Environmental Protection Network Comments on Draft Human Health Toxicity Assessments for GenX and PFBS

January 22, 2018

The Environmental Protection Network (EPN) is an organization comprised of over 350 EPA alumni volunteering their time to protect the integrity of US EPA, human health and the environment. We harness the expertise of former US EPA career staff and confirmation-level appointees to provide an informed and rigorous defense against current Administration efforts to undermine public health and environmental protections. We have the following comments on the draft human health toxicity assessments for GenX and PFBS.

On November 14, 2018 EPA published in the Federal Register draft human health toxicity assessments for hexafluoropropylene oxide dimer acid and its ammonium salt (GenX chemicals) and for perfluorobutane sulfonic acid (PFBS) and related compound potassium perfluorobutane sulfonate. For both chemicals, EPA states that the agency plans to develop only these toxicity assessments and will not add exposure assessments or address the legal, political, social, economic, and technical considerations involved in risk management of these chemicals. In taking this position, EPA is failing to exercise its authority under the Safe Drinking Water Act (SDWA) to publish drinking water health advisories for unregulated contaminants. This is a gross neglect of duty on EPA's part, particularly as the draft toxicity assessments document the presence of these chemicals in drinking water supplies in multiple areas of the country. SDWA authorized the use of drinking water health advisories so that EPA could provide the states with the best available information on toxicity, exposure, and risk management issues whenever an unregulated contaminant poses a health risk to communities. It is unreasonable to expect each state with these contaminants to assess all the available data and decide whether to base their health advice for these chemicals on a bottle fed infant, a toddler, a pregnant woman, a lactating woman, or an adult male. This is a key decision that will substantially affect the concentration of these chemicals considered safe to drink. Further, each state will have to evaluate all the analytical detection methods available for these chemicals and analyze all the possible treatment methodologies in order to decide how to address this contamination. It is irresponsible for EPA to refuse to conduct this work for the states and instead offer to provide the states with "technical assistance" on these critical issues.

With regard to the GenX toxicity assessment, EPN is deeply concerned that EPA evaluated all the studies considered for derivation of the RfDs using the draft 2018 guidance entitled "Application of Systematic Review in TSCA Risk Evaluations". On August 16, 2018, EPN submitted detailed criticisms of that draft systematic review process. Our comments documented EPA's failure to follow necessary internal and external peer review procedures in developing this process, serious flaws permeating the entire TSCA systematic review process, and critical flaws in evaluating individual studies for use in toxicity assessments. This draft TSCA process is inconsistent with best practices in systematic review and should not be used for any purpose, let alone for an influential toxicity assessment of a new contaminant in drinking water.

Regarding the PFBS toxicity assessment, EPN is very supportive of EPA's use of the ORD systematic review process in evaluating all the studies considered for derivation of the RfDs. EPN feels that the

ORD systematic review process, endorsed by the National Academy of Science, follows all the best practices in systematic review and undoubtedly produced the best selection of studies. That said, we have two comments on the PFBS toxicity assessment. First, we do not understand EPA's statement that "due to the lack of epidemiology studies on PFBS, subchronic and chronic RfDs for both kidney and thyroid were derived". We understand that the existing epidemiology studies on PFBS were not found informative and were, therefore, not considered in the toxicity assessment. However, we do not understand why EPA failed to choose thyroid as the critical study for RfDs. We note that overall confidence in subchronic and chronic RfDs based on both thyroid and kidney have the same rating; that would lead the agency to select thyroid effects as the critical study in light of the consistent observation of thyroid effects across life stages and greater dose-response sensitivity, relative to kidney effects. EPN's second comment is perhaps directly related to this first comment. We are concerned that there is no document in the record which provides a response to peer review comments on PFBS. This is a critical supporting document which must be available to enable a comprehensive review of the PFBS toxicity assessment. It is possible that the response to peer review comments would show why EPA is proposing both thyroid and kidney based RfDs, a rationale which is missing from the toxicity assessment itself.

Respectfully Submitted on Behalf of the Environmental Protection Network,

Michelle Roos, Executive Director, Environmental Protection Network
michelle.roos@environmentalprotectionnetwork.org