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EPN Letter in Support of TSCA Section 21 Petition to Require Testing on PFAS
October 27, 2020

Andrew Wheeler, Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20004

Dear Administrator Wheeler:

The Environmental Protection Network (EPN) is an organization comprised of over 500 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of the EPA, human health, and the environment.

We are writing today to express our strong support for the petition filed under section 21 of the Toxic Substances Control Act (TSCA) to require health and environmental effects testing on 54 per- and polyfluoroalkyl substances (PFAS) manufactured by Chemours in Fayetteville, NC. The petitioners are the Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, Toxic Free NC, and The NC Black Alliance. As noted by the petitioners, these PFAS have been identified in drinking water sources serving over 250,000 people in the Cape Fear watershed, in human blood, and in environmental media, including air emissions, surface water, sediment, stormwater, groundwater, and locally grown produce. Significant attention has been focused on the newer "GenX" and other "short-chain" PFAS introduced as replacements for perfluorooctanoic acid (PFOA). Under a consent order between EPA and Chemours, GenX compounds have undergone some toxicological testing but, as EPA has recognized, available studies are incomplete. There is also some testing underway on a small number of other PFAS under a North Carolina consent order, but these studies are limited in scope. And despite a research program conducted by the National Toxicology Program (NTP) to better understand PFAS toxicity to human health, there remain huge data gaps on the health effects of these chemicals.

To date, EPA has failed to use its testing authorities under TSCA section 4 to fill the extensive data gaps on PFAS. Congress included these authorities in TSCA to ensure that responsibility for developing information on the health and environmental impacts of chemicals is assigned to manufacturers and processors who are engaged in the production, processing, distribution in commerce, use, and disposal of those chemicals. While the federal government and academic institutions have an important role to play in PFAS research, they should not and cannot shoulder the entire testing burden. A full understanding of this large, problematic chemical class will be impossible unless industry contributes its sizable resources to determining their risks to human health and the environment. Using its expanded TSCA authority, EPA should have imposed this responsibility on PFAS producers long ago; the North Carolina section 21 petition is a call to action to reenergize the dormant TSCA testing program for chemicals like PFAS that lack sufficient information to determine their health impacts on highly exposed populations such as citizens of the Cape Fear watershed.

According to EPA, there are >4,000 PFAS that may have been manufactured globally. The number of PFAS listed on the TSCA Inventory is smaller but does not include PFAS, including those found in the Cape Fear watershed, that were produced as impurities or byproducts and released into the environment. Because of the similarities in persistence, mobility, and toxicity among PFAS, all members of the class have the potential to cause the same adverse effects as well-characterized compounds such as PFOA and perfluorooctane sulfonate (PFOS).

Based on the known hazards of these analogues, untested PFAS with potential for exposure would meet the criteria for testing in section 4(a)(1)(A) of TSCA because they (1) "may present an unreasonable risk of injury to human health and the environment," (2) have "insufficient information and experience" to reasonably predict or determine their effects on health or the environment, and (3) "that testing is necessary" to generate the needed information. EPA took this approach in reviewing GenX compounds under the "new chemicals" provisions in section 5 of TSCA. The agency issued a section 5(e) consent order requiring testing based on findings that these compounds "may present an unreasonable risk" because of their similarities to PFOS and PFOA and that "the information available to the Agency is insufficient to permit a reasoned evaluation of their human health and environmental effects." The same conclusions are required under TSCA section 4(a)(1)(A), and when they are made in conjunction with the "testing is necessary finding," the administrator "shall by rule, order, or consent agreement, require that testing be conducted on such substance or mixture to develop information with respect to the health and environmental effects for which there is an insufficiency of information."

The petition is quite detailed in specifying the testing to be conducted. It divides the chemicals into two tiers based on exposure. Tier 1 chemicals are those that are found in human serum, food, and/or drinking water. Tier 2 chemicals are those that demonstrate a potential for human exposure based on their occurrence in environmental media.

The petition proposes the following testing program:

Experimental Animal Studies

• Compounds in both Tiers would undergo 28-day repeated dose rodent toxicology studies coupled with reproductive and developmental toxicity screening assays, examining critical PFAS endpoints including hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity.

• These studies would also be conducted on three mixtures of PFAS representative of the groups of substances to which residents have been exposed through drinking water, human serum, and other pathways.

• The 14 Tier 1 substances would be the subject of multigeneration or extended one-generation and two-year rodent carcinogenicity studies in recognition of the evidence of direct and substantial human exposure and the concerns for these endpoints demonstrated by legacy PFAS.

• Most studies would be carried out in two species (mice and rats) and by oral routes of administration; inhalation would be used for volatile chemicals.

• Toxicokinetic studies would be conducted to characterize relationships between serum concentrations and dermal, oral, and inhalation exposures in the test species, and to evaluate biological half-life and potential for bioaccumulation.

• Testing requirements would be based on EPA and the Organization for Economic Cooperation and Development (OECD) guidelines, with appropriate adjustments to reflect sensitive endpoints that have been reported for PFOA, PFOS, and GenX.

Human Studies

• A human health study for the Cape Fear watershed would be conducted using a similar study design to that used for the Parkersburg, WV, PFOA (C8) study. The goal of the study would be to determine the relationship between exposure to the mixtures of PFAS that characterize current and historical exposure in the Cape Fear watershed and health outcomes among exposed populations.

• EPA would require development of analytical standards where not currently available, physical-chemical properties tests, and fate and transport studies to identify and predict exposures.

To maximize the credibility and objectivity of the data and key findings, EPA would contract with the National Academy of Sciences (NAS) to form an independent expert science panel with responsibility for overseeing all aspects of the testing program. The public and Chemours would have the opportunity to submit nominations for membership on the panel.

This approach to testing is thoughtful and scientifically sound. We urge EPA to expeditiously grant the petition and issue a rule or order to begin this testing as soon as possible.

Respectfully submitted,

Michelle Roos
Executive Director
Environmental Protection Network

cc: Alexandra Dunn
Yvette Collazo