REVIEW OF INTERIM USEPA HEALTH ADVISORIES FOR PFOA AND PFOS AND OTHER RELEVANT INFORMATION

New Jersey Drinking Water Quality Institute
Health Effects Subcommittee

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Background

- DWQI previously recommended three MCLs for PFAS that have been adopted by NJDEP
  - 13 ng/L for PFNA in 2015
  - 14 ng/L for PFOA in 2017
  - 13 ng/L for PFOS in 2018
- DWQI MCLs consider Health-based MCLs, analytical Practical Quantitation Levels (PQLs), and treatment removal capabilities
- PFAS MCLs were set at Health-based MCLs; were not limited by analytical or treatment removal considerations
- New Jersey Practical Quantitation Levels (PQLs)
  - 5 ng/L for PFNA
  - 4 ng/L for PFOA
  - 6 ng/L for PFOS

USEPA Interim Health Advisories

- USEPA issued non-regulatory Health Advisories in June 2022
  - 0.004 ng/L for PFOA (interim)
  - 0.02 ng/L for PFOS (interim)
  - 10 ng/L for GenX (final)
  - 2000 ng/L for PFBS (final)
- USEPA Health Advisories do not consider analytical and treatment removal limitations
- USEPA has stated that final PFOA and PFOS Health Advisories will differ from the interim advisories
  - Interim Health Advisories are being revised based on Science Advisory Board (SAB) comments
  - Expected to remain below the USEPA minimum reporting levels (MRLs) of 4 ng/L for both PFOA and PFOS
  - Final Health Advisories and proposed National Primary Drinking Water Standards (MCLs or treatment technique) expected soon

Use of Human Epidemiology Data in Interim USEPA Health Advisories

- USEPA Interim Health Advisories for PFOA and PFOS are based on health effects data from human epidemiological studies.
- Previous PFOA and PFOS advisories and guidelines are based on toxicity data from laboratory animal studies.
  - USEPA (2016) Health Advisories (70 ng/L for total of PFOA and PFOS)
  - NJ MCLs
  - Drinking water guidelines from other States
- PFOA and PFOS guidelines based on human data are generally more stringent than those based on animal data.

Commissioner Request

- June 2022 - NJDEP Commissioner requested DWQI to review the scientific basis of the USEPA Health Advisories for the four PFAS
  - Requested PFOA and PFOS be prioritized
- For PFOA and PFOS:

  1. Determine whether current scientific information supports health-based drinking water concentrations below NJ PQLs
     - Note: Updated health-based drinking water concentrations were not requested
     - Final USEPA drinking water standards will supersede NJ MCLs if they are lower

  2. If health-based concentrations below current PQLs are supportable, DWQI should reevaluate PQLs and treatment capabilities

Report Overview: Documents Reviewed

- Interim USEPA Health Advisories for PFOA and PFOS
- Draft USEPA PFOA and PFOS health effects assessments (which provide the scientific basis for the interim USEPA Health Advisories)
- USEPA Science Advisory Board (SAB) review of draft USEPA health effects assessments
- Key recent peer-reviewed publications not considered by USEPA
- Recent PFOA and PFOS evaluations based on human data by other authoritative organizations
- Draft USEPA document on approaches for risk assessment of PFAS mixtures
- Previous Subcommittee conclusions on PFAS health effects and risk assessment
- Recent information on higher infant exposure via breastmilk and approaches for considering this pathway

Report Overview: Scope

- In general, USEPA Health Advisories are based only on non-cancer effects while NJ MCLs consider cancer and non-cancer effects.
- Therefore, the Subcommittee's review considered both.
- Subcommittee review focused on key human health effects of PFOA and PFOS:
  - Decreased antibody response to vaccination
  - Hepatic effects including increased serum ALT (liver enzyme indicative of liver damage)
  - Decreased birth weight and related endpoints
  - Increased serum lipids particularly cholesterol
  - Increased risk of cancer
  - Increased overall mortality

Review of USEPA Interim Health Advisories, Draft Health Assessments, and SAB Review

Subcommittee agrees with the following USEPA and SAB conclusions:

- Human data are appropriate basis for non-cancer Reference Doses (RfDs) for PFOA and PFOS and cancer slope factor for PFOA
- The health endpoints with strongest human evidence for PFOA and PFOS are:
  - Increased serum cholesterol
  - Decreased antibody response to vaccination
  - Decreased fetal growth (i.e., birth weight)
  - Increased serum levels of the liver enzyme ALT
  - For PFOA, increased risk of kidney cancer
- PFOA is "*Likely to Be Carcinogenic to Humans*" and PFOS has *"Suggestive Evidence of Carcinogenic Potential."*
  - PFOA and PFOS were previously classified as "Suggestive" by both USEPA and DWQI.
  - "Likely" designation for PFOA is based on additional recent human and animal data.

Review of USEPA Interim Health Advisories, Draft Health Assessments, and SAB Review (continued)

Subcommittee also agrees with the following additional USEPA and SAB conclusions:

- A clearance factor (ml/kg/day) should be used to relate external exposures (ng/kg/day) of PFOA and PFOS to internal doses (i.e., blood serum levels; ng/ml).
  - This approach was used by Subcommittee for DWQI Health-based MCLs for PFOA and PFOS
- For health endpoints resulting from prenatal and/or early life exposure, a transgenerational toxicokinetic model that considers prenatal exposure and the higher exposures of infants, particularly those who are breastfed, should be used
  - This approach was not available when Subcommittee developed DWQI Health-based MCLs

Multiple Lines of Evidence Support Health-based MCLs below PQLs

Subcommittee concluded that multiple lines of evidence indicate that current scientific information supports Health-based MCLs below the current NJ PQLs of 4 ng/L for PFOA and 6 ng/L for PFOS:

- Human data are appropriate for RfD development for PFOA and PFOS.
  - Health-based MCLs based on RfDs developed from human data are consistently very close to or below the New Jersey PQLs.
- Increased risk of human kidney cancer is an appropriate basis for a cancer slope factor (CSF) for PFOA.
  - Health-based MCL for PFOA based on available CSFs for increased risk of human kidney cancer and the one in one million (10^{-6}) cancer risk level used by New Jersey is far below the New Jersey PQL of 4 ng/L.

Multiple Lines of Evidence (continued)

- Previous evaluations by the Health Effects Subcommittee and its members indicate that low dose developmental effects of PFOA in laboratory animals support a Health-based MCL for PFOA below the New Jersey PQL of 4 ng/L.
- Exposure to PFOA and PFOS in infants is of particular concern because they are a susceptible subpopulation.
  - Consideration of the much higher exposures to PFOA and PFOS in breastfed infants supports Health-based MCLs below the New Jersey PQLs.
- PFOA, PFOS, and other PFAS typically occur in drinking water as mixtures.
  - Consideration of toxicological interactions of PFAS that co-occur in drinking water supports more stringent Health-based MCLs.

Summary

- **Evidence supports PFOA and PFOS Health-based MCLs below NJ PQLs:**
  - Current Health-based MCLs were determined to be public health protective and scientifically supportable based on the available information when they were developed.
  - Current scientific information now supports Health-based MCLs below the current NJ PQLs.
- Several earlier Subcommittee conclusions were accepted by USEPA in its recent PFOA and PFOS evaluations and have been used by other states, including:
  - Relationship between administered dose and serum PFOA/PFOS levels
  - Importance of considering higher exposure to infants through breast milk
- Subcommittee's general recommendation for re-evaluation of PQLs:
  - The Subcommittee suggests that PQLs for all MCLs developed by the DWQI that are above Health-based MCLs should be reevaluated on a regular basis to determine if they can be decreased to closer to or below the Health-based MCL.