# Maximum Contaminant Level Recommendation for 1,4-Dioxane in Drinking Water

**Basis and Background** 

New Jersey Drinking Water Quality Institute

September 24, 2021

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# State of New Jersey Department of Environmental Protection

DRINKING WATER QUALITY INSTITUTE 401 East State Street P.O. Box 402, Mail Code 401-07 Trenton, New Jersey 08625-0420

SHAWN M. LATOURETTE Commissioner

September 24, 2021

Commissioner LaTourette New Jersey Department of Environmental Protection P.O. Box 402 Trenton, NJ 08625-0402

Dear Commissioner LaTourette,

The members of the New Jersey Drinking Water Quality Institute (Institute) are pleased to submit their recommendation for a Maximum Contaminant Level (MCL) for 1,4-dioxane in drinking water.

Three subcommittees within the Institute were established to address the essential considerations for development of MCLs as outlined in the New Jersey Safe Drinking Water Act (N.J.S.A. 58:12A-20). The Health Effects Subcommittee is responsible for recommending health-based levels (Health-based MCLs) for contaminants of concern, the Testing Subcommittee is responsible for evaluating and recommending appropriate analytical methods and developing Practical Quantitation Levels (PQLs; the levels to which a contaminant can be reliably measured by drinking water laboratories), and the Treatment Subcommittee is responsible for evaluating water available treatment technologies for removal of the contaminants of concern from drinking water.

The three subcommittees thoroughly reviewed the available scientific information relevant to the health effects, analytical methods, and treatment options associated with 1,4-dioxane in drinking water. The three subcommittees then developed detailed technical reports to support the recommendations that are described below. These recommendations were presented at a public meeting of the Institute on September 30, 2020, and the draft subcommittee reports were posted for a 60-day public comment period following the September meeting. Each Subcommittee presented responses to the comments submitted during the public comment period, and any changes to the draft documents in response to the comments, at the August 5, 2021 Institute meeting.

The Health Effects Subcommittee used a risk assessment approach intended to protect for chronic (lifetime) exposure to develop a Health-based MCL of  $0.33 \mu g/L$ , and the Testing Subcommittee determined a PQL of  $0.10 \mu g/L$  for 1,4-dioxane. The Treatment Subcommittee concluded that 1,4-dioxane can be removed to levels below the recommended Health-based MCL of  $0.33 \mu g/L$  with treatment technologies, such as Advanced Oxidation Processes (AOPs). While source water quality characteristics must be carefully considered, AOP has the advantage

PHILIP D. MURPHY Governor

SHEILA Y. OLIVER Lt. Governor of removing multiple other contaminants including perchlorate, MTBE, PCE, TCE, pesticides, VOCs, and many others.

The conclusions reached by the three subcommittees, which are detailed in the attached documents, were approved by a unanimous vote (12-0) at an Institute meeting on August 5, 2021. Therefore, the Institute recommends that the Department propose and adopt a Health-based MCL of  $0.33 \mu g/L$  for 1,4-dioxane in drinking water.

Please feel free to contact me if you have any questions or need additional information related to these recommendations.

Respectfully,

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Keith R. Cooper, Ph.D. Chair, DWQI

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# **Appendices:**

**Appendix A:** Health-Based Maximum Contaminant Level Support Document 1,4-Dioxane

**Appendix B:** Report on the Development of a Practical Quantitation Level for 1,4-Dioxane in Drinking Water

Appendix C: Recommendation on 1,4-Dioxane Treatment Options for Drinking Water

#### **Executive Summary**

The New Jersey Drinking Water Quality Institute (the Institute), established by the 1984 amendments to the New Jersey Safe Drinking Water Act (SDWA) at N.J.S.A. 58:12A- 20, is charged with developing standards (Maximum Contaminant Levels; MCLs) for hazardous contaminants in drinking water and for recommending those standards to the New Jersey Department of Environmental Protection (NJDEP).

Three subcommittees are established within the Institute to address the essential considerations for development of MCLs as outlined in the New Jersey SDWA. The Health Effects Subcommittee is responsible for recommending health-based levels (Health-based MCLs) for contaminants of concern, the Testing Subcommittee is responsible for evaluating and recommending appropriate analytical methods and developing Practical Quantitation Levels (PQLs; the levels to which a contaminant can be reliably measured by drinking water laboratories), and the Treatment Subcommittee is responsible for evaluating best available treatment technologies for removal of the contaminants of concern from drinking water.

The three Institute subcommittees have reviewed the available scientific information relevant to the health effects, analytical methods, and treatment options associated with 1,4-dioxane. Detailed documents presenting the technical basis for each of the subcommittee's recommendation are attached in Appendices A, B, and C.

The Health Effects Subcommittee developed a Health-based MCL protective for chronic drinking water exposure of  $0.33 \mu g/L$ , and the Testing Subcommittee developed an analytical PQL of  $0.10 \mu g/L$ . The Treatment Subcommittee recommended that the use of Advanced Oxidation Processes (AOPs) and/or an equally efficient treatment removal technology should be considered when 1,4-dioxane is detected above recommended MCLs, subject to on-site pilot testing performance results, and it concluded that the availability of treatment options is not anticipated to be a limiting factor in the development of a recommended MCL for 1,4-dioxane.

Since neither treatment removal nor analytical methods are limiting factors for achieving the Health-based MCL of 0.33  $\mu$ g/L, the Institute recommends an MCL for 1,4-dioxane of 0.33  $\mu$ g/L to the Department as both protective and technically feasible.

#### Introduction

#### A. Background

In 2018, Commissioner Catherine McCabe of the New Jersey Department of Environmental Protection (NJDEP) requested that the New Jersey Drinking Water Quality Institute (the Institute) recommend a drinking water standard for 1,4-dioxane, the subject of this recommendation.

The New Jersey Safe Drinking Water Act at N.J.S.A. 58: 12A-20, established the New Jersey Drinking Water Quality Institute, consisting of six ex officio and nine appointed members, to make recommendations to the NJDEP regarding drinking water quality. The members represent the public, the academic community, the water purveyors, NJDEP, New Jersey Department of Health, and the New Jersey Water Supply Advisory Council.

The Institute is responsible for providing recommendations to the Commissioner of NJDEP on implementation of the State's drinking water quality program, including MCLs. Three subcommittees are established to address the important considerations in the development of an MCL. The Health Effects Subcommittee recommends Health-based Maximum Contaminant Levels; these are target drinking water levels based solely on health effects. The Testing Subcommittee reviews existing analytical methods to identify those methods with practical quantitation levels (PQLs). The Treatment Subcommittee evaluates best available treatment technologies for removal of contaminants from drinking water.

The Institute has accepted the recommendations from each of its three subcommittees that are presented in this Basis and Background document and its Appendices. These recommendations form the basis for the recommended MCL for 1,4-dioxane.

# B. Drinking Water Quality Institute Membership

*Chair* Keith Cooper, Ph.D., Rutgers University

Health Effects Subcommittee Chair: Jessie Gleason, M.S.P.H., NJ Department of Health Keith Cooper, Ph.D. Rutgers University Judith Klotz, Dr.P.H. Gloria Post, Ph.D., DABT, NJ Department of Environmental Protection

*Testing Subcommittee* Chair: Tina Fan, Ph.D., NJ Department of Health Michele Potter, NJ Department of Environmental Protection Leslie Brunell, Ph.D., Stevens Institute of Technology Mike Furrey, Agra Environmental

#### Treatment Subcommittee

Chair: Anthony Matarazzo, NJ American Water Norm Nelson, Van Note-Harvey Associates Patricia Ingelido, NJ Department of Environmental Protection Rich Calbi, P.E., P.P., Ridgewood Water

#### **Health Effects Considerations and Recommendations**

A Health-based MCL for 1.4-dioxane was developed using a risk assessment approach intended to protect for chronic (lifetime) drinking water exposure. All current federal and state ground water and drinking water guidelines for 1,4-dioxane that were identified by the Health Effects Subcommittee are based on the USEPA IRIS (2013) cancer slope factor of 0.10 (mg/kg/day)<sup>-1</sup>. The validity of this cancer slope factor was confirmed by a recent USEPA Office of Chemical Safety and Pollution Prevention (USEPA OCSPP, 2020) evaluation. For this reason, the Subcommittee's review focused primarily on the carcinogenicity studies and related mode of action information for 1,4-dioxane. Non-carcinogenic effects of this chemical were also reviewed. The Subcommittee's review used the USEPA IRIS (2013) evaluation as its starting point, and it also included more recent information identified through literature searches and submissions to the DWQI.

The Health Effects Subcommittee agreed with USEPA IRIS (2013) and USEPA OCSPP (2020) that, based on the occurrence of several types of tumors in multiple rodent studies, 1,4-dioxane is "likely to be carcinogenic to humans" under the USEPA (2005) Guidelines for Carcinogen Risk Assessment. The Subcommittee reviewed information relevant to 1,4-dioxane's carcinogenic mode of action including studies cited by USEPA IRIS (2013), more recent peer reviewed publications, USEPA OCSPP (2020), and the NJDEP (2015, 2018) responses to comments on the NJDEP (2010) Interim Specific Ground Water Quality Standard and promulgated NJDEP (2018) Ground Water Quality Standard. The Subcommittee also reviewed additional information submitted by two organizations in response to the December 2018 DWQI request for public input that questioned a non-threshold approach for cancer risk assessment of 1,4-dioxane. A detailed summary of this review can be found in the Health Effects Subcommittee Report (Appendix A). Additionally, the Subcommittee conducted a detailed review of the comments submitted during the public comment period for the draft Institute documents. The responses to these comments are shown in the Subcommittee's presentation at the August 5, 2021 Institute meeting which is posted at https://www.state.nj.us/dep/watersupply/pdf/health-based-dioxanemcl-response-to-comments.pdf.

Based on its review, the Subcommittee agreed with USEPA IRIS (2013) and USEPA OCSPP (2020) that the mode of action by which 1,4-dioxane causes tumors has not been established. Therefore, the Subcommittee's cancer risk assessment for 1,4-dioxane was based on low-dose linear extrapolation (i.e., a non-threshold approach based on a cancer slope factor) as specified by the USEPA (2005) guidelines when the mode of carcinogenic action is not understood. The Health-based MCL is based on the USEPA IRIS (2013) slope factor of 0.10 (mg/kg/day)<sup>-1</sup>. This slope factor is based on the incidence of liver tumors in female mice (Kano et al., 2009), since these tumors were the most sensitive of the tumor types caused by 1,4-dioxane in several chronic studies of male and female mice and rats. USEPA OCSPP (2020) developed a very similar, but

slightly more stringent, slope factor also based on the liver tumors in female mice from Kano et al. (2009). Details on the Subcommittee's cancer risk assessment can be found in Appendix A.

Based on the cancer slope factor of  $0.10 \text{ (mg/kg/day)}^{-1}$ , the one in one million ( $10^{-6}$ ) cancer risk level specified in the NJ Safe Drinking Water Act, and the current USEPA default exposure assumptions of adult body weight of 80.0 kg and drinking water ingestion of 2.4 L/day, a Health-based MCL of 0.33 µg/L is recommended.

#### **Analytical Considerations and Recommendations**

The role of the Testing Subcommittee was to identify acceptable analytical methods for detecting 1,4-dioxane and evaluate performance data from laboratories using these methods to develop a practical quantitation level (PQL). A PQL is the minimum concentration that can be reliably quantitated within acceptable limits of uncertainty. Development of a PQL involves researching analytical methods that are reliable and sufficiently sensitive to measure the contaminant at, or as close as possible to, the Health-based MCL developed by the Health Effects Subcommittee.

When developing the PQL, the Testing Subcommittee reviewed analytical methods and evaluated performance data from drinking water laboratories certified for 1,4-dioxane analysis by the NJDEP Office of Quality Assurance (OQA), as well as the National Environmental Laboratory Accreditation Program (NELAP), or USEPA, that had USEPA approval to analyze for the third iteration of the Unregulated Contaminant Monitoring Rule (UCMR3). A summary of laboratory methods and performance data is found in the full Testing Subcommittee report (Appendix B).

The Subcommittee used several approached for determining the PQL, including an approach based on the Method Detection Level (MDL) for six OQA-certified labs and several statistical approaches for the data for seven laboratories that analyzed New Jersey UCMR3 samples, as described in detail in the report found at Appendix B. For the parameter 1,4-dioxane, the Testing Subcommittee derived the PQL of  $0.10 \mu g/L$  for 1,4-dioxane using the median value from all of the approaches used for the PQL derivation. Therefore, the Testing Subcommittee recommends a PQL of  $0.10 \mu g/L$  for 1,4-dioxane.

#### **Treatment Considerations and Recommendations**

The Treatment Subcommittee is responsible for identifying available treatment technologies or methods for removal of hazardous contaminants from drinking water. The Treatment Subcommittee researched and reported on treatment options for 1,4-dioxane. According to published literature, 1,4-dioxane can be removed from water with varying success using several treatment options, which are described in detail in the Subcommittee report found in Appendix C. The most common treatment for 1,4-dioxane removal both in the literature and in practice is Advanced Oxidation Processes (AOPs).

The Treatment Subcommittee concluded, based on case studies of full scale operations including at a site in New Jersey, that 1,4-dioxane can be reliably and feasibly removed to levels below the recommended Health-based MCL of  $0.33 \mu g/L$  using carefully designed AOP treatment. This treatment method has been successfully used in New Jersey for removal of 1,4-dioxane. The Treatment Subcommittee therefore recommends that AOPs and/or an equally efficient

technology, as identified in the Subcommittee report, can be used for treatment of 1,4-dioxane, subject to the on-site pilot testing performance results.

# **MCL Recommendation**

A Health-based MCL of  $0.33 \ \mu g/L$  is recommended by the Health Effects Subcommittee. The Testing and Treatment Subcommittees concluded that analytical limitations and treatment removal are not limiting factors for achieving this Health-based MCL. The Institute has accepted the recommendations of each of the three subcommittees, and these recommendations form the basis for the recommended MCL for 1,4-dioxane. Accordingly, the Institute recommends an MCL for 1,4-dioxane of 0.33  $\mu$ g/L to the Department as both protective and technically feasible.

# References

Kasai, T, Kano, H, Umeda, Y, Sasaki, T, Ikawa, N, Nishizawa, T, Nagano, K, Arito, H, Nagashima, H, Fukushima, S. (2009). Two-year inhalation study of carcinogenicity and chronic toxicity of 1,4-dioxane in male rats. Inhal Toxicol 21: 889-897.

NJDEP (2010). New Jersey Department of Environmental Protection. Memorandum. Recommendation of revised interim specific ground water criterion for 1,4-dioxane. Accessed March 12, 2019. <u>https://www.nj.gov/dep/dsr/supportdocs/1,4-Dioxane\_TSD.pdf</u>

NJDEP (2015). New Jersey Department of Environmental Protection. Response to Public Input on Draft Interim Ground Water Quality Criteria and Draft Interim Practical Quantitation Levels for Eleven Chemicals. https://www.nj.gov/dep/dsr/supportdocs/11%20Chemicals\_Response.pdf

NJDEP (2018). New Jersey Department of Environmental Protection. Ground Water Quality Standards; Discharges of Petroleum and Other Hazardous Substances Rules. Adopted Amendments: N.J.A.C. 7:1E Appendix A and 7:9C-1.7 and 7:9C Appendix; January 16, 2018. https://www.nj.gov/dep/rules/adoptions/adopt\_20180116c.pdf

USEPA (2005). United States Environmental Protection Agency. Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum, USEPA, Washington, DC. EPA/630/P03/001F, March 2005.

USEPA IRIS (2013). United States Environmental Protection Agency. Toxicological Review of 1,4-Dioxane (with Inhalation Update). In Support of Summary Information on the Integrated Risk Information System (IRIS). September 2013, Washington, DC. https://cfpub.epa.gov/ncea/iris/iris\_documents/documents/toxreviews/0326tr.pdf

USEPA (2020). United States Environmental Protection Agency. Final Risk Evaluation for 1,4-Dioxane. EPA-740-R1-8007. United States Office of Chemical Safety and Pollution Prevention. December 2020. <u>https://www.epa.gov/sites/production/files/2020-</u> <u>12/documents/1. risk\_evaluation\_for\_14-dioxane\_casrn\_123-91-1.pdf</u>.