC coupled to a Quattro Premier XE tandem mass spectrometer (Waters Corporation, Milford, CT, USA) with an atmospheric electrospray*

[t] Dickenson ERV and Higgins C, 2016. Treatment Mitigation Strategies for Poly- and Perfluoroalkyl Substances. Water Research Foundation, Web Report #4322 http://www.waterrf.org/PublicReportLibrary/4322.pdf

interface operating in the negative ion mode (ES-MS/MS)". Reporting limits or limits of quantification were not reported for this study.

Another study, conducted in Germany, was aimed at determining concentrations of PFAS in various sources of water intended for human consumption.[145] The study analyzed up to 19 PFAS compounds, including PFOS, PFOA, PFNA, and PFHxS, and the limits of quantification, or reporting limits, for all 19 compounds were 1 ppt. The researchers note that the water samples were measured *"using UPLC-MS/MS (Aquity with a TQ-detector, both from Waters, Eschborn, Germany) on a Kinetex column (2.6 µm, C18, 100A, 100 × 2.1 mm; Phenomenex, Aschaffenburg, Germany)."*

A third study conducted in Australia evaluated the fate of perfluorinated sulfonates (PFSAs) and carboxylic acids (PFCAs) in two water reclamation plants.[146] For this study, instrumental detection limits ranged from 0.2–0.7 ppt and reporting limits were set at double this, ranging from 0.4–1.5 ppt. Authors describe the analysis as "*using a QTRAP 4000 MS/MS (AB/Sciex, Concord, Ontario, Canada) coupled with a Shimadzu prominence HPLC system (Shimadzu, Kyoto Japan) using a gradient flow of mobile phase of methanol/water with 5 mM ammonium acetate. A Gemini C18 column (50 mm _ 2 mm i.d. 3 lm 110 Å) (Phenomenex, Torrance, CA) was used for separation, and an additional column (Altima, C18, 150 mm _ 2 mm i.d. 5 lm, 100 Å)(Grace Davison, Deerfield, IL) was installed between the solvent reservoirs and sample injector to separate peaks consistently present in the system from those in the samples (e.g. small peaks for PFDoDA (C12 PFCA), and for PFOA present in the mobile phase, and/or from fluoropolymer components in the LC system).*"

Table 10: Detection and Reporting Limits for PFOA, PFOS, PFNA, PFHxS Internationally

Contaminant	Detection Limit (ppt)[u]	Reporting Limit (ppt)[v]
PFOS	0.12	1
PFOA	0.85	1
PFNA	0.15	1
PFHxS	0.02	1

Table 10 provides examples of detection and reporting limits achieved by two different international studies for PFOA, PFOS, PFNA, and PFHxS.

Comprehensive PFAS Assessment Techniques

At present, there is no single methodology for isolating, identifying, and quantifying all PFAS in drinking water. Current commercial laboratory methodologies are typically able to quantify

[u] Ericson I, et al., 2009. Levels of Perfluorinated Chemicals in Municipal Drinking Water from Catalonia, Spain: Public Health Implications. *Arch Environ Contam Toxicol* 57:631–638

[v] Gellrich V, et al., 2013. Perfluoroalkyl and polyfluoroalkyl substances (PFASs) in mineral water and tap water. *J Environ Sci Health* 48:129–135

between 14 and 31 PFAS compounds and only a very small number of PFAA precursors can be quantitatively analyzed by commercial laboratories.[147] For instance, N-ethyl perfluorooctanesulfonamidoacetic acid and N-methyl perfluorooctanesulfonamidoacetic acid are the only two precursors included in EPA Method 537.1. For classes other than PFCAs between 4-14 carbons long and PFSAs that are 4, 6, or 8 carbons long, methodologies are generally not available outside academic settings.[26] The Michigan PFAS Science Advisory Panel summarizes the advantages and disadvantages of some available analytical methodologies to quantify PFAS as a class. These are included in Table 11 below (with additional information as cited).[26]

We recommend that the state explore an analytical method, or combination of methods, that can be used as a surrogate for total PFAS. In particular, we recommend the state evaluate alternative detection methodologies, particularly TOPA, to measure the concentration of non-discrete and difficult to measure PFAS compounds that are not determined by conventional analytical methods.

Table 11: Comparison of Various Analytical Approaches to Quantifying PFAS

Method	Advantages	Limitations
Method 537 V 1.1 Liquid Chromatography-Tandem Mass Spectrometry LC- MS/MS	• commercially available • QA/QC extensive • UCMR3/Method 537/SW-846 8327&8328/ASTM based on instrument • Differentiates branched/linear • Suited for analysis of ionic compounds[w]	• expensive • approved for a limited number of PFAS (18 in drinking water)[x] • value for forensics depends on number of PFAS evaluated
Total Oxidizable Precursor (TOP) assay	• commercially available • QA/QC improving • some chain length & branched and linear isomer information • reveals presence of significant precursors in AFFF-contaminated water, sediment, soil, and wastewater • data sets obtained by this methodology are comparable between sites and across states	• twice as expensive • no information on individual PFAS • conservative (lower estimate) • limited comparative data at this time • results treated with caution, especially for health and ecological risk assessments[y] • limited value for forensics
Suspect screening (LC-HRMS)	• unlimited number of PFAS • stored data can be searched in future • value as a forensics tool • a reference standard is not needed, the exact mass and isotopic pattern calculated from the molecular formula is used to screen for substances[z]	• instruments available but PFAS analysis by LC-HRMS not commercially available in US (research tool) • expensive • no standards for the other PFAS • data are 'screening' level or semi-quantitative

[w] https://pfas-1.itrcweb.org/wp-content/uploads/2018/03/pfas_fact_sheet_site_characterization_3_15_18.pdf
[x] https://www.epa.gov/water-research/epa-drinking-water-research-methods
[y] https://www.alsglobal.com/-/media/als/resources/services-and-products/environmental/data-sheets-canada/pfas-by-top-assay.pdf
[z] https://link.springer.com/article/10.1007/s00216-018-1028-4

		• limited comparable data - data obtained on different instruments, ratioing to various internal standards may not be comparable between sites and across states (generates lab- specific data until standardized)
Particle Induced Gamma Ray Emission (PIGE)	• quantifies fluorine • currently captures anionic PFAS, currently being adapted for cationic/zwitterionic PFAS • less expensive • availability through academic institutions	• only quantifies total fluorine (the atom) • no information on individual PFAS • small database (few comparative data) • cannot analyze different isotopes[aa] • limited value for forensics • detection limits are in the µg/L range, regulatory standards are now increasingly at ng/L levels[bb]
Total adsorbable organic fluorine (AOF)	• quantifies total fluorine • captures broad spectrum of PFAS • can be compared to individual PFAS analysis to determine presence of other PFAS (e.g., precursors)	• measures total fluorine (the atom) • no information on individual PFAS • not commercially available in US (or elsewhere) • must convert total fluorine in units of molar F to equivalents, assuming a specific PFAS to compare measurements • few comparable data • detection limits are in the µg/L range, regulatory standards are now increasingly at ng/L levels[cc]

Table 11 summarizes advantages and limitations of various analytical approaches to quantifying PFAS.[dd]

Treatment

There are a number of treatment options available to public water systems to address PFAS contamination.

On August 23, 2018, EPA published the results of its efforts to study a variety of technologies used to remove PFAS from drinking water.[148] The EPA's treatability analysis for PFAS compounds demonstrates that current treatment technologies can reduce concentrations of PFOA, PFOS, PFNA, and PFHxS to concentrations below 2 ppt. Full-scale treatment facilities in the U.S., Europe, and Australia have demonstrated effective removal of PFAS compounds through a variety of treatment technologies, most successfully with activated carbon or membrane filtration. The EPA's treatability analysis did not include data on the treatment of

[aa] https://www.sciencedirect.com/science/article/pii/0168583X86903812
[bb] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895726/
[cc] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895726/
[dd] Michigan PFAS Science Advisory Panel, 2018. Scientific Evidence and Recommendations for Managing PFAS Contamination in Michigan. December 7, 2018.

GenX, but pilot studies conducted in North Carolina have demonstrated reductions of GenX to below 2 ppt. [149]

Under federal law, standards for synthetic organic contaminants such as PFAS must be "feasible," and that term is defined to be a level that is at least as stringent as the level that can be achieved by Granular Activated Carbon (GAC). Specifically, the Safe Drinking Water Act provides, *"granular activated carbon is feasible for the control of synthetic organic chemicals, and any technology, treatment technique, or other means found to be the best available for the control of synthetic organic chemicals must be at least as effective in controlling synthetic organic chemicals as granular activated carbon."* Safe Drinking Water Act §1412(b)(4)(D). Therefore, the state should establish MCLs for PFAS at levels at least as stringent as can be achieved by GAC.

In this report, we recommend MCLs for PFOS, PFOA, PFNA, PFHxS, and GenX that have been demonstrated to be achievable with GAC. However, for total PFAS greater protections can be achieved with reverse osmosis than GAC (discusses below), therefore we recommend a treatment technique of reverse osmosis, or other treatment method that has been demonstrated to be at least as effective as reverse osmosis for removing all identified PFAS chemicals.

Granular Activated Carbon (GAC) Treatment

According to the EPA, "*Activated carbon treatment is the most studied treatment for PFAS removal. Activated carbon is commonly used to adsorb natural organic compounds, taste and odor compounds, and synthetic organic chemicals in drinking water treatment systems. Adsorption is both the physical and chemical process of accumulating a substance, such as PFAS, at the interface between liquid and solids phases. Activated carbon is an effective adsorbent because it is a highly porous material and provides a large surface area to which contaminants may adsorb.*"[148] Activated carbon is made from organic materials with high carbon contents and is often used in granular form called granular activated carbon but can also be used in a powdered form called powdered activated carbon.

Granulated active carbon has been used for more than 15 years to remove PFOA and PFOS from water. The most common carbonaceous materials include raw coal, coconut, and wood. According to the Rapid Scale Small Column Testing Summary Report by Calgon Carbon, *"bench scale studies have shown that reagglomerated bituminous coal-based GAC significantly out performs other GAC materials including direct activated coconut GAC."*[150]

While the EPA notes that, "*GAC has been shown to effectively remove PFAS from drinking water when it is used in a flow through filter mode after particulates have already been removed,*"[148] it should be noted that GAC has only been demonstrated to be effective for a certain PFAS chemicals. Factors impacting the effectiveness of GAC treatment include:

- the type of carbon used,

- the depth of the bed of carbon,
- flow rate of the water,
- the specific PFAS to be removed,
- temperature, and
- the degree and type of organic matter as well as other contaminants, or constituents, in the water.

A report reviewing the effectiveness of emerging technologies for treatment of PFAS chemicals noted that "*GAC is a widely used water treatment technology for the removal of PFOS and PFOA, and, to a lesser extent, other PFAAs from water... It is an established technology that can be deployed at scales between municipal water treatment and domestic point of entry systems, either as a standalone technology or part of a treatment train.*"[151] And while GAC can consistently remove PFOS at parts per billion concentrations with an efficiency of more than 90 percent, it can be inefficient at removing PFOA[152] and becomes progressively less effective for removing shorter chain PFCAs such as PFHxA, PFPeA, PFBS, and PFBA as the chain length diminishes.[153,154]

There are several examples of full-scale treatment systems using GAC to remove PFAS from drinking water sources. A report prepared for the New Jersey Department of Environmental Protection[155] included several case studies, two of which are included below.

Amsterdam, Netherlands - A study of the removal of a number of PFAS from several steps in the treatment process from raw water to finished water found that longer chain PFAA were readily removed by the GAC treatment step.[156] In this study, a final GAC adsorber was able to reduce both PFOS and PFNA measured in the raw samples at values of 6.7 to 10 ppt and 0.5 to 0.8 ppt, respectively to levels measured below the limits of quantitation (0.23 ppt and 0.24 ppt, respectively). PFOA concentrations in the influent ranged between 3.8 to 5.1 ppt and in the final GAC adsorber ranged between 3.6 to 6.7 ppt. GAC adsorption for this study was done in two stages with adsorbers operated in series, each with a 20-minute empty bed contact time. The GAC in the lag adsorber is placed in the lead position after 15 months of operation and replaced with fresh GAC. The GAC used in this study was Norit ROW 0.8S.

New Jersey American Water, Logan System Birch Creek - Water samples from the Logan System Birch Creek had detectable levels of PFNA (18 – 72 ppt) and of PFOA (33 – 60 ppt), in addition to three other PFAS.[155] GAC treatment removed all detectable PFAS below the reporting level of 5 ppt. GAC adsorbers were operated with an empty-bed contact time of approximately 15 minutes. The GAC used in this study was Calgon F-400.

Additionally, on-going pilot studies being conducted by engineering firm CDM demonstrates effective GAC treatment for GenX and other PFAS with reductions below detection limits of 2 ppt.[149] According to an April 2018 report by CDM for Brunswick County Public Utilities, long-term effective treatment with GAC requires media changeout to avoid breakthrough of compounds and the study indicates approximately 8,000 bed volumes (approximately 4 months

at 20-minute contact time) is the appropriate frequency of media changeout for GenX and most PFAS.

GAC treatment can produce contaminated spent carbon or, if regenerated, contaminated air emissions, which require safe disposal. Importantly, the Michigan PFAS Science Advisory Panel notes that,

> *"When regenerating PFAS-loaded activated carbon, the off-gases should be treated by high temperature incineration to capture and destroy any PFAS in the stack gases and to prevent the release of PFAS and/or partially oxidized byproducts to the atmosphere. However, this treatment technology is costly and consumes large amounts of energy. The Concawe (2016) report recommends incineration temperatures of between 1,000 and 1200°C for complete destruction of PFOS. MDEQ (2018) states that incinerators operating in Michigan function at temperatures between 590 and 980°C. As such, incomplete destruction and the formation of reaction byproducts is likely (Concawe Soil and Groundwater Taskforce 2016) and stack treatment to remove fluorinated chemicals would be required."* [26]

In sum, use of GAC by multiple water utilities at scale have achieved reductions of greater than 90 percent to below detection limits for certain PFAS chemicals, including PFOS, PFOA, PFNA, PFHxS, and GenX. GAC has not been demonstrated to be effective for removing other PFAS chemicals, particularly short-chain PFAS.

Ion Exchange (IX) Treatment

Ion exchange resins essentially act as "magnets," attracting the contaminated materials as it passes through the water system.[148] Ion exchange resins can be cationic or anionic; positively charged anion exchange resins (AER) are effective for removing negatively charged contaminants, like PFAS. Ion exchange resins are made up of highly porous, polymeric hydrocarbon materials that are acid, base, and water insoluble.

As summarized by the EPA,

> *"AER has shown to have a high capacity for many PFAS; however, it is typically more expensive than GAC. Of the different types of AER resins, perhaps the most promising is an AER in a single use mode followed by incineration of the resin. One benefit of this treatment technology is that there is no need for resin regeneration so there is no contaminant waste stream to handle, treat, or dispose. Like GAC, AER removes 100 percent of the PFAS for a time that is dictated by the choice of resin, bed depth, flow rate, which PFAS need to be removed, and the degree and type of background organic matter and other contaminants of constituents."*[148]

Reverse Osmosis Treatment

According to the EPA, high-pressure membranes, such as nanofiltration or reverse osmosis (RO), have been effective at removing a broad array of PFAS compounds.[148] High-pressure membranes can be more than 90 percent effective at removing a wide range of PFAS, including shorter chain PFAS.

In a 2011 paper, researchers examined the fate of PFAS in two water reclamation plants in Australia.[146] The authors found that:

> *"Both facilities take treated water directly from wastewater treatment plants (WWTPs) and treat it further to produce high quality recycled water. The first plant utilizes adsorption and filtration methods alongside ozonation, whilst the second uses membrane processes and advanced oxidation to produce purified recycled water. At both facilities perfluorooctane sulfonate (PFOS), perfluorohexane sulfonate (PFHxS), perfluorohexanoic acid (PFHxA) and perfluorooctanoic acid (PFOA) were the most frequently detected PFCs [perfluorinated compounds]. At the second plant, influent concentrations of PFOS and PFOA ranged up to 39 and 29 ppt. All PFCs present were removed from the finished water by reverse osmosis (RO) to concentrations below detection and reporting limits (0.4–1.5 ppt)."*[146]

Preliminary results of an on-going pilot study at Northwest Water Treatment Plant in North Carolina indicate that RO is expected to provide high level of removal (90 percent or greater) for the PFAS compounds, including GenX.[149] The RO membranes being proposed for this project and being tested in the pilot study are standard commercially available brackish water RO membranes rated for 99.3 percent rejection of a standard 2000 mg/L sodium chloride salt solution; this is considered a high rejection, broad spectrum RO membrane. The study also evaluated GAC, IX, and advanced treatment trains and concluded that low-pressure reverse osmosis was the preferred alternative for both removal efficiency and cost-effectiveness. The CDM report states:

> *"RO is recommended over the other options for the following reasons:*
>
> - *RO is the Best Technology for Removal of PFAS. Some PFAS, such as GenX, PFMOAA and PFO2HxA would require very frequent change-out of GAC and IX for removal.*
> - *GAC and IX would likely result in higher finished water concentrations of GenX, PFMOAA, and PFO2HxA than RO (technologies are not equal).*
> - *RO has the lowest net present worth costs for removing 90% or more of the Target Contaminants.*
> - *RO is the most robust technology for protecting against unidentified contaminants.*
> - *RO treated water concentrations will not vary as much with influent concentrations as with GAC and IX. RO treated water quality does not rely on frequent media change-out to protect from the spills and contaminants in the Cape Fear River.*
> - *RO does not release elevated concentrations after bed life is spent as can happen with GAC and IX if feed concentration drops."*[149]

Like GAC, RO treatment technology generates contaminated waste material including liquid concentrate and spent/used membranes. We recommend Michigan evaluate the safest disposal method, and that disposal require full destruction of PFAS compounds before entering the environment.

Furthermore, the EPA also suggests,

> "*Because reverse osmosis removes contaminants so effectively, it can significantly lower the alkalinity of the product water. This can cause decreased pH and increased corrosivity of the product water. The product water may need to have corrosion inhibitors added or to have the pH and alkalinity adjusted upwards by the addition of alkalinity. These actions may avoid simultaneous compliance issues in the distribution system such as elevated levels of lead and copper.*"[157]

Treatment Trains

A treatment train is a sequence of multiple treatment techniques designed to meet specific water quality parameters. According to the Water Research Foundation, when evaluating treatment trains,

> *"Quiñones and Snyder (2009) saw the best removal of PFOA, PFOS, PFNA, and PFHxS using an integrated membrane treatment consisting of microfiltration (MF) and RO and ultraviolet (UV) (medium pressure) followed by SAT [soil aquifer treatment]. This treatment train caused concentrations to drop from the low ng/L [ppt] range to below detection levels. Their success in removing these substances was most likely due to the use of RO. Takagi (2008) looked at the effectiveness of rapid sand filtration followed by GAC and then chlorination on PFOA and PFOS and measured a drop from 92 ng/L to 4.1 ng/L and 4.5 ng/L to <0.1 ng/L, respectively. GAC was most likely responsible for the majority of the removal. Snyder et al. (2014) detected >90% removal of PFOA and >95% removal of PFOS using a treatment train (70 MGD) consisting of MF/RO/UV-advanced oxidation process (AOP)/direct injection (DI). Again, their success was likely due to the RO membrane step using Hydranautics EPSA2 RO dismembranes."*[143]

Although there is still additional research that can be done, removal rates of greater than 90 percent and effluent concentrations of less than 2 ppt for PFOA, PFOS, PFNA, PFHxS, and GenX can be achieved currently with a combination of treatment technologies, along with careful monitoring.

Innovative Technologies

This section describes promising innovative technologies that are designed to treat and/or destroy PFAS chemicals.

- Diamond Technology – According to researchers at Michigan State University-Fraunhofer USA, Inc. Center for Coatings and Diamond Technologies (MSU-Fraunhofer), "*the MSU-Fraunhofer team has a viable solution to treat PFAS-contaminated wastewater that's ready for a pilot-scale investigation. The electrochemical oxidation system uses boron-doped diamond electrodes. The process breaks down the contaminants' formidable molecular bonds, cleaning the water while systematically destroying the hazardous compounds.*"[158] While this treatment technology has been developed to treat wastewater, further research may demonstrate effectiveness for removing PFAS from drinking water or waste streams produced by membrane filtration as well.

- AECOM DE-FLUORO Technology – This technology was designed to destroy PFAS compounds concentrated on spent media after treatment.[159] According to AECOM's informational sheet:

  > "*Mass transfer technologies (e.g., granular activated carbon, ion exchange resin, reverse osmosis) do not destroy PFAS but concentrate PFAS on the spent media. The spent media may require off-site incineration or regeneration for filtration media reuse that will produce regenerant wastes requiring further management and treatment ... As of today, electrochemical oxidation is one of the most documented PFAS destruction technologies. AECOM has successfully used a proprietary electrode to complete mineralization of C4 ~C8 perfluoroalkyl acids (PFAAs) with evidence of complete defluorination and desulfurization. PFAS are destructed via direct electron transfer on "nonactive" anodes under room temperature and atmospheric pressure with relatively low energy consumption. AECOM has also successfully used this proprietary electrode to treat PFAS in ion-exchange regenerant waste and other PFAS-impacted wastewater.*"[159]

  In the information sheet, AECOM notes that this technology may also be effective for treating drinking water.

The available research demonstrates that both GAC and IX can be effective treatment techniques for certain PFAS compounds that have been studied, including PFOA, PFOS, PFNA, PFHxS, and GenX, when there is appropriate design, operation, and maintenance. RO has been demonstrated to be an effective treatment technology for removing all PFAS that have been studied and is the most effective treatment technique for effectively removing unknown contaminants. Due to the nature of GAC and IX treatment, water suppliers run the risk of releasing PFAS compounds back into the finished water after GAC bed life is spent or if IX feed concentration drops. Additionally, frequent changeout of GAC or IX to maintain removal efficiency can make the lifecycle costs more expensive than alternatives, such as RO. While GAC, IX, or RO can be effective at removing certain PFAS, RO is advantageous for treating total PFAS because it is the most robust technology for protecting against unidentified contaminants and provides greater protection from future unidentified PFAS. Potential considerations for RO are that it often has a higher capital cost, it can require a 10 to 20 percent

higher treatment capacity because it produces a reject stream, and it requires safe disposal of the reject water which will have higher concentrations of contaminants than the source water.

PART VI: CONCLUSIONS AND RECOMMENDATIONS

Taking into consideration the information provided in this report, the following actions are recommended to address PFAS contamination in Michigan drinking water:

1. Continue and Expand Comprehensive Surveys of Drinking Water

We commend Michigan for performing the most extensive survey of drinking water in the nation. However, private water systems serving no more than 25 people, and having no more than 15 service connections, and private wells not serving schools, are not presently tested under the state's program. Site investigations performed by MDEQ show significant contamination not fully reflected by PWS data. For example, although here are there are two contamination sites Alpena county, no detections were reported for PWS within the county. Therefore, Michigan should expand it statewide survey of drinking water sources to include private water systems and private wells serving residences that are near known or suspected PFAS contamination sites, or as requested by a private well user.

Additional rounds of PFAS testing should be performed to account for testing variability, to ensure no additional discharges of PFAS are occurring, and to evaluate treatment effectiveness. The analyses should continue to be conducted using the most sensitive detection methods for a comprehensive assessment, which at minimum should now include the expanded EPA 537.1 list at reporting limits of 2 ppt for all PFAS covered by the method, except for GenX, whose reporting limit should be no greater than 5 ppt. We also recommend that the state evaluate newer methodologies, particularly the total oxidizable precursor assay, as an analytical technique to help measure the concentration of non-discrete and difficult to measure PFAS compounds that are not determinable by conventional analytical methods.

> *"Monitoring of levels of a wide range of PFAS substances at ppt ... levels can be costly but is essential for addressing the fate of PFAS following treatment." - Michigan PFAS Science Advisory Panel*

Priority for additional testing and monitoring should be public water supplies where sources of water (ground and/or surface) are near former PFAS manufacturing or processing facilities; near fire-fighting stations where PFAS was or continues to be used for training; near military bases and airports which may still use PFAS; and near landfills.

Data on PFAS in drinking water supplies should be provided to residents served by the tested water supplies, researchers, and the public. Where both biomonitoring data and water testing data are available, that information should be provided to individuals participating in the biomonitoring program so that participants are informed of their own body burden and drinking

water exposures. Biomonitoring data and water testing data should also be provided to researchers (in matched pairs, if possible, and with identifying information removed to protect the confidentiality of participants) so that the contribution of PFAS-contaminated drinking water to total PFAS exposure can be studied further. Additionally, at present, the state only publicly reports combined concentrations for PFOA and PFOS and total PFAS detected in drinking water systems; MDEQ should publicly report unique values for all detected levels of individual PFAS compounds. All data should be provided in a timely manner and in a common format on a publicly-available database.

2. Set a MCLG of Zero for Total PFAS.

PFAS share similar structure and properties, including extreme persistence and high mobility in the environment. Many PFAS are also associated with similar health endpoints, some at extremely low levels of exposure. There is additionally potential for additive or synergistic toxicity among PFAS. Given the similarity among chemicals of the PFAS class and the known risk of the well-studied PFAS, there is reason to believe that other members of the PFAS class pose similar risk. Therefore, health-protective standards for PFAS should be based on the known adverse effects of the well-studied members of the PFAS class.

First, there is sufficient evidence to classify PFOA as a known or probable carcinogen. Therefore, a MCLG of zero should be promulgated for PFOA, consistent with EPA's approach to regulating known or probable carcinogens (see Box 10). Both IARC's and EPA's findings on PFOA's carcinogenic potential are based heavily on the C8 study, whose Science Panel determined that PFOA is a probable carcinogen. There is also significant additional animal and human evidence for an association between PFOA exposure and cancer, particularly kidney and testicular cancer.

Box 10: Maximum Contaminant Level Goals for Carcinogens

The EPA derives a MCLG under the Federal Safe Drinking Water Act by first considering the carcinogenic potential of the contaminant, or suite of contaminants. For known or probable carcinogens, EPA sets a MCLG of zero for the contaminant, or for the contaminant class, under the federal framework. This is because EPA assumes that, in the absence of other data, there is no known threshold at which no adverse health effects would occur. For chemicals suspected as carcinogens, the agency considers the weight of evidence, including animal bioassays and epidemiological studies. Information that provides indirect evidence, such as mutagenicity and other short-term test results, is also considered by the agency. Known human carcinogens, under EPA's classification scheme, are chemicals for which there exists sufficient evidence of carcinogenicity from epidemiological studies. Probable human carcinogens demonstrate either limited evidence of carcinogenicity in humans or sufficient evidence in animals without corresponding human data, under this classification scheme. See *56 Fed. Reg. 20, 3532* (Jan. 30, 1991).

In addition to being a carcinogen, PFOA causes adverse non-cancer health effects at exceedingly low doses. A MCLG based on altered mammary gland development would be well below 1 ppt for PFOA, further supporting our recommendation of zero for a MCLG (see Table 12 below).

Although the evidence of carcinogenic potential for PFOS is not as well established as PFOA, given the similarities in structure and toxicity of PFOS to PFOA, we recommend a MCLG of zero for PFOS as well. The weight of evidence indicates that PFOS also causes adverse non-cancer health effects at exceedingly low doses. A MCLG based on immunotoxicity would be well below 1 ppt for PFOS, further supporting our recommendation of zero for a MCLG (see Table 12 below).

There is less information on the carcinogenic potential of PFNA, PFHxS, and GenX, however, given the similarities in structure and toxicity of these PFAS to PFOA and PFOS, their potential for the carcinogenicity cannot be ruled out. Other shared health effects that occur at extremely low levels, such as immunotoxicity, developmental harm, and liver damage, along with their co-occurrence in our environment, must also be considered in setting a health protective MCLG for PFNA, PFHxS, and GenX.

A MCLG for PFNA based on developmental toxicity is below 1 ppt, approximately 2 ppt for PFHxS based on thyroid toxicity, and below 1 ppt for GenX based on liver toxicity (see Table 12 below).

Please see Appendices A, B, C, D and F for more detailed calculations

Table 12: NRDC Recommended MCLGs for PFOA, PFOS, PFNA, PFHxS, and GenX

Threshold (ppt)	Threshold type	Study Endpoint	Total UFs	Critical Dose includes UFs (mg/kg/day)	Drinking water exposure assumptions	Notes
PFOA						
0	proposed MCLG (goal)	cancer and altered mammary gland development				
0.01		altered mammary gland development	300**	1×10^{-8}	0.175 L/kg/day for a infants, RSC = 20%	**additional UF of 10, to protect fetuses, infants, children
PFOS						
0	proposed MCLG (goal)	class similarity to PFOA (supported by immunotoxicity)				
0.002		Immunotoxicity	300**	2×10^{-9}	0.175 L/kg/day for a infants, RSC = 20%	**additional UF of 10, to protect fetuses, infants, children
PFNA						
0	proposed MCLG (goal)	class similarity to PFOA (supported by develomental toxicity)				
0.3		Develomental toxicity	3000**	3×10^{-7}	0.175 L/kg/day for a infants, RSC = 20%	**additional UF of 10, to protect fetuses, infants, children
PFHxS						
0	proposed MCLG (goal)	class similarity to PFOA (supported by developmental and thyroid toxicity)				
2		developmental and thyroid toxicity	3000**	2×10^{-6}	0.175 L/kg/day for a infants, RSC = 20%	**additional UF of 10, to protect fetuses, infants, children
GenX						
0	proposed MCLG (goal)	class similarity to PFOA (supported by liver toxicity)				
0.2		liver toxicity	100000#	2×10^{-6}	0.175 L/kg/day for a infants, RSC = 20%	# due to data limitations, uncertainty could be up to 100,000
**An additional uncertainty factor of 10 to protect fetuses, infants and children is recommended by the National Academy of Sciences (NAS 1993) for pesticides and as required in the Food Quality Protection Act. 21 U.S.C. §346a(b)(2)(C)(ii)(II).						

PFOA, PFOS, PFNA, PFHxS, and GenX share similar structure and properties and are associated with similar health endpoints, many at extremely low levels of exposure, across animal and epidemiological studies. Thus, because they often co-occur in our environment, there is potential for additive toxicity among these PFAS. New Jersey noted that the modes of action and health effects are generally similar for PFAS and acknowledged the possibility that the effects may be additive.[95] Given the above information we recommend a combined MCLG of zero for PFOA, PFOS, PFNA, PFHxS, and GenX.

However, this reasoning should be applied to the PFAS class as a well. Information on and lessons learned from these more extensively studied PFAS need to be used to guide regulations and ensure actions taken are adequately protective of human health in the long term. While there is limited toxicity data on many of the newer short-chain or other alternative PFAS replacing long-chain PFAS in various applications, evidence suggests that they collectively pose similar threats to human health and the environment. The rise in use of alternative PFAS and concerns with the environmental fate and persistence of these alternative PFAS have led to a call from independent scientists from around the globe to address PFAS as a class both in terms of their impacts and in limiting their uses.[12]

Box 11: Regulating Classes in Tap Water - The PCB Precedent

There is precedent for regulating a group of chemicals as a class. For example, polychlorinated biphenyls (PCBs) are a class hundreds of man-made chlorinated hydrocarbons that are persistent in the environment, can bioaccumulate, and have a range of toxicity, including cancer and disruption of the immune, reproductive, endocrine, and nervous systems.[160] Drinking water standards and regulations regarding their clean up, disposal and storage apply to the class and are not set separately for each PCB in use.

In promulgating drinking water regulations for the large class of PCBs, EPA found that although statistically significant evidence of carcinogenicity had been demonstrated only in PCBs that were 60 percent chlorinated, the evidence justified regulation of the whole class of PCB compounds, given the structural complexity of the compounds, and the incomplete data regarding toxicity of the isomers in PCB compounds. EPA, 56 Fed. Reg. 3526, at 3546 (January 30, 1991)[161]

The structure of the fluorine-carbon bond and the impacts documented on the studied PFAS already available support concern over the health impacts of the entire class. This is supported by the constant exposure to short-chain chemicals, even if they have a relatively short presence in the body, as well as the fact that in many cases the use of these chemicals may be much higher than their long-chain cousins. Furthermore, many PFAS can convert into PFAAs (a PFAS subgroup, which includes PFOA and PFOS, that is linked to many adverse health effects) or PFAAs are used in their manufacture and can be contaminants in their final product.

Setting a MCLG of zero for the class is needed to provide an adequate margin of safety to protect public health from a class of chemicals that is characterized by extreme persistence, high mobility, and is associated with a multitude of different types of toxicity at very low levels of exposure. If we regulate only a handful of PFAS, there will be swift regrettable substitution with other, similarly toxic PFAS - creating an ongoing problem where addressing one chemical at a time incentivizes the use of other toxic chemicals and we fail to ever establish effective safeguards to limit this growing class of dangerous chemicals.

3. Immediately Set a Combined MCL of 2 ppt for PFOA, PFOS, PFNA, and PFHxS, and a MCL of 5 ppt for GenX

As discussed in our second recommendation, NRDC's review of the toxicity studies for five PFAS compounds finds evidence that they are linked to cancer and other serious adverse health effects. Following conventional risk assessment protocols, we determine that the goal for PFOA, PFOS, PFNA, PFHxS and GenX should be zero exposure to these chemicals in drinking water.

As technologies for detection and water treatment do not currently allow for the complete removal of PFAS from drinking water, a MCL for PFOA, PFOS, PFNA, PFHxS, and GenX should be based on the best detection and treatment technologies available. Our review suggests a combined MCL of 2 ppt is feasible for PFOA, PFOS, PFNA, and PFHxS, with a separate MCL of 5 ppt for GenX.

Laboratory methods support a reporting limit of 2 ppt with EPA Method 537.1 (5 ppt for GenX), and therefore all water testing should be required to achieve this limit for the PFAS chemicals detectable with this method. Further, the removal of PFOA, PFOS, PFNA, PFHxS, and GenX has been demonstrated to be effective with technologies such as GAC and RO to below detection levels, supporting our determination that the MCL meets technological feasibility.

In 2018, Michigan promulgated enforceable groundwater cleanup criteria for combined levels of PFOA and PFOS at 70 ppt.[162] Michigan's current groundwater cleanup standard of 70 ppt for PFOA and PFOS – adopting EPA's advisory level – is both insufficiently protective of human health and fails to fully address the state's many drinking water systems contaminated by the toxic chemicals. Because Michigan residents relying on private wells for drinking water depend on the safety of the state's groundwater, the state's groundwater cleanup standard should be decreased to 2 ppt, consistent with the recommended MCL for public water systems. Groundwater standards should also be set for PFNA and PFHxS at 2 ppt and 5 ppt for GenX.[ee]

[ee] As discussed in the accompanying regulatory petition, Part 201, Environmental Remediation, of the Natural Resources and Environmental Protection Act, 1994 PA 451, as amended, may present an obstacle to the issuance of

4. Develop a Treatment Technique Requirement for the PFAS Class Within Two Years

As discussed in our second recommendation, setting a MCLG of zero for the class is needed to protect public health and the environment from all types of PFAS that share common negative qualities including extreme persistence, high mobility, and the association with a multitude of different types of toxicity at very low levels of exposure. The replacement of PFOA with GenX is a perfect example of regrettable substitution where a well-studied, toxic PFAS was replaced by a poorly-studied but structurally similar PFAS.

Technology for detection and treatment cannot achieve a MCLG of zero for total PFAS. In the absence of a reliable method that is economically and technically feasible to measure a contaminant at concentrations to indicate there is not a public health concern, the state should establish a treatment technique. A treatment technique is a minimum treatment requirement or a necessary methodology or technology that a public water supply must follow to ensure control of a contaminant (MICH. ADMIN CODE R 325.10109(g)).

At present, there is no single methodology for isolating, identifying, and quantifying all PFAS in drinking water. We recommend that the state explore an analytical method, or combination of methods, that can be used as a surrogate for total PFAS. In particular, we recommend the state evaluate alternative detection methodologies, such as the total oxidizable precursor assay, to measure the concentration of non-discrete and difficult to measure PFAS compounds that are not determined by conventional analytical methods.

Importantly, the Michigan PFAS Science Advisory Panel notes that,

> "*Many PFAS remain unidentified since sophisticated analytical techniques and time are required to identify unknown PFAS and because new PFAS are continually being developed without much information available to the public about their chemistry. Minimal information is available about these new chemicals or their degradation products including levels in drinking water.*" [26]

Furthermore, we recommend reverse osmosis, or other treatment method that has been demonstrated to be at least as effective as reverse osmosis for removing all identified PFAS chemicals, as the treatment technique for public water supplies. Reverse osmosis is currently the preferred treatment technology for the following reasons:

- Reverse osmosis has been demonstrated to effectively remove a broad range of PFAS compounds.[149]

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the recommended regulatory standards for combined levels of PFOA, PFOS, PFNA, and PFHxS and for GenX in groundwater. However, the accompanying regulatory petition argues that the restrictions imposed by the amended law are likely to be deemed unlawful and unconstitutional by courts, and should be rejected and repealed by the Michigan legislature.

- Reverse osmosis is the most robust technology for protecting against unidentified contaminants.[149]
- Reverse osmosis would likely result in lower finished water concentrations of GenX and other PFAS compounds such as PFMOAA and PFO2HxA.[149]
- Reverse osmosis does not require frequent change out of treatment media and does not release elevated concentrations after granular activated carbon bed life is spent or ion exchange feed concentration drops.[149]

Reverse osmosis requires considerations for the safe disposal of high-strength waste streams and spent/used membranes. We recommend Michigan evaluate the safest disposal method, and that disposal require full destruction of PFAS compounds before entering the environment.

UNITS AND DEFINITIONS

AER - anion exchange resins

ATSDR – Agency for Toxic Substances and Disease Registry

C8 - PFOA

CDC - Centers for Disease Control and Prevention

EPA – U.S. Environmental Protection Agency

EtFOSAA - 2-N-Ethyl-perfluorooctane sulfonamide

FOSE – perfluorooctane sulfonamide ethanol

FTOH - fluorotelomer alcohol

GAC – granular activated carbon

GenX – HFPO dimer acid and its ammonium salt

HFPO - hexafluoropropylene oxide

IARC – International Agency for Research on Cancer

IX - strong base anion exchange resin

LCMRL - lowest concentration minimum reporting limit

LC/MS/MS - liquid chromatography/tandem mass spectrometry

LOAEL – lowest-observable-adverse-effect-level

LOQ – limit of quantitation

MCL - maximum contaminant level

MCLG – maximum contaminant level goal

MDL – minimum detection level

MeFOSAA - 2-N-Methyl-perfluorooctane sulfonamide

MRL - minimal risk level

NAS – National Academy of Sciences

NHANES – National Health and Nutrition Examination Survey

NOAEL – no-observable-adverse-effect-level

OEHHA – California Office of Environmental Health Hazard Assessment

PBT – persistent bioaccumulative toxic

PFAA – perfluoroalkyl acid

PFAS – per- and polyfluoroalkyl substances

PFBS - perfluorobutane sulfonic acid, also known as PFBuS

PFCA – perfluorocarboxylic acid

PFDeA - perfluorodecanoic acid, also known as PFDeDA

PFDoA - perfluorododecanoic acid, also known as PFDoDA

PFHpA - perfluoroheptanoic acid

PFHxS - perfluorohexane sulfonic acid

PFNA - perfluorononanoic acid

PFOA - perfluorooctanoic acid

PFOS - perfluorooctane sulfonic acid

PFOSA - perfluorooctane sulfonamide

PFSA – perfluorosulfonic acid

PFTeA – perfluorotetradecanoic acid, also known as PFTDA

PFUA - perfluoroundecanoic acid, also known as PFUnDA or PFUnA

PMT – persistent mobile toxic

ppt - parts per trillion = nanograms per liter (ng/L) (usually used to express water concentration)

ppb - parts per billion = micrograms per liter (ug/L) (usually used to express blood serum concentration)

PWS – public water system

RfD - reference dose

RO – reverse osmosis

RSC – relative source contribution

THPFOS - 1H,1H,2H,2H-perfluorooctanesulfonic acid

TOP or TOPA – total oxidizable precursor assay

UCMR3 – EPA's Unregulated Contaminant Monitoring Rule 3

UF - uncertainty factor

APPENDIX A - MRL CALCULATIONS FOR PFOS USING IMMUNOTOXICITY ENDPOINT

Based on information from: https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf

Immunotoxicity is currently the most sensitive health endpoint for PFOS exposure. Although ATSDR states concern that immunotoxicity is a more sensitive endpoint than developmental toxicity, it stops short of deriving a MRL from this endpoint. Instead, ATSDR claims that a modifying factor of 10 is sufficient to address the doses where immunotoxic effects have been observed. This statement is based on ATSDR calculating a candidate MRL for one of the four immunotoxicity studies in rodents identified by ATSDR, Dong et al., 2011, but not the other studies (ATSDR, 2018, see page A-43 of Appendix A).

However, Dong et al. 2011 is the immunotoxicity study with the highest LOAEL, which is not consistent with ATSDR's practice of choosing the study with the lowest LOAEL when selecting the principle study for MRL derivation. The other immunotoxicity studies all result in MRLs approximately 2.5-100 times lower than the MRL proposed by ATSDR (Table 1, calculations to follow, performed as described in ATSDR, 2018, Appendix A).

Table 13: Comparison of candidate MRLs for PFOS

Source	Year	Critical Endpoint	Minimal Risk Level (mg/kg/day)
ASTDR	2018	Developmental toxicity (delayed eye opening, decreased pup weight) + Modifying Factor	2 x 10-6 MRL
Dong et al.	2011	Immunotoxicity (impaired response to sRBC)	2.7 x 10-6 Estimated MRL[a]
Dong et al.	2009	Immunotoxicity (impaired response to sRBC)	7.8 x 10-7 Estimated MRL[a]
Guruge et al.	2009	Immunotoxicity (decreased resistance to influenza virus)	2.2 x 10-7 Estimated MRL[a]
Peden-Adams et al.	2008	Immunotoxicity (impaired response to sRBC)	2.1 x 10-8 Estimated MRL[a]

a – Calculated using the derivation method described on pg. A43 of the ATSDR profile

In equation A-6 from Appendix A, ATDSR defines an expression relating the external steady-state dosage and steady-state serum concentration:

$$Dss = (Css \times k_e \times V_d) / AF$$

Where:

Dss = steady-state absorbed dosage (mg/kg/day)

Css = steady-state serum concentration in humans (mg/L)

k_e = elimination rate constant (day-1)

V_d = assumed apparent volume of distribution (L/kg)

AF = gastrointestinal absorption fraction

ATSDR provided the following First Order One-Compartment Model Parameters for PFOS in Table A-4:

$K_e = 3.47 \times 10^{-4}$

$V_d = 0.2$

AF=1

ATSDR made the assumption that "humans would have similar effects as the laboratory animal at a given serum concentration." Therefore, the time weighted average serum levels from animal studies (C_{TWA}) are used to back-calculate Dss by imputing C_{TWA} as Css in equation A-6.

The immunotoxicity studies, are the most sensitive endpoints, having NOAELs 6-625 times lower than the NOAEL for the developmental endpoint chosen for deriving the MRL. Though they did report serum levels, the immunotoxicity studies were performed in different strains/species of animals than those used for the pharmacokinetic modeling completed by Wambaugh et al. As such, they were not chosen for calculation of an MRL, though the ATSDR used other methods to calculate TWA concentrations for PFHxS and PFNA (the trapezoid rule) which were also lacking pharmacokinetic modeling.

From ATSDR (Appendix A, pg. A-43):

"A candidate MRL was calculated using the NOAEL of 0.0167 mg/kg/day identified in the Dong et al. (2011)...A TWA concentration was estimated using a similar approach described for

PFHxS and PFNA in the MRL approach section. The estimated TWA concentration was 1.2 µg/mL for the 0.0167 mg/kg/day; this estimated TWA concentration was used to calculate a human equivalent dose (HED) of 0.000083 mg/kg/day. A candidate MRL of 3x10-6 was calculated using an uncertainty factor of 30 (3 for extrapolation from animals to humans using dosimetric adjustments and 10 for human variability)."

Following this logic:

The time weighted average (TWA) serum levels for the other immunotoxicity studies can be predicted by using the trapezoid rule, as was done for PFNA, PFHxS, and the candidate PFOS MRL based on Dong et al., 2011.

Dong et al. 2009:

Measured serum level at NOAEL dose of 0.0083 mg/kg/day: 0.674 ug/mL

Estimated TWA = (0.674 ug/mL - 0 ug/mL) / 2 = 0.337 ug/mL = 0.337 mg/L

Guruge et al. 2009:

Measured serum level at NOAEL dose of 0.005 mg/kg/day: 0.189 ug/mL

Estimated TWA = (0.189 ug/mL - 0 ug/mL) / 2 = 0.0945 ug/mL = 0.0945 mg/L

Peden-Adams et al. 2008:

Measured serum level at NOAEL dose of 0.00016 mg/kg/day: 0.0178 ug/mL

Estimated TWA = (0.0178 ug/mL - 0 ug/mL) / 2 = 0.0089 ug/mL = 0.0089 mg/L

These estimated TWA serum levels can then be inputted into equation A6 as the steady state serum concentration, Css, using the same values used by ATSDR for the other parameters to generate candidate MRLs for these immunotoxicity studies.

$$Dss = (Css \times 0.000347\ day^{-1} \times 0.2\ L/kg) / 1$$

Dong et al. 2009:

D_{SS} = (0.337 mg/L x 0.000347 day-1 x 0.2 L/kg) / 1 = 2.34×10^{-5} mg/kg/day

Then, divide by UF of 30

MRL = 7.8×10^{-7} mg/kg/day

Guruge et al. 2009:

D_{SS} = (0.0945 mg/L x 0.000347 day-1 x 0.2 L/kg) / 1 = 6.56×10^{-6} mg/kg/day

Then, divide by UF of 30

MRL = 2.2×10^{-7} mg/kg/day

Peden-Adams et al. 2008:

D_{SS} = (0.0089 ug/mL x 0.000347 day-1 x 0.2 L/kg) / 1 = 6.2×10^{-7} mg/kg/day

Then, divide by UF of 30

MRL = 2.1×10^{-8} mg/kg/day

APPENDIX B - MRL CALCULATIONS FOR PFNA USING LONGER HALF-LIFE

Based on information from: https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf

In equation A-6 from Appendix A, ATDSR defines an expression relating the external steady-state dosage and steady-state serum concentration:

$$Dss = (Css \times k_e \times V_d) / AF$$

Where:

Dss = steady-state absorbed dosage (mg/kg/day)

Css = steady-state serum concentration in humans (mg/L)

k_e = elimination rate constant (day-1)

V_d = assumed apparent volume of distribution (L/kg)

AF = gastrointestinal absorption fraction

ATSDR provided the following First Order One-Compartment Model Parameters for PFNA in Table A-4:

$k_e = 7.59 \times 10^{-4}$

V_d=0.2

AF=1

The $k_e = 7.59 \times 10^{-4}$ is based on a half-life estimate of 900 days for young women. Based on Eq. A-5, a half-life of 1570 days for all other adults would result in a k_e of 4.4×10^{-4} (k_e = ln(2) / half-life).

Thus, if the k_e representing the longer, more representative half-life for PFNA was used, along with ATSDR's estimated Css of 6.8 mg/L:

Dss = (6.8 mg/L x 0.000441 day-1 x 0.2 L/kg) / 1 = 6×10^{-4} mg/kg/day

Then, divide by UF of 300

MRL = 2×10^{-6} mg/kg/day

APPENDIX C - MCLG CALCULATIONS

From EPA's Drinking Water Health Advisory for PFOA and PFOS (EPA, 2016 a and b)

The EPA used drinking water intake and body weight parameters for lactating women in the calculation of a lifetime health advisory for PFOA and PFOS. EPA used the rate of 54 mL/kg-day representing the consumers only estimate of combined direct and indirect community water ingestion at the 90th percentile for lactating women (see Table 3-81 in EPA 2011).

First, a Drinking Water Equivalent Level (DWEL) is derived from the reference dose (RfD) and assumes that 100% of the exposure comes from drinking water. The RfD is multiplied by body weight and divided by daily water consumption to provide a DWEL.

$$DWEL = (RfD \times bw) / DWI = RfD / (DWI/bw)$$

Where:

RfD = critical dose (mg/kg/day)

bw = body weight (kg)

DWI = drinking water intake (L/day)

DWI/bw = 0.054 L/kg-day

Then, the DWEL is multiplied by the relative source contribution (RSC). The RSC is the percentage of total drinking water exposure, after considering other exposure routes (for example, food, inhalation). Following EPA's Exposure Decision Tree in its 2000 methodology (EPA, 2000), significant potential sources other than drinking water ingestion exist; however, information is not available to quantitatively characterize exposure from all of these different sources (Box 8B in the Decision Tree). Therefore, EPA recommends a RSC of 20% (0.20) for PFOA and PFOS.

Thus, the lifetime health advisory (HA) is calculated after application of a 20% RSC as follows:

$$HA = DWEL \times RSC$$

The two above equations can be combined to generate:

HA = (RfD / (DWI/bw)) x RSC

For these purposes, we can assume that ATSDR's MRL is equivalent to a RfD, and an HA equivalent to a MCLG.

MCLG = (MRL / (DWI/bw)) x RSC

The EPA used estimated drinking water parameters for lactating mothers, making the equation:

MCLG = (MRL / 0.054 L/kg-day) x 0.2

*NOTE:

DWI/bw for average adult = 0.029 L/kg-day, used by New Jersey;

DWI/bw for lactating mother = 0.054 L/kg-day, used by EPA; and

DWI/bw for breastfeeding or formula-fed infant = 0.175 L/kg-day, used by Vermont

This equation can be applied to proposed and candidate MRLs from ATSDR (final values are rounded):

Using ATSDR's proposed MRLs and drinking water assumptions for lactating women:

PFOA

MCLG = (3 x 10^{-6} mg/kg/day / 0.054 L/kg-day) x 0.2 = 1.11 x 10^{-5} mg/L = 11 ng/L or ppt

PFOS

MCLG = (2 x 10^{-6} mg/kg/day / 0.054 L/kg-day) x 0.2 = 7.41 x 10^{-6} mg/L = 7 ng/L or ppt

PFNA

MCLG = (3 x 10^{-6} mg/kg/day / 0.054 L/kg-day) x 0.2 = 1.11 x 10^{-5} mg/L = 11 ng/L or ppt

PFHxS

MCLG = (2 x 10^{-5} mg/kg/day / 0.054 L/kg-day) x 0.2 = 7.41 x 10^{-5} mg/L = 74 ng/L or ppt

Using NRDC's estimated MRLs for immunotoxicity studies and drinking water assumptions for lactating women:

In Appendix A we noted that ATSDR did not choose to use the most sensitive endpoint for PFOS. Here we show the MCLGs that would result if the studies with most sensitive endpoints were to be chosen for calculation of MRL as in Appendix A and translated to MCLGs using the drinking water assumptions for lactating women.

Dong et al. 2011

MCLG = (3 x 10^{-6} mg/kg/day / 0.054 L/kg-day) x 0.2 = 1.11 x 10^{-5} mg/L = 11 ng/L or ppt

Dong et al. 2009

MCLG = (8 x 10^{-7} mg/kg/day / 0.054 L/kg-day) x 0.2 = 2.96 x 10^{-6} mg/L = 3 ng/L or ppt

Guruge et al. 2009

MCLG = (2 x 10^{-7} mg/kg/day / 0.054 L/kg-day) x 0.2 = 7.41 x 10^{-7} mg/L, **0.7 ng/L (< 1 ppt)**

Peden-Adams et al. 2008

MCLG = (2 x 10^{-8} mg/kg/day / 0.054 L/kg-day) x 0.2 = 7.41 x 10^{-8} mg/L, **0.07 ng/L (< 1 ppt)**

In Appendix B we noted that ATSDR did not use the half-life for PFNA that was the most representative. Here we show the MCLG that would result if the longer, more representative half-life were to be chosen for calculation of the MRL as in Appendix B and translated to a MCLG using drinking water assumptions for lactating women.

MCLG = (2 x 10^{-6} mg/kg/day / 0.054 L/kg-day) x 0.2 = 7.41 x 10^{-6} mg/L = 7 ng/L or ppt

Using ATSDR's proposed MRLs and drinking water assumptions for infants:

Vermont used the drinking water assumptions for breastfeeding or formula-fed infants of 0.175 L/kg-day. If this value is used, the equation becomes:

MCLG = (MRL / 0.175 L/kg-day) x 0.2

This equation can be applied to proposed and candidate MRLs from ATSDR (final values are rounded):

PFOA

MCLG = (3×10^{-6} mg/kg/day / 0.175 L/kg-day) x 0.2 = 3.43×10^{-6} mg/L = 3 ng/L or ppt

PFOS

MCLG = (2×10^{-6} mg/kg/day / 0.175 L/kg-day) x 0.2 = 2.29×10^{-6} mg/L = 2 ng/L or ppt

PFNA

MCLG = (3×10^{-6} mg/kg/day / 0.175 L/kg-day) x 0.2 = 3.43×10^{-6} mg/L = 3 ng/L or ppt

PFHxS

MCLG = (2×10^{-5} mg/kg/day / 0.175 L/kg-day) x 0.2 = 2.29×10^{-5} mg/L = 23 ng/L or ppt

Using NRDC's estimated MRLs for immunotoxicity studies and drinking water assumptions for infants:

Candidate MRL's (rounded) for immunotoxicity studies identified by ATSDR, calculated in Appendix B:

Dong et al. 2011

MCLG = (3×10^{-6} mg/kg/day / 0.175 L/kg-day) x 0.2 = 3.43×10^{-6} mg/L = 3 ng/L or ppt

Dong et al. 2009

MCLG = (8×10^{-7} mg/kg/day / 0.175 L/kg-day) x 0.2 = 9.14×10^{-7} mg/L, **0.9 ng/L (< 1 ppt)**

Guruge et al. 2009

MCLG = (2×10^{-7} mg/kg/day / 0.175 L/kg-day) x 0.2 = 2.28×10^{-7} mg/L, **0.2 ng/L (< 1 ppt)**

Peden-Adams et al. 2008

MCLG = (2×10^{-8} mg/kg/day / 0.175 L/kg-day) x 0.2 = 2.28×10^{-8} mg/L, **0.02 ng/L (< 1 ppt)**

Candidate MRL's (rounded) for PFNA using longer half-life estimate, calculated in Appendix C:

MCLG = (2 x 10^{-6} mg/kg/day / 0.175 L/kg-day) x 0.2 = 2.28 x 10^{-6} mg/L = **2 ng/L or ppt**

****ALSO NOTE:** All estimated MCLGs presented here would be an order of magnitude lower/stricter if an additional UF of 10 was applied to the RfD or MRL to protect fetuses, infants and children as recommended by the National Academy of Sciences (NAS, 1993) for pesticides and as required in the Food Quality Protection Act. 21 U.S.C. §346a(b)(2)(C)(ii)(II).

APPENDIX D - MCLG CALCULATIONS FOR PFOA BASED ON REFERENCE DOSE CALCULATED BY NEW JERSEY FOR ALTERED MAMMARY GLAND DEVELOPMENT

Based on information from Gleason et al., 2017, found at:
https://www.nj.gov/dep/watersupply/pdf/pfoa-appendixa.pdf

Selected Study

The New Jersey Drinking Water Quality Institute selected the late gestational exposure study conducted by Macon et al. 2011[67] because it was the only developmental exposure study of mammary gland development that provides serum PFOA data from the end of the dosing period (PND 1) that can be used for dose-response modeling.

Determination of Point of Departure (POD)

EPA Benchmark Dose Modeling Software 2.1.2 was used to perform Benchmark Dose (BMD) modeling of the data for two endpoints, mammary gland developmental score and number of terminal endbuds, at PND 21 from Macon et al. 2011[67], using serum PFOA data from PND 1 as the dose. Continuous response models were used to obtain the BMD and the Benchmark Dose Lower (BMDL) for a 10% change from the mean for the two endpoints. The lowest significant BMDL, for decreased number of terminal endbuds, of 22.9 ng/ml in serum was used as the POD for reference dose (RfD) development.

Target Human Serum Level

Uncertainty factors (UFs) were applied to the POD to obtain the Target Human Serum Level. The Target Human Serum Level (ng/ml in serum) is analogous to a RfD but is expressed in terms of internal dose rather than administered dose. The total of the uncertainty factors (UFs) applied to the POD serum level was 30 (10 for human variation and 3 for animal-to-human extrapolation).

The target human serum level is: (22.9 ng/ml) / 30 = 0.8 ng/ml (800 ng/L).

Refereuce Dose (RfD)

EPA used a pharmacokinetic modeling approach to develop a species-independent clearance factor, 1.4×10^{-4} L/kg/day that relates serum PFOA level (μg/L) to human PFOA dose (μg/kg/day). The clearance factor can be used to calculate the RfD, as follows:

RfD = Target Human Serum Level x Clearance factor

RfD = 800 ng/L x 1.4 x 10^{-4} L/kg/day = 0.11 ng/kg/day

Where:

Target Human Serum Level = 800 ng/L

Clearance factor = 1.4 x 10-4 L/kg/day

RfD = Reference Dose = 0.11 ng/kg/day

Maximum Contaminant Level Goal (MCLG) for Drinking Water

Default relative source contribution (RSC) of 20% is used to develop the Health-based MCLG.

To calculate a Health-based MCLG based on mammary gland effects instead of hepatic effects:

MCLG = (RfD x bw x RSC) / DWI

MCLG = (0.11 ng/kg/day x 70 kg x 0.2) / (2 L/day) = **0.77 ng/L (< 1 ppt)**

Where:

RfD = Reference Dose for altered mammary gland development = 0.11 ng/kg/day

bw = assumed adult body weight = 70 kg

RSC = Relative Source Contribution from drinking water = 0.2

DWI = assumed adult daily drinking water intake = 2 L/day

***NOTE:** A MCLG based on mammary gland effects using EPA's drinking water exposure assumptions (for a lactating mother) or Vermont's drinking water exposure assumptions (breastfeeding infant) would result in an even lower MCLG than calculated above. (See Appendix C)

For example, if the drinking water exposure parameters for lactating mothers (EPA) is used:

MCLG = (0.11 ng/kg/day / 0.054 L/kg-day) x 0.2 = **0.41 ng/L (<1 ppt)**

If drinking water exposure parameters for infants under 1 year of age is used (as was done in Vermont):

MCLG = (0.11 ng/kg/day / 0.175 L/kg-day) x 0.2 = **0.13 ng/L (<1 ppt)**

APPENDIX E – APPROXIMATION OF RSC USED BY ATSDR FOR DRINKING WATER ENVIRONMENTAL MEDIA EVALUATION GUIDES

In November 2018 ATSDR published the webpage https://www.atsdr.cdc.gov/pfas/mrl_pfas.html, which stated:

"When ATSDR uses an average adult's or child's weight and water intake to convert these MRLs into drinking water concentrations, the individual PFOA, PFOS, PFHxS, and PFNA concentrations are

- PFOA: 78 ppt (adult) and 21 ppt (child)
- PFOS: 52 ppt (adult) and 14 ppt (child)
- PFHxS: 517 ppt (adult) and 140 ppt (child)
- PFNA: 78 ppt (adult) and 21 ppt (child)"

In posting this webpage, ATSDR provided minimal information as to how the proposed drinking water values were calculated and what assumptions were made and used in their derivation. According to ATSDR, their calculations were based on,

"...the guidelines published in the Public Health Assessment Guidance Manual, and the EPA 2011 Exposure Factors Handbook External. For example, for an estimate of a child's drinking water exposure, ATSDR bases this calculation on an infant (age birth to one year old) weighing 7.8 kg and an intake rate of 1.113 liters per day. For an adult's drinking water exposure, ATSDR bases this calculation on a body weight of 80 kg and an intake rate of 3.092 liters per day. Scientists may use different assumptions when calculating concentrations from dosages."

In this Appendix we back calculate to derive the missing information, namely the relative source contribution (RSC).

From Appendix C:

$$MCLG = (MRL / (DWI/bw)) \times RSC$$

Where (values provided by ATSDR on website):

DWI for adults = 3.092 L/day

and

bw for adults = 80 kg

thus,

DWI/bw for adults = 0.0387 L/kg/day

DWI for children = 1.113 L/day

and

bw for children = 7.8 kg

thus,

DWI/bw for children = 0.142 L/kg/day

So, for adults:

MCLG = (MRL / (0.039 L/kg/day)) x RSC*

And for children:

MCLG = (MRL / (0.142 L/kg/day)) x RSC*

*RSC not provided by ATSDR, however, drinking water values provided by ATSDR can be used with these equations to solve for the RSC used by ATSDR. For example, for PFOA:

Adults:

RSC = (MCLG x DWI/bw) / MRL

RSC = (78 ng/L x 0.0387 L/kg/day) / 3 ng/kg/day

RSC = 1

Children:

RSC = (MCLG x DWI/bw) / MRL

RSC = (21 ng/L x 0.142 L/kg/day) / 3 ng/kg/day

RSC = 1

APPENDIX F – RFD AND MCLG CALCULATIONS FOR GENX

From EPA's Draft Toxicity Assessment of GenX chemicals:

https://www.epa.gov/sites/production/files/2018-11/documents/genx_public_comment_draft_toxicity_assessment_nov2018-508.pdf

"…POD human equivalent dose is 0.023 mg/kg/day. UF applied include a 10 for intraspecies variability, 3 for interspecies differences, and 3 for database deficiencies, including immune effects and additional developmental studies, to yield a subchronic RfD of 0.0002 mg/kg/day. In addition to those above, a UF of 3 was also applied for extrapolation from a subchronic to a chronic duration in the derivation of the chronic RfD of 0.00008 mg/kg/day."

If uncertainty factors that properly reflected the deficiencies in toxicity data (database, sub-chronic/chronic, children's vulnerability, inter/intra species) were used, the combined uncertainty factor could be as high as 100,000 (see Part IV, section GenX).

From pg. 58 of EPA's Draft Toxicity Assessment of GenX chemicals:

RfD = POD/total UF

With NRDC recommended UFs:

RfD = (0.023 mg/kg/day)/100,000 = 2.3×10^{-7} mg/kd/day

Where:

POD = Point of departure human equivalent dose

Total UF = 10 for intraspecies variability, 10 for interspecies differences, 10 for database limitations, 10 for extrapolation from subchronic to chronic duration, and 10 to protect fetuses, infants and children.

From Appendix C:

MCLG = (RfD / (DWI/bw)) x RSC

Using drinking water exposure parameters for lactating mothers, DWI/bw = 0.054 L/kg-day, the MCLG based on liver toxicity would be (rounded):

MCLG = (2 x 10^{-7} mg/kd/day / 0.054 L/kg-day) x (0.2 RSC) = 7.41 x 10^{-7} mg/L = **0.7 ppt**

Using drinking water exposure parameters for an infant under 1 year, DWI/bw = 0.175 L/kg-day, the MCLG based on liver toxicity would be (rounded):

MCLG = (2 x 10^{-7} mg/kd/day / 0.175 L/kg-day) x (0.2 RSC) = 2.29 x 10^{-7} mg/L = **0.2 ppt**

*NOTE: A MCLG based on EPA's proposed RfD for GenX based on liver toxicity would be (rounded):

Using drinking water exposure parameters for lactating mothers

MCLG = (8 x 10^{-5} mg/kd/day / 0.054 L/kg-day) x (0.2 RSC) = 2.96 x 10^{-4} mg/L = 296 ppt

Using drinking water exposure parameters for an infant under 1 year

MCLG = (8 x 10^{-5} mg/kd/day / 0.175 L/kg-day) x (0.2 RSC) = 9.14 x 10^{-5} mg/L = 91 ppt

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Smith, Ian (EGLE)

From: Doris Meier [redacted]@healthyfoodaction.net>
Sent: Friday, January 31, 2020 3:25 PM
To: EGLE-PFAS-RuleMaking
Subject: Proposed changes to the Supplying Water to the Public rule set
Attachments: Michigan Letter__1.31.20.pdf

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: **Suzann Ruch**
PO Box 30817
Lansing, Michigan 48909-8311
EGLE-PFAS-RuleMaking@Michigan.gov

Dear Ms. Ruch:

Please accept the attached letter signed by health professionals and others concerned for the impact of the proposed rule set on Michiganders' public health.
Collectively, they urge Michigan to take the lead in setting the most health-protective standards for PFAS in drinking water in the nation. Unfortunately, the proposed rules fail to meet that goal.

On their behalf, Healthy Food Action is submitting this letter as public comment. If you wish to respond to the group collectively, please use [redacted]@healthyfoodaction.net as a point of contact.

Thank you for your consideration.

Michael Dimock
Steering Committee Co-Chair
Healthy Food Action

Re: Proposed changes to the Supplying Water to the Public rule set

January 31, 2020

Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
Attention: **Suzann Ruch**
PO Box 30817
Lansing, Michigan 48909-8311

Dear Michigan Department of Environment, Great Lakes, and Energy:

As Michiganders, and also as physicians, nurses, dietitians and other health professionals, we are keenly aware that clean and safe drinking water is essential for life.

That's also why we welcome proposed rules to help reduce exposure to "forever" PFAS chemicals in our drinking water. So far, PFAS have been found in the drinking water of over 1.9 million Michigan residents. It's likely PFAS are detectable in our blood, as they are in nearly everyone on Earth. It's not only their persistence in human tissue that makes PFAS a danger. Robust and ever-stronger science has also now linked PFAS exposure to an array of serious health problems such as cancer, liver damage, immune system dysfunction, and harm to developing fetuses and children.

We do appreciate the Michigan Department of Environment, Great Lakes, and Energy's (EGLE) efforts to advance new drinking water rules. **Given the extent of PFAS contamination in Michigan, however, we urge Michigan to take the lead in setting the most health-protective standards in the nation. The proposed rules don't meet that goal.**

In particular, we urge the agency to:

- Make sure, using the best available science, that the final standards will protect the most vulnerable among us, such as nursing mothers, infants, and developing fetuses. If the standards protect them, we can be assured that all Michiganders likely will be protected;
- Set standards that protect individuals fully from their total exposure to PFAS, including different types of exposure, as well as the cumulative exposure to mixtures of multiple types of PFAS.
- Require water systems detecting PFAS to install water treatment(s) to remove a broad range of different types of PFAS substances, instead of focusing on only a few PFAS at a time.

Given the persistence and toxicity of PFAS, combined with the certainty that millions of Michiganders already are currently exposed, our state should and must lead the country in its standard-setting.

Please do everything in your power to ensure Michigan plays that critical role. Thank you so much for your consideration.

Sincerely,

Michelle Storms-Van Howe, MD, Physician, Marquette, MI

Meghan Damman, RD, BSD, Registered Dietitian, Munson Health Center, Traverse City, MI

Sara Gleicher, MSW Social Worker, Beaumont Health System, Southfield, MI

Colleen Synk, MSPH Lansing, MI

Natalie Sampson, PhD, MPH, Professor, University of Michigan-Dearborn, Dearborn, MI

Mark Gleason, PhD, Grand Rapids, MI

Courtney Carignan, PhD, Okemos, MI

Randi Lesagonicz, Grand Valley State University, Belding, MI

Dolores Leonard, Ed.D, Detroit, MI

Theresa Landrum, Cancer Survivor, Detroit, MI

Susan Stanley Principal, Salina Elementary School, Dearborn, MI

Samraa Lugman, Dearborn, MI

Ali Almaklani, Dearbon, MI

Jennifer Holtz, BS, Van Buren Township, MI

Allyn Kantor, JD, BS, Ann Arbor, MI

Margaret Justusson, MSN, ANP Nurse Practitioner, Henry Ford Medical System, Gross Ile, MI

Cc: Governor Gretchen Whitmer

Smith, Ian (EGLE)

From: Aguilar, Josue [redacted]@nrdc.org>
Sent: Friday, January 31, 2020 3:55 PM
To: EGLE-PFAS-RuleMaking
Cc: Friend, Megan
Subject: FW: EGLE-PFAS-Rule Making - NRDC Public Comments
Attachments: Michigan Department of Environment PFAS Cover Letter.pdf; Michigan PFAS Final Comments 1.31.20.xlsx

Importance: High

Dear Suzann Ruch,

Please kindly accept the attached cover letter and 1301 public comments from Michigan members and activists of the Natural Resources Defense Council (NRDC), in support of new drinking water rules that would help reduce exposure to toxic PFAS chemicals.

These dangerous chemicals have been linked to serious health risks like cancer, liver damage, immune system dysfunction, and harm to developing fetuses, infants, and children. And, so far, they've been found in the drinking water of over 1.9 million Michiganders.

While we appreciate that EGLE is advancing these drinking water rules, the agency should:

• Use the best available, current science to ensure the standards protect Michigan's most vulnerable populations, like developing fetuses, infants, children, pregnant women, and nursing moms.
• Set standards that fully protect individuals from all types of PFAS exposure in drinking water, including exposures to mixtures of multiple types of PFAS.
• Require water systems that detect PFAS to install water treatment that will remove a broad range of PFAS substances, instead of focusing on only a few PFAS at a time.

Given the extensive PFAS contamination in Michigan, we should be leading the country by setting the nation's most health-protective standards. Please do everything in your power to ensure that our state plays that critical role.

Thank you so much for your time.

Regards,
Josue

JOSUE AGUILAR
Communications Assistant,
Digital Advocacy & Fundraising

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To the Michigan Department of Environment, Great Lakes, and Energy
Pending rule set #: 2019-35 EG

Suzann Ruch
Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
PO Box 30817
Lansing, Michigan 48909-8311

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• Use the best available, current science to ensure the standards protect Michigan's most vulnerable populations, like developing fetuses, infants, children, pregnant women, and nursing moms.
• Set standards that fully protect individuals from all types of PFAS exposure in drinking water, including exposures to mixtures of multiple types of PFAS.
• Require water systems that detect PFAS to install water treatment that will remove a broad range of PFAS substances, instead of focusing on only a few PFAS at a time.

Given the extensive PFAS contamination in Michigan, we should be leading the country by setting the nation's most health-protective standards. Please do everything in your power to ensure that our state plays that critical role.

Thank you so much for your time.

Best,
Josue

JOSUE AGUILAR
Communications Assistant,
Digital Advocacy & Fundraising

NATURAL RESOURCES DEFENSE COUNCIL
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Smith, Ian (EGLE)

From: Tom Frazier [redacted]@michigantownships.org>
Sent: Friday, January 31, 2020 4:45 PM
To: EGLE-PFAS-RuleMaking
Subject: PFAS Rules Public Comments
Attachments: PFAS rule comments cover ltr 01.31.2020.docx; PFAS MTA Public Comment 01.31.2020.docx

Dear EGLE:

Please find attached a cover letter from Neil Sheridan, Executive Director of the Michigan Townships Association as well as our public comments with respect to the draft PFAS rules.

Tom Frazier
Legislative Liaison
Michigan townships Association
[redacted]@michigantownshipis.org

MTA
MICHIGAN TOWNSHIPS ASSOCIATION

January 30, 2020

Drinking Water and Environmental Health Division
Department or Environment, Great Lakes and Energy
Attn: Suzann Ruch
P.O. Box 30817
Lansing, Michigan 48909-8311

RE: Public Comments – Supplying Water to the Public (PFAS) Draft Rules 2019-35 EG

Dear Ms. Ruch:

On behalf the Michigan Townships Association (MTA), attached please find public comments in response to the Supplying Water to the Public (PFAS) Draft Rules 2019-35 EG.

While the Association and its members with public water systems want to ensure a long-term safe water supply for all residents, the rules place a financial burden on municipalities with water supplies. The enclosed comments include concerns about the cost impact as well as expanding the coverage of the rules without a science-based approach.

Associated with the rule process, MTA would urge EGLE and Governor Whitmer to include additional funding for municipal water supplies in the state budget to assist communities with the implementation of the proposed rules. Other suggestions include access to grants, low interest loans, and debt pooling.

If MTA can provide any additional information, please do not hesitate to contact me.

Sincerely,

Neil Sheridan

Neil Sheridan
MTA Executive Director

Enclosure

Michigan Townships Association
Public Comments on the
Michigan Department of Environment, Great Lakes and Energy's
Supplying Water to the Public Draft Rules (PFAS) 2019-35 EG
January 30, 2020

This public comment document is provided in response to the Michigan Department of Environment, Great Lakes and Energy's Supplying Water to the Public Draft Rules (PFAS) 2019-35 EG.

In setting enforceable standards for drinking water, it is critical to have those standards be science-based. The draft rules incorporate the recommendations of the Science Advisory Workgroup - health based values for seven different PFAS (per-and polyfluoroalkyl) substances, which are appropriate. However, many have called for additional standards to be included in the rules where science-based evidence is currently unavailable. MTA does not support the inclusion of additional substances at this time. The inclusion of additional substances should be considered through an imminent threat to public health and/or the science is available to substantiate consideration. It is important for the rules not to get ahead of the science on various other PFAS substances.

The draft rules will add additional drinking water standards that result in new sampling and response requirements. These sampling and response requirements will impose costs on local units of government that own water supplies. There are 733 community water supplies that are owned by local units of government. In addition, of the approximately 1,300 non-transient non-community water supplies in the state, 291 are owned publicly—some of which could be owned by a municipality. By the department's own estimation, sampling will cost $600.00 per sample to collect and to test. Initially, these samples must be taken quarterly and therefore will cost municipal water supplies a minimum of $1,759,200 (733 water supplies x $2,400) in the first year alone. Many of our water supplies do not have the resources to incorporate these costs into their current budget. It is our contention that smaller systems will be hit the hardest as the $2,400.00 sampling cost per year will be very difficult to incorporate under current revenue streams. Small, medium, and larger water systems alike will likely need to pass these costs along to their ratepayers without additional financial assistance. The smaller the water system, the fewer ratepayers to spread the costs.

There will also be additional costs for municipal water systems when treatment is necessary. The recommended treatment option of Granular Activated Carbon (GAC) is expensive and must be replaced periodically. Plainfield Township (Kent County) is finalizing the installation of a GAC system in its water treatment plant over the next two years. They have spent approximately $1 million on this system to date with additional funding needed for the final two phases of implementation. System filters will need to be replaced approximately every three to five years. While the township was a recipient of a state

grant covering approximately 75 percent of the cost of the GAC system to date, this does address future operation/maintenance costs, eventual replacement costs of the GAC system or the need for well fields for a new water source. The costs outlined in this example are only for one municipality. Many more will face these costs in the future.

The rules will also increase costs for training of municipal water supply personnel as well as costs for notification and reporting requirements contained within the rules. Training will be required for personnel to ensure samples are not contaminated. We would recommend the state provide training to water supply personnel to help alleviate training costs. Further, additional staff may be needed to fully implement the PFAS rules. Finally, additional costs will be incurred for proper disposal of contaminated media.

It is estimated that approximately 1.9 million citizens of Michigan are currently drinking water with some level of PFAS contamination. Citizens are concerned and rightfully so. However, even in situations where PFAS levels do not exceed standards contained in the rules, public education will be required—placing additional costs on the water supplier. And, the draft rules do not address the costs of possible PFAS contamination in many private wells (serving 25 percent of Michigan's population) which may require municipal water supplies be extended to provide safe drinking water.

The costs to municipal water supplies outlined above are in addition to the estimated $2.5 billion necessary for local governments to implement the 2018 lead and copper. While the draft PFAS rules are important to protect the health, safety and welfare of Michigan's residents, they come at a high financial burden for municipal water suppliers.

Section Break

Form Letter #1 – via (email)@everyactioncustom.com

694 comments in this form, classified as ***In Support***

Example follows

Section Break

Smith, Ian (EGLE)

From: [redacted]@everyactioncustom.com on behalf of Matthew Nossal [redacted]@everyactioncustom.com>
Sent: Tuesday, January 28, 2020 12:44 AM
To: EGLE-PFAS-RuleMaking
Subject: Michigan needs the toughest standards for toxic PFAS chemicals in our water

Dear Drinking Water and Environmental Health Division Suzann Ruch,

I'm writing to urge you to move quickly to set a strong standard for PFAS that is based on the best available science and is protective of public health.

PFAS contamination impacts the drinking water of more than 1.9 million Michiganders, and we can't delay action on protecting the health of our communities. We know PFAS causes health impacts, and we know where it is coming from, which is why the state must move swiftly to pass a standard that is protective of public health.

Michigan should be a leader on addressing the PFAS contamination crisis, and that starts with strong standards for these toxic chemicals.

The PFAS limits proposed by the state are a step in the right direction, but key changes need to be made to ensure they protect the health of Michigan communities.

Those include:

-Taking a class-based approach that sets a standard for the combined total of the various PFAS chemicals instead of individual limits for each.

-Ensuring the standards are protective of our most vulnerable populations, like developing infants and children.

-Basing the standards on the best and most recent science.

Michigan should be leading the country on setting the toughest standards for toxic PFAS chemicals in our water.

Sincerely,

Sincerely,
Matthew Nossal
[redacted] Milan, MI 48160-1339
[redacted]@gmail.com

Section Break

Form Letter #2 – via National Resources Defense Council, Inc.

1,299 comments in this form, classified as ***In Support***

Example follows

Section Break

Kirsten Lietz

Grayling, MI 49738

Dear Michigan Department of Environment, Great Lakes, and Energy:

Cc: Governor Gretchen Whitmer

As a Michigan resident, I'm encouraged to hear that the Department of Environment, Great Lakes, and Energy (EGLE) has proposed new drinking water rules that would help reduce exposure to toxic PFAS chemicals in a big way.

These dangerous chemicals have been linked to serious health risks like cancer, liver damage, immune system dysfunction, and harm to developing fetuses, infants, and children. And, so far, they've been found in the drinking water of over 1.9 million Michiganders.

While I appreciate that EGLE is advancing these drinking water rules, the agency should:

- Use the best available, current science to ensure the standards protect Michigan's most vulnerable populations, like developing fetuses, infants, children, pregnant women, and nursing moms.

- Set standards that fully protect individuals from all types of PFAS exposure in drinking water, including exposures to mixtures of multiple types of PFAS.

- Require water systems that detect PFAS to install water treatment that will remove a broad range of PFAS substances, instead of focusing on only a few PFAS at a time.

Given the extensive PFAS contamination in Michigan, we should be leading the country by setting the nation's most health-protective standards. Please do everything in your power to ensure that our state plays that critical role.

Thank you so much for your time.

Section Break

Form Letter #3 – via Do Gooder

42 comments in this form, classified as ***In Support***

Example follows

Section Break

Smith, Ian (EGLE)

From: Kristen Turick [redacted]@good.do>
Sent: Friday, January 31, 2020 3:21 PM
To: EGLE-PFAS-RuleMaking
Subject: I favor rules that protect the public from PFAS in Michigan's drinking water

I'm writing to support the proposed Michigan Safe Drinking Water Act rules that would impose a strong standard to protect the public health from PFAS chemicals in public drinking water supplies.

The discovery of PFAS in drinking water across Michigan is alarming. There is strong science supporting a link between PFAS and human health impacts, from immune and reproductive system effects to increased cancer risks.

The proposed rules are a major step in the right direction, giving Michigan for the first time an enforceable standard for PFAS in drinking water. Waiting for the federal government to act is simply not an option with the health of Michigan's people and environment at immediate risk. But I support strengthening of the proposed rules to assure protection of human health through the following changes:

Instead of considering just adults, the standards should consider PFAS impacts to children, pregnant women, those suffering from chronic illness, the elderly, and other vulnerable populations.

The rules should set a combined total standard for all PFAS contaminants.

Michigan's PFAS standards should take into account the best available research and studies.

I commend your agency for moving ahead on these science-based rules and support their adoption, with the improvements described above, as soon as possible.

Yours sincerely,

Kristeb Turick

_____

This email was sent by Kristen Turick via Do Gooder, a website that allows people to contact you regarding issues they consider important. In accordance with web protocol FC 3834 we have set the FROM field of this email to our generic no-reply address at campaigns@good.do, however Kristen provided an email address ([redacted]@[redacted].com) which we included in the REPLY-TO field.

Please reply to Kristen Turick at [redacted]@[redacted].com.

To learn more about Do Gooder visit https://gcc01.safelinks.protection.outlook.com/?url=www.dogooder.co&data=02%7C01%7Cegle-pfas-rulemaking%40michigan.gov%7Cbff7c05ba45c4963a46308d7a68b224e%7Cd5fb7087377742ad966a892ef47225d1%7C0%7C1%7C637160988817170660&sdata=YZAkFCsAF1Smh5Kc3cAZ1QKkVW7aBS5RfCMJ51ij4e0%3D&reserved=0

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Section Break

Form Letter #4 – via Clean Water Action

527 comments in this form, classified as ***Neutral***

Example follows

Section Break

Re: PFAS Maximum Contaminant Level Rules — Public Comment

To: Drinking Water and Environmental Health Division
Michigan Department of Environment, Great Lakes, and Energy
P.O. Box 30817
Lansing, Michigan 48909-8311

We are in the midst of a public health crisis. PFAS chemicals, which have been linked to serious health concerns including reproductive problems and cancer, are in the drinking water of over 1 million Michigan residents. I urge you to protect Michiganders by setting the ***strongest possible drinking water standards for PFAS***. Please consider the following when finalizing the PFAS MCL:

- **Take a class-based approach to regulating PFAS in drinking water:** Considering health based values (HBVs) for seven individual PFAS chemicals is not protective against the likelihood of additive or synergistic effects from exposure to multiple PFAS chemicals. Water testing has confirmed that when drinking water is contaminated with PFAS, people are nearly always ingesting multiple chemicals.
- **Ensure drinking water standards for PFAS protect those most vulnerable to harm:** PFAS chemicals are more toxic during pregnancy, early life, and for people who are elderly or already suffering from other chronic illness. We must set standards that are protective of our most vulnerable populations.
- **Take into account the most recent science when setting HBVs:** Recent studies show a relationship between exposure to PFHxS and impaired reproduction. Given the rapid pace at which new information on the effects of PFAS chemicals on human health is emerging, we should strive to reflect the very best science in our assessment of water safety.

Thank you for your attention to these comments.

Sincerely,

NAME: Christie Reay

ADDRESS: [redacted]

CITY, STATE, ZIP: East Lansing, MI 48823

PHONE: _____ EMAIL: _____

Section Break

Form Letter #5 – (unknown origin) with Subject: Michigan needs the strongest possible MCL for PFAS

182 comments in this form, classified as ***Neutral***

Example follows

Section Break

Smith, Ian (EGLE)

From: Sam Inglot <[redacted]@gmail.com>
Sent: Friday, January 31, 2020 11:28 AM
To: EGLE-PFAS-RuleMaking
Subject: Michigan needs the strongest possible MCL for PFAS

Dear PFAS Rulemaking,

We are in the midst of a public health crisis. PFAS chemicals, which have been linked to serious health concerns including reproductive problems and cancer, are in the drinking water of over 1 million Michigan residents. I urge you to protect Michiganders by setting the strongest possible drinking water standards for PFAS. Please consider the following when finalizing the PFAS MCL:

Take a class-based approach to regulating PFAS in drinking water: Considering health based values (HBVs) for seven individual PFAS chemicals is not protective against the likelihood of additive or synergistic effects from exposure to multiple PFAS chemicals. Water testing has confirmed that when drinking water is contaminated with PFAS, people are nearly always ingesting multiple chemicals.

Ensure drinking water standards for PFAS protect those most vulnerable to harm: PFAS chemicals are more toxic during pregnancy, early life, and for people who are elderly or already suffering from other chronic illness. We must set standards that are protective of our most vulnerable populations.

Take into account the most recent science when setting HBVs: Recent studies show a relationship between exposure to PFHxS and impaired reproduction. Given the rapid pace at which new information on the effects of PFAS chemicals on human health is emerging, we should strive to reflect the very best science in our assessment of water safety.

Thank you for your attention to these comments.

Sincerely,
Sam Inglot
[redacted]
Lansing, MI 48912

Section Break

Form Letter #6 – via Sierra Club

425 comments in this form, classified as ***In Support***

Example follows

Section Break

Smith, Ian (EGLE)

From: Norrie Zaret ([redacted].com) Sent You a Personal Message <automail@knowwho.com>
Sent: Thursday, January 30, 2020 7:22 PM
To: EGLE-PFAS-RuleMaking
Subject: Get PFAS out of our water

Dear The Department of the Environment Great Lakes and Energy,

I am very concerned about the quality of the drinking water in MI. We should not EVER have to worry about PFA?s in drinking water.

The PFAS limits proposed by the state are a step in the right direction, but key changes need to be made to ensure they protect the health of Michigan communities:

-Michigan should be leading the country on setting the toughest standards for toxic PFAS chemicals in our water.

-The state should set a combined total limit for all of the toxic contaminants, instead of smaller limits for each chemical.

-Establishing a combined total standard for PFAS contaminants will set the baseline for ensuring Michiganders have safe, clean water to drink.

The PFAS standards must be protective of our most vulnerable populations and be based on the best available science:

-Children, pregnant women, and those suffering from chronic illness and the elderly are the most susceptible to the negative health impacts of exposure to PFAS.

-Standards should consider PFAS' impacts on children, the elderly and other vulnerable populations instead of just adults.

-Michigan?s PFAS standards should take into account the best available research and studies, like those done in New Hampshire, to ensure the limits are protective of public health.

Sincerely,

Norrie Zaret
[redacted]
Saline, MI 48176
[redacted].com
[redacted]