Maximum Contaminant Level Recommendations for Perfluorononanoic Acid in Drinking Water

Basis and Background

New Jersey Drinking Water Quality Institute

July 1, 2015

[This page left intentionally blank]

State of New Jersey

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

DEPARTMENT OF ENVIRONMENTAL PROTECTION
DRINKING WATER QUALITY INSTITUTE
401 EAST STATE STREET
P.O. BOX 420
Trenton, NJ 08625-0420

BOB MARTIN
Commissioner

July 1, 2015

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 Perfluorononanoic Acid (PFNA, C9) in drinking water.

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. Over the last year, at your request, the three subcommittees met to review the available scientific information relevant to the health effects, analytical methods, and treatment options associated with PFNA.

The Institute also embarked on a new public input process by soliciting technical information (May 2014), inviting interested parties to present technical information directly to the subcommittees, and accepting oral and written comments on the individual subcommittee draft recommendation reports. The input received through this process resulted in amendments to the draft documents that have been incorporated into the final documents submitted to you with this correspondence.

Perfluorinated chemicals (PFCs), including PFNA, occur in raw and finished public drinking water from both ground and surface water sources in the U.S. and worldwide, and PFNA has been found more frequently and at higher concentrations in New Jersey drinking water than elsewhere. Based

on a thorough analysis of the available scientific data, the Health Effects Subcommittee concluded that a Health-based MCL of 13 ng/L is scientifically defensible and is protective for chronic (lifetime) exposure, and the Testing Subcommittee determined a PQL of 5 ng/L for PFNA. Information reviewed by the Treatment Subcommittee demonstrates that PFNA can be removed to levels below the recommended Health-based MCL of 13 ng/L and the recommended PQL of 5 ng/L with granulated activated carbon (GAC). GAC has been successfully installed at New Jersey public water systems to treat a number of different compounds including PFNA. Given the conclusions reached by the three subcommittees, which are detailed in the documents attached, the Institute recommends that the Department propose and adopt an MCL of 13 ng/L for PFNA 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

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). In 2014, New Jersey Department of Environmental Protection Commissioner Bob Martin requested that the Institute recommend MCLs for perfluorononanoic acid (PFNA) and two other long-chain perfluorinated compounds (PFCs), perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS).

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 PFNA. 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 13 ng/L (0.013 µg/L), and the Testing Subcommittee developed an analytical PQL of 5 ng/L (0.005 µg/L). The Treatment Subcommittee recommended that the use of granular activated carbon or an equally efficient treatment removal technology should be considered when PFNA, PFOA, or PFOS is detected above recommended MCLs, 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 these three PFCs.

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

ED_004850_00000872-00005

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 perfluorononanoic acid (PFNA), the subject of this recommendation, as well as two other long-chain perfluorinated compounds (PFCs), perfluorooctanoic acid (PFOA) 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 PFNA.

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
George Van Orden, Ph.D.

Testing Subcommittee
Chair: Bahman Parsa, Ph.D., NJ Department of Health
Sandy Krietzman, M.S., NJ Department of Environmental Protection
Sheng-Lu Soong, Ph.D., United Water

ED_004850_00000872-00006

Treatment Subcommittee
Chair: Laura Cummings, P.E., Southeast Morris County MUA
Anthony Matarazzo, NJ American Water
Norm Nelson, Van Note-Harvey Associates
Fred Sickels, NJ Department of Environmental Protection
Carol T. Storms, Aqua NJ

Health Effects Considerations and Recommendations
The Health Effects Subcommittee conducted an extensive literature search to identify scientific studies relevant to development of a Health-based MCL protective for chronic (lifetime) drinking water exposure to PFNA. PFNA is persistent in humans with a half-life for elimination of several years, and exposure to relatively low drinking water concentrations is expected to substantially increase human body burden. From epidemiological studies of the general population, evidence of associations with PFNA is strongest for increases in serum cholesterol and the liver enzyme, ALT. Toxicological effects in rodent studies include weight loss; toxicity to the liver, immune system, kidney, and testes; and developmental effects including neonatal mortality, persistent growth decrements, and delays in reaching developmental milestones. The carcinogenic potential of PFNA has not been evaluated in humans or animals. Based on evaluation of studies of the mode of action of PFNA, it was concluded that its toxicological effects are relevant to humans.

The Health-Based MCL is based on increased maternal liver weight in a study of developmental effects in which pregnant mice were exposed to PFNA for 16 days. This study and endpoint were selected because they provide PFNA serum data needed for dose-response modeling at the same time point at which toxicity was assessed. The Health-based MCL is further supported by data on effects in the offspring in the same study and on other effects at similar or lower doses in other toxicology studies. Human epidemiology studies which found associations with health effects at levels of exposure prevalent in the general population provide support for the Health-based MCL, but were not used as the basis for quantitative risk assessment.

Because the same administered dose results in a much higher internal dose in humans than in experimental animals, interspecies comparison for PFNA are made on the basis of internal dose (serum level) rather than administered dose. Benchmark dose modeling was performed on PFNA levels in blood serum that caused increased maternal liver weight in the pregnant mice. The BMDL (95th percentile lower confidence limit on the Benchmark Dose) serum level for a 10% increase in liver weight, 4,900 ng/ml, was used as the point of departure for the risk assessment. A total uncertainty factor of 1000 was applied to the BMDL including 10 for intra-individual human variability, 3 for toxicodynamic differences between human and experimental animals, 10 for less than chronic exposure duration, and 3 to account for the incomplete toxicology database for PFNA. The resulting target human serum level, 4.9 ng/ml, is analogous to a Reference Dose but on the basis of serum level rather than administered dose. Based on available toxicokinetic data from animal and humans, a ratio of 200:1 was used to estimate the increase in PFNA in human blood serum from ongoing exposure to a given concentration of PFNA in drinking water. To account for sources of exposure to PFNA other than drinking water, a chemical specific Relative Source Contribution factor of 50% was developed based on the most recent (2011-12) NHANES data for the 95th percentile PFNA serum level in the U.S. general population. Using this information, a Health-based MCL protective for chronic drinking water exposure of 13 ng/L (0.013 µg/L) was derived. Refer to Appendix A to view the Health Effects Subcommittee Report in its entirety.

ED_004850_00000872-00007

Analytical Considerations and Recommendations
The role of the Testing Subcommittee in the recommendation of a PFNA MCL was to identify acceptable methods for PFNA analysis and to develop a PQL for PFNA. 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 drinking water PFC database for PFNA data from public drinking water system samples collected from September 2009 through August 2014. Due to the limited number (2) of laboratories performing analyses for PFNA in the NJDEP PFC database, the Testing Subcommittee also reviewed analytical information from other laboratories performing PFC analyses.

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 and the PQL for PFNA were developed simultaneously by the Health Effects and Testing Subcommittees, respectively. In the absence of a Health-based MCL as a goal, the Testing Subcommittee considered the NJDEP's March 2014 proposed Interim Specific Ground Water Criterion (ISGWC) of 20 ng/L as a target, and throughout the PQL development process, those laboratories with minimum reporting limits greater than 20 ng/L were excluded from consideration.

The Subcommittee evaluated four approaches for calculating the PQL, described in detail in the report found at Appendix B. To derive the PFNA PQL, the Testing Subcommittee decided to use the approach considers both the precision and accuracy of the analytical method. Therefore, the Testing Subcommittee relied on the actual reporting limits from laboratories currently performing PFNA analyses for determining its recommendation of a PQL of 5 ng/L for PFNA.

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 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, who are evaluating 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 for PFC removal both in the literature and in practice is granulated activated carbon (GAC). The Treatment Subcommittee concluded, based on case studies of full scale operations including at sites in New Jersey, that removal to levels below reporting limits and the recommended PQL for PFNA can be consistently achieved using GAC. This method of treatment has been successfully used in New Jersey for removal of PFCs including PFNA, as well as removal of synthetic organic chemicals, natural organic compounds, and other

ED_004850_00000872-00008

compounds affecting taste and odor. Based on these successful applications, it is therefore considered practical and feasible. The Treatment Subcommittee recommends that the use of GAC or an equally efficient technology, as identified in the Subcommittee report, should be considered for treatment of PFNA, PFOA and PFOS 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 PFNA, PFOA or PFOS.

MCL Recommendation

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

ED_004850_00000872-00009