

TSCA PETITION FOR HEALTH AND ENVIRONMENTAL TESTING ON PFAS MANUFACTURED BY CHEMOURS IN FAYETTEVILLE, NORTH CAROLINA

Frequently Asked Questions (FAQs)

1. Who are the petitioners?

Petitioners are non-profit public health, environmental and environmental justice groups committed to protecting North Carolina communities and ecosystems from the threat of toxic pollution. They are Center for Environmental Health, Cape Fear River Watch, Clean Cape Fear, Democracy Green, the NC Black Alliance, and Toxic Free NC.

2. Why was the petition filed?

The petitioners are concerned that PFAS in drinking water and the environment are affecting the health of Cape Fear communities but there is little information about the health and environmental effects of these chemicals. For residents and their families, the inability to determine the health impacts of their historical, ongoing, and future PFAS exposure is a deep source of concern. The petition asks the Environmental Protection Agency (EPA) to use its authority under the Toxic Substances Control Act (TSCA) to require the manufacturer of these chemicals, Chemours, to fund an extensive testing program that will ascertain the risks that Cape Fear communities face.

3. What is the status of the petition?

The petition was filed on October 14, 2020. The Trump EPA responded by denying the petition on January 7, 2021. Petitioners believe the denial was without justification. On March 4, 2021, they asked the EPA Administrator to reconsider the denial and grant the petition. They also filed suit to challenge the petition denial. The Biden Administration has underscored its commitment to advancing environmental justice and addressing PFAS and the new head of EPA, Michael Regan, is deeply familiar with the impact of PFAS pollution on communities in Eastern North Carolina. We are hopeful that the Biden EPA will move quickly to grant the petition.

4. What are PFAS?

Per- and Polyfluoroalkyl substances (or PFAS) are a class of chemicals that have common characteristics and are used in a wide variety of applications. PFAS have raised significant concern in the US and globally because of their persistence and potential to bio-accumulate, widespread presence in living organisms, products, and the environment, and demonstrated adverse health effects at low doses. Many communities across the US are struggling with PFAS contamination.

5. Who is Chemours?

Chemours is a large international producer of PFAS that was spun off by DuPont in 2015. It operates a major production facility near Fayetteville, North Carolina. The plant is adjacent to the Cape Fear River upstream of the city of Wilmington, which is a significant population center in the Eastern part of the State. The city and surrounding communities use the Cape Fear River as a source of drinking water. PFAS have been manufactured and used at the facility since the 1970s.

6. How has Chemours Harmed the Cape Fear Watershed?

In the last few years, several PFAS manufactured by Chemours have been identified in drinking water sources serving over a quarter of a million 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 risks of “GenX” compounds, which Chemours commercialized in 2015 as a replacement for perfluorooctanoic acid (PFOA), after it was phased out because of serious health and environmental concerns. However, GenX is only one of many PFAS produced at the facility which have been shown to have actual or likely human exposure and presence in the environment. Petitioners have identified 54 such PFAS based on studies by researchers and Chemours itself and there are likely hundreds of additional PFAS of unknown chemical composition that are present in the environment as well.

7. What’s the legal basis for requiring Chemours to conduct testing?

Under TSCA section 4, EPA can issue test orders or rules requiring manufacturers to conduct health and environmental effects studies on their chemicals. This authority was included in the law because Congress recognized that inadequate data are available on most chemicals and that the responsibility for developing information on chemical safety should rest with the companies who put these chemicals in commerce and cause people and the environment to be exposed to the risk of harm. TSCA sets a low bar for requiring testing. EPA need only show that there is a basis for concern about the harmful effects of the chemical, that exposure may be occurring and that insufficient data are available to determine whether the chemical presents an unreasonable risk.

8. Do citizens have the right to petition EPA to require testing?

Yes. Section 21 of TSCA authorizes members of the public to petition EPA to take action under several provisions of the law. This includes asking EPA to issue testing rules and orders under section 4. EPA must respond to petitions within 90 days and petitioners can take EPA to court if it denies the petition or fails to act.

9. How were chemicals selected for testing?

Petitioners and their technical advisors did an exhaustive search of the scientific literature and Chemours’ chemical analyses of environmental releases, discharges, and waste streams. Based on this search, 54 PFAS were identified that are attributable to the Chemours facility and have been detected in environmental media and/or people in the Cape Fear River watershed adjacent to and downstream of the plant site. These substances were assigned to two groups: Tier 1 (detection in human sera, food or drinking water) and Tier 2 (significant potential for human exposure based on detection in environmental media and other evidence).

10. What is the justification under TSCA for requiring testing on the 54 PFAS?

Leading authorities have recognized that, 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. Thus, the 54 substances warrant testing under TSCA based on their similarities to other well-studied PFAS and evidence of actual or likely human exposure.

11. Have the 54 substances previously been tested?

To support their request for reconsideration, petitioners' scientific consultants conducted a comprehensive literature search on the 54 PFAS. Some testing on GenX and a few other PFAS has been required by EPA and the State of North Carolina but these studies are limited and incomplete. Virtually no health or environmental effects testing has been conducted on the remainder of the 54 PFAS. Thus, for all 54 substances, we lack sufficient data to determine risks to the large, exposed population within range of the Fayetteville facility and the surrounding ecosystem.

12. What studies are you asking for?

The petition outlines in detail the studies that should be conducted. These studies were selected to address the critical harmful effects that have been identified for PFOA, PFOS, and other studied PFAS. Studies on these compounds show an overlapping set of adverse effects, including cancer, hormone disruption, liver and kidney damage, developmental and reproductive harm, changes in serum lipid levels, and immune system toxicity. The proposed testing program includes studies to address these effects. More extensive studies (including 2-year cancer bioassays and multigenerational developmental and reproductive tests) would be conducted on the 14 Tier 1 substances in recognition of the strong evidence of direct and substantial human exposure. In the few cases where studies proposed in the petition have already been conducted, duplicating these studies would be unnecessary.

13. How does the testing program account for the fact that real-world exposure in the Cape Fear watershed is to a mixture of PFAS?

In addition to testing on the 54 individual PFAS, animal studies would be conducted on three mixtures of PFAS representative of the groups of substances to which residents have been exposed through drinking water, human blood, and other pathways. Also, a human health study would be conducted in the exposed community to evaluate past and current exposures in the Cape Fear watershed and associated health effects.

14. Beyond health studies, what other testing would be required?

The testing program would include ecological effects, fate and transport, and physical-chemical properties studies. These studies are important to understand ecological impacts of the 54 PFAS and how they behave and spread in the environment.

15. Why hasn't EPA required this testing before?

When Congress strengthened TSCA in 2016, it signaled that it wanted EPA to require more testing on chemicals of concern. Unfortunately, in the Trump Administration, the EPA leadership made virtually no use of the tools in the new law and no health effects testing was required under section 4. This testing gap is a concern for the many chemicals in commerce that have not been adequately tested but particularly for PFAS because of the large number of untested substances, their widespread exposure and buildup in people and the environment, and the evidence of harmful effects. We are hopeful that the new leadership at EPA under President Biden will be more proactive in requiring testing on PFAS and other high concern chemicals.

16. How can we be sure the testing will be done objectively and independently?

This is an important concern. To maximize the credibility of the data and key findings, the petition recommends that EPA 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.

17. Will Chemours continue to reduce human exposure and environmental releases while testing is underway?

Chemours is required to reduce environmental releases of PFAS under the consent order issued by the State of North Carolina in February 2019. Because we know that all PFAS raise serious concerns, reducing human exposure to the 54 PFAS is imperative and should not be delayed while the testing proposed by petitioners is underway. At the same time, even if exposure is reduced, testing will remain essential because the 54 PFAS remain in drinking water and the environment and understanding the health impacts of both ongoing and historical exposure is necessary to make decisions about how to protect exposed communities.

18. Shouldn't the government be doing this research?

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 and problematic chemical class will be impossible unless industry contributes its sizable resources to determining their risks to human health and the environment.

19. Should this testing be an excuse to delay legislative and regulatory action at the state and federal level to restrict production and use of the PFAS chemical class?

Absolutely not. The testing requested in the petition is necessary to understand the effects of PFAS contamination from the Chemours facility on people and the environment in the Cape Fear area. The petitioners strongly believe that, regardless of the test results, PFAS chemicals should be addressed as a single class and all nonessential uses should be eliminated. Although industry agreed to stop using certain long-chain PFAS (PFOA & PFOS), they switched to short-chain PFAS (e.g., GenX), without meeting their responsibility to conduct the health and environmental testing necessary to determine the safety of these substitutes. Having failed to discharge this fundamental obligation, it is unconscionable for industry now to seek to block regulation of PFAS by hiding behind a lack of data. While we need more information to understand the health impacts of PFAS on populations already exposed, there is ample evidence to demonstrate that *all* PFAS have sufficient potential for serious and widespread harm to warrant eliminating future exposure from all but essential uses.

20. Is the scope of the testing too much to ask for?

No, the amount of testing outlined in the petition is proportional to the serious risks of harm it seeks to address. 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.

21. Is the proposed testing too costly?

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.

22. How does the cost of testing compare to the financial burdens of PFAS pollution on impacted communities?

The financial burdens that PFAS contamination has placed on Cape Fear communities greatly exceed the costs of the testing proposed in our petition. Brunswick County is spending \$100 million and New Hanover County is spending \$43 million, with \$3 million in annual operating costs, to upgrade water treatment systems to address the PFAS contamination. Over 3,000 owners of private drinking water wells near the Chemours plant have also incurred costs to reduce contamination and their properties have lost value. Conducting this testing so these communities can understand the health risks they face is a small price to pay considering decades of corporate inaction and environmental contamination.

23. Is animal testing necessary or can adequate data be obtained from non-animal test methods, known as New Approach Methods (NAMs)?

The 2016 TSCA amendments directed 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. NAMs are not ready to be used to assess whether other PFAS cause the toxic effects observed with PFOA, PFOS and GenX. In fact, the studies proposed in the petition will produce precisely the type of data that EPA needs to develop NAMs and verify that they can predict toxicity as reliably as traditional testing.

24. Why did the Trump EPA deny the petition?

The denial affirmed EPA's "high concern" about PFAS and did not dispute that all PFAS are of concern for numerous health effects based on the properties of the class. Nor did it deny that most of the 54 PFAS have been detected in the environment, resulting in exposure by North Carolina residents and putting them at risk of harm. Instead, the main reason given for the denial was that the petition failed to demonstrate "that existing information and experience are insufficient . . . for each of the 54 PFAS" and that testing "is necessary" to develop data on their health and environmental effects.

25. How do petitioners respond to the petition denial?

It is disingenuous and irresponsible for EPA to put the onus on petitioners to “prove” that adequate test data is lacking for each of the 54 PFAS. EPA’s 2019 [PFAS Action Plan](#) recognizes that “[t]here are many PFAS of potential concern to the public that may be found in the environment [and] [m]ost of these PFAS lack sufficient toxicity data to inform our understanding of the potential for adverse human or ecological effects.” Moreover, it is EPA’s responsibility – not petitioners’ -- to be informed about the amount of information available on these PFAS and to use its TSCA authority to fill data gaps where this information is inadequate.

As noted above, petitioners’ request for reconsideration has eliminated any doubt about the need for testing by presenting the results of a comprehensive search of several public databases for relevant information on the 54 PFAS. As expected, this comprehensive search shows that, overwhelmingly, these PFAS lack most or all of the studies proposed in our petition. To the extent data are available, they are extremely limited and generally fail to adequately address critical PFAS-specific end-points. Thus, there is no possible basis for EPA to continue to refuse using its broad TSCA authority to require testing on the 54 PFAS.

26. Can the new Biden Administration EPA reconsider the January 7, 2021, denial of the petition?

Yes. EPA has taken the position and the courts have uniformly concluded that EPA has the inherent authority to reconsider its denials of Section 21 petitions.

27. Why did the petitioners file suit in federal court challenging the denial of the petition?

On March 3, 2021, the petitioners filed a lawsuit in the Northern District of California under section 21 of TSCA challenging the Trump EPA’s denial of their petition. The groups hope that speedy reversal of the denial by the new EPA Administrator will make litigation unnecessary. However, because the 60-day filing deadline under section 21 of TSCA was about to expire, the groups felt it was essential to preserve their legal remedies in the event EPA fails to grant the petition. The lawsuit was filed in the Northern District of California because CEH is headquartered in Oakland, California.

28. What happens next?

Now that Michael Regan, President Biden’s nominee to be EPA Administrator, has been confirmed, the North Carolina groups have asked Administrator Regan to meet with them to discuss the petition and how EPA can move forward to achieve its objectives. As a life-long North Carolina resident and Secretary of the state’s Department of Environmental Quality (DEQ) for the last four years, Administrator Regan has deep first-hand knowledge of Cape Fear communities and the serious threat to human health and the natural environment they face from PFAS pollution. A decision by Administrator Regan to reverse the denial of a petition by frontline North Carolina communities bearing the brunt of PFAS pollution would be an early demonstration of the Administration’s commitment to strong action on PFAS and environmental justice.