



February 5, 2018

VIA ELECTRONIC MAIL

watersupply@dep.nj.gov

Drinking Water Quality Institute

RE: REQUEST FOR PUBLIC INPUT FOR PERFLUOROOCTANE SULFONATE

To Whom It May Concern:

On behalf of our members, the Chemistry Council of New Jersey (CCNJ) and the Site Remediation Industry Network (SRIN) appreciate the opportunity to provide comments to the Drinking Water Quality Institute (DWQI) pursuant to the Institute's request for public input regarding the recently released subcommittee reports on Perfluorooctane Sulfonate (PFOS). CCNJ/SRIN have long advocated for greater transparency and public input with respect to DWQI's activities and we appreciate the steps taken to provide this opportunity.

General Concerns

Based upon available science and data, as further detailed below, we have significant concerns that DWQI's current recommendations related to PFOS are not justified, could not be feasibly implemented by New Jersey water providers, and is not supported by an objective analysis of the available science and data. As such, CCNJ/SRIN strongly recommend that DWQI's current draft Maximum Contaminant Level (MCL) for PFOS be held until such time that scientific evidence can support its recommendation. In the alternative, we urge DWQI to further review the detailed scientific data and literature that was either ignored or missed in its current review of PFOS before submitting a recommendation to the New Jersey Department of Environmental Protection (NJDEP); the following are specific examples:

- Rutgers Environmental Health and Occupational Health Sciences Institute and School of Public Health. 2017. Rutgers Pilot Study of Perfluorochemical Compounds in Paulsboro Residents, Preliminary Study Report. September 13.
- enHealth. 2016. Statement: Interim national guidance on human health reference values for per- and poly-fluoroalkyl substances for use in site investigations in Australia. June. <http://www.health.nsw.gov.au/environment/factsheets/Documents/pfas-interim-health-values-ahppc.pdf>

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- Chang ET, Adami HO, Boffetta P, Cole P, Starr TB, and Mandel JS. 2014. A critical review of perfluorooctanoate and perfluorooctanesulfonate exposure and cancer risk in humans. *Crit Rev Toxicol.* 44(S1):1-81.

We believe that it is in the best interests of public policy and public health in New Jersey to review this science prior to any final PFOS MCL recommendation from DWQI. These resources will provide valuable insight to DWQI and allow for the review of the best information currently available. The Rutgers report is further discussed below.

CCNJ/SRIN and our members continue to advocate for DWQI's and NJDEP's transparent and thorough consideration of the *Rutgers Pilot Study of Perfluorochemical Compounds in Paulsboro Residents, Sept. 13, 2017* (Attachment 1), and the underlying Perfluorinated Compound (PFC) blood sampling data from Paulsboro.

The data gathered by Rutgers is the only available scientifically-gathered evidence of PFC blood serum levels in residents who consumed water from municipal wells affected by Perfluorononanoic Acid (PFNA), and one of the few paired data sets for Perfluorooctanoic Acid (PFOA) or PFOS. To date, DWQI has not acknowledged that these data exist. Ignoring these data undermines the credibility of DWQI's PFC recommendations. The Paulsboro data are readily available, reliable, recent and *local*, and directly relevant to DWQI's recommendations, including for PFOS, which was detected in both the Paulsboro water supply and in residents' blood serum. CCNJ/SRIN urge DWQI to include these data in its regulatory consideration/calculation.

The more than 1,000-page report by the DWQI Health Effects Subcommittee, which includes more than 30 pages of references alone, does not mention Paulsboro or the fact that more than 1,000 residents of Paulsboro had their blood sampled for PFCs, including PFNA, PFOA, and PFOS, in 2016. Nor does it mention that Rutgers enrolled 181 Paulsboro residents in a study and, in cooperation with Rutgers, those residents shared their blood serum results and information about their use of the Paulsboro water system with the Rutgers research team. Additionally, a large subset, 116 residents, answered detailed questions for Rutgers, including water consumption information and health conditions that may be associated with PFCs.

Based on the existence of a questionnaire that was formally developed and approved by Rutgers (Attachment 2), we believe that water consumption data was collected during the Paulsboro study. This questionnaire includes very specific questions about water consumption; please see excerpt below:

“SECTION 3

The next questions are about the time BEFORE you knew about the PFNA in the drinking water and BEFORE you or the borough of Paulsboro took steps to reduce your PFNA exposure.

During the time that you lived in a home served by Paulsboro public water supply, and **BEFORE you knew about the PFNA in the drinking water**, about how many **8 oz cups** of tap water or beverages prepared with tap water did you usually drink per day?

Note: 1 Gallon (128 oz.) = 16 cups; 1 quart (32 oz.) = 4 cups; 1 pint (16 oz.) = 2 cups

_____ Cups per day”

According to the final, published Rutgers report, 116 long form surveys were completed by Paulsboro residents, so it appears that very direct questions were asked of residents and collected by Rutgers about water consumption.

Rutgers published and provided to the residents a report that analyzed those 181 blood serum results. That report, entitled *Rutgers Pilot Study of Perfluorochemical Compounds in Paulsboro Residents, Sept. 13, 2017*, and the underlying data gathered by Rutgers upon which it is based, should be evaluated as part of DWQI and NJDEP regulatory considerations for PFCs, as the data would allow a direct assessment of some of the key assumptions made by DWQI regarding the association between PFC drinking water concentrations and blood serum levels. In addition to the detailed information collected on a subset of the residents, Paulsboro itself has records of when it used its various wells to supply its residents with drinking water and, therefore, there exists a basis for understanding residents’ drinking water exposures and associated PFC blood serum levels. However, in the event that Rutgers ultimately did not collect the water consumption data, CCNJ/SRIN would like an explanation as to why not given its direct relevance to the study. In terms of advancing the science, if this data was collected, it would be far more useful for the data’s existence to be publicly acknowledged and an explanation given by Rutgers and the State regarding why they are not taking the logical next step to evaluate it.

In addition, we understand that it is possible that there were data quality issues. Yet, this would be puzzling given that Rutgers did use information obtained from other questions in the same survey, for example to help group results by age and sex. If New Jersey is going to be the first in the United States to regulate far and beyond the United States Environmental Protection Agency (USEPA)’s standards, then the data puts researchers in a unique position to support such an action. They can examine available data from the surveys and water sample results to provide

some clarity to assumptions that DWQI and NJDEP are relying upon in their calculations. This can also advance the scientific understanding for PFNA, PFOA, and PFOS, in general.

The Paulsboro study is relevant to DWQI's PFOS MCL recommendation because it includes measurements of multiple PFCs, including PFOA and PFOS. If the assumption is that human health effects of PFNA, PFOA, and PFOS are driven by concentrations in our bodies, the link between external exposure through drinking water and someone's internal dose needs to be calculated with extreme rigor.

There are simply not that many datasets available that provide this information. This is a study of approximately 200 individuals, each of whom provides a direct measure of the same variable that NJDEP is trying to estimate. By comparison, in terms of sample size alone, this study is four times the size of the one and only study in humans NJDEP and DWQI relied upon to support their estimate of the half-life of PFNA in serum; that study only had 50 participants. NJDEP defended its position to use that study in its public response-to-comments, indicating that they were confident such information would support a central tendency estimate of the serum:water ratio. Why not take the next step to evaluate this study?

On the sample design itself, CCNJ/SRIN agree that the data were not collected in a scientifically rigorous way. However, the data still provide important information, not the least of which would be a check on whether the assumptions adopted by DWQI and NJDEP are consistent with data for each of the PFCs (PFNA, PFOA, and PFOS) for this specific sample. For example, Rutgers could examine data on serum and water levels to determine if individuals with elevated serum levels (higher than NHANES) also have higher exposures based on the reported water consumption rates and the concentrations in water (compared to the proposed MCL).

The Paulsboro dataset may prove useful to explore many of the assumptions made for PFNA, PFOA, and PFOS. There should be a transparent discussion of its strengths and weaknesses.

DWQI and NJDEP rely heavily on their assumptions about how PFCs are retained in human blood (versus actual data) to recommend MCLs as extremely low and unprecedented as 13 parts per trillion (ppt) for PFNA and PFOS and 14 ppt for PFOA. These levels are far lower than guidance from USEPA without scientific justification or evidence. Importantly, the levels do not appear defensible when compared to actual empirical data.

For example, for PFNA, the DWQI MCL recommendation is based on the assumption that 4.9 parts per billion (ppb) of PFNA in human blood is an appropriate protective target serum level.

However, according to Rutgers, the measured mean level of PFNA in the blood of 181 Paulsboro residents is 3.6 ppb. In other words, the actual data are below the target level that NJDEP and DWQI have determined is protective. And, yet, Paulsboro drinking water well No. 7 had measured levels of PFNA near 100 ppt or more in August of 2009 and in October 2013 through when the well was taken offline in April 2014. This concentration of PFNA in drinking water is over 7 times higher than the recommended MCL; however, the residential blood serum data shows that serum PFNA levels did not exceed DWQI's target human blood level.

The concentrations of PFNA, PFOA, and PFOS in blood serum of almost 200 residents in Paulsboro have been accurately measured. If 100 ppt in drinking water did not cause the average level in blood serum to exceed the level DWQI and NJDEP used to calculate the MCL, then why would NJDEP and DWQI insist that water suppliers across the state must test for PFNA down to 2 ppt, and install expensive treatment to keep the level of PFNA in their water supplies below 13 ppt?

In addition, we advocate consideration of the study and the underlying data because:

- 1. The data *are* reliable.** Phlebotomists were used to gather the samples and a New Jersey certified lab was used to analyze them. Rutgers itself relies on the data in issuing its report.
- 2. They are the *only* available empirical data involving measured quantities of PFCs in drinking water and in human blood serum of New Jersey system users.**
- 3. More than 1,000 Paulsboro residents chose to have their blood serum levels sampled for PFCs and 181 of that group chose to make the results available to Rutgers, in response to its request. No one claims that this is a random sampled population necessary for a health study, but it is false to suggest that this data could have no scientific value as to the very assumptions, especially the serum:drinking water ratio, that DWQI has made in their proposed MCLs for several PFCs.**

Scientists are trained and able to recognize and evaluate sample size and selection bias, as well as time of exposure versus time of sampling, and use empirical data for appropriate purposes. In this case, *valid, directly relevant data are available* to compare to assumptions being relied on by DWQI and NJDEP to the PFCs actually detected in New Jersey residents using affected water. The residents of Paulsboro and all New Jerseyans deserve a straightforward discussion and consideration of the Paulsboro residents' blood results.

If these unwarranted proposed MCLs are adopted, towns and small public water purveyors will simply be unable to manage testing and treatment to low ppt levels. Consumers will pay the

price for water sampling and treatment costs that are not scientifically justified. Public water providers are not represented on DWQI and may have no choice but to sell their systems to investor-owned water utilities, who will pass the costs through to consumers through rate hikes.

Importantly, we support the use of the best available science; CCNJ/SRIN have always held this position. One recent example is the Site Remediation & Waste Management Program (SRWMP)'s revisions to Soil Remediation Standards (SRS). We submitted a letter of support to then-NJDEP Commissioner Bob Martin because we agreed that the latest USEPA Integrated Risk Information System (IRIS) toxicity values should be incorporated into NJDEP's calculations in determining revised SRS. CCNJ/SRIN stated our support of SRWMP's efforts because we support the use of the best available science, irrespective of whether the numbers ultimately increase or decrease.

Comments on Subcommittee Reports

Please refer to our third attachment for a discussion of specific examples of limitations in DWQI's evaluation of health effects and treatment.

Summary

As discussed above and in Attachment 3, DWQI is proposing an MCL for New Jersey that is far lower than the guideline the federal government recently determined is protective for drinking water. No additional known health protection is achieved, suggesting the DWQI proposal does not overcome the additional cost and reporting/regulatory burden that would unnecessarily hinder economic growth and success in New Jersey.

CCNJ/SRIN strongly urge that the report entitled *Rutgers Pilot Study of Perfluorochemical Compounds in Paulsboro Residents, Sept. 13, 2017*, and the underlying data gathered by Rutgers upon which it is based, be evaluated by DWQI and NJDEP, as the data would allow a direct assessment of some of the key assumptions made by DWQI regarding the association between PFC drinking water concentrations and blood serum levels.

DWQI must be mindful of the science being developed in other states and by the federal government. The works completed by other states/countries and USEPA are also informative to DWQI's PFOS review. It is imperative that the Institute review these works, as they clearly help identify the flaws in New Jersey's current scientific literature regarding PFOS. In situations where urgency is required and federal guidance is available, it is a sound policy for the State to rely on



the federal guidance and allow the scientific process to develop data to support MCLs and other New Jersey environmental standards.

Thank you for the consideration of our comments on this very important issue. We look forward to working with DWQI as it continues its work in recommending drinking water quality standards in New Jersey. If I can be of further assistance, please let me know.

Sincerely,

A handwritten signature in black ink, appearing to be "D Hart", written over a horizontal line.

Dennis Hart
Executive Director

Attachments

References

Chang ET, Adami HO, Boffetta P, Cole P, Starr TB, and Mandel JS. 2014. A critical review of perfluorooctanoate and perfluorooctanesulfonate exposure and cancer risk in humans. *Crit Rev Toxicol.* 44(S1):1-81.

enHealth. 2016. Statement: Interim national guidance on human health reference values for per- and poly-fluoroalkyl substances for use in site investigations in Australia. June. <http://www.health.nsw.gov.au/environment/factsheets/Documents/pfas-interim-health-values-ahppc.pdf>

Rutgers Environmental Health and Occupational Health Sciences Institute and School of Public Health. 2017. Rutgers Pilot Study of Perfluorochemical Compounds in Paulsboro Residents, Preliminary Study Report. September 13.