# Summary of Public Comments for Rule Set # 2020-130 EQ: Cleanup Criteria Requirements for Response Activity

The Michigan Department of Environment, Great Lakes, and Energy (EGLE) per- and polyfluoroalkyl substances (PFAS) rulemaking public comment period ran from July 8, 2021, through August 9, 2021, during which time 66 **written public comments** were received via the designated email inbox (<u>EGLE-RRD@Michigan.gov</u>) and by mail via the Remediation and Redevelopment Division (RRD) mailbox:

Michigan Department of Environment, Great Lakes, and Energy Remediation and Redevelopment Division Attention: Kevin Schrems P.O. Box 30426 Lansing, Michigan 48909-7926

An additional 2 **oral public comments** were presented to EGLE representatives during the Zoom public hearing July 8, 2021:

The template utilized in drafting the Joint Committee on Administrative Rules (JCAR) Agency Report Package dictates a breakdown by two categories: *persons submitting comments of support* and *persons submitting comments of opposition*. This model does not easily address the number of recommendations for improvements included with the vast majority of the comments. In order to meet the requirements of the JCAR Agency Report Package, only the two required categories are included in the form – however, EGLE's considerations are summarized in this report.

The comments were individually read and reviewed by EGLE-RRD staff, assigned categories of concern based on the content of each comment, and classified as in support, or not in support of promulgating the seven per- and polyfluoroalkyl substances (commonly referred to as PFAS) as a new table under Rule 44, that contains the generic PFAS cleanup criteria for groundwater. A comment did not apply to the proposed rule set, it was classified as "not pertaining to proposed rules," and was not counted as in support or not in support.

Criteria for the comment categories are summarized as follows:

## IV. Comments in Support: 63 (95%)

Comments were classified as *in support* in cases where language directly indicated overall support for the rulemaking effort. Examples include:

- "Our groundwater is inextricably linked to our surface water and groundwater is often a drinking water source for Michigan families, so I fully support having the same standards for all groundwater that we do for drinking water."
- "We strongly support the proposed rules. It is imperative for Michigan to promulgate the proposed rules as soon as practicable. The promulgation of these cleanup criteria rules to include the PFAS MCLs is an important step to ensure all Michigan citizens have the

- same drinking water protection, whether they are served by a public water system or a private well."
- "We support EGLE's actions for the seven PFAS that EGLE proposes to regulate under Part 201. ... We commend EGLE for developing new generic cleanup criteria values for perfluorononanoic acid ("PFNA"), perfluorohexane sulfonic acid ("PFHxS"), perfluorohexanoic acid ("PFHxA"), perfluorobutane sulfonic acid ("PFBS"), and hexafluoropropylene oxide dimer acid ("HFPO-DA"), and for updating existing criteria values for perfluorooctane sulfonic acid ("PFOS") and perfluorooctanoic acid ("PFOA"). Use of these generic cleanup criteria to identify and guide remediation at contaminated sites will benefit both human health by protecting the residential wells upon which millions of people in Michigan rely and wildlife."
- "We commend the Whitmer Administration and EGLE for taking expeditious steps towards regulating PFAS in both public and private drinking water supplies to protect human health. ... strongly supports quick action to adopt the strongest possible groundwater cleanup standards for PFAS in Michigan. We urge the Administration and EGLE 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 Cleanup Criteria Requirements for Response Activity, Rule Set 2020-130 EQ.
- "...EGLE should level the playing field for all Michiganders by adopting these proposed cleanup criteria for groundwater used for drinking water.
- "EGLE should not attempt to balance industry's acceptance of the proposed cleanup criteria with the clear public health benefits provided by this rule set.
- "We see the proposed rules as a valuable mechanism to protect resources from risks associated with PFAS."

Often, comments *in support* included feedback regarding recommendations for the rule making process for PFAS cleanup criteria. These are reflected in *III. Categories of Concern*, below.

# V. Comments not in Support: 2 (3%)

Comments were classified as *not in support* in cases where language directly indicated concerns with adopting the PFAS state drinking water standards (MCLs) as cleanup criteria. Examples include:

- "Because the Cleanup Criteria Requirements for Response Activity rules are based, in part, on the promulgation of State Drinking Water Standards for PFAS under Supplying Water to the Public rules, the MMA is respectfully resubmitting the peer review findings and recommendations [for the MCLs] for consideration. MMA believes the state endeavored to establish appropriate standards, though our peer review identified some areas lacking in the kind of robust scientific and

- technical integrity needed to complete the effort. We believe the issues identified in the peer review report and associated recommendations would result in the state's rulemaking initiative achieving the process and confidence milestones expected of state agencies.
- "If finalized, the Proposed Rule would add extremely burdensome groundwater cleanup criteria for certain PFAS to Michigan's Groundwater Cleanup Criteria under Rule 299.44. ... The RIS does not provide a sufficient level of detail for the conclusions it puts forward, nor does it provide either qualitative or quantitative estimates of the costs and benefits of the Proposed Rule. ... request that EGLE correct certain inaccurate or misleading statements regarding purported impacts to public health and provide a more detailed cost benefit analysis in the draft Regulatory Impact Statement and Cost Benefit Analysis (RIS) in support of the Proposed Rule."

# III. Categories of Concern

Three *categories of concern*, were identified by EGLE- staff during review.

1. EGLE should consider utilizing a class-based approach in developing PFAS criteria.

A class-based approach is not presently feasible, as PFAS analytical techniques are currently only useful in quantifying a set of known PFAS compounds. Semi-quantitative and qualitative analysis for non-targeted PFAS analytes are available but must be paired with well-established quantitative analyses to accurately assess PFAS analyte levels in groundwater used as a source of drinking water. Additionally, the orders-of-magnitude variations in MCLs for PFAS do not lend themselves to a single combined level. This number would necessarily be lower than all but the lowest individual proposed values.

It is recognized that the science of PFAS is evolving. The rule-making process allows for new information to be considered in future reassessments of the PFAS drinking water criteria rules.

2. EGLE must update the PFAS criteria to reflect most recent data and/or science to ensure they are properly protective. EGLE must continue to evaluate additional PFAS compounds and pursue development of generic cleanup criteria for any such compounds.

MPART and EGLE recognize that this class of emerging contaminants will require ongoing assessment of available science as new information may come to light which requires a re-assessment of the PFAS cleanup criteria, or the development of additional PFAS cleanup criteria. The existing rulemaking process allows this as needed.

3. Development of PFAS MCLs that are the basis of the PFAS cleanup criteria.

The MCLs were developed by the Michigan PFAS Action Response Team (MPART) Science Advisory Work Group (SAWG), a group of experts in the fields of epidemiology, toxicology, and risk assessment. In order to address the comments submitted as a peer review, EGLE requested that MPART perform a review of the arguments presented and provide a response. The MPART Human Health Workgroup completed this task and concluded that none of the comments submitted raise concerns which would meaningfully alter the SAWG's conclusions. The MCLs were adopted as proposed and the PFAS cleanup criteria use of the MCLs are consistent with the statutory requirements of Part 201.

# IV. Regulatory Impact Statement/Cost Benefit Analysis

A comment in opposition questioned the appropriateness of the Regulatory Impact Statement (RIS) prepared by EGLE-RRD. Having reviewed these comments, EGLE-RRD has determined that the existing RIS provides the necessary detail and analysis as required by law.

# V. Proposed Rule Changes

Having reviewed the public comments, EGLE identified no necessary rule changes.

From: Matthew D. Schneider < @bdlaw.com>

Sent: Monday, August 9, 2021 4:43 PM

To: EGLE-RRD

**Subject:** Comments on Proposed Rule Set No. 2020-130 EQ

**Attachments:** 2021-08-09 FINAL Comments on Michigan EGLE PFAS Groundwater Standards.pdf

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Please find attached 3M's Comments on Proposed Rule Set No. 2020-130 EQ, to Establish Groundwater Cleanup Criteria for Per- and Polyfluoroalkyl Substances.

3M appreciates the opportunity to comment. Please feel free to contact me with any questions regarding these comments.

### Matthew D. Schneider

Associate



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August 9, 2021

Kevin Schrems P.O. Box 30426 Lansing, MI 48909

Submitted electronically via: <u>EGLE-RRD@michigan.gov</u>

Re: Comments on Proposed Rule Set No. 2020-130 EQ, to Establish Groundwater Cleanup Criteria for Per- and Polyfluoroalkyl Substances

Dear Mr. Schrems:

The 3M Company ("3M") appreciates the opportunity to comment on the proposed Cleanup Criteria Requirements ("Proposed Rule") for per- and Polyfluoroalkyl substances ("PFAS") published in the Michigan Register by the Michigan Department of Environment, Great Lakes, and Energy ("EGLE") on July 1, 2021. If finalized, the Proposed Rule would add extremely burdensome groundwater cleanup criteria for certain PFAS to Michigan's Groundwater Cleanup Criteria under Rule 299.44. As a science-based company with substantial experience, expertise, and product stewardship of certain fluorinated compounds, 3M is well positioned to provide input to EGLE regarding the Proposed Rule.

The RIS does not provide a sufficient level of detail for the conclusions it puts forward, nor does it provide either qualitative or quantitative estimates of the costs and benefits of the Proposed Rule. 3M requests that EGLE correct certain inaccurate or misleading statements regarding purported impacts to public health and provide a more detailed cost benefit analysis in the draft Regulatory Impact Statement and Cost Benefit Analysis (RIS) in support of the Proposed Rule.

## I. The RIS is Inaccurate and Misleading

The RIS inaccurately claims that the Proposed Rule "will provide the basis for identifying hazardous levels of PFAS in the environment" and that the Proposed Rule will "protect the public from unhealthy exposure to these hazardous substances." These Proposed Rules are based on the MCLs established in August 2020 for the seven regulated PFAS. As EGLE states on its website, the MCLs are "set at amounts that pose little to no health risk for those that drink the water over their lifetime." *See* 

https://www.michigan.gov/pfasresponse/0,9038,7-365-95571\_99970---,00.html (last visited August 6, 2021). There is no basis for the statement that identifying an exceedance of the proposed groundwater criteria, which are set at the same levels as the MCLs, will identify hazardous levels of PFAS in the environment. To the contrary, the MCLs identify levels that

pose "little to no health risk" over a lifetime. This inflammatory language regarding potentially hazardous exposure is inaccurate and risks misleading the public about the safety of their water.

Moreover, the RIS's statement that "[e]xposure to PFAS chemicals has been shown to cause numerous adverse health impacts" is a misleading and inaccurate characterization of the Science Advisory Workgroup's (the "Workgroup") conclusions. The Workgroup did not find that exposure to PFAS chemicals "cause" any health impacts. It did not determine a cause and effect relationship for any PFAS. In addition, the Workgroup's conclusions were subject to significant flaws and constraints given the accelerated timeline within which the Workgroup was required to conclude its work.

Finally, there is no basis for the statement in the RIS that failure to establish these standards "puts public health at risk." The RIS cites nothing to support this statement, and it is subject to the same flaws regarding claims about health risks as identified elsewhere in these comments. Although the RIS alludes to certain purported health impacts of PFAS exposure, it does not list or describe these health effects or analyze whether those purported health effects are relevant at the levels of exposure contemplated by the Proposed Rule. To the extent that scientific studies on the health effects of exposure to the seven regulated PFAS contribute to identifying and quantifying benefits in the Proposed Rule, that information should be included in the RIS. In addition, the RIS itself states that the "same treatment technology can be used to address all seven PFAS." EGLE relies on the fact that there are already PFOA and PFOS groundwater cleanup criteria in place for its conclusion that the rule will not require additional actions beyond what is already required. Given that standards already exist for two of the seven regulated PFAS and EGLE asserts that the same treatment addresses all seven, this statement regarding public health risk is baseless and misleading.

# II. EGLE Should Make Additional Efforts to Evaluate the Costs and Benefits Associated with the Proposed Rule

EGLE's analysis of the costs and benefits of the Proposed Rule is severely lacking. Rather than undertake any estimated analysis, EGLE simply states that because there are unknowns it cannot make any estimate at all. EGLE can do more to estimate the costs, including providing estimated costs to implement the Proposed Rule at the 154 sites it has identified as having exceedances of the proposed groundwater criteria. EGLE has also identified only vague and general public health benefits, without any attempt to quantify or describe the specific anticipated benefits of the Proposed Rule.

<sup>&</sup>lt;sup>1</sup> This is consistent with the conclusions of numerous authoritative bodies such as the Agency for Toxic Substances and Disease Registry (ATSDR) and the Australian Expert Health Panel. *See* ATSDR 2018 Analysis at 635-36 available at <a href="https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf">https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf</a> ("The available human studies have identified some potential targets of toxicity; however, cause and effect relationships have not been established for any of the effects, and the effects have not been consistently found in all studies."); Expert Health Panel for Per- and Poly-Fluoroalkyl Substances (PFAS), March 2018, Summary at 2 available at <a href="https://www1.health.gov.au/internet/main/publishing.nsf/Content/C9734ED6BE238EC0CA2581BD00052C03/\$File/summary-panels-findings.pdf">https://www1.health.gov.au/internet/main/publishing.nsf/Content/C9734ED6BE238EC0CA2581BD00052C03/\$File/summary-panels-findings.pdf</a>. ("After considering all of the evidence, the Panel's advice...is that the evidence does not support any specific health or disease screening or other health interventions for highly exposed groups in Australia, except for research purposes.")

For example, EGLE's compliance cost estimate for businesses and groups is insufficient. EGLE is required to develop a comprehensive economic analysis for businesses and individuals. However, the RIS for the Proposed Rule simply states that EGLE "does not have the ability to estimate the actual statewide compliance costs of the rule amendments on business [or individuals]" due to a lack of PFAS reporting requirements for groundwater contamination. EGLE did not put forth any numerical estimates, even hypothetical estimates, on the potential compliance costs for businesses or groups despite having information about at least the 154 sites it claims to have identified as exceeding the proposed standard in the RIS. *See* RIS ¶29A ("To date, EGLE has identified 154 facilities where PFAS exceeds the generic cleanup criteria for groundwater used for drinking water for PFOA and PFOS. EGLE has also identified locations where concentrations of PFNA, PFHxS, PFBS, PFHxA, and HFPO-DA have been detected above their respective criteria in addition to PFOA and PFOS.")

Additionally, for businesses required to conduct cleanups based on the standards set in the Proposed Rule, the RIS merely states that "[t]he costs associated with each cleanup would vary location to location depending on a number of factors – the proximity of wells used for the drinking water supply, the ability to contain and properly manage the release, the volume and concentration of the pollutant in the groundwater, etc." The enormous difference in potential costs alluded to in the RIS does little to instruct impacted businesses and sectors on how to best prepare for potential rule implementation. There is no range of potential costs given, and costs are not broken down by substance, so an impacted entity cannot clearly identify the potential scope of impact. This cursory statement is not nearly detailed enough to provide the regulated community a meaningful opportunity to comment on the Proposed Rule.

Further, the RIS does not provide a numerical estimate of impacts on small businesses, stating that EGLE "does not have the necessary data" to make an estimate. EGLE should obtain the data it needs in order to actually assess costs of the Proposed Rule to small businesses, as it is required to do. The purpose of allowing stakeholders to comment on a draft RIS is to solicit stakeholder feedback on the agency's analysis – not to give the agency material with which to retroactively develop that analysis. Stakeholders should be given adequate opportunity to comment on a robust economic analysis, rather than solely fill in gaps in EGLE's analysis. The lack of analysis in the draft RIS undermines the purpose of holding a public comment period, as it deprives stakeholders of an opportunity to meaningfully comment on the agency's action. For that reason, EGLE should provide a further public comment period once it has compiled information received during this comment period and any further analysis EGLE conducts.

\*\*\*

3M appreciates the opportunity to provide comments and encourages EGLE to provide more transparency regarding its conclusions about the appropriate groundwater cleanup standards for PFAS, as well as the corresponding compliance, implementation, and remediation costs. Thank you for your consideration.

From: Joanne Bauer < @gmail.com>

**Sent:** Thursday, July 1, 2021 9:53 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

#### Comment

RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

For decades Michigan residents and our water resources have been contaminated with PFAS chemicals. I strongly urge the Department of Environment, Great Lakes, and Energy to enforce groundwater standards for PFAS that are as protective of human health and our water resources as possible. Our groundwater is inextricably linked to our surface water and groundwater is often a drinking water source for Michigan families, so I fully support having the same standards for all groundwater that we do for drinking water.

As we learn more about PFAS chemicals and their impact on human health, it may be necessary to consider regulating these chemicals as a class instead of regulating them individually. Please keep working to ensure that both drinking and groundwater standards are properly protective of human health and updated to reflect the most recent scientific evidence about the potential impacts of PFAS on humans, wildlife, and our water resources.

Thank you,

Sincerely, Joanne Bauer

Lansing, MI 48917

From: Mary Brady-Enerson < @gmail.com>

**Sent:** Thursday, July 1, 2021 10:13 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Thank you,

Sincerely,

Mary Brady-Enerson

Lansing, MI 48910

From: Kay Brainerd < @gmail.com>

**Sent:** Sunday, July 4, 2021 1:53 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Kay Brainerd

Belleville, MI 48111

From: janet Cannon < @gmail.com>
Sent: janet Cannon < @gmail.com>
Thursday, July 1, 2021 11:04 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, janet Cannon

From: Abigail Clark < @gmail.com>
Sent: Saturday, July 3, 2021 3:25 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Abigail Clark

Lansing, MI 48912

From: Alan Connor < @gmail.com>

Sent: Saturday, July 3, 2021 4:53 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Alan Connor

From: Christine Dingeman < @gmail.com>

**Sent:** Thursday, July 8, 2021 12:32 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Christine Dingeman

Lapeer, MI 48446

From: FLOW < @flowforwater.org>
Sent: Wednesday, July 28, 2021 2:02 PM

To: EGLE-RRD

**Cc:** Dave Dempsey; Liz Kirkwood; Roper, Cyndi

**Subject:** RE: Administrative Rules for Cleanup Criteria Requirements for Response Activity Rule

Set 2020-130 EQ

**Attachments:** FLOW groundwater cleanup criteria statement.pdf

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July 28, 2021

### EGLE-RRD@michigan.gov

Department of Environment, Great Lakes and Energy Remediation and Redevelopment Division

# **RE:** Administrative Rules for Cleanup Criteria Requirements for Response Activity Rule Set 2020-130 EQ

On behalf of FLOW (For Love of Water), a law and policy center based in Traverse City, I am writing to support Rule Set 2020-130, proposed by the Michigan Department of Environment, Great Lakes, and Energy (EGLE) to apply the Maximum Contaminant Levels (MCLs) for per- and polyfluoroalkyl substances (or PFAS) in drinking water as the generic cleanup criteria for groundwater used for drinking water.

We strongly support the proposed rules.

PFAS present a significant risk to human health. They do not break down quickly in the environment, can move rapidly, and are associated with a wide array of harmful human health effects including cancer, immune system suppression, liver and kidney damage, and developmental and reproductive harm.

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.

Michigan became one of the nation's leading states in protecting public health from toxic PFAS contamination with the promulgation of the PFAS MCLs in 2020. This is a major accomplishment. To its credit, EGLE convened an expert panel to review state of the art science to develop the MCLs and conducted a thorough public comment and review process. The rules have a sound scientific and legal basis.

It only makes sense to establish the MCLs as generic cleanup criteria for groundwater contaminated by PFAS that is or may be used as drinking water. To allow higher PFAS concentrations runs the risk of leaving groundwater used for drinking water out of compliance with what the state has already determined is the maximum safe level.

The promulgation of these cleanup criteria rules to include the PFAS MCLs is an important step to ensure all Michigan citizens have the same drinking water protection, whether they are served by a public water system or a private well.

Thank you for the opportunity to comment.

Sincerely,



Liz Kirkwood Executive Director FLOW



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

July 28, 2021

### EGLE-RRD@michigan.gov

Department of Environment, Great Lakes and Energy Remediation and Redevelopment Division

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Thank you for the opportunity to comment.

Sincerely,

Liz Kirkwood

**Executive Director** 

Jiz Kirlund

**FLOW** 

From: Alicia Fukada < @gmail.com>
Sent: Saturday, July 3, 2021 12:28 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Alicia Fukada

Farmington Hills, MI 48334

From: Steve Garwood < @gmail.com>

**Sent:** Thursday, July 1, 2021 10:13 AM

To: EGLE-RRD

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Thank you,

Sincerely, Steve Garwood

Lansing, MI 48910

From: Janet Ginepro < @gmail.com>

**Sent:** Thursday, July 1, 2021 9:39 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

#### Comment

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Thank you,

Sincerely, Janet Ginepro

Monroe, MI 48162

From: Tabitha Groat < @gmail.com>

**Sent:** Friday, July 9, 2021 6:47 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Tabitha Groat

Marlette, MI 48453

From: Graham Grubb < @gmail.com>

**Sent:** Thursday, July 15, 2021 7:24 PM

To: EGLE-RRD

**Subject:** establishing cleanup rules for PFAS in groundwater used as drinking water

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Hi. I missed the Zoom hearing on the 8th regarding establishing cleanup rules for PFAS in groundwater. I'd like to voice me support for the cleanup rules using the drinking water standards established in August of 2020.

Thank you.

Graham Grubb Ypsilanti, MI

From: Richard Han < @umich.edu>
Sent: Saturday, July 3, 2021 12:58 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Richard Han

From: Andrea Hill < @umich.edu>
Sent: Thursday, July 1, 2021 10:59 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Andrea Hill

From: Martha Hill < @umich.edu>
Sent: Martha Hill < 2021 10:29 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Martha Hill

From: Kate Hutchens < @gmail.com>

**Sent:** Thursday, July 1, 2021 10:18 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Kate Hutchens

From: Robert Jankowski < @gmail.com>

Sent: Wednesday, July 7, 2021 10:32 AM

To: EGLE-RRD

Subject: RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

#### Comment

RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

As a board member for Wolverine Lake, I have particular interest in maintaining a healthy lake ecology not only for Wolverine Lake, but especially so for our Great Lakes that are such a vital resource for our region.

For decades Michigan residents and our water resources have been contaminated with PFAS chemicals. I strongly urge the Department of Environment, Great Lakes, and Energy to enforce groundwater standards for PFAS that are as protective of human health and our water resources as possible. Our groundwater is inextricably linked to our surface water and groundwater is often a drinking water source for Michigan families, so I fully support having the same standards for all groundwater that we do for drinking water.

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Thank you,

Sincerely, Robert Jankowski

Wolverine Lake, MI 48390

From: Ron Katz < @gmail.com>
Sent: Thursday, July 1, 2021 10:10 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Ron Katz

Huntington Woods, MI 48070

From: Brenda Kennedy < @gmail.com>

**Sent:** Thursday, July 1, 2021 11:26 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Brenda Kennedy

Grand Rapids, MI 49525

From: Mark Kennedy < @gmail.com>

**Sent:** Thursday, July 1, 2021 4:33 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Mark Kennedy

From: Katherine Kinas < @gmail.com>

Sent: Thursday, July 1, 2021 2:44 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Katherine Kinas

Kalamazoo, MI 49008

From: Philip Koster < @gmail.com>

**Sent:** Thursday, July 1, 2021 10:42 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Philip Koster

Norton Shores, MI 49441

From: Kira Kozakiewicz < @gmail.com>

**Sent:** Tuesday, July 6, 2021 2:35 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Kira Kozakiewicz

Ypsilanti, MI 48198

From: Lara Kramer-Smith < @gmail.com>

**Sent:** Thursday, July 1, 2021 2:32 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Lara Kramer-Smith

From: Andrew Kryszak < @gmail.com>

**Sent:** Thursday, July 1, 2021 11:45 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Andrew Kryszak

Madison Heights, MI 48071

From: Steven Kuntzman < @gmail.com>

**Sent:** Thursday, July 1, 2021 10:12 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Steven Kuntzman

Kalamazoo, MI 49008

From: John Altan Kusku < @gmail.com>

Sent: Thursday, July 1, 2021 9:24 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Thank you,

Sincerely, John Altan Kusku

Commerce Township, MI 48382

From: Robert LaJeunesse < @mail.com>

Sent: Thursday, July 1, 2021 5:40 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Robert LaJeunesse

ANN ARBOR, MI 48105

From: Cynthia Ann Larson Richard < @gmail.com>

**Sent:** Friday, July 2, 2021 3:32 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Cynthia Ann Larson Richard

Austin, TX 78731

From: John Lorand < @gmail.com>
Sent: Thursday, July 1, 2021 4:58 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, John Lorand

Mount Pleasant, MI 48858



# Little Traverse Bay Bands of Odawa Indians Natural Resource Department 7500 Odawa Circle Harbor Springs, MI 49740 Phone: Fax:



August 5th, 2021

Kevin Schrems Environment, Great Lakes and Energy Remediation and Redevelopment Division P.O. Box 30426 Lansing, MI 48909-7926

Re: Cleanup Criteria Requirements for Response Activity

Dear Mr. Schrems,

On behalf of The Little Traverse Bay Bands of Odawa Indians (LTBB), please accept this comment letter regarding to the proposed rules regarding "Cleanup Criteria Requirements for Response Activity." LTBB appreciates this opportunity to provide feedback on this important proposal.

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 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.

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 compounds 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 compounds which are still potentially dangerous. LTBB would like to see these MCLs reviewed and updated, if needed, every 2 years based on available science. The proposed MCLs and these considerations will aid in public health throughout the 1836 Ceded Territory and beyond.

We see the proposed rules as a valuable mechanism to protect resources from risks associated with PFAS and look forward to potential PFAS MCLs regarding surface 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,

Douglas Craven Natural Resources Department, Director Little Traverse Bay Bands of Odawa Indians

From: Spencer McCormack < @LTBBODAWA-NSN.GOV>

**Sent:** Monday, August 9, 2021 10:19 AM

To: EGLE-RRD

**Cc:** Caroline E. Moellering

**Subject:** Cleanup Criteria Requirements for Response Activity (2020-130 EQ)

**Attachments:** 2021 EGLE PFAS Cleanup Criteria.pdf

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Dear Mr. Schrems,

On behalf of the Little Traverse Bay Bands of Odawa Indians, please accepts these comments regarding, "Cleanup Criteria Requirements for Response Activity" (2020-130 EQ). LTBB appreciates the opportunity to provide feedback on this important proposal. If you have any questions, please feel free to contact me or the Environmental Services Manager, Caroline Moellering at <a href="@ltbbodawa-nsn.gov">@ltbbodawa-nsn.gov</a> or <a href="Little-

Miigwech,

#### Spencer McCormack

Great Lakes Policy Specialist Little Traverse Bay Bands of Odawa Indians Harbor Springs, MI 49740

From: Manjot Matharu < @gmail.com>

**Sent:** Tuesday, July 6, 2021 3:19 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Manjot Matharu

Saline, MI 48176

From:	Mary McNair <@gmail.com>
Sent:	Thursday, July 1, 2021 12:50 PM
To:	EGLE-RRD
Subject:	RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,
Sincerely,
Mary McNair

Rochester Hills, MI 48306

From: A'Milliana McNeil < @gmail.com>

**Sent:** Thursday, July 15, 2021 3:18 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

#### Comment

RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

For decades Michigan residents and our water resources have been contaminated with PFAS chemicals. I strongly urge the Department of Environment, Great Lakes, and Energy to enforce groundwater standards for PFAS that are as protective of human health and our water resources as possible. Our groundwater is inextricably linked to our surface water and groundwater is often a drinking water source for Michigan families, so I fully support having the same standards for all groundwater that we do for drinking water.

As we learn more about PFAS chemicals and their impact on human health, it may be necessary to consider regulating these chemicals as a class instead of regulating them individually. Please keep working to ensure that both drinking and groundwater standards are properly protective of human health and updated to reflect the most recent scientific evidence about the potential impacts of PFAS on humans, wildlife, and our water resources.

Thank you,

Sincerely, A'Milliana McNeil

Laurel, MD 20707

From: Roshaun Memon < @gmail.com>

**Sent:** Tuesday, July 6, 2021 2:41 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Roshaun Memon

Ann Arbor, MI 48104

From: John Messer < @mail.com>

**Sent:** Thursday, July 1, 2021 5:54 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, John Messer

**Brutus, MI 49716** 



August 9, 2021

Remediation and Redevelopment Division Michigan Department of Environment, Great Lakes, and Energy Attention: Kevin Schrems P.O. Box 30426 Lansing, Michigan 48909-7926

\*\*Transmitted via e-mail\*\*

Dear Mr. Schrems,

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 considering 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,

Caroline Liethen

Director of Environmental & Regulatory Policy

Attachment: Professional qualifications, overview of findings, recommendations, and peer review technical comments

## **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);

- 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 after the development of proposed rules. MMA trusts that the peer-reviewed 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 to properly and credibly inform its members of proposed ruleset soundness, and 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, the 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 HealthBased 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 Michigan 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).

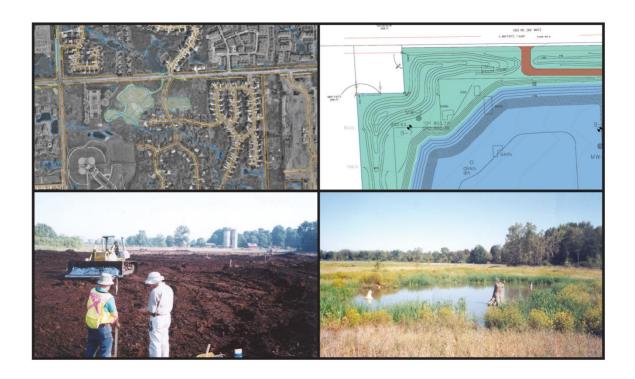
Recognizing and understanding that the SAW had a more than 40,000-fold difference in safe doses based on the different PFAS constituents, **EGLE should not use SAW's proposed levels as an automatic trigger as a point of violation as is proposed in draft ruleset.** Rather than adopting these levels as 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.

# Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan

January 30, 2020



# **Report Prepared For:**

Michigan Manufacturers Association

Lansing, MI 48933

# **Report Prepared By:**

Dr. Michael L. Dourson, TERA Dr. Edward J. Calabrese, UMass Mr. Richard J. Welsh, ASTI





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#### **Tables**

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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).





<u>Table 1. The Primary Issue: Risks Among National Authorities Are Widely Disparate: "Safe"</u>
<u>PFOA Doses</u>

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.

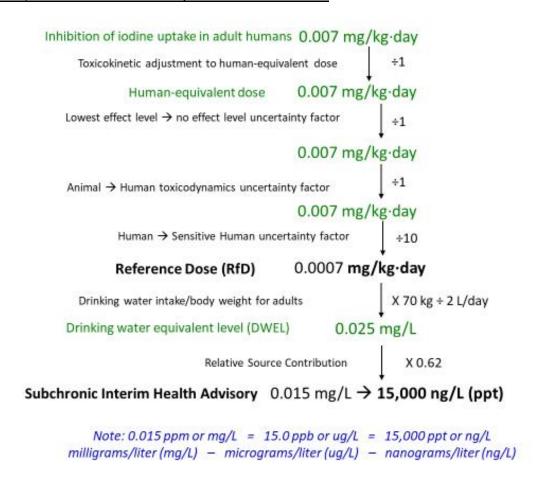




We looked at other MCLs generated by the USEPA and their Point of Departure (POD). It is curious from a "gut-check" perspective that the POD doses identified for PFAS are similar to many of the chemicals with existing MCLs, yet these other chemicals have much higher MCLs in the parts-per-million (ppm) 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.

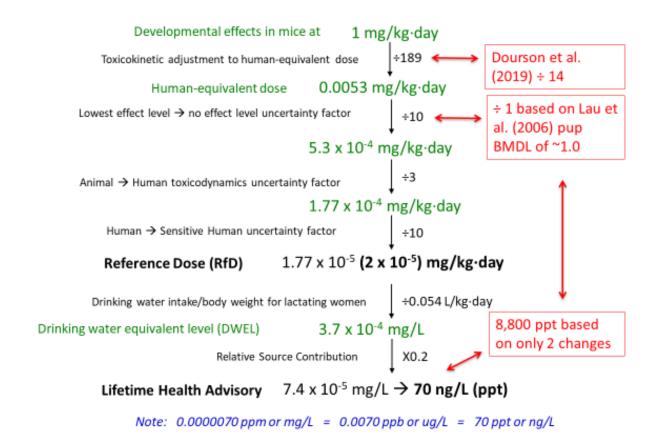
As an example of studies not discussed by SAW in the HBVs, there is a human clinical cancer treatment dosing study for PFOA (Elcombe et al., 2013), and published in part by Convertino et al. (2018). Dourson et al. (2019) also conducted a review of this clinical study, and recently received an award for 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

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.

other words, what is happening at the high dose levels in laboratory animal studies does not

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 decisionmaking 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.

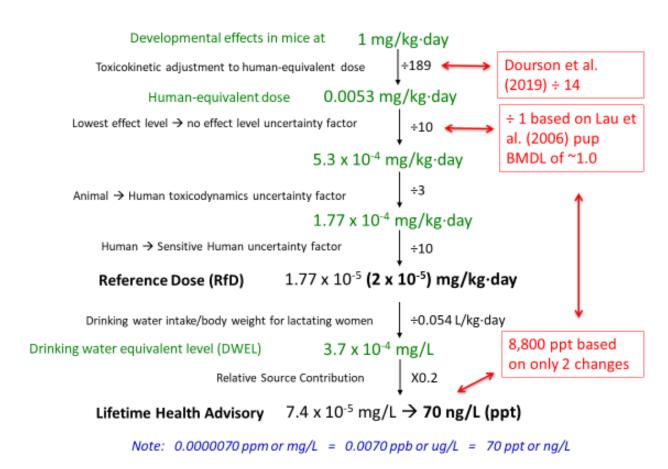




Dourson et al. (2019) provides an analysis of the Elcombe human clinical data with the intent to compare them with relevant kinetic data in mice. This comparison can then be used to consider whether Cmax (maximum plasma concentration) is the relevant dosimenter, rather than area under the curve or AUC (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 ("Concentration maximum" 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



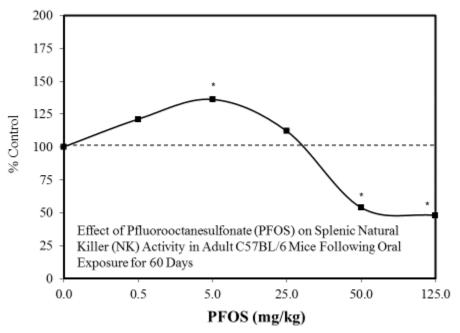


as this would radically change the HBV calculations, since existing safe doses appear to be well below the hormetic dose range (i.e., the range of enhanced performance).

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.,

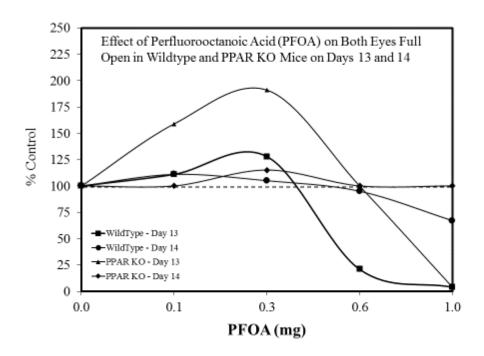




2007) with PFOA, one not cited as a key study - using a broader range of exposures, reported that eye opening in the low dose groups occurred earlier than in the control group (Figure 4). This indicated not only a threshold response but also a potentially enhanced performance at doses below the threshold. 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 <u>PFHxA, Page 14</u>

**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 40 mg/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 <u>Laboratory Animal Studies – Stress & Behavioral Effects</u>

**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 <u>Uncertainty Factors for Database Deficiencies</u>

**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)

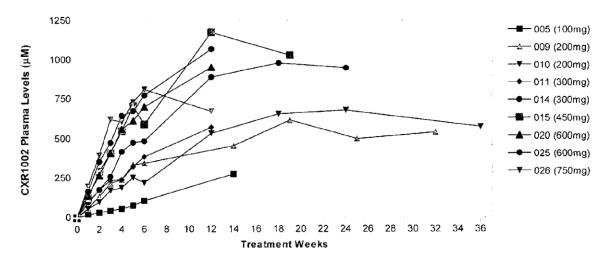
Forty-three patients in the Elcombe et al. (2013) study received PFOA once a week by capsule for 6 weeks at different doses. Nine of them continued after 6 weeks and an apparent plateau was reach as shown in the figure below. Tentative conclusion from this figure is that the apparent half-life of PFOA is 5 weeks (~1/5<sup>th</sup> the plateau time).

# Elcombe et al. (2013) weekly doses in excess of 6 weeks, shown as Figure 78 of their text.

Ciarra 70

Conclusion: ½ life is 5 weeks

# CXR1002 Plasma Exposure Levels beyond the Initial 6-week Assessment Period





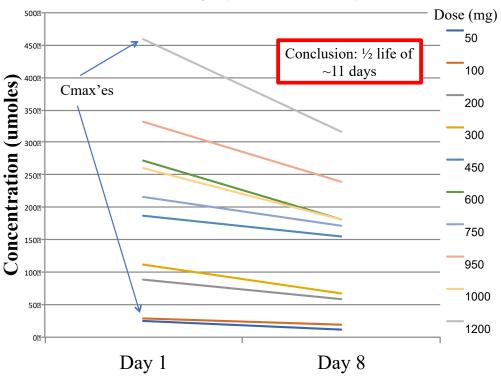




Forty-three patients in the Elcombe et al. (2013) study received PFOA once a week by capsule for 6 weeks at different doses. The figure below shows the average decrease in PFOA in each dose group over the first week, that is from the first dose to the time just before the second dose. The apparent half-life is 11 days, very different from the previous figure. Why the difference?



Average Concentrations of PFOA on days 1 and 8 after a single dose on day 1 (Elcombe et al., 2013)



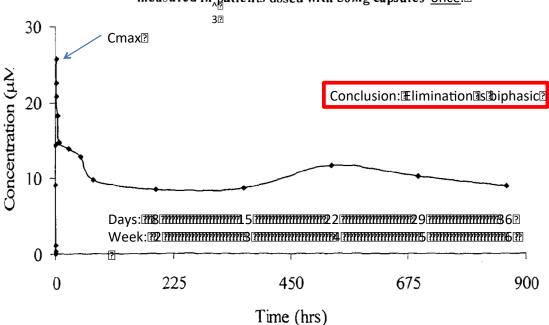




Three patients in the Elcombe et al. (2013) study received only one dose of PFOA at 50 mg and were followed for 6 weeks. The average decline in serum concentration is shown below. The tentative conclusion from this figure is that the apparent half-life of PFOA is biphasic, which helps explain why the estimated half-lives from the first two figures were different.

**Figure 14** Elcombe et al. (2013) ☑

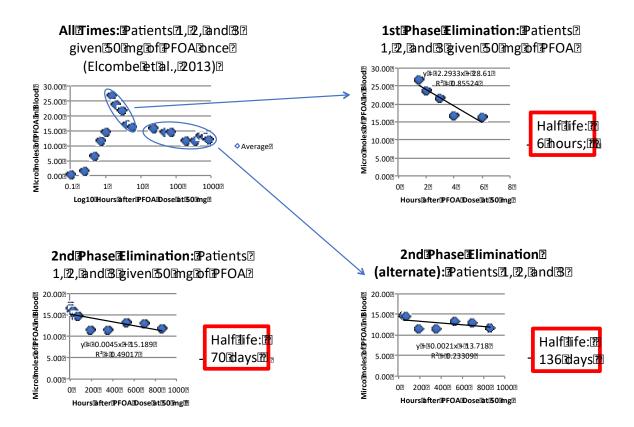
Average concentrations of Ammonium Perfluorooctanoate, up to day 37, measured in patients dosed with 50mg capsules once. 2







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.







August 9, 2021

Remediation and Redevelopment Division Michigan Department of Environment, Great Lakes, and Energy Attention: Kevin Schrems P.O. Box 30426 Lansing, Michigan 48909-7926

\*\*Transmitted via e-mail\*\*

## Re: Cleanup Criteria Requirements for Response Activity / Proposed Ruleset 2020-130 EQ

Dear Mr. Schrems,

The Michigan Manufacturers Association (MMA) respectfully submits these comments on proposed ruleset 2020-130 EQ, otherwise known as "Cleanup Criteria Requirements for Response Activity."

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 the state GDP.

MMA has actively engaged 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 regarding the previously adopted Supplying Water to the Public ruleset, MMA commissioned an independent peer review by leading PFAS researchers. The purpose of the peer review was to provide technical comments on the recommendations used to establish the health-based drinking water values (HBVs) for PFAS.

MMA's intent in providing this peer review was to aid in the rulemaking process by providing scientific, technical information to take into consideration. Because the Cleanup Criteria Requirements for Response Activity rules are based, in part, on the promulgation of State Drinking Water Standards for PFAS under Supplying Water to the Public rules, the MMA is respectfully resubmitting the peer review findings and recommendations for consideration.

Again, 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 rules 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 endeavored to establish appropriate standards, though our peer review identified some areas lacking in the kind of robust scientific and technical integrity needed to complete the effort. We believe the issues identified in the peer review report and associated recommendations would result in the state's rulemaking initiative achieving the process and confidence milestones expected of state agencies.

Thank you for your consideration. Ensuring the safety of public drinking water supplies while also ensuring Michigan's continued economic vitality are paramount to our shared goals.

Respectfully,

Caroline Liethen

Caroling

Director of Environmental & Regulatory Policy

Attachments: <u>Professional Qualifications, Overview of Findings, Recommendations, and Peer Review Technical Comments</u>

<u>Independent Technical Review of the Health-Based Drinking Water Value Recommendations for PFAS in Michigan</u>

@mimfg.org> From: Eleanor Surtman <

Monday, August 9, 2021 4:08 PM Sent:

**EGLE-RRD** To: Caroline Liethen Cc: **Subject: MMA Comments** 

**Attachments:** cl\_pfas\_comments-signed-letterhead\_210809.pdf

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

### Good afternoon,

MMA is submitting the attached comments on proposed rule set 2020-130 EQ, otherwise known as "Cleanup Criteria Requirements for Response Activity."

Thank you for your consideration. Please let me know if you have questions.

Sincerely,



| Fax: | Email:

Elea<u>nor Surtman</u> | Gov<u>ernment Affa</u>irs Coord<u>inator</u> | Michigan Manufacturers Association @mimfg.org







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From: Dharma Montagno < @gmail.com>

**Sent:** Tuesday, July 6, 2021 2:24 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

#### Comment

RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

For decades Michigan residents and our water resources have been contaminated with PFAS chemicals. I strongly urge the Department of Environment, Great Lakes, and Energy to enforce groundwater standards for PFAS that are as protective of human health and our water resources as possible. Our groundwater is inextricably linked to our surface water and groundwater is often a drinking water source for Michigan families, so I fully support having the same standards for all groundwater that we do for drinking water.

As we learn more about PFAS chemicals and their impact on human health, it may be necessary to consider regulating these chemicals as a class instead of regulating them individually. Please keep working to ensure that both drinking and groundwater standards are properly protective of human health and updated to reflect the most recent scientific evidence about the potential impacts of PFAS on humans, wildlife, and our water resources.

Thank you,

Sincerely, Dharma Montagno

Ann Arbor, MI 48103

From: Shannon Morton < @gmail.com>

**Sent:** Thursday, July 1, 2021 11:57 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Shannon Morton

Ann Arbor, MI 48103

From: Kathleen Mulka < @ameritech.net>

**Sent:** Thursday, July 1, 2021 10:43 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

#### Comment

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Thank you,

Kathy Mulka

Sincerely, Kathleen Mulka

Livonia, MI 48152

From: Christina Ng < @gmail.com>

**Sent:** Friday, July 2, 2021 11:46 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

Comment

RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

To the public servant who is reading this: please help the planet heal.

Thank you,

**CNg** 

Sincerely,

Christina Ng

Independence Township, MI 48346

From: Renee Nilan < @gmail.com>

**Sent:** Thursday, July 1, 2021 3:47 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Renee Nilan

Ann Arbor, MI 48105



### EGLE-RRD@michigan.gov

Department of Environment, Great Lakes and Energy Remediation and Redevelopment Division Re: Administrative Rules for Cleanup Criteria Requirements for Response Activity Rule Set 2020-130 EQ

On behalf of our more than 3 million members and online activists, including roughly 70,000 members in Michigan, the Natural Resources Defense Council strongly supports the Michigan Department of Environment, Great Lakes, and Energy's (EGLE) proposed rules to apply the Maximum Contaminant Levels (MCLs) for per- and polyfluoroalkyl substances (or PFAS) as the generic cleanup criteria for groundwater used for drinking water.

By adopting these rules, EGLE will better ensure all Michiganders have the same PFAS in drinking water protections regardless of whether their drinking water comes from a private well or a public water system.

Given the extensive PFAS contamination in Michigan, EGLE should not attempt to balance industry's acceptance of the proposed cleanup criteria with the clear public health benefits provided by this rule set.

The Natural Resources Defense Council has played a leadership role in advancing solutions to the nation's PFAS crisis through our efforts in Washington, DC and in states throughout the U.S. In Michigan, we released a PFAS in drinking water report in March of 2019 and called on EGLE to establish MCLs that would best protect public health. We engaged extensively in the MCL rulemaking process to help ensure the strongest possible drinking water protections were adopted. While the MCLs didn't go as far as the scientific evidence leads, they filled a critical void left by the federal government and established important public health protections for Michigan residents connected to public water systems.

Now, EGLE should level the playing field for all Michiganders by adopting these proposed cleanup criteria for groundwater used for drinking water.

Thank you for this opportunity to comment.

Sincerely, Cyndi

**Cyndi Roper** 

Senior Policy Advocate Safe Water Initiative

East Lansing, MI 48823. M

@NRDC.ORG

NRDC.ORG

From: Roper, Cyndi < @nrdc.org>
Sent: Monday, August 9, 2021 4:59 PM

To: EGLE-RRD

**Subject:** Rule Set 2020-130 EQ

**Attachments:** NRDC Comments in support of EGLE Rule Set 2020-130 .pdf

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### EGLE-RRD@michigan.gov

Department of Environment, Great Lakes and Energy

Remediation and Redevelopment Division

Re: Administrative Rules for Cleanup Criteria Requirements for Response Activity

Rule Set 2020-130 EQ

On behalf of our more than 3 million members and online activists, including roughly 70,000 members in Michigan, the Natural Resources Defense Council **strongly supports** the Michigan Department of Environment, Great Lakes, and Energy's (EGLE) proposed rules to apply the Maximum Contaminant Levels (MCLs) for per- and polyfluoroalkyl substances (or PFAS) as the generic cleanup criteria for groundwater used for drinking water.

By adopting these rules, EGLE will better ensure all Michiganders have the same PFAS in drinking water protections regardless of whether their drinking water comes from a private well or a public water system.

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Now, EGLE should level the playing field for all Michiganders by adopting these proposed cleanup criteria for groundwater used for drinking water.

Thank you for this opportunity to comment.

Sincerely, Cyndi

**Cyndi Roper** 

Senior Policy Advocate Safe Water Initiative East Lansing, MI 48823 M @NRDC.ORG NRDC.ORG



#### **National Wildlife Federation**

Great Lakes Regional Center

Ann Arbor, MI 48104-1398

August 9, 2021

Kevin Schrems
Michigan Department of Environment, Great Lakes, & Energy
Remediation and Redevelopment Division
P.O. Box 30426
Lansing, MI 48909-7926
EGLE-RRD@michigan.gov

Re: Comments on Proposed Changes to Part 201 Administrative Rules, Rule Set 2020-130 EQ

Dear Mr. Schrems,

On behalf of the National Wildlife Federation ("NWF"), we thank you for the opportunity to submit these comments concerning the Michigan Department of Environment, Great Lakes, and Energy's ("EGLE") proposal to add and update per- and polyfluoroalkyl substances ("PFAS") generic cleanup criteria for groundwater used for drinking water to the Part 201 rules. We support EGLE's actions for the seven PFAS that EGLE proposes to regulate under Part 201. Furthermore, we encourage EGLE to develop generic cleanup criteria for additional PFAS.

We commend EGLE for developing new generic cleanup criteria values for perfluorononanoic acid ("PFNA"), perfluorohexane sulfonic acid ("PFHxS"), perfluorohexanoic acid ("PFHxA"), perfluorobutane sulfonic acid ("PFBS"), and hexafluoropropylene oxide dimer acid ("HFPO-DA"), and for updating existing criteria values for perfluorooctane sulfonic acid ("PFOS") and perfluorooctanoic acid ("PFOA"). Use of these generic cleanup criteria to identify and guide remediation at contaminated sites will benefit both human health – by protecting the residential wells upon which millions of people in Michigan rely – and wildlife.

We also urge EGLE to evaluate the need to designate other PFAS as hazardous substances under Part 201 and to pursue the development of generic cleanup criteria for any such compounds. PFAS are a class of over 5,000 individual compounds, though the exact number may be higher depending on the scope (e.g. including reaction products, polymers, etc.). Many are associated at relatively low levels

<sup>1</sup> U.S. EPA, PFAS Master List of PFAS Substances (Version 2). https://comptox.epa.gov/dashboard/chemical lists/pfasmaster. with serious health effects such as cancer, hormone disruption, liver and kidney damage, and immune system toxicity. In addition, PFAS are mostly persistent in the environment, can be mobile, and many can bioaccumulate in humans and wildlife. They are used widely in industrial processes and commercial products, which has led to their ubiquity in environmental media including groundwater and other media in the Great Lakes region.<sup>3</sup>

We urge EGLE to expand monitoring for PFAS, including around contaminated sites, and for a broader suite of PFAS. Furthermore, the relevant scientific literature involving PFAS and risks from the compounds continues to grow dramatically, including on factors affecting human and wildlife exposures to PFAS,<sup>4</sup> as well as potential approaches to prioritize PFAS for risk assessment.<sup>5</sup> This research can assist in informing decisions around selection of compounds for which groundwater cleanup and other standards are appropriate.

We also have several recommendations concerning displaying physical-chemical properties for the compounds, including water solubility in the eighth column in Table 1a of the draft rule. First, the table should be clear on both the form of the individual compound for which data are available (e.g. potassium salt, etc.), as well as the data source. Second, EGLE should consult all possible data sources for the PFAS of concern in the rule. For example, a search of the PubChem database shows measured or estimated water solubilities are generally available for the PFAS compounds of focus in the proposed rule, not just PFOA and PFOS.<sup>6</sup>

While establishing generic cleanup criteria for the few PFAS targeted in this rulemaking is certainly a much-needed step in the right direction, it is clear that the PFAS crisis will only be addressed through more comprehensive approaches, including regulation. To that end, in addition to evaluating the need to develop generic cleanup criteria for more individual PFAS, EGLE should consider whether a grouped regulatory approach is appropriate at this time to manage PFAS that share similar exposure and risk concerns.<sup>7</sup>

<sup>&</sup>lt;sup>2</sup> Sunderland, E. M., Hu, X. D. C., Dassuncao, C., Tokranov, A. K., Wagner, C. C., & Allen, J. G. 2019. A review of the pathways of human exposure to poly- and perfluoroalkyl substances (PFASs) and present understanding of health effects. *Journal of Exposure Science and Environmental Epidemiology*, *29*(2), 131-147. doi:10.1038/s41370-018-0094-1

<sup>&</sup>lt;sup>3</sup> Remucal, C. K. 2019. Spatial and temporal variability of perfluoroalkyl substances in the Laurentian Great Lakes. *Environmental Science: Processes & Impacts*. doi:10.1039/C9EM00265K; Murray, M.W. and Salim, O. 2019. The science and policy of PFASs in the Great Lakes Region: A roadmap for local, state and federal action, National Wildlife Federation, Great Lakes Regional Center, Ann Arbor, MI.

<sup>&</sup>lt;sup>4</sup> De Silva, A. O., Armitage, J. M., Bruton, T. A., Dassuncao, C., Heiger-Bernays, W., Hu, X. C., Kärrman, A., Kelly, B., Ng, C., Robuck, A. (2021). PFAS exposure pathways for humans and wildlife: a synthesis of current knowledge and key gaps in understanding. *Environmental Toxicology and Chemistry*, *40*(3), 631-657.

<sup>&</sup>lt;sup>5</sup> East, A., Anderson, R. H., & Salice, C. J. (2021). Per- and Polyfluoroalkyl Substances (PFAS) in Surface Water Near US Air Force Bases: Prioritizing Individual Chemicals and Mixtures for Toxicity Testing and Risk Assessment. *Environmental Toxicology and Chemistry*, *40*(3), 859-870. doi:10.1002/etc.4893.

<sup>&</sup>lt;sup>6</sup> U.S. National Library of Medicine, PubChem. <a href="https://pubchem.ncbi.nlm.nih.gov/">https://pubchem.ncbi.nlm.nih.gov/</a>.

<sup>&</sup>lt;sup>7</sup> See Cousins, I. T. et al. 2020. Strategies for grouping per- and polyfluoroalkyl substances (PFAS) to protect human and environmental health. *Environ. Sci.: Processes Impacts*, 22, 1444-1460, doi:10.1039/D0EM00147C.

We appreciate Michigan's efforts to date to address the PFAS crisis in the state, and urge EGLE to continue to carry out the necessary research, monitoring, and development of rules sufficient to protect human health and the environment throughout the state from this problematic class of chemicals. If you have any questions or need for follow-up, please contact our staff attorney, Oday Salim, at <a href="mailto:one-up-number-new-number-num

Sincerely,

s/ Mike Shriberg

Mike Shriberg Regional Executive Director

For example, Massachusetts has adopted a combined drinking water standard for six PFAS (PFOA, PFOS, PFNA, PFHxS, perfluoroheptanoic acid ("PFHpA"), and perfluorodecanoic acid ("PFDA")) at 20 ppt. 310 CMR 22.07G(3). EGLE could take a similar approach with its own drinking water standards, which would trigger changes to the corresponding Part 201 generic cleanup criteria for groundwater used for drinking water, or develop grouped generic cleanup criteria as a separate process. MCL § 324.20120a(3)–(5).

From: Oday Salim < @nwf.org>
Sent: Monday, August 9, 2021 1:40 PM

To: EGLE-RRD

**Subject:** Comment by NWF on proposed groundwater criteria for PFAS, Rule Set 2020-130 EQ **Attachments:** Comment by NWF to MI EGLE on draft groundwater PFAS criteria, final 20210809.pdf

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Attention: Kevin Schrems

Attached is a comment by National Wildlife Federation on the proposed groundwater cleanup criteria for PFAS.



### **Oday Salim**

he / him / his

### **Staff Attorney**

National Wildlife Federation, Great Lakes Regional Center
, Ann Arbor, MI 48104

o • c

**Director** 

Environmental Law & Sustainability Clinic, University of Michigan Law School
Ann Arbor, MI 48109-3091

@umich.edu • o • f • c

Uniting all Americans to ensure wildlife thrive in a rapidly changing world

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From: Kyle Peterson < @att.net>

Sent: Thursday, July 1, 2021 3:14 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

#### Comment

RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

For decades Michigan residents and our water resources have been contaminated with PFAS chemicals. I strongly urge the Department of Environment, Great Lakes, and Energy to enforce groundwater standards for PFAS that are as protective of human health and our water resources as possible. Our groundwater is inextricably linked to our surface water and groundwater is often a drinking water source for Michigan families, so I fully support having the same standards for all groundwater that we do for drinking water.

As we learn more about PFAS chemicals and their impact on human health, it may be necessary to consider regulating these chemicals as a class instead of regulating them individually. Please keep working to ensure that both drinking and groundwater standards are properly protective of human health and updated to reflect the most recent scientific evidence about the potential impacts of PFAS on humans, wildlife, and our water resources.

Thank you,

Sincerely, Kyle Peterson

Sterling Heights, MI 48313

From: JoAnn Render < @umich.edu>
Sent: Thursday, July 1, 2021 10:13 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, JoAnn Render

East Lansing, MI 48823

From: Terry Ring < @gmail.com>
Sent: Thursday, July 1, 2021 10:37 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Terry Ring

Warren, MI 48088

From: Geoffrey Robb < @gmail.com>
Sent: Thursday, July 1, 2021 11:57 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Geoffrey Robb

Ann Arbor, MI 48103

From: JoEllen Rudolph < @charter.net>

Sent: Wednesday, July 7, 2021 9:42 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, JoEllen Rudolph

Petoskey, MI 49770

From: Roxy Sammone < @gmail.com>

**Sent:** Thursday, July 1, 2021 2:07 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

### Comment

RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

Ensure that both drinking and groundwater standards protect human health and are updated to reflect the most recent scientific evidence about of PFAS on humans, wildlife, and our water resources. It is shameful that these chemicals have polluted our state.

Thank you,

Sincerely, Roxy Sammone

Clio, MI 48420

From: Tracy Schalk < @gmail.com>
Sent: Thursday, July 1, 2021 11:00 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Tracy Schalk

Grand Rapids, MI 49507

From: Virginia Seppala < @gmail.com>

**Sent:** Thursday, July 1, 2021 3:43 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Thank you,

Sincerely, Virginia Seppala

Grandville, MI 49418

From: Julia Skelton < @msn.com>

**Sent:** Friday, July 2, 2021 10:06 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Julia Skelton

Van Buren Twp, MI 48111

From: Julia Smith < @gmail.com>

**Sent:** Friday, July 2, 2021 7:25 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Julia Smith

Grand Rapids, MI 49506

From: Jan Sockness < @gmail.com>
Sent: Thursday, July 1, 2021 1:50 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Jan Sockness

Ann Arbor, MI 48108

From: Lynn Spencer < @gmail.com>

**Sent:** Saturday, July 3, 2021 10:07 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

CAUTION: This is an External email. Please send suspicious emails to abuse@michigan.gov

Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

#### Comment

RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

For decades Michigan residents and our water resources have been contaminated with PFAS chemicals. I strongly urge the Department of Environment, Great Lakes, and Energy to enforce groundwater standards for PFAS that are as protective of human health and our water resources as possible. Our groundwater is inextricably linked to our surface water and groundwater is often a drinking water source for Michigan families, so I fully support having the same standards for all groundwater that we do for drinking water.

As we learn more about PFAS chemicals and their impact on human health, it may be necessary to consider regulating these chemicals as a class instead of regulating them individually. Please keep working to ensure that both drinking and groundwater standards are properly protective of human health and updated to reflect the most recent scientific evidence about the potential impacts of PFAS on humans, wildlife, and our water resources.

Thank you,

Sincerely, Lynn Spencer

Dearborn, MI 48124

From: Jennevie Stephenson < @gmail.com>

**Sent:** Sunday, July 11, 2021 3:39 PM

To: EGLE-RRD

Subject: RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

#### Comment

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Thank you,

Sincerely, Jennevie Stephenson

Zeeland, MI 49464



August 9, 2021

Michigan Department of Environment, Great Lakes, and Energy Remediation and Redevelopment Division Attention: Kevin Schrems P.O. Box 30426 Lansing, Michigan 48909-7926

RE: Administrative Rules for Cleanup Criteria Requirements for Response Activity, Rule Set 2020-130 EQ.

Dear Mr. Schrems:

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 Remediation and Redevelopment Division Administrative Rules for Cleanup Criteria Requirements for Response Activity, Rule Set 2020-130 EQ. The proposed rules would provide a framework for the development of residential and non-residential generic criteria and site-specific criteria for hazardous substances necessary for the evaluation of exposure risks and to implement the requirements for response activities and corrective actions under Part 201, Environmental Remediation, and Part 213, Leaking Underground Storage Tanks, of the Natural Resources and Environmental Protection Act, Act 451 of 1994, as amended, respectively.

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 fully supported 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. The proposed rule for Cleanup Criteria Requirements for Response Activity builds upon that rule, and we are, again, fully supportive of the Department's efforts.

We appreciate that EGLE is making progress toward protecting 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. This proposed rule

will ensure that the drinking water of all Michigan citizens, whether from a public water supply or for a private well, are equally protected.

Currently, nearly 3 million people obtain their drinking water from a private well and are not protected from PFAS contamination. This rule would create regulatory certainty by determining a threshold for all responsibilities and requirements associated with PFAS contamination and a cleanup program. Throughout Michigan, there are at least 154 sites where groundwater is impacted by the release of PFAS into the environment, representing a persistent and ongoing risk to public health and safety and the environment.

In the Watershed Council's service area, we have a current PFAS site – the Pellston Regional Airport site - that, to date, has impacted over 55 residential wells. Recent sample results exceeded groundwater cleanup criteria. The highest result was 410 ppt PFOS, 48 ppt PFOA, and 340 ppt PFHxS. Without the groundwater cleanup criteria, these residents, fellow community members, and Watershed Council members would be subject to PFAS contamination and the significant health associated with drinking PFAS.

### Conclusion

We commend the Whitmer Administration and EGLE for taking expeditious steps towards regulating for taking steps towards regulating PFAS in both public and private drinking water supplies to protect human health. The Watershed Council strongly supports quick action to adopt the strongest possible groundwater cleanup standards for PFAS in Michigan. We urge the Administration and EGLE 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 Cleanup Criteria Requirements for Response Activity, Rule Set 2020-130 EQ.

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 <a href="mailto:@watershedcouncil.org">@watershedcouncil.org</a> or

Sincerely,

Jennifer McKay Policy Director

From: Jennifer McKay < @watershedcouncil.org>

**Sent:** Monday, August 9, 2021 9:39 PM

To: EGLE-RRD

**Subject:** TOMWC Comments on EGLE Rule Set 2020-130 EQ. Attachments: TOMWC Comments on EGLE Rule Set 2020-130 EQ.pdf

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Please see the attached comments on behalf of Tip of the Mitt Watershed Council.

Thank you.

P

Sennifer Mc Xay
Policy Director

Tip of the Mitt Watershed Council

@watershedcouncil.org
http://www.watershedcouncil.org/

From: Robert Vandervennet < @gmail.com>

**Sent:** Thursday, July 1, 2021 10:09 AM

To: EGLE-RRD

Subject: RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Robert Vandervennet

Tipton, MI 49287

From: Nicole Vioujas < @gmail.com>

**Sent:** Thursday, July 1, 2021 11:16 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Thank you,

Sincerely, Nicole Vioujas

Ann Arbor, MI 48103

From: Gale Dunn Volkerding < @gmail.com>

**Sent:** Thursday, July 1, 2021 6:51 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Remediation and Redevelopment Division, Michigan Department of Environment, Great Lakes, and Energy,

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Thank you,

Sincerely, Gale Dunn Volkerding

Grand Rapids, MI 49506

From: Jacqueline Wolfe < @gmail.com>

**Sent:** Thursday, July 1, 2021 10:46 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Thank you,

Sincerely, Jacqueline Wolfe

Calumet, MI 49913

From: Emily Woodcock < @gmail.com>

**Sent:** Tuesday, July 6, 2021 2:20 PM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Thank you,

Sincerely, Emily Woodcock

Ypsilanti, MI 48197

From: Steven Yankoviak < @gmail.com>

**Sent:** Thursday, July 1, 2021 10:41 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Thank you,

Sincerely, Steven Yankoviak

Kalamazoo, MI 49006

From: Mike Zanto < @umich.edu>
Sent: Thursday, July 1, 2021 10:05 AM

To: EGLE-RRD

**Subject:** RE: Rule Set 2020-130 EQ Cleanup Criteria Requirement for Response Activity

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Thank you,

Sincerely, Mike Zanto

ANN ARBOR, MI 48103