Maximum Contaminant Level Recommendation for Perfluorooctane Sulfonate in Drinking Water

Basis and Background

New Jersey Drinking Water Quality Institute

June 8, 2018

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State of New Jersey

PHILIP D. MURPHY Governor

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CATHERINE R. MCCABE Acting Commissioner

June 8, 2018

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

Dear Acting Commissioner McCabe:

The members of the New Jersey Drinking Water Quality Institute (Institute) are pleased to submit their recommendation for a Maximum Contaminant Level (MCL) for perfluorooctane sulfonate (PFOS) 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.

At the request of the Department, the three subcommittees thoroughly reviewed the available scientific information relevant to the health effects, analytical methods, and treatment options associated with PFOS 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 November 28, 2017, and the draft subcommittee reports were posted for a 60-day public comment period following the November meeting.

The Health Effects Subcommittee used a risk assessment approach intended to protect for chronic (lifetime) exposure to develop a Health-based MCL of 13 ng/L, and the Testing Subcommittee determined a PQL of 4.2 ng/L for PFOS. The Treatment Subcommittee concluded that PFOS can be removed to levels below the recommended Health-based MCL of 13 ng/L with treatment technologies, such as granular activated carbon (GAC) and reverse osmosis. GAC has been

successfully installed at New Jersey public water systems to treat perfluoroalkyl acids (PFAAs) including PFOS. An additional benefit of the treatment technologies used to remove PFOS is that they may also remove many other contaminants that may also be present.

The conclusions reached by the three subcommittees, which are detailed in the documents attached, were approved by a unanimous vote at an Institute meeting on May 25, 2018. Therefore, the Institute recommends that the Department propose and adopt a Health-based MCL of 13 ng/L for PFOS 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

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Executive Summary

The New Jersey Drinking Water Quality Institute (the Institute) was established by the 1984 amendments to the New Jersey Safe Drinking Water Act (SDWA) at N.J.S.A. 58:12A-20. It 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). In 2014, the New Jersey Department of Environmental Protection requested that the Institute recommend MCLs for perfluorooctanesulfonic acid (PFOS) and two other long-chain perfluoroalkyl acids (PFAAs), perfluorononanoic acid (PFNA) and perfluorooctanoic acid (PFOA). The Institute recommended an MCL for PFNA on July 1, 2015, an MCL for PFOA on March 15, 2017 and it now recommends an MCL for PFOS herein.

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 PFOS. Detailed documents presenting the technical basis for each of the subcommittee's recommendation are attached in Appendices A, B, and C.

Also attached, as Appendix D, is an additional document presenting the Health Effects Subcommittee's response to public comments on the scientific basis of the Health-based MCL. As the Drinking Water Quality Institute (DWQI) serves as an advisory body which makes recommendations to the NJDEP, and DWQI's recommendation is not a rulemaking that is subject to the requirements of the Administrative Procedure Act, a formal response to public comments received on draft subcommittee documents is not required. However, the subcommittee wanted an opportunity to address public comments in more detail than a presentation would allow, in order to provide clarification with respect to its draft document and to address any changes made to the draft document based on those comments when appropriate.

The Health Effects Subcommittee used a risk assessment approach intended to protect for chronic drinking water exposure to develop a Health-based of 13 ng/L (0.013 μ g/L), and the Testing Subcommittee developed an analytical PQL of 4.2 ng/L (0.0042 μ g/L). The Treatment Subcommittee recommended that granular activated carbon or an equally efficient treatment removal technology can be used when PFOS is detected above the recommended MCL, subject to on-site pilot testing performance results, and concluded that the availability of treatment options is not anticipated to be a limiting factor in the development of a recommended MCL for PFOS or the other two PFAAs (i.e. PFNA and PFOS) that were evaluated by the Institute. An additional benefit of the treatment technologies used to remove PFOS is that they also remove other synthetic organic chemicals, natural organic compounds, and other compounds affecting taste and odor that may be present.

As neither treatment removal nor analytical methods are limiting factors for achieving the Health-based MCL of 13 ng/L (0.013 μ g/L), the Institute recommends an MCL for PFOS of 13 ng/L (0.013 μ g/L) to the Department as both health protective and technically feasible.

Introduction

A. Background

In 2014, 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 perfluorooctane sulfonic acid (PFOS), the subject of this recommendation, as well as two other long-chain perfluoroalkyl acids (PFAAs), perfluorononanoic acid (PFNA) and perfluorooctanoic acid (PFOA).

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 MCLs; 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 PFOS.

B. Drinking Water Quality Institute Membership

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

Health Effects Subcommittee

Chair: Jessie A. Gleason, NJ Department of Health Keith R. Cooper, Ph.D., Rutgers University Judith B. Klotz, Dr.P.H., Adjunct Associate Professor, Rutgers University and Drexel University Gloria B. Post, Ph.D., DABT, NJ Department of Environmental Protection George Van Orden, Ph.D., Adjunct Professor, Rutgers University and Drew University

Testing Subcommittee

Chair: Tina Fan, Ph.D., NJ Department of Health Sandra Krietzman, NJ Department of Environmental Protection Daniel Salvito, Ph.D, Research Institute for Fragrance Materials Dave Pranitis, Passaic Valley Water Commission *Treatment Subcommittee* Chair: Anthony Matarazzo, NJ American Water Patricia Gardner, NJ Department of Environmental Protection Norm Nelson, Water Supply Advisory Council, Van Note-Harvey Associates

Health Effects Considerations and Recommendations

A Health-based MCL for PFOS was developed using a risk assessment approach intended to protect for chronic (lifetime) drinking water exposure. A public health-protective approach in developing a Health-based MCL based on animal toxicology data is supported by epidemiological associations of PFOS with health effects in the general population, as well as its biological persistence and bioaccumulation from drinking water in humans. Both non-carcinogenic and carcinogenic effects were evaluated for Health-based MCL development. PFOS causes a number of different types of toxicological effects in animals including hepatic, endocrine, developmental, immune system toxicity, and hepatocellular and thyroid tumors. The most sensitive non-cancer effect with data needed for Health-based MCL development was identified as immune suppression, specifically, a decrease in antibody response to an exogenous antigen challenge (i.e., plaque-forming cell response) following 60 days of PFOS exposure in adult male mice in a study by Dong et al. $(2009)^1$. Use of the data on decreased antibody response from Dong et al. (2009) as the quantitative basis for the Health-based MCL is supported by decreased plaqueforming cell response in mice in other studies and by the association of PFOS with decreased vaccine response in humans within the general population. A Target Human Serum Level (analogous to a Reference Dose but on a serum level basis) of 23 ng/ml was developed by applying a total uncertainty factor of 30 to the PFOS serum level, 674 ng/ml, at the No Observed Adverse Effect Level (NOAEL) in Dong et al. (2009). A clearance factor (8.1 x 10⁻⁵ L/kg/day) which relates serum PFOS concentrations to human external PFOS doses was applied to the Target Human Serum Level to develop a Reference Dose of 1.8 ng/kg/day. Default values for drinking water exposure assumptions (2 L/day water consumption; 70 kg body weight) and Relative Source Contribution factor (20%) were used to develop a Health-based MCL of 13 ng/L. PFOS caused liver and thyroid tumors in a chronic rat study and was characterized as having "suggestive evidence of carcinogenic potential," consistent with the conclusion of USEPA Office of Water. Cancer risk was estimated based on dose-response modeling of liver tumors in female rats. It was concluded that the cancer risk assessment is too uncertain for use as the basis of the Health-based MCL. However, the estimated cancer risk at the Health-based MCL of 13 ng/L is close to the New Jersey cancer risk goal of one in one million. The Health-based MCL of 13 ng/L based on immune system toxicity is therefore considered to be both scientifically appropriate and health protective.

Analytical Considerations and Recommendations

The role of the Testing Subcommittee was to identify acceptable analytical methods for detecting PFOS and to evaluate performance data from laboratories using PFOS methods to develop a PQL. A PQL is the minimum concentration that can be reliably quantitated within acceptable limits of uncertainty. PQL development 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.

¹ Dong et al. (2009). Arch Toxicol. 83:805-815.

When developing the PQL, the Testing Subcommittee evaluated analytical methods and performance data from drinking water laboratories that participated in NJDEP PFAA drinking water studies; laboratories certified for PFOS analysis by the NJDEP Office of Quality Assurance; and select national laboratories with USEPA approval to analyze PFAAs for UCMR3. A summary of laboratory methods and performance data is found in the full Testing Subcommittee report (Appendix B).

The Subcommittee evaluated several approached for calculating the PQL, described in detail in the report found at Appendix B. During its evaluation, the Subcommittee noted that the minimum reporting levels (MRL) reported by labs were often much higher than their low calibration standards, indicating that labs could reliably quantitate at much lower concentrations.

Therefore, the Testing Subcommittee applied the bootstrap technique to the low calibration standards to normalize this data and recommended a PQL of 4.2 ng/L for PFOS.

Treatment Considerations and Recommendations

The Treatment Subcommittee is responsible for identifying available treatment technologies or methods for removal of hazardous contaminants from drinking water. In June 2015, the Treatment Subcommittee issued a final report, entitled "<u>Recommendation on Perfluorinated Compound</u> <u>Treatment Options for Drinking Water</u>" that described treatment options for all three PFAAs under consideration by the Institute (i.e. PFNA, PFOA, and PFOS). The treatment options for all three did not differ due to their similar properties (e.g. persistence, water solubility, similar structure, strong carbon-fluorine bonds, and high polarity). This approach contrasts with the other two subcommittees, which evaluated each compound separately. According to published literature, long-chain PFAAs such as PFNA, PFOA and PFOS can be removed from water with varying success using a number of treatment options, which were described in detail in the Subcommittee's 2015 report. The most common treatment approach for removal of PFNA, PFOA and PFOS, both in the literature and in practice, is granular activated carbon (GAC).

An addendum to the 2015 report entitled "<u>Addendum to Appendix C: Recommendation on</u> <u>Perfluorinated Compound Treatment Options for Drinking Water</u>" was issued by the DWQI Treatment Subcommittee in August 2016. The attached second addendum to Appendix C updates and supplements both the 2015 report and the 2016 addendum. The update is based on a more recent data from water systems treating for PFOS as well as advances by treatment technology companies. The addendum also references certification of point-of-use treatment technologies by NSF International.

The Treatment Subcommittee concluded, based on full scale treatment operations including sites in New Jersey, that PFOS can be reliably and feasibly removed using carefully designed GAC treatment to levels below the recommended health-based MCL of 13 ng/L. This method of treatment has been successfully used in New Jersey for removal of PFAAs including PFOS, as well as for removal of synthetic organic chemicals, natural organic compounds, and other compounds affecting taste and odor. The Treatment Subcommittee therefore recommends that GAC and/or an equally efficient technology, as identified in the Subcommittee report, can be used for treatment of PFOS, subject to the on-site pilot testing performance results. Furthermore, the Treatment Subcommittee recommends that private well owners with PFOS contamination exceeding the recommended MCL consider the installation of NSF-certified treatment to reduce exposure.

MCL Recommendation

A Health-based MCL for PFOS of 13 ng/L (0.013 μ 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 PFOS. Accordingly, the Institute recommends an MCL for PFOS of 13 ng/L (0.013 μ g/L) to the Department as both health protective and technically feasible.