



New Jersey Drinking Water Quality Institute (DWQI)

August 5, 2021, 1 PM via Microsoft Teams

Meeting Minutes

Members Present (12):

Keith Cooper	Jessie Gleason	Gloria Post	Tina Fan
Patricia Ingelido	Norm Nelson	Judith Klotz	Rich Calbi
Leslie Brunell	Anthony Matarazzo	Mike Furrey	Michele Potter

Members Absent (0):

Public Attendees:

Chelsea Brook, Brandon Carreno, Mingzhu Fang, Pat Gardner, Sabrina Hill, Lee Lippincott, Joe McNally, Kelley Meccia, Emily Nanneman, Brian Pachkowski, Tyler Rowe, Kristin Tedesco, Linda Walsh (New Jersey Department of Environmental Protection)

John Kuehne (New Jersey Office of the Attorney General)

Zoltan Szabo (United States Geological Survey)

Alison Aminto, Brian Rademaekers (Philadelphia Water Department)

Quang Vo (DSM)

Matt Csik, Vince Monaco (New Jersey American Water)

Corey Chad (HDR, Inc.)

Raquel Gonoretzky (Hughes, Hubbard & Reed)

Jack Murray (Phillips Lytle)

Jon Hurdle (NJ Spotlight)

Kathleen Stanton (American Cleaning Institute)

Mark Theiler (Middlesex Water Company)

Megan Steele (Sierra Club New Jersey)

Samantha Jones (Chemistry Council of New Jersey)

Tracy Carluccio (Delaware Riverkeeper Network)

Erin Desantis, Kuper Jones, Steve Risotto (American Chemistry Council)

Andrew Wilensky (Odyssey Logistics)

Alissa R Vanim (Aqua America)

Doug O'Malley (Environment New Jersey)

Mark LaFranconi (ERM: Environmental Resources Management)

Lynn Marie DeCarlo, Carol Walczyk (Suez Water)

Trevor Mulhall (MBI)

1. Chairman's Remarks

- **Introductions** – At the request of the Chair, Keith Cooper, members of the Drinking Water Quality Institute (Institute or DWQI) introduced themselves to the attendees.
- **Meeting Focus** – Chairman Cooper explained that the purpose of this meeting will be to discuss the DWQI's Maximum Contaminant Level (MCL) recommendation for 1,4-dioxane. Additionally, Chairman Cooper reiterated that the primary role of the DWQI Subcommittees is to review the



available science and not to determine policy, which is at the discretion of NJDEP. It is the responsibility of the Commissioner to review the recommendation and determine if rulemaking is appropriate. During rulemaking, an economic assessment will be taken into consideration in the promulgation of the MCL. There will be additional availability for public comment at that point.

2. Review of December 3, 2020 Meeting Minutes – The Institute members reviewed the minutes and offered no substantive changes. Anthony Matarazzo moved to accept the minutes; Rich Calbi seconded the motion. There were no objections from any members.

3. Introduction of New Members & Status of DWQI Vacancies – Patricia Ingelido provided background on DWQI membership and vacancies. Two vacancies remain, as follows: two Environmental Health Experts to be appointed by the Governor and the Assembly. The NJDEP sent recommendations to the Governor’s office for these positions and is currently awaiting a response.

Recently appointed members were then introduced:

Patricia (Trish) Ingelido is the Director of NJDEP’s Division of Water Supply and Geoscience. She is taking over this role for Pat Gardner who recently was appointed Assistant Commissioner of NJDEP’s Water Resource Management. She has over 20 years of experience in water resources management at the New Jersey Department of Environmental Protection. She previously served as the Assistant Director of the Water System Operations Element in the Division of Water Supply and Geoscience. She earned a B.S. in Environmental Science from Rutgers University, an M.S. in Environmental Policy from New Jersey Institute of Technology and is a Certified Public Manager.

As manager of the Office of Quality Assurance, Michele Potter oversees the Department’s laboratory certification program and serves as the DEPs main quality assurance officer responsible for implementing the Department’s Quality Management Plan. Michele has a Bachelor’s degree in marine biology from Stockton College. For approximately three years prior to working for the Department, Michele performed inorganic and microbiological testing at two commercial laboratories as well as at a sewage treatment plant. She started with the Department in 2001 where she was a laboratory certification officer for inorganics, microbiology, and whole effluent toxicity for 14 years before becoming the manager of the Office of Quality Assurance in 2015.

Trish Ingelido will serve on the Treatment Subcommittee, and Michele Potter will serve on the Testing Subcommittee.

4. Health Effects Subcommittee Recommendation Response to Public Comment, Jessie Gleason .

Jessie Gleason gave a presentation on the comments submitted on the draft Health-based MCL Support Document and the Subcommittee’s detailed responses. Comments were received from six submitters. Several changes from the draft document were made in the final document to reflect new information and in response to comments, as follows: Information from final USEPA Office of



Chemical Safety and Pollution Prevention (2020) 1,4-dioxane evaluation replaced information from draft OCSP (2019) document. It was noted that the cancer slope factor in the draft document was revised in the final document, and that the final OCSP (2020) slope factor is consistent with the IRIS slope factor used to develop the Health-based MCL. Discussion of Lafranconi et al. (2020), a 90-day drinking water study in female mice, published subsequent to draft Health-based MCL Support Document was added. Problematic issues with this paper and its conclusions are discussed. The discussion of mutagenicity studies was expanded and clarified. Clarification of evaluation of nasal pathology in Torkelson et al. (1974) was added. The cancer slope factor and body weight are shown with two significant figures (0.10 [mg/kg/day] -1; 80.0 kg), consistent with USEPA sources of these parameters. Discussion of three recent studies (Chappell et al., 2021; Charkoftaki et al., 2021; Totsuka et al., 2020) that became available since the draft document was written was added. The presentation is posted at: <https://www.state.nj.us/dep/watersupply/pdf/health-based-dioxane-mcl-response-to-comments.pdf>

5. Testing Subcommittee, Tina Fan

No comments were received on the draft Subcommittee document. Therefore, no presentation was made.

6. Treatment Subcommittee, Anthony Matarazzo

Anthony Matarazzo gave a presentation on the comments received on the draft "Recommendations for Treatment Options for 1,4-dioxane for Drinking Water" document and the Subcommittee's responses. Comments were received from four submitters. One change from the draft document was made in the final document to correct information regarding formation of bromate as a disinfection by-product of bromide when UV AOP is utilized. The presentation is posted at: <https://www.state.nj.us/dep/watersupply/pdf/treatment-sc14-dioxane20210805.pdf>

7. Public Comments - Chairman Cooper then opened the meeting up for comments from both DWQI members and the public. Each commenter's remarks are summarized:

Steve Risotto, Senior Director, American Chemistry Council (ACC). [Note the following comments come from a written statement submitted to the DWQI]

S. Risotto stated that the ACC has provided multiple comments to DEP and the Health Effects Subcommittee regarding the carcinogenic potential of 1,4-dioxane and the substantial evidence for a threshold mode of action (MOA) for cancer in laboratory animals. As the DWQI considers the recommendation for an MCL based on a default, non-threshold MOA, he would like to briefly summarize the evidence that has led authoritative bodies around the world to conclude that there is a threshold of exposure below which 1,4-dioxane does not present a cancer risk.



First and foremost, neither 1,4-dioxane nor its metabolite HEAA are mutagenic. The non-threshold approach used to derive the Subcommittee's recommendation is based on a mutagenic MOA, although it is also applied as a default when an alternative MOA has not clearly been established. For 1,4-dioxane, the Subcommittee has applied the default assumption despite the significant evidence for an alternative MOA.

Nevertheless, the Subcommittee's draft report points to evidence that 1,4-dioxane causes DNA damage in laboratory animals to incorrectly suggest mutagenicity. [Note: The discussion of mutagenicity in the draft document was revised in the final document.] However, such DNA damage only occurs at the highest doses and is the result of cytotoxic regenerative or proliferative responses – not mutagenic activity.

What is also clear from the available evidence is that, while 1,4-dioxane is readily metabolized to HEAA and excreted, the metabolic pathway becomes saturated at higher doses and the parent compound begins to accumulate in the body. This kinetic pattern has been demonstrated directly by monitoring plasma levels and indirectly from studies monitoring the elimination of the metabolite in urine. Once saturated, increased exposures result in a disproportional increase in circulating levels of 1,4-dioxane. Lafranconi et al (2021) observed this saturation phenomenon in female mice exposed to 6,000 parts per million in drinking water for up to 90 days in a recently completed subchronic study sponsored by ACC and submitted to the Subcommittee.

The available data also indicate that the metabolite HEAA does not play a role in the substance's toxicity, and it has been generally concluded that the parent compound, 1,4-dioxane, is the toxic moiety. The observations in rat studies, and most of the studies in mice, support the conclusion that liver and nasal toxicity and subsequent tumor development, only occur at exposures that exceed the metabolic threshold. It is therefore reasonable to conclude that metabolic saturation is an essential early key event to enable the sequence of events leading to tumor formation. This is the position taken by Health Canada, the World Health Organization, the Australian NICNAS, the Health Council of the Netherlands, and the German MAK Commission in their assessments of health risks from 1,4-dioxane exposure, supporting a drinking water guideline of 50 parts per billion.

Previous analysis has suggested that the liver tumors in animals result from regenerative hyperplasia – a pattern of cell damage and repair – that results from exposure to 1,4-dioxane once saturation occurs. This MOA is supported by the results from the available rat studies, from the 2-year mouse study conducted by the National Cancer Institute, and from the sub chronic study in mice conducted by the Japan Bioassay Research Center (JBRC) – although evidence for liver cell damage was not reported in the Japanese mouse bioassay.

The results from the latest study by Lafranconi et al, and the companion transcriptomics paper by Chappell et al (2021), provide further evidence for the metabolic saturation of clearance pathways as a key event leading to accumulation of systemic 1,4-dioxane in the body and offer insight into the early time course of events in the mouse liver. The studies observed a five-fold increase in liver cell proliferation at the highest dose prior to the development of cytotoxicity and regenerative repair. While such cell proliferation may precede the damage and repair reported in other studies that is a cornerstone of the regenerative hyperplasia MOA – such a



direct mitogenic response is itself recognized as a cancer MOA by the Environmental Protection Agency's 2005 cancer guidelines.

Based on the available evidence, we urge the Committee to reject the recommendation for an MCL based on the default, non-threshold assumption of a mutagenic MOA and more carefully evaluate the significant evidence for a threshold mode of action.

Tracy Carluccio, Deputy Director of the Delaware Riverkeeper Network (DRN)

T. Carluccio stated that she would like to point out that the DRN has confidence in extensive research, analysis and risk assessment performed by the DWQI over the past two years regarding 1,4-dioxane. DRN would like to thank the DWQI for their excellent work. There are multiple pathways of exposure to the public for 1,4-dioxane including drinking water and consumer products. 1,4-Dioxane must be removed from our drinking water, and additional actions need to be taken into consideration to address its presence in consumer products. The DWQI's job, according to the NJ Safe Drinking Water Act, is to take action when the public is exposed to a contaminant at dangerous levels in their drinking water. According to the Treatment Subcommittee, treatment to remove this contaminant is available. We also know that it causes major health effects and is considered a likely human carcinogen by EPA from long term exposure. Additionally, we are aware of short-term health effects such as damage to the liver, kidney, and respiratory system. Since we know that 1,4-dioxane can be tested for and removed, and we are aware of adverse health effects, the DRN recommends and supports an MCL of 0.33 ug/L and hopes that the Commissioner initiates expedited rulemaking to remove this toxic compound from the drinking water.

Doug O'Malley, Director with Environment New Jersey

D. O'Malley would like to thank NJDEP support staff and members of the DWQI for recommending an MCL for this contaminant which needs to have strict standards. It is critical to have a DWQI and for the DWQI to do research and look at risk factors, as EPA is not. As was discussed in the Subcommittee presentations, NJ would not be the only state to have an MCL for 1,4-dioxane; however, the MCL recommended by the DWQI would be one of the strictest in the county, in response to the threat that we see in NJ's drinking water systems. Specifically, it is important to cite that NJ found 1,4-dioxane above the EPA Health Reference Concentration at 17% of NJ's public water systems in testing conducted between 2013 – 2015. Research shows there is a public health impact even at lower levels. D. O'Malley would like to highlight comments and responses to comments presented by the DWQI, specifically that tumors at sites other than the liver were only seen at the highest dose, which is not accurate. Tumors were shown both the low and highest dose groups. This demonstrates a range of health impacts from this contaminant.



Environment New Jersey is strongly supportive of the MCL being considered by DEP and of taking action on all forever chemicals, such as the work that has been done for PFAS. The DEP should accept this recommendation, and it is critical to move forward and act on it quickly, especially for drinking water systems that already have 1,4-dioxane.

Chairman Cooper stated that the draft Subcommittee reports, as well as all comments, were reviewed by the Subcommittees. The mode of action discussion, and all other evaluations, are included in the Subcommittee reports.

Tina Fan added that the DOH has been working on EPA 522 method development. They are currently awaiting final proficiency test samples for full validation completion. If anyone from the public has any questions, they can contact the DOH lab for assistance.

Vince Monaco asked how the DWQI would reconcile the Testing Subcommittee recommended PQL as 0.1 µg/L (one significant figure) with an MCL recommendation of two significant figures?

Mike Furrey responded that from an analytical standpoint, this is a point well taken.

Chairman Cooper mentioned that the PQL would not be the limiting factor for this MCL, and therefore this would not be the most significant challenge to resolve.

T. Fan added that the detection limit based on previous data ranged from 0.02 – 0.26 ug/L. Therefore, T. Fan is confident that the Testing Subcommittee can go to two decimal points, but she will review the data and confirm with the Subcommittee.

M. Furrey stated that he is a new Institute member, and he is fully supportive of the MCL recommendations. All of the subcommittees have done an excellent job and should be commended.

Chairman Cooper agreed with this statement. It is also important to note that the DWQI responded to all the comments and reevaluated the literature during this process.

Chairman Cooper then requested a roll call vote, with members voting yea or nay when their name was called. All members voted in favor of recommending an MCL for 1,4-dioxane of 0.33 ug/L to the Commissioner (12-0).

8. Future Meetings – Chairman Cooper advised the Department to send out a survey to DWQI members for potential dates for future meetings and that he would like the DWQI to meet every 2 to 3 months.

9. New Business – There was no additional business. Chairman Cooper noted that the slides from the presentations at the meeting would be posted on the DWQI website soon.

10. Adjourn Meeting - The meeting was adjourned at 2:22 PM.