Environmental Protection Network

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August 17, 2023

Lisa D. Daniels, Chair
Elizabeth Corr, Designated Federal Officer
National Drinking Water Advisory Council
Environmental Protection Agency
Office of Ground Water and Drinking Water
Mail Code 4601M
1200 Pennsylvania Ave, N.W.
Washington, D.C. 20460

Dear Ms. Daniels and Ms. Corr:

Members of the Environmental Protection Network (EPN) listened to EPA's August 8, 2023, consultation with the National Drinking Water Advisory Council (NDWAC) on the proposed PFAS national drinking water rule. EPN is an organization of nearly 600 former EPA career and political appointee scientists and regulators who provide pro bono technical assistance to communities with environmental problems and analyze EPA policies, regulations, and guidance.

Our members are concerned that NDWAC received very little information on the significance of PFAS exposures, namely the health effects of PFAS, and the scientific justification for use of the hazard index. The discussion at the August 8 meeting principally focused on the costs of implementing the proposed maximum contaminant levels (MCLs) and difficulties communicating the hazard index to the public. This letter summarizes the extensive health effects information on the six PFAS included in EPA's rule and justifies the use of a hazard index for four of those PFAS.

In addition to EPA's 2022 review of the PFAS health effects literature, systematic reviews were also conducted by the European Food Safety Authority in 2020, the Agency for Toxic Substances and Disease Registry in 2021, and the National Academies of Sciences, Engineering and Medicine (NASEM) in 2022. All these reviews found extensive human and animal data on the health effects of PFOA and PFOS. The animal health data were highly consistent with the human health effects data. Both human and animal studies link exposure to PFOA, PFOS, and other PFAS with multiple health effects, including immune system effects; increased cholesterol; liver, kidney, and thyroid problems; reproductive and developmental harm; and multiple types of cancer. These reviews document multiple health effects within the general population's range of exposure to PFOA and PFOS with blood serum or plasma levels in nanograms per milliliter (ng/mL) or parts per billion (ppb), not just in the range of highly exposed workers.

NDWAC is aware of the 2022 NASEM findings,[1] which focused on seven PFAS, four of which are included in EPA's proposed drinking water rule and are the most commonly detected PFAS in the blood of the U.S. population (PFOA, PFOS, PFHxS, and PFNA). NASEM reports that they found sufficient evidence of an association between exposure to these four PFAS and three others (MeFOSAA, PFDA, and PFUnDA) and the following diseases and health outcomes: decreased antibody response in adults and children; dyslipidemia in adults and children; decreased infant and fetal growth; and increased risk of kidney cancer in adults. NASEM also found limited or suggested evidence between exposure to these PFAS and the following health effects: increased risk of breast cancer in adults; liver enzyme alteration in adults and children; increased risk of testicular cancer in adults; thyroid disease and dysfunction in adults; and increased risk of ulcerative colitis in adults. In short, NASEM documented evidence of an association of those general population exposures across multiple body systems: immune system, reproductive and development system, metabolism, and renal carcinogenicity. NASEM found suggestive effects for five other adverse effects: breast and testicular cancers, liver damage in both children and adults, thyroid effects and damage to the gastrointestinal system. Again, note these effects are evident in the range of general population exposures which are associated with blood levels in the ng/mL or ppb range.

Consequently, NASEM recommends that clinicians measure PFAS in blood serum or plasma for patients with occupational or locational exposure to sources of PFAS contamination. For patients with blood serum or plasma concentrations between 2 ng/mL and 20 ng/mL (2 and 20 ppb, respectively), NASEM recommends clinicians encourage PFAS exposure reduction and screen for dyslipidemia, hypertensive disorder during pregnancy, and breast cancer. For patients with blood serum or plasma concentrations at or above 20 ng/mL (20 ppb), NASEM recommends clinicians encourage PFAS exposure reduction and screen for dyslipidemia; conduct thyroid function testing for those over 18 years old; assess for signs of kidney cancer for those over 45 years old; and assess for signs of testicular cancer and ulcerative colitis for those over 15 years old. NASEM recommends that this clinical guidance be updated every five years in order to keep current with the evolving science on PFAS.

Because this is the first time drinking water standards have been based on a hazard index, water systems do not have experience with communicating such a standard. For years, the Superfund program has successfully communicated to communities living near contaminated sites the risks of multiple pollutants using a hazard index approach. EPA's drinking water program is fortunate to have such in-house expertise and can build on the Superfund risk communication materials to develop information for public water systems. While those communication materials are being developed, NDWAC should understand that the hazard index accounts for the combined toxic effects of four frequently occurring PFAS in drinking water on thyroid hormone levels, lipid synthesis and metabolism, fetal and infant development, and immune and liver function.

Participants in the August 8 NDWAC meeting expressed concern that the health-based water concentrations (HBWCs) for the four PFAS used in the hazard index were not based on the same target organ. Because studies on all four PFAS have documented toxic effects on the thyroid, liver, and fetal/infant development, EPA could have selected any one of these common effects as the basis of the HBWCs. In order to be more health protective, however, EPA based the HBWCs on the most sensitive health effect for each of the PFAS as follows: thyroid effects for PFHxS; developmental effects for PFNA; liver effects for GenX; and thyroid effects for PFBS. The hazard index then adds the toxicity of all four PFAS to account for their effects on

[1] National Academies of Sciences, Engineering, and Medicine. 2022. Guidance on PFAS Exposure, Testing, and Clinical Follow-Up. Washington, DC: The National Academies Press. https://doi.org/10.17226/26156

multiple biological systems and functions. Given the weight of the evidence of damage throughout the human body, this approach is clearly more appropriate than a single target-organ hazard index.

In summary, EPN is concerned that NDWAC was not well-served by the August 8, 2023, consultation and should be better informed of the serious health risks posed by these six PFAS chemicals in advising EPA on how best to regulate these toxic chemicals in the nation's public water systems. The August 8, 2023, consultation failed to communicate the extent and severity of those risks.

Sincerely,

Michelle Roos
Executive Director
Environmental Protection Network

cc: Bruno Pigott, Principal Deputy Assistant Administrator, EPA Office of Water
Jennifer McClain, Director, Office of Groundwater and Drinking Water, EPA Office of Water