November 25, 2020

Ms. Alexandra Dunn
Assistant Administrator for Chemical Safety and Pollution Prevention
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: TSCA Section 21 Petition to Require Testing of 54 PFAS under Section 4

Dear Assistant Administrator Dunn:

Thank you for meeting with us on November 18 to discuss our October 14 petition under section 21 of the Toxic Substances Control Act (TSCA). The petition calls on the Environmental Protection Agency (EPA) to use its authority under TSCA section 4 to require health and environmental effects testing on 54 PFAS produced at the Chemours plant in Fayetteville, North Carolina and discharged to drinking water sources and other environmental media.

We are writing to follow up on two comments you made in our meeting that raise concerns that the Agency may deny our petition for unjustified reasons.

1. **The Proposed Testing Program is not Excessive in Scope**

You described the testing proposed in the petition as a "big ask," implying that the studies we seek are too costly and unnecessarily extensive. This is simply incorrect. The amount of testing outlined in the petition is proportional to the serious risks of harm it seeks to address. The 54 PFAS released from the Chemours facility and included in our petition have been measured in human blood, drinking water, groundwater, soil, air, and/or locally produced food adjacent to and downstream of the Fayetteville plant. For the drinking water pathway, nearly 300,000 residents experienced substantial exposure for decades, and several of the PFAS from the Chemours discharges are still detected in public drinking water despite recent reductions in discharges. In addition, a number of the 54 PFAS are known to be used commercially, may have consumer exposure, and have been detected at sites remote from the Fayetteville plant.

The potential consequences of widespread exposure to these chemicals are significant and alarming. The similarities between the 54 substances and other PFAS such as PFOA, PFOS, and GenX point to the potential for serious health effects but there is virtually no data with which to evaluate these risks. These PFAS are likely to be toxic but the absence of data has deprived communities and regulatory authorities of an understanding of the long-term health impacts of exposure, making informed medical treatment and management of ongoing risks impossible.

The proposed testing is carefully targeted at specific endpoints that have been previously linked to the PFAS class and that are drivers for risk-based exposure limits. It includes the smallest number of studies necessary to determine whether the 54 substances are of concern for these endpoints and to understand dose-response relationships. Human and animal studies are proposed because of the importance of identifying health human risks that might otherwise be missed in studies of one of these species. Similarly, mixtures would be tested because real-world exposure is to multiple PFAS simultaneously. Limiting the scope of testing to reduce cost would run the risk of inconclusive or incomplete findings, resulting in inadequate protection of at-risk communities. Indeed, the testing

program as proposed is now incomplete and under-protective because it fails to include many PFAS (over 250 according to Chemours) that were released into the environment but cannot now be tested because their identities are unknown.

The costs of the proposed testing are modest and reasonable when compared to its significant public health benefits and Chemours' considerable financial resources. PFAS have been produced at the Fayetteville plant for over four decades. Chemours has annual revenues in the $6 billion range; its predecessor DuPont had far greater revenues. Even if the proposed testing program costs tens of millions of dollars, these costs would be dwarfed by the much larger sales and profits that Chemours and DuPont derived over time from their PFAS operations. Indeed, the companies were able to boost profits by avoiding the upfront testing and controls on environmental releases that would have prevented the contamination of drinking water supplies that has now occurred.

The companies' lack of diligence has forced public water systems and their ratepayers to bear the substantial costs of additional treatment to remove PFAS contaminants from drinking water. For example, Brunswick County is spending $100 million and New Hanover is spending $43 million, with $3 million in annual operating costs, to upgrade water treatment systems. Owners of private drinking water wells near the Chemours plant have also incurred costs to reduce contamination and their properties have lost value. Medical care from PFAS-related illnesses has imposed additional costs.

In short, the financial burdens that PFAS contamination has placed on Cape Fear communities greatly exceed the costs of the testing proposed in our petition. Conducting this testing so these communities can understand the health risks they face is a small price to pay in light of decades of corporate inaction and environmental contamination.

2. Animal Testing Is Necessary to Determine the Health Effects of the 54 PFAS

You also expressed concern about the animal studies proposed by the petition and suggested that an adequate understanding of the health and environmental effects of the 54 PFAS could be obtained from non-animal test methods (New Approach Methods or NAMs). This is simply not realistic or scientifically defensible and would be contrary to EPA's obligations under TSCA.

Concern about animal welfare and the cost of animal testing has spurred interest in reducing reliance on animal testing systems. However, the goal of TSCA is protection of *human health.* Animal studies have historically been and remain essential in understanding the effects of chemicals on people. The 2016 TSCA amendments direct EPA to develop a strategy to encourage the development of NAMs and reduce reliance on traditional animal studies while filling the many data gaps that exist on the health and environmental effects of chemicals. However, the law is clear that, before NAMs can replace animal tests, they must be shown to "provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures."

EPA's efforts to develop NAMs to predict the toxicity of chemicals have simply not progressed to the point where they come close to satisfying this standard. While NAMs may be ready for regulatory use for some simple and direct toxicity endpoints such as skin irritation, reliable non-animal methods for predicting complex systemic toxicities do not yet exist.

NAMs are nowhere near ready to be used to assess whether other PFAS cause the toxic effects observed with PFOA, PFOS and GenX, such as developmental immunotoxicity, pancreatic tumors, and effects on

hormones, metabolism, cholesterol, and glycogen storage in the fetal liver. As EPA has discovered, toxicokinetic parameters of PFAS are especially challenging to model without *in vivo* data. Moreover, EPA scientists have admitted that PFAS are difficult compounds to test *in vitro* because of stability and formulation concerns. EPA has in fact already removed 20 compounds from the list of 150 PFAS chosen for NAM assays because of these concerns, which underscore the need for the basic physical-chemicals properties testing proposed in our petition.

For PFAS and many other chemical classes, NAMs cannot be validated without a robust *in vivo* data set across a broad cross-section of individual compounds that can be used to assess NAMs' utility for predicting health effects and dose response. *The testing we propose in our petition would provide exactly the kind of data set needed to develop and validate NAMs for application during future PFAS risk evaluations. But without the studies requested in our petition, there is no reasonable path forward to use NAMs to understand the health effects of these (or other) PFAS.*

In sum, a PFAS testing program based on NAMs alone would fail to achieve TSCA section 4's goal of developing "sufficient information and experience" so that the effects of PFAS on health and the environment "can reasonably be determined or predicted."

We look forward to EPA's decision on our petition. If you have any further questions, please reach out to our counsel, Bob Sussman, at bobsussman1@comcast.net.

Please put this letter in the administrative record for our petition.

Sincerely yours,

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Thomas R. Fox, Senior Policy Advisor

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cc: Deputy Assistant Administrator David Fischer
OPPT Director Yvette Collazo-Reyes