Maximum Contaminant Level Recommendation for Perfluorooctanoic Acid in Drinking Water

Basis and Background

New Jersey Drinking Water Quality Institute

March 15, 2017

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State of New Jersey

DEPARTMENT OF ENVIRONMENTAL PROTECTION
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BOB MARTIN
Commissioner

March 15, 2017

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

Dear Commissioner Martin:

The members of the New Jersey Drinking Water Quality Institute (Institute) are pleased to submit their recommendation for a Maximum Contaminant Level (MCL) for perfluorooctanoic acid (PFOA) in drinking water.

The occurrence of PFOA and other perfluorinated compounds (PFCs) in public water supplies (PWS) has been evaluated more extensively in New Jersey than in most or all other states. More than 1,000 samples from 80 NJ PWS were analyzed with relatively low Reporting Levels (RLs; generally, < 5 ng/L) in 2006-2016. PFOA was the most frequently detected PFC and was found in samples from approximately 60% of the 80 NJ PWS tested. In the 2013-2015 USEPA Unregulated Contaminant Monitoring Rule 3 (UCMR3) survey of all large (>10,000 users) and a subset of smaller PWS in the U.S., PFOA was detected more than five times more frequently in New Jersey PWS (10.3%) than in the rest of the U.S. (2.1%). The RL in UCMR3 was 20 ng/L, much higher than the RLs for most other NJ PWS monitoring for PFOA has also been detected in NJ private wells near sources of industrial discharge.

As you are aware, 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 best available treatment technologies for removal of the contaminants of concern from drinking water.

At your request, the three subcommittees thoroughly reviewed the available scientific information relevant to the health effects, analytical methods, and treatment options associated with PFOA in drinking water, including the information received through a public request for relevant technical information in the summer of 2014. 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 22, 2016, and the draft subcommittee reports were posted for a 60-day public comment period following the September meeting.

The Health Effects Subcommittee used a risk assessment approach intended to protect for chronic (lifetime) exposure to develop a Health-based MCL of 14 ng/L, and the Testing Subcommittee determined a PQL of 6 ng/L for PFOA. The Treatment Subcommittee concluded that PFOA can be removed to levels below the recommended Health-based MCL of 14 ng/L and the recommended PQL of 6 ng/L with treatment technologies, such as granulated activated carbon (GAC) and reverse osmosis. GAC has been successfully installed at New Jersey public water systems to treat PFCs including PFOA. An additional benefit of the treatment technologies used to remove PFOA is that they 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 February 16, 2017. Therefore, the Institute recommends that the Department propose and adopt a Health-based MCL of 14 ng/L for PFOA in drinking water.

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

Respectfully,

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, New Jersey Department of Environmental Protection Commissioner Bob Martin requested that the Institute recommend MCLs for perfluorooctanoic acid (PFOA) and two other long-chain perfluorinated compounds (PFCs), perfluorononanoic acid (PFNA) and perfluorooctanesulfonic acid (PFOS). The Institute recommended an MCL for PFNA on July 1, 2015, and it now recommends an MCL for PFOA 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 PFOA. Detailed documents presenting the technical basis for each of the subcommittee's recommendation are attached in Appendices A, B, and C.

Also attached is an additional document presenting the Health Effects Subcommittee's response to technical public comments. 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 MCL of 14 ng/L (0.014 µg/L), and the Testing Subcommittee developed an analytical PQL of 6 ng/L (0.006 µg/L). The Treatment Subcommittee recommended that granular activated carbon or an equally efficient treatment removal technology can be used when PFOA 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 PFOA or the other two PFCs (PFNA and PFOS) that have been, or will be, evaluated by the Institute. An additional benefit of the treatment technologies used to remove PFOA is that they also remove other synthetic organic chemicals, natural organic compounds, and other compounds affecting taste and odor that may be present.

Since neither treatment removal nor analytical methods are limiting factors for achieving the Health-based MCL of 14 ng/L (0.014 µg/L), the Institute recommends an MCL for PFOA of 14 ng/L (0.014 µg/L) to the Department as both health protective and technically feasible.

Introduction

A. Background

In 2014, Commissioner Bob Martin 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 perfluorooctanoic acid (PFOA), the subject of this recommendation, as well as two other long-chain perfluorinated compounds (PFCs), perfluorononanoic acid (PFNA) and perfluorooctanesulfonic acid (PFOS).

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 PFOA.

B. Drinking Water Quality Institute Membership

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

Health Effects Subcommittee
Chair: Jessie A. Gleason, M.S.P.H., 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: Bahman Parsa, Ph.D., NJ Department of Health
Sandra Krietzman, M.S., NJ Department of Environmental Protection
Daniel Salvito, Ph.D, Research Institute for Fragrance Materials
Sheng-Lu Soong, Ph.D., Suez Water

Treatment Subcommittee
Chair: Vacant
Patricia Gardner, NJ Department of Environmental Protection
Anthony Matarazzo, NJ American Water
Norm Nelson, Van Note-Harvey Associates
Carol T. Storms, Aqua NJ

Health Effects Considerations and Recommendations

A Health-based Maximum Contaminant Level (Health-based MCL) for PFOA 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 associations of PFOA with a number of health effects in the general population and communities with drinking water exposure, as well as PFOA's biological persistence and bioaccumulation from drinking water in humans. PFOA was described as "likely to be carcinogenic to humans" by the USEPA Science Advisory Board, "possibly carcinogenic to humans" by the International Agency for Research on Cancer (IARC), and as having "suggestive evidence of carcinogenic potential" by the USEPA Office of Water. Both non-carcinogenic and carcinogenic effects were evaluated for Health-based MCL development. Delayed mammary gland development and increased liver weight were the most sensitive non-carcinogenic endpoints with data needed for dose-response modeling. For each of these endpoints, benchmark dose modeling of serum PFOA levels from mouse studies was performed and appropriate uncertainty factors were applied to develop a Target Human Serum Level (analogous to a Reference Dose but on a serum level basis). A clearance factor (1.4×10^{-4} L/kg/day) which relates serum PFOA concentrations to human PFOA doses was applied to the Target Human Serum Levels to develop Reference Doses. For delayed mammary gland development, the Target Human Serum Level is 0.8 ng/ml, which is below the median serum PFOA level in the U.S. general population. The Reference Dose for this endpoint is 0.11 ng/kg/day. Because the use of delayed mammary gland development as the basis for quantitative risk assessment is a currently developing topic, a Health-based MCL using this endpoint as its primary basis was not recommended. However, it was concluded that an uncertainty factor for sensitive endpoints is needed to protect for this and other effects that occur at similarly low doses. A Health-Based MCL protective for increased relative liver weight was derived based on a study in which male mice were exposed to PFOA for 14 days. For increased relative liver weight, the Target Human Serum Level is 14.5 ng/ml and the Reference Dose is 2 ng/kg/day. This Target Human Serum Level and Reference Dose incorporate uncertainty factors to protect sensitive human subpopulations, to account for toxicodynamic differences between human and experimental animals, and to protect for more sensitive endpoints that occur from developmental exposures (delayed mammary gland development, persistent hepatic toxicity, and others). 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 14 ng/L based on the Reference Dose for increased relative liver weight. A cancer slope factor of 0.021 $(mg/kg/day)^{-1}$ was developed based on increased incidence of testicular tumors in a chronic rat study. This slope factor was used to develop a Health-based MCL protective for cancer effects at the 1×10^{-6} (one in one million) lifetime cancer risk level of 14 ng/L, identical to the Health-based MCL based on non-cancer endpoints. The recommended Health-based MCL is therefore 14 ng/L (0.014 µg/L).

Analytical Considerations and Recommendations

The role of the Testing Subcommittee in the recommendation of an MCL for PFOA was to identify acceptable methods for PFOA analysis and to develop a PQL for PFOA. A PQL is the minimum concentration to which the contaminant under review 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

In determining the availability of analytical methods with adequate sensitivity, the Testing Subcommittee queried the existing NJDEP database for PFCs in NJ public water systems for PFOA data collected from June 2006 through April 2016. Due to the limited number of laboratories performing analyses of the PFOA samples in the NJDEP PFC database, the Testing Subcommittee also reviewed analytical information from other laboratories performing analyses of PFCs in drinking water.

When developing the PQL, the Testing Subcommittee considered analytical methods and laboratory performance. A summary of laboratory performance data is found in the full Testing Subcommittee report (Appendix B). In addition, if the Health-based MCL is available, the goal of the Testing Subcommittee is to establish the PQL at a level less than the Health-based MCL. However, the Health-based MCL for PFOA was not available while the Testing Subcommittee was developing the PFOA PQL. In the absence of a Health-based MCL to use as a goal, the Testing Subcommittee considered both the reporting limit recommendation of 10 ng/L provided by the NJDEP Office of Quality Assurance prior to the 2006 NJDEP study of PFCs in NJ public water systems, and the MRL of 20 ng/L required for the USEPA UCMR3. Therefore, while the UCMR3 MRL demonstrated that national laboratories could reliably report PFOA at an MRL of 20 ng/L, the 2006 and 2009-10 NJDEP studies of PFCs in NJ public water systems, and other data in the NJDEP PFC database, establish that lower reporting levels are achievable for PFOA.

The Subcommittee evaluated four approaches for calculating the PQL, described in detail in the report found at Appendix B. To derive the PFOA PQL, the Testing Subcommittee decided to use an approach that considers both the precision and accuracy of the analytical method. Therefore, the Testing Subcommittee relied on the actual reporting limits from laboratories currently performing PFOA analyses for determining its recommendation of a PQL of 6 ng/L for PFOA.

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 on treatment options for all three PFCs under consideration by the Institute (PFNA, PFOA, and PFOS), as the treatment options are not expected to differ from compound to compound 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 evaluate each compound separately. According to published literature, long-chain PFCs such as PFNA, PFOA and PFOS can be removed from water with varying success using a number of treatment options, which are described in detail in the Subcommittee report found in Appendix C. The most common treatment approach for PFC removal both in the literature and in practice is granulated activated carbon (GAC). The attached addendum to Appendix C updates and supplements the June 2015 Treatment Subcommittee report for the recommendation of an MCL for PFNA. The update is based on a more recent 2016 Water Research Foundation (WRF) document entitled, "Treatment Mitigation Strategies for Poly- and Perfluoroalkyl Substances" (also referred to as WRF Web Report #4322), and takes into consideration the recommendations for PFOA made by the Health Effects and Testing Subcommittees.

The Treatment Subcommittee concluded, based on case studies of full scale operations including at sites in New Jersey, that removal to levels below the recommended PQL for PFOA can be consistently achieved using GAC. This method of treatment has been successfully used in New Jersey for removal of PFCs including PFOA, as well as for removal of synthetic organic chemicals, natural organic compounds, and other compounds affecting taste and odor. Based on these successful applications, the use of GAC is therefore considered practical and feasible. The Treatment Subcommittee therefore recommends that GAC or an equally efficient technology, as identified in the Subcommittee report, can be used for treatment of PFOA when detected above the DWQI recommended MCL, subject to the on-site pilot testing performance results. The Subcommittee concluded that the ability of treatment options to remove these contaminants is not anticipated to be a limiting factor in the development of a recommended MCL for PFOA or the other two PFCs (PFNA and PFOS) that have been, or will be, evaluated by the Institute.

MCL Recommendation

A Health-based MCL for PFOA of 14 ng/L (0.014 µg/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 PFOA. Accordingly, the Institute recommends an MCL for PFOA of 14 ng/L (0.014 µg/L) to the Department as both health protective and technically feasible.