Michael Regan

Administrator Designate

Environmental Protection Agency

Re: Urgency of Addressing PFAS Threats to Health and the Environment

Dear Administrator-Designate Regan:

Per- and Polyfluoroalkyl Substances (PFAS) are one of the most important public health challenges facing the Biden-Harris Administration. We are writing as active scientists involved in PFAS science to give input into how the incoming EPA leadership can uphold the campaign commitments made by President-elect Biden to strengthen protection from the serious risks of these chemicals.

Our scientific perspective is detailed below and includes the following elements:

- Given the known persistence, bioaccumulation, and toxicity of many PFAS, and that EPA has identified over 9,000 PFAS compounds, it is critical to apply a class-based approach to regulation, and to eliminate non-essential uses of these chemicals. EPA should also issue a moratorium on new pre-manufacture notices (PMNs) and new uses of existing PFAS under the Toxic Substances Control Act (TSCA).
- EPA should use testing authority under TSCA to require comprehensive health and
 environmental testing of the many PFAS that are widely present in the environment and people.
 Strategically-directed in vivo toxicity testing and human studies will provide necessary
 information to support a class-based regulatory approach and to validate in vitro and in silico
 screening approaches that are being developed.
- As a first step towards achieving this goal, EPA should grant a <u>petition under TSCA</u> filed on October 14, 2020 by six North Carolina non-profit groups that would hold Chemours, a major PFAS producer, accountable for funding environmental and health data on 54 PFAS chemicals that have been released into the environment from its manufacturing facility.

PFAS are readily transported around the globe and build up in people and wildlife. EPA has identified over 9,000 PFAS but the number of substances in current production or the environment may be much greater. Known as "forever chemicals," these chemicals take thousands of years to break down in the environment. People are exposed to PFAS by eating food, drinking water, breathing air and through consumer products, food packaging and pesticides. PFAS are present in the bodies of nearly all people living in the U.S., Europe, and most of the world. The PFAS that have been studied are known to cause serious toxic effects, including cancer, thyroid disease, birth defects, hormone disruption, decreased fertility, and immune system suppression, among many others. There is growing evidence that PFAS exposures may cause more severe cases of COVID-19 and may reduce the effectiveness of vaccines.

In its Environmental Justice Plan, the Biden-Harris Campaign committed to designate PFAS as hazardous substances under Superfund, set enforceable limits for PFAS under the Safe Drinking Water Act, prioritize PFAS substitutes through procurement, accelerate toxicity studies and research on PFAS, and ensure adequate testing and remediation for widespread PFAS water contamination, especially in disadvantaged communities.

In carrying out these commitments, EPA should manage PFAS as a class in light of their similar molecular structures, properties, and human health hazards. PFAS are well-suited to treatment as a class because of their extreme persistence, accumulation potential, toxicity, and potential risk. Rather than inefficiently addressing each chemical individually, a class approach would provide an orderly and expeditious process for phasing out all but essential PFAS uses, greatly reducing future exposure. As a first step in implementing a class approach, it is essential that EPA place a moratorium under TSCA on all PMNs for new PFAS and on new uses of existing PFAS.

Class-based approaches have been successfully applied to numerous other groups of chemicals, including PCBs, dioxins, organophosphate pesticides, organochlorine pesticides, and organohalogen flame retardants.

Eliminating non-essential uses of PFAS going forward, however, would not remove PFAS from the environment or undo the widespread exposure which has already occurred from decades of production and use. For example, millions of people in communities across all 50 States are struggling with PFAS contaminated drinking water as a result of years of discharges from manufacturing facilities and use of aqueous film-forming foam (AFFF) for fire suppression at military installations and airports. The health effects of past, current and future exposure from historical PFAS manufacture and use are poorly understood because of inadequate testing, subjecting communities to largely undefined risks and depriving medical professionals of the ability to treat PFAS-related health conditions.

To address this information need, on October 14, 2020, six North Carolina non-profit groups filed a petition under section 21 of TSCA requesting that the agency require health and environmental effects testing on 54 PFAS being manufactured by The Chemours Company (Chemours) at its chemical production facility in Fayetteville, North Carolina. Hundreds of thousands of residents in the Cape Fear River watershed have been exposed for decades to a mixture of PFAS chemicals discharged into the river by Chemours. These communities may have experienced serious health problems in response to PFAS exposures and they and their doctors deserve to know what these health effects are. However, there is currently little health or environmental effects information about most of these 54 PFAS.

On January 7, 2021, the Trump EPA denied the North Carolina petition, refusing to hold Chemours accountable for the necessary testing. The Biden EPA should reconsider and grant the petition. This would both benefit the impacted communities and establish a template for holding other PFAS manufacturers responsible for funding studies on the impacts of their chemicals.

The animal and human studies called for in the North Carolina petition are critical to obtain informative and reliable information about PFAS health effects. We support efforts to develop new approach methodologies/non-animal methods (NAMs) that reduce the need for animal testing. However, NAMs have simply not progressed to the point where they are appropriate for understanding the effects of PFAS. While NAMs may be feasible for some simple and direct toxicity endpoints such as skin irritation, reliable non-animal methods for predicting complex systemic toxicities do not exist. In fact, the animal and human studies proposed in the petition will produce the very data that EPA needs to develop NAMs and verify that they can predict PFAS toxicity as precisely as traditional testing.

In summary, we recommend a class-based ban on all PFAS except essential uses. We further recommend EPA reconsider the previous administration's denial of the North Carolina petition and use

its TSCA authority to order Chemours to conduct the animal and human testing on the 54 PFAS proposed in the petition.

Respectfully Submitted,

Click this link to add your signature

Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.
Scientist Emeritus and Former Director
National Institute of Environmental Health Sciences and National Toxicology Program
Scholar in Residence, Duke University

Ruthann Rudel, M.S.
Research Director, Silent Spring Institute*

Laurel Schaider, Research Scientist, Silent Spring Institute*

^{*}Institutional affiliation is for identification purposes only