

HEALTH-BASED MAXIMUM CONTAMINANT LEVEL SUPPORT DOCUMENT: PERFLUORONONANOIC ACID (PFNA) PUBLIC COMMENTS

New Jersey Drinking Water Quality Institute
Health Effects Subcommittee

Subcommittee Members:

Jessie A. Gleason, M.S.P.H., Chair

Keith R. Cooper, Ph.D.

Judith B. Klotz, M.S., Dr. P.H.

Gloria B. Post, Ph.D., DABT

George Van Orden, Ph.D.

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Background

- Health Effects Subcommittee presented draft health-based MCL document on April 8th, 2015
- Written public comments were accepted until May 7th, 2015
- Four submissions include comments relevant to Health Effects Subcommittee documents
 - One suggested lower Health-based MCL
 - Three suggested higher Health-based MCL and/or not enough information for Health-based MCL

Background (*continued*)

- All comments are posted online
- All comments were considered by Health Effects Subcommittee
 - Comments on Draft Interim Specific Ground Water Criterion were previously considered
- Summary of comments resulting in revisions, and other significant comments, are presented here

General Comments

- **Comment:** General support of approach used to develop Health-based MCL
 - Comment is acknowledged
- **Comment:** There is not enough information to develop health-based standard for PFNA
 - Data on toxic effects in animals and associations with human health endpoints are sufficient to develop Health-based MCL

Epidemiology - Causality

- **Comment:** Currently available epidemiological evidence is insufficient to establish any adverse human health effects caused by PFNA exposure
 - Currently there are limitations to the available epidemiologic data. Therefore it is not used as the basis for the quantitative risk assessment
- **Comment:** The document does not provide systematic weight of evidence to establish causal relationships
 - Current language sufficiently states inability to draw conclusions about causality

Epidemiology - Presentation

- **Comment:** The document selectively highlights positive associations as compared to null associations
 - Review of summary findings reveals 18% of positive results were not presented and 22% of null results were not presented in summary tables
- **Comment:** Thorough review of tables and text were performed – discrepancies noted
 - Each of the study endpoints mentioned by reviewer was evaluated. Revisions were made when appropriate.
- **Comment:** A concerted effort to capture and report all of the relevant data was made.
 - This comment is acknowledged

Epidemiology - continued

- **Comment:** Epidemiologic studies were evaluated superficially, without critical analysis of study methods and results.
 - Methods and biases were considered and discussed with an appropriate level of detail for the purpose of the document.
- **Comment:** Conclusions concerning certain endpoints are exaggerated (positively/negatively)
 - Reviews of data by different reviewers may lead to differences in conclusions. Some symbol definitions in the summary table were revised.

Source of Data for Dose-Response Modeling

- **Comment:** “Unpublished data” were used as the basis for dose-response modeling
 - The data used for dose-response modeling are published and were the same as those used to generate the figures and graphs presented in Das et al., 2015.

Benchmark Dose Modeling

- **Comments** were submitted on the basis for the BMD modeling for increased liver weight in pregnant mice (Das et al., 2015)
 - All inputs into the BMD modeling software, including data from EPA investigator were reviewed.
 - The investigator informed the Subcommittee that serum data for a few animals not part of the liver weight evaluation had been inadvertently included. Also, the value for the number of animals in one dose group had been transcribed incorrectly.
 - Modeling was redone with the corrected values using a more recent version of the EPA BMD modeling software.
 - Although the BMDL decreased slightly, the resulting Health-based MCL, 13 ng/L, is unchanged.

Benchmark Dose Modeling (continued)

- **Comment:** The document does not present all of the statistical parameters from the BMD models.
 - The revised document includes a new table (Table 10) with the full suite of statistical parameters from all 7 of the BMD models, as well as an Appendix containing the output from the BMD modeling software for all of the models.

Uncertainty Factors (UFs)

- **Comment:** Commenter concurs with choice of UFs.
 - This comment is acknowledged.
- **Comment:** Why do the UFs chosen by the Health Effects Subcommittee differ from those used by NJDEP in its draft Interim Specific Ground Water Criterion for PFNA?
 - The Subcommittee independently evaluated the basis for the UFs. This included a detailed review of application of UFs in previous EPA, NJDEP, and DWQI risk assessment.
- **Comment:** A UF of 3 to extrapolate from rodents to humans is not needed because rodents are more sensitive than humans to PFCs
 - There is considerable evidence that PFCs cause toxicity through modes of action that do not affect rodents more than humans.

Relative Source Contribution Factor

- **Comment:** Use more stringent default 20% RSC instead of chemical-specific RSC.
- **Comment:** Use less stringent 80% RSC based on median (50th percentile) from NHANES as recommended in EPA guidance.
 - Subcommittee continues to conclude that 50% RSC based on the 95th percentile of NHANES is both appropriate and sufficiently protective

Relative Source Contribution Factor

(continued)

- The median (50th percentile) serum concentration for the U.S. as a whole may not be representative of NJ exposures, particularly where drinking water has been impacted by past industrial use and discharge of PFNA.
- EPA recommends more protective assumptions for state-specific criteria when local exposures could be higher than in the general U.S. population.

Serum:Drinking Water Ratio

- **Comment:** An upper percentile value, rather than a central tendency value, should be used
 - The Subcommittee concludes that the 200:1 ratio is sufficiently protective
- **Comment:** Exposures from non-drinking water sources were not considered in developing the ratio
 - Non-drinking water exposures were considered in developing the ratio.

Exposure Assumptions for Children

- **Comment:** Exposure assumptions for children (whose drinking water intake per body weight is greater than in adults) should be used.
 - The Health-based MCL is based on lifetime exposure and is expected to be protective of all age groups.
 - The commenters use of a time-weighted average for different age groups over a 70 year old lifetime would involve additional assumptions and would result in only a small change (8%) in the Health-Based MCL.

Consideration of PFNA Serum Data from Paulsboro Residents

- **Comment:** A report containing data on PFNA serum levels from 25 Paulsboro residents and one other resident with PFNA private well contamination was submitted. This report provides an estimate for serum:drinking water ratios much lower than the 200:1 ratio used in the health-based MCL development.
 - The collection of the serum samples and the reporting of information related to the subjects and the serum samples did not involve scientists, a protocol, or other components of a valid scientific study.

Summary

- All comments were considered by Health Effects Subcommittee
- The Health-based MCL Support Document was revised where appropriate
- Data used for BMDL modeling were reviewed and minor changes resulted in a slightly lower BMDL
- Health-based MCL recommendation remains unchanged, 13 ng/L