



February 19, 2019

Heidi O'Neill  
New Jersey Department of Environmental Protection  
Office of Legal Affairs  
Mail Code 428-01  
P. O. Box 420  
Trenton, NJ 08625

**Re: Draft Interim Specific Ground Water Quality Criteria (ISGWQC) and Draft Interim Practical Quantitation Levels (PQLs) for PERFLUOROOCTANE SULFONATE (PFOS; CAS #: 1763-23-1) and PERFLUOROOCTANOIC ACID (PFOA; CAS #: 335-67-1)**

Dear Ms. O'Neill,

Delaware Riverkeeper Network submits these comments on **Draft Interim Specific Ground Water Quality Criteria (ISGWQC) and Draft Interim Practical Quantitation Levels (PQLs) for PERFLUOROOCTANE SULFONATE (PFOS; CAS #: 1763-23-1) and PERFLUOROOCTANOIC ACID (PFOA; CAS #: 335-67-1)** in support of amending the Interim Specific Ground Water Quality Criteria to include PFOS and PFOA and establishing an interim PQL for these compounds. We urge stricter Interim Specific Ground Water Quality Criteria for PFOS and PFOA based on the comments of Dr. Fardin Oliaei, included in this comment and independent expert technical reports, attached. These expert reports were submitted to the New Jersey Drinking Water Quality Institute (DWQI) by Delaware Riverkeeper Network regarding recommended maximum contaminant levels (MCLs). We support Dr. Oliaei's below recommendation for, alternatively, an ISGWQC combined PFOS and PFOA concentrations no higher than 11 ng/L. Also based on Dr. Fardin Oliaei's included comment, we support DEP's draft Practical Quantitation Level for PFOS and we recommend a lower Interim Practical Quantitation Level for PFOA.

Delaware Riverkeeper Network submits these comments in support of DEP regulatory action, advocating that the public be protected from PFOS and PFOA contamination and that discharges to groundwater be strictly limited to avoid any further spread of these highly toxic compounds into groundwater and aquifers. We also support DEP action so that New Jersey's groundwater can be cleaned up to a standard that is protective of public health and the environment. It is important to adopt these on an interim basis so that cleanup can move ahead with consistent and enforceable criteria immediately. DEP's

DELAWARE RIVERKEEPER NETWORK  
925 Canal Street, Suite 3701  
Bristol, PA 19007  
Office: (215) 369-1188  
fax: (215) 369-1181  
drm@delawareriverkeeper.org  
www.delawareriverkeeper.org

application of these criteria and PQLs will provide protection from continuing pollution transport and will provide much needed remediation of groundwater contamination for the benefit of the state's water, public health and the effected ecological systems and habitats.

We submit with this comment copies of technical analyses by Cambridge Environmental Consulting on recommended MCLs and PQLs for PFOS submitted January 31, 2018 and for PFOA submitted November 19, 2016 to the DWQI. Dr. Oliaei's comment on the proposed revisions is imbedded herein:

**PROPOSED REVISIONS TO THE DRAFT INTERIM SPECIFIC GROUND WATER QUALITY CRITERIA (ISGWQC) AND DRAFT INTERIM PRACTICAL QUANTITATION LEVELS (PQLS) FOR PERFLUOROOCCTANE SULFANATE (PFOS) and PERFLUOROOCCTANOIC Acid (PFOA)**

**Prepared by Fardin Oliaei, Ph.D.**

**February 18, 2019**

The following is in response to the New Jersey Department of Environmental Protection (NJDEP) request for public comment on draft Interim Specific Ground Water Quality Criteria (ISGWQC) for PERFLUOROOCCTANE SULFANATE (PFOS; CAS #: 1763-23-1) and PERFLUOROOCCTANOIC ACID (PFOA; CAS#: 335-67-1), posted on January 17, 2019.

**We recommend that NJDEP lower its proposed ISGWQC for PFOS to 5 ng/L and for PFOA to 1.0 ng/L or not greater than 6 ng/L in order to assure greater health protection of all population segments, especially children.**

**Alternatively, we recommend an ISGWQC such that the combination of PFOS and PFOA concentrations be no higher that 11 ng/L, ISGWQC [PFOA + PFOS] ≤ 11 ng/l.**

The following recommendations are based on our technical analysis and calculations used in our previous reports for evaluating the proposed health based maximum contaminant levels (MCLs) and proposed Practical Quantitation Levels (PQLs) developed by New Jersey Drinking Water Quality Institute (NJDWQI) for PFOA and PFOS in drinking water.

***Technical Analysis of draft Interim Specific Ground Water Quality Criteria (ISGWQC) and Draft Interim Practical Quantitation Level (PQL) for Perfluorooctane Sulfonate (PFOS)***

Please see attached our January 2018 report: Technical Analysis of New Jersey's Proposed Health-Based Maximum Contaminant Level (MCL) for Perfluorooctane Sulfonate (PFOS). Referenced here as (*Oliaei and Kriens, 2018*).

***Developing Draft ISGWQC for PFOS Based on Children-Specific Exposure Variables***

The Reference Dose (RfD) for PFOS (perfluorooctane sulfonate) derived by the New Jersey Department of Environmental Protection (NJDEP) is the most stringent and protective in the U.S., and is based on a rigorous analysis of all available PFOS animal and epidemiologic toxicological studies. We agree with process used to derive RfD for PFOS based on immunotoxic effect shown in the test animals (Dong et. al., 2009).

However, in its use of adult default exposure values to determine an Interim Specific Ground Water Quality Criteria (ISGWQC) for PFOS, younger children would not be protected since their dose intakes would exceed the allowable RfD. This is disconcerting since existing PFOS serum levels in children in the normal population are already within or near the serum PFOS levels associated with immunotoxic effects found in epidemiologic studies. In addition, other toxic effects found associated with children and PFOS exposure may lead to increased potential for later disease manifestation. Therefore, it is essential that the NJDEP depart from the typical use of adult default exposure values and use children-specific weight and water intake exposure values. Using appropriate children exposure values, we recommend an **ISGWQC for PFOS of 5 ng/L**.

Uncertainty Factors (UF) - Although the RfD of 1.8 ng/kg/day determined by NJDEP is significantly lower than RfD of 20 ng/kg/day developed by USEPA, we disagree with UF of 1.0 used to determine the target human serum level. Dong et al (2009) study of 60 days is of sub-chronic duration and an UF of 10 is normally applied when sub-chronic is used instead of chronic testing to estimate a NOAEL. In lieu of limited evidence of no increase in effect in dose-response between the 7-day and 60-day short-term sub-chronic studies, we recommend adding an UF of 3 versus 10 to extrapolate from sub-chronic to chronic testing in the Dong et al. (2009) study. Therefore, **adjusting the total UF from 30 to 100 will lower the ISGWQC to 4 ng/L** (Oliaei and Kriens, 2018).

Draft Interim Practical Quantification Level (PQL) for PFOS - To develop an appropriate PQL requires evaluation of analytical methods with adequate sensitivity to detect PFOS at or below the draft Interim Specific Ground Water Quality Criteria (ISGWQC) for PFOS.

We concur with the NJDEP methodology that determined a **PQL of 4 ng/l for PFOS**. This PQL concentration is below our proposed ISGWQC of 5 ng/L for PFOS (based on children specific exposure values) and is equal to our proposed ISGWQC of 4 ng/L for PFOS (based on adjustment of total UF for Sub-chronic to Chronic testing).

### ***Technical Analysis of draft Interim Specific Ground Water Quality Criteria (ISGWQC) and Draft Interim Practical Quantitation Level (PQL) for Perfluorooctanoic Acid (PFOA)***

Please see attached our November 2016 report: Technical Analysis of NJDWQI Proposed Health-Based Maximum Contaminant Level (MCL) for Perfluorooctanoic Acid (PFOA) Referenced here as (*Oliaei and Kriens, 2016*).

The development of ISGWQC for PFOA by NJDEP is based on an evaluation of PFOA done by the Health Effects Subcommittee of the New Jersey Drinking Water Quality Institute (DWQI, 2017). Using the same argument we presented in our technical analysis of NJDWQI proposed Health Based MCL for PFOS (*Oliaei and Kriens, 2016*), we conclude that the proposed draft Interim Specific Ground Water Quality Criterion (ISGWQC) of 10 ng/L for perfluorooctanoic acid (PFOA) based on increased relative liver weight is not adequately protective of all population segments, especially younger children.

The criterion may be developed on the basis of epidemiologic evidence of a significant immunotoxic association in children or, alternatively, evidence of significant adverse developmental effects shown in

rodent studies. Both of these offer more sensitive endpoints with quantitative data to develop an ISGWQC for PFOA to assure greater population health protection of all ages. An approximate ISGWQC of 0.5 ng/L for PFOA can be calculated based on the BMDL determined and the association found between immune suppression and serum PFOA levels in children as reported by Grandjean and Budtz-Jørgensen, or an ISGWQC of 1.0 ng/L based on the BMDL determined in the delayed mammary gland developmental effects in mice studies. Alternatively, we propose an ISGWQC of 6 ng/L for children group ages 1-6 using the increased liver weight endpoint, with exposure values we determined for mean weight and 90<sup>th</sup> percentile water intake in that group.

Therefore, we recommend that **NJDEP lower its proposed draft ISGWQC for PFOA from 10 ng/L to 1.0 ng/L**, consistent with the values found pursuant to the immunotoxic epidemiologic study and/or animal studies showing adverse developmental effects. Excluding use of more protective values mentioned above **the ISGWQC for PFOA should be no greater than 6 ng/L to assure protection of children.**

*Draft Interim Practical Quantification Level (PQL) for PFOA* - To develop an appropriate PQL requires evaluation of analytical methods with adequate sensitivity to detect PFOA at or below its draft Interim Specific Ground Water Quality Criteria (ISGWQC).

The draft Interim Practical Quantitation Level of 6 ng/L proposed for PFOA is considerably higher than our proposed ISGWQC of 0.5 ng/L based on the BMDL determined and the association found between immune suppression and serum PFOA levels in children, or ISGWQC of 1.0 ng/L based on the BMDL determined in the delayed mammary gland developmental effects in mice studies. However, the proposed draft Interim PQL concentration is equal to our proposed ISGWQC of 6 ng/L for children group ages 1-6 using the increased liver weight endpoint.

Since 2007 many laboratories have demonstrated that lower reporting limits are achievable. In fact, NYDEC contracted the services of a laboratory capable of providing a PFOA reporting limit of 2 ng/L. Studies in Southeast Queensland, Australia, reported the Minimum Reporting Levels (MRLs) for PFCs, including PFOA, ranged from 0.4 to 1.5 ng/l.

In order to determine a PQL for PFOA based on minimum reporting levels we propose a MRL of 2 ng/L. This is a value that most credible laboratories are currently capable to achieve.

However, considering serious adverse health impacts of PFOA, uncertainty inherent in toxicological studies to develop a protective MCL, and challenges in developing appropriate PQL, the best available control technology for removal of PFOA should be applied in order to protect public health.

**Responses to NJDEP request for public input for the following focus questions on the Draft Interim Specific Ground Water Quality Criteria (ISGWQC) and Draft Interim Practical Quantitation Levels:**

**Draft Interim Specific Water Quality Criteria:**

1. Are you aware of additional data or technical information concerning the toxicology, epidemiology, toxicokinetics, or other topics related to health effects of PFOA or PFOS that should be considered in the development of the ISGWQC?

Although the Reference Dose (RfD) for PFOS derived by the NJDEP is the most stringent and protective in the U.S., but in its use of adult default exposure values to determine an Interim Specific Ground Water Quality Criteria (ISGWQC) for PFOS, younger children would not be protected. This is disconcerting since existing PFOS serum levels in children in the normal population are already within or near the serum PFOS levels associated with immunotoxic effects found in epidemiologic studies. In addition, other toxic effects found associated with children and PFOS exposure may lead to increased potential for later disease manifestation. To assure protection of children it is important that children-specific weight and water intake exposure values be used in calculating ISGWQC value for PFOS. Therefore, it is essential that the NJDEP depart from the typical use of adult default exposure values and use children-specific weight and water intake exposure values. Using appropriate children exposure values, we recommend an **ISGWQC for PFOS of 5 ng/L.**

Developing ISGWQC for PFOA - The proposed ISGWQC calculated using adult default values for body weight results in a PFOA dose to children (ages 1-6) that is 50% higher at mean water intake levels, and 2½ times higher at 90<sup>th</sup> percentile water intake levels, than the reference dose (RfD) allowed to assure that serum levels remain below a protective maximum target level. Thus, the proposed ISGWQC of 10 ng/L using default adult exposure values is not protective of all age groups. This is concerning since, based on animal developmental studies that likely relate to humans, toxic effects from PFOA exposures in early childhood may persist into adulthood and could result in more profound disease in later life.

**Absent lowering the proposed ISGWQC to 1 ng/L, the ISGWQC for PFOA should be no higher than 6 ng/L.**

2. Is the supporting document factually accurate, e.g., are the data sources correctly cited; are the calculations correct?  
Please see my comments in 1 and 3 and 4.
3. Are the studies and toxicological endpoints selected for use as the basis for the Reference Doses appropriate? **No**

The proposed draft Interim Specific Ground Water Quality Criterion (ISGWQC) of 10 ng/L for perfluorooctanoic acid (PFOA) based on increased relative liver weight is not adequately protective of all population segments. We recommend that NJDEP lower the proposed ISGWQC for PFOA from 10 ng/L to 0.5 ng/L (based on our calculation of MCL using quantitative immunotoxicity to assure more sensitive toxicological endpoints with quantitative data are used

Developing ISGWQC for PFOA - The NJDWQI's reliance upon Increased Relative Liver Weight in animal studies as an endpoint to develop a RfD disregards more sensitive toxicity endpoints. We believe that animal studies showing significant delayed mammary gland development are sufficient and appropriate to use in the MCL determination, irrespective of whether there is absence of precedence, where benchmark dose modeling allows calculation of an approximate MCL of 1 ng/L. Substantial epidemiological evidence showing a range of toxic effects should also be taken into account versus reliance solely upon animal studies. One such study, the Immunotoxicity study by Grandjean and Budtz-Jørgensen 2013 showing a significant association between PFOA and suppression of antibody responses in children, provides benchmark dose response data to calculate a MCL of  $\leq 1$  ng/L (Oliaei and Kriens, 2016).

4. Have the key uncertainties in the assessments been identified and appropriately characterized? Have the uncertainties factors been applied appropriately? Are you aware of any additional data that would inform the uncertainties listed in these documents? **No**

In developing ISGWQC for PFOS based on the immunotoxic effect shown in the test animals (Dong et. al., 2009), the NJDEP assert that an uncertainty factor to extrapolate sub-chronic to chronic is not needed because the immunotoxicity studies of sub-chronic duration did not show a greater effect (response) at longer duration. AS described in Oliaei and Kriens, 2018 (Pages 5 and 6), omission of an UF for sub-chronic-to-chronic in risk assessment should not be done on the basis of results taken solely from short term studies, especially without an understanding of the mechanism of toxicity. An UF of 10 is normally applied when sub-chronic is used instead of chronic testing to estimate a NOAEL. We suggest that in lieu of some (limited) evidence of no increase in effect in dose-response between the 7-day and 60-day short-term sub-chronic studies we add an UF of 3 versus 10 to extrapolate from sub-chronic to chronic testing in the Dong et al. (2009) study. **Adjusting the total UF from 30 to 100 will lower the ISGWQC to 4 ng/L** (Oliaei and Kriens, 2018).

#### **Draft Interim Practical Quantitation Levels:**

1. Are you aware of additional data or technical information concerning analytical methods to detect PFOA and PFOS that would affect the selected draft Interim PQLs? Using the children exposure

To develop an appropriate PQL requires evaluation of analytical methods with adequate sensitivity to detect PFOS and PFOA at or below the draft Interim Specific Ground Water Quality Criteria (ISGWQC) for PFOS.

We concur with the NJDEP methodology that determined a PQL of 4 ng/L for PFOS. This PQL concentration is below our proposed ISGWQC of 5 ng/L for PFOS (based on children specific exposure values) and is equal to our proposed ISGWQC of 4 ng/L for PFOS (based on adjustment of total UF for Sub-chronic to Chronic testing).

But the draft Interim Practical Quantitation Level of 6 ng/L proposed for PFOA is considerably higher than our proposed ISGWQC of 0.5 ng/L based on the BMDL determined and the association found

between immune suppression and serum PFOA levels in children, or ISGWQC of 1.0 ng/L based on the BMDL determined in the delayed mammary gland developmental effects in mice studies. However, this PQL concentration is equal to our proposed ISGWQC of 6 ng/L for children group ages 1-6 using the increased liver weight endpoint.

It is important to note that since 2007 many laboratories have demonstrated that lower reporting limits are achievable. In fact, NYDEC contracted the services of a laboratory capable of providing a PFOA reporting limit of 2 ng/L. Studies in Southeast Queensland, Australia, reported the Minimum Reporting Levels (MRLs) for PFCs, including PFOA, ranged from 0.4 to 1.5 ng/l.

In order to determine a PQL for PFOA based on minimum reporting levels we propose a MRL of 2 ng/L. This is a value that most credible laboratories are currently capable to achieve (Oliaei and Kriens, 2016).

Prepared by Fardin Oliaei, Ph.D.  
February 18, 2019

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In closing, DEP's proposed Draft Interim Specific Ground Water Quality Criteria and Draft Interim Practical Quantitation Levels are both extremely important regulatory actions. These are necessary to assure that the sources of PFOA/PFOS contamination are remediated and water systems are not always on the hook to clean up a never-ending stream of contamination. Without the proposed action, water suppliers are forever struggling to remove the compounds to a maximum contaminant level to provide safe water, at the public's expense, economically and in terms of health costs. We advocate that DEP adopt Dr. Fardin Oliaei's recommendations immediately.

Submitted by:

  
Maya van Rossum  
the Delaware Riverkeeper

  
Tracy Carluccio  
Deputy Director

Enclosures:

Technical Analysis of New Jersey's Proposed Health-Based Maximum Contaminant Level (MCL) for Perfluorooctane Sulfonate (PFOS) prepared by Fardin Oliaei, Ph.D. and Don L. Kriens, Sc.D., Cambridge Environmental Consulting, January 2018.

Review of NJDWQI Report on the Development of a Practical Quantitation Level for PFOS in Drinking Water prepared by Fardin Oliaei Ph.D. and Don L. Kriens Sc.D., Cambridge Environmental Consulting, January 2018.

Technical Analyses of New Jersey Drinking Water Quality Institute Proposed Health-Based Maximum Contaminant Level for Perfluorooctanoic Acid (PFOA) in Drinking Water, Fardin Z. Oliaei, Don Kriens, Cambridge Environmental Consulting, Nov. 18, 2016.

Technical Analysis of Proposed DWQI Development of a Practical Quantitation Level for Perfluorooctanoic Acid (PFOA) in Drinking Water, Fardin Z. Oliaei, Don Kriens, Cambridge Environmental Consulting, Nov. 18, 2016.