



The Chemours Company
Fayetteville Works
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July 13, 2022

Sushma Masemore
Assistant Secretary
N.C. Department of Environmental Quality
1601 Mail Service Center
Raleigh, NC 27699-1601
sushma.masemore@ncdenr.gov

Re: Response to June 15, 2022 Letter re EPA GenX Health Advisory

Dear Ms. Masemore,

This submission is in response to your June 15th letter concerning the issuance by EPA earlier that day of a Final Health Advisory (the “Final Advisory”) for GenX Chemicals, including HFPO-Dimer Acid (“HFPO-DA”).

As your letter states, EPA “announced the establishment of a drinking water health advisory for GenX of 10 parts per trillion (ppt) or nanograms per liter (ng/L).” You further reference paragraph 19 of the February 2019 Consent Order which requires Chemours to “establish permanent replacement drinking water supplies in the form of public water or a whole building filtration system for any party . . . with a private drinking water well that has been found through testing validated by DEQ to be contaminated by concentrations of GenX compounds in exceedance of 140 ng/L, or any applicable health advisory, whichever is lower.” You assert that the Final Advisory is such a lower “applicable health advisory” and ask Chemours to “revise its Drinking Water Compliance Plan and Feasibility Study Report and provide public water or whole building filtration systems to any party with a private drinking water well contaminated by GenX chemicals in exceedance of 10 ppt.”

Your letter requested that Chemours respond by today to four specific points you raised. This letter contains that response. Before turning to those four points, we emphasize that Chemours strongly believes that the Final Advisory is fundamentally flawed, inconsistent with the best available science, and legally unsupported and insufficient. Accordingly, earlier today Chemours filed a Petition for Review of the Final Advisory, including the October 25, 2021 GenX Chemicals Toxicity Assessment (the “Toxicity Assessment”), on which the Final Advisory is based, in the United States Court of Appeals for the Third Circuit. A copy of the Petition for Review is attached.

Nonetheless, and to be responsive to concerns of DEQ and the impacted community, Chemours is prepared to move forward now, and while the litigation is pending, with the extension of paragraph 19 options to properties that have tested above 10 ppt for HFPO-DA, as

further described in this letter. In doing so, Chemours reserves its rights to take appropriate actions with respect to paragraph 19 based upon the results of the pending federal litigation, including in the event EPA's Final Advisory is found to be invalid. With that reservation of rights, we address the four specific requests in your letter:

Request: Chemours must submit a report identifying affected parties entitled to public water or whole building filtration under paragraph 19 as a result of the new drinking water health advisory of 10 ppt for GenX chemicals. Such report shall identify those affected parties who have previously received reverse osmosis systems pursuant to paragraph 20 of the Consent Order.

Response: As of July 8, 2022, there were **1697** residences or other properties in Cumberland, Bladen, and Robeson Counties with wells that have been tested and found to have HFPO-DA levels between 10 ppt and 140 ppt. All have been offered replacement drinking water under paragraph 20 of the Consent Order, and the current status of those properties is as follows:

- **885** have reverse osmosis systems that were installed by Chemours and are operating;
- **124** already have public water connections, including 84 that were connected by Chemours to public water systems, and are receiving public water;
- **108** are under consideration for public water connections and in the interim are receiving bottled water or have reverse osmosis systems already installed;
- **3** have had new deeper wells constructed by Chemours, producing water tested to have below 10 ppt for HFPO-DA;
- **5** (all non-residential properties) have granulated activated carbon ("GAC") systems that were installed by Chemours and are operating;
- **4** of the wells are no longer in use;
- **519** have not accepted Chemours's offer for reverse osmosis systems and are receiving bottled water deliveries or vouchers; and
- **49** have declined Chemours's offer for reverse osmosis systems, and are not currently receiving replacement drinking water.

The attached Table 1 shows the above breakdown by county and by status of each well with HFPO-DA levels between 10 ppt and 140 ppt. Also attached is a map (Figure 1) showing the location of those wells. If you need more detailed information about the identity or location of wells and residents, please let us know.

In addition, as of the end of June, there are seven such wells in New Hanover County. Those properties have been provided with bottled water deliveries or vouchers. Longer term replacement water will be addressed in accordance with the June 1, 2022 Interim Four Counties Sampling and Drinking Water Plan.

Request: Chemours must submit for review and approval a draft communication to affected parties notifying them of their eligibility for whole house filtration or public water.

Response:

For the properties in Cumberland, Bladen, and Robeson Counties with wells that have been tested and found to have HFPO-DA levels between 10 ppt and 140 ppt and that either have (i) reverse osmosis systems installed, (ii) are receiving bottled water deliveries or vouchers, or (iii) are not receiving any replacement water, Chemours would send within 30 days of DEQ approval a letter in the form attached, informing them that they now qualify under paragraph 19 (subject to Chemours's reservation of rights), and that they have potentially three options: (i) public water connection (if feasible); (ii) have Chemours install and maintain additional reverse osmosis systems on every kitchen and bathroom sink which does not already have one; or (iii) installation of a whole house GAC system. This letter would inform the recipients that further information would be forthcoming on the feasibility and timing of public water connections at which point a selection among the available options would need to be made. These recipients would also be informed that if they have already determined that they would not want to be connected to public water even if it were available, they could select between the other two options (whole house GAC or every-sink reverse osmosis system), with the understanding that they would be foregoing the ability to seek a public water connection (or a different filtration option) from Chemours in the future. These responses will be taken into account in any public water feasibility study.

Request: Chemours must submit a plan outlining steps and a proposed schedule, with the final scheduled deadline to occur within 90 days from receipt of this letter, for revising and supplementing Chemours' assessment of public water feasibility for all affected parties under paragraph 19. This submittal shall include a reevaluation of areas where public water was previously determined to be infeasible based on the previously applicable GenX threshold of 140 ng/L.

Response:

Chemours agrees with DEQ that making public water connections available to as many impacted private well users as feasible is the preferred long-term approach to addressing the objectives of paragraph 19, and is referenced in paragraph 19 as the presumptive remedy "except" where (i) the resident prefers whole house filtration or reverse osmosis on every sink, or (ii) public water is not feasible. In the impacted counties here, such connections may necessitate the expansion of public water distribution systems to areas that do not presently have service. But if there is widespread interest in public water connections, the costs per connection may drop into the feasibility range.

In Cumberland County, where 1487 of the 1697 wells tested between 10 and 140 ppt for HFPO-DA are located, prior analysis submitted by Chemours had concluded that public water connections were not feasible from a cost perspective as provided in the Consent Order.

Chemours will now assess whether with this increased number of potentially eligible properties, an expansion covering at least some portion of the properties at issue is now feasible. If it were, it would also allow properties in the expansion area that do not qualify under paragraph 19 to also have access to public water. It would also potentially provide the opportunity for Chemours to offer public water connections to residents eligible for replacement water under paragraph 20, as Chemours has done at 31 wells already. Such expansions, as you know, take time to plan and implement, and will certainly require more time than the nine months referenced in paragraph 19.

Chemours will update its prior feasibility studies for Cumberland County areas using the same methodology as those earlier studies but with the larger number of potentially eligible residences included. Chemours will use its best efforts to complete these studies by September 13, 2022, as requested by DEQ. However, Chemours's ability to do so will be very much dependent on the level of cooperation and information it receives in conducting the steps outlined in this letter. Chemours will start its outreach as soon as it has gotten approval from DEQ and if it is not able to complete the studies by September 13th, it will submit an interim report by that date with a proposed schedule for completion and a description of the steps yet to be accomplished.

For Robeson County, public water connection was previously determined to be feasible and should remain so for newly eligible properties. Chemours will work with the County to confirm this and address timing issues.

For Bladen County west of the Cape Fear River, Chemours and the County entered into a 2021 "Agreement to Fund Public Water System Upgrades and Connections." This Agreement provides for connection to public water for eligible properties west of the River that elect public water. Given the increased number of eligible properties, Chemours will have further discussions with the County to address the timing of such connections.

For Bladen County east of the River, public water connections were previously determined (based on 6 eligible properties) not to be feasible. This analysis will be updated to reflect the 36 newly eligible properties.

Request: Chemours must submit a plan for transitioning affected parties who have previously received reverse osmosis systems to public water or whole house filtrations systems where required.

Response:

With respect to your reference to "transitioning" residents who are now utilizing reverse osmosis systems, we note that paragraph 19 explicitly gives eligible parties the option of selecting "under sink reverse osmosis systems (installed at every kitchen and bathroom sink at the election of the affected party) approved by DEQ." In light of the fact that the reverse osmosis systems that have already been installed at 885 eligible properties have been shown to

be highly effective, certain of those residents may elect to keep and utilize these reverse osmosis systems that are working.

In any event, any “transitioning” will be part of Chemours’s overall plan to address the impact of the Final Advisory. The elements of the overall plan are as follows:

1. Chemours is proceeding with this plan subject to its reservation of rights with respect to its pending Petition for Review of the Final Advisory.
2. Chemours will promptly make bottled water deliveries or vouchers available to any residence with a well above 10 ppt for HFPO-DA that had previously declined reverse osmosis systems and is no longer receiving bottled water.
3. Chemours will send the communication outlined above in the form attached within 30 days of approval of this plan by DEQ.
4. Chemours will undertake the feasibility studies with respect to the availability of public water connections as described above as well as assessing the level of interest among the eligible properties to be connected to public water if that were to be available.
5. Once the feasibility studies have been approved by DEQ, Chemours will inform the affected residences of their options and solicit selections among those options. Such selections must be made within six months of the notifications, and Chemours will continue to provide bottled water to those now receiving it until the selection is made and permanent replacement water provided, or for six months if no election is received during the six-month period.
6. For any residence that selects a public water connection, and if that connection is expected to take more than two years, Chemours will offer to install and maintain one under sink reverse osmosis system, if one has not already been installed, for the period until public water is connected in lieu of bottled water being provided.
7. For any residence that selects whole house GAC, Chemours will arrange for such installation consistent with prior installations with the following additional points:
 - a. Chemours will make clear that the selection is done with the understanding that the residence will not be able to seek a public water connection (or a different filtration method) from Chemours at a later date.
 - b. The installation of GAC systems, and the use of sheds to house the systems, may vary from those installed to date in the following ways:
 - i. With the expanded scope for potential GAC installations, Chemours may also utilize the services of commercial vendors similar to the ones that have successfully implemented the reverse osmosis installations at more than 3400 homes. These vendors would offer GAC installation to residential properties and maintain the systems.
 - ii. While there would be a change in the installation procedure, and the use of sheds, the same or similar carbon and vessels that are currently approved by DEQ will be used. A similar commercial system was previously approved by DEQ on January 5, 2021, as an alternative to reverse osmosis systems at non-residential establishments. Chemours’s vendors have already completed 5 such installations. A detailed description of the

system, relevant line diagrams, and cut sheets including the carbon specifications, and carbon usage models based on water quality data will be provided for DEQ review and approval by August 15, 2022. The document will also outline an initial monitoring period during which quarterly samples will be collected and analyzed to document the efficacy of the systems. Following this initial monitoring period, a longer-term (20-year) monitoring and carbon change-out schedule will be utilized.

- iii. Once DEQ approves this change in procedures and carbon systems, Chemours will provide DEQ with an updated Drinking Water Compliance Plan.
- c. Chemours will provide priority in GAC installation to those residences that do not have reverse osmosis systems already in place.
8. For any property that has had reverse osmosis systems already installed and elects to transition to whole house GAC or public water, Chemours will arrange for the removal of the existing reverse osmosis systems, provided that any residents that have elected whole house GAC or public water and also would like to keep the reverse osmosis systems in place may do so subject to their taking on responsibility to maintain the systems.
9. DEQ's June 7, 2022 "Action Strategy for PFAS" indicates that DEQ is planning a series of rulemakings to develop binding regulatory standards for HFPO-DA and other PFAS. We would like to discuss with you further whether that process may impact this plan, and if so we may need to make appropriate modifications to the plan and schedule.

We believe that this submission is fully responsive to your letter and ask for an opportunity to meet to discuss your reaction and any questions that you may have.

Sincerely,



Dawn M. Hughes
Plant Manager
Chemours – Fayetteville Works

Attachments:

- Table 1 - Private drinking water wells with HFPO-DA levels between 10 ppt and 140 ppt
- Figure 1 - Map of private drinking water wells
- Proposed letter to residences
- Petition for Review

Table 1: Status of Private Drinking Water Wells With Dimer Acid (DA) GT 10 and LT 140

Area	Total	Well No Longer Used for DW	Connected to PW by Chemours	Connected to PW by Others	PW Feasible and Under Consideration	Deep Well Installed by Chemours	GAC Installed by Chemours	GAC Installed at RO by Chemours	RO Installed by Chemours	Receiving Bottle Water	Other ⁽¹⁾	Total
Cumberland West	201	0	81	2	5	1	0	0	56	51	5	201
Grays Creek ⁽²⁾	806	0	0	6	5	2	1	3	499	263	27	806
Cumberland East	480	2	2	1	7	0	0	1	295	159	13	480
Bladen West	103	2	0	21	42	0	0	0	13	23	2	103
Bladen East	36	0	0	1	0	0	0	0	16	18	1	36
Robeson West	71	0	1	9	49	0	0	0	6	5	1	71
Total	1,697	4	84	40	108	3	1	4	885	519	49	1,697

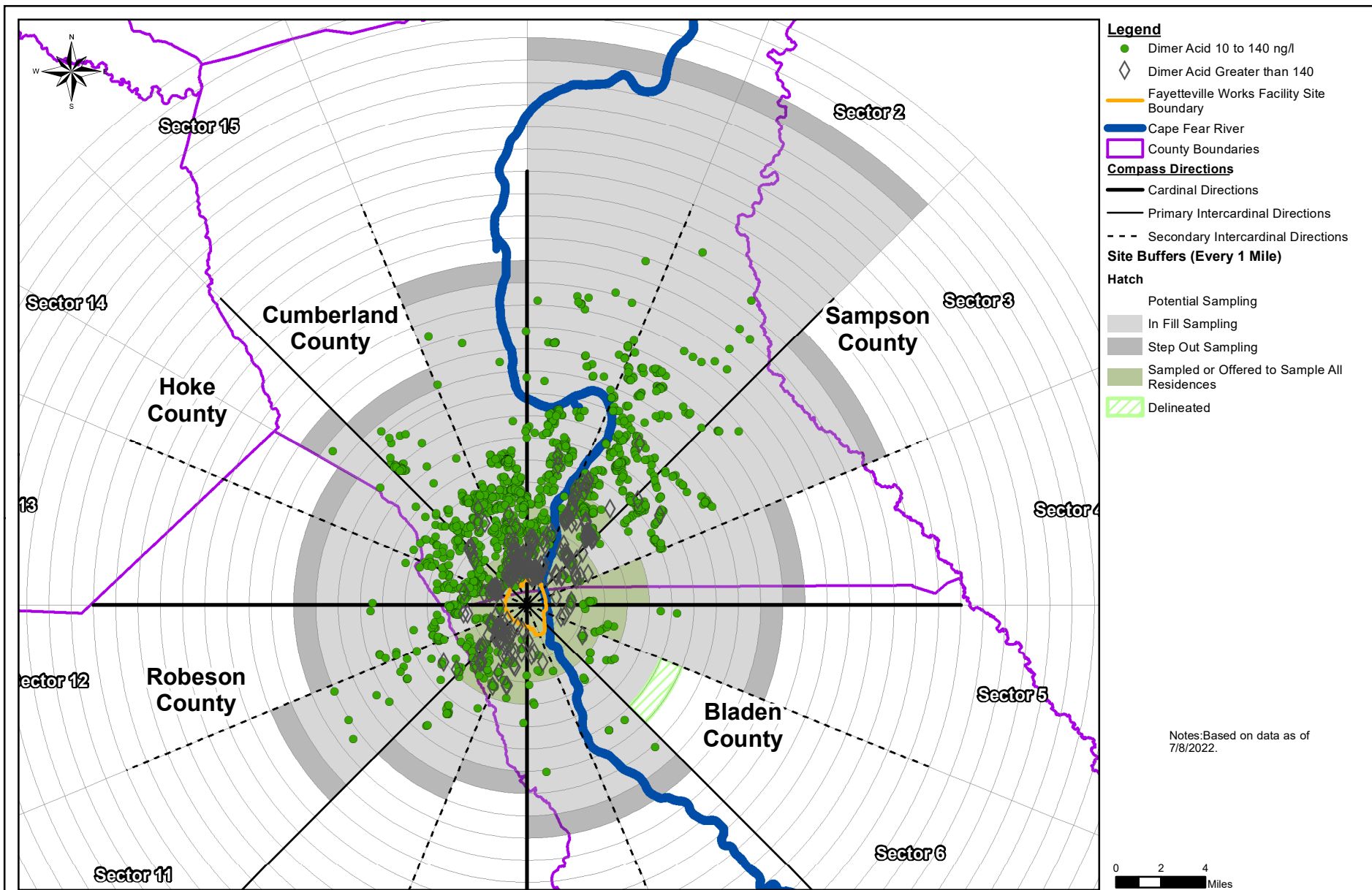
Notes:

Residences were assigned to categories by work from left to right in the table and were only assigned to the first category, e.g., connected to PW, where they met the criterion.

⁽¹⁾ Other category includes residences that are vacant or where residents declined either public water, GAC, RO, Bottle Water, or contact.

⁽²⁾ Cumberland County

All estimates were calculated based on data received as of July 8, 2022 and are subject to change as additional analytical data/residential information are received.



Dimer Acid Concentrations in Private Drinking Well Samples
 July 12th, 2022
 Fayetteville Consent Order
 Fayetteville, North Carolina

Figure 1

United States Court of Appeals
for the
THIRD CIRCUIT

THE CHEMOURS COMPANY FC, LLC,)
)
<i>Petitioner,</i>)
)
v.)
)
UNITED STATES ENVIRONMENTAL)
PROTECTION AGENCY and MICHAEL S.)
REGAN, in his official capacity as Administrator of)
the United States Environmental Protection Agency,)
)
<i>Respondents.</i>)

PETITION FOR REVIEW

Pursuant to Section 1448(a)(2) of the Safe Drinking Water Act, 42 U.S.C. § 300j-7(a)(2), Rule 15 of the Federal Rules of Appellate Procedure, and Rule 15 of the Third Circuit Local Appellate Rules, Petitioner The Chemours Company FC, LLC (Chemours) hereby petitions the Court for review of Respondent the United States Environmental Protection Agency’s Final Drinking Water Health Advisory of June 15, 2022, entitled *Hexafluoropropylene Oxide (HFPO) Dimer Acid (CASRN 13252-13-6) and HFPO Dimer Acid Ammonium Salt (CASRN 62037-80-3), Also Known As “GenX Chemicals”* (hereinafter referred to as “HFPO Dimer Acid Health Advisory” or “Health Advisory”). A copy of the Health Advisory is attached as Exhibit A.

Among other claims, Chemours intends to argue that:

- EPA’s HFPO Dimer Acid Health Advisory is arbitrary and capricious, and otherwise inconsistent with the law, because EPA incorporated toxicity assumptions that dramatically deviate from its own standard methods, such that

EPA's own peer reviewer called aspects of EPA's toxicity assessment "extreme" and "excessive."

- EPA's HFPO Dimer Acid Health Advisory is arbitrary and capricious, and otherwise inconsistent with the law, because EPA incorporated grossly incorrect and overstated exposure assumptions—in essence, EPA used the wrong chemical when making its exposure assumptions, thereby resulting in a significantly less tolerant health advisory for HFPO Dimer Acid than is warranted by the data.
- EPA's HFPO Dimer Acid Health Advisory violates basic requirements of due process and other legally required procedures because, among other things, EPA failed to submit its Health Advisory for public notice and comment; failed to consider the costs and benefits of its actions; and failed to take into account the major consequences of its actions on the broader American economy.
- EPA exceeded its statutory authority under the Safe Drinking Water Act by promulgating a Health Advisory based upon an assumption that 80% of HFPO Dimer Acid exposure occurs through pathways other than drinking water.
- The manner in which EPA has used its Safe Drinking Water Act authority to issue health advisories violates constitutional requirements, including the nondelegation doctrine, because EPA has utilized unfettered discretion to publish health advisories, thereby affecting the legal rights and obligations of companies, water utilities, and others across the country without sufficient legislative direction or regulatory safeguards.

For these reasons, as well as others that will be discussed below and in future briefing, EPA's Health Advisory is unlawful and should be vacated.

Nearly 15 Years Ago, EPA Reviewed and Approved the Use of GenX Technology in the Manufacturing of Fluoropolymers

Fluoropolymers—extremely stable molecules composed of multiple carbon-fluorine bonds—are essential to a variety of key industries. To provide just a few examples, fluoropolymers are used in every car, airplane, and cellphone. They are also critical to maintaining the integrity and quality of the vast majority of prescription drugs; to producing medical equipment such as catheters, saline bags, and filtration devices for newborns; and to manufacturing computer chips.

Fluoropolymers are also necessary for the advancement of green technology: They are used to produce hydrogen from renewable sources and are at the heart of the hydrogen fuel cell. In sum, the responsible manufacturing of fluoropolymers in the United States is critical to furthering U.S. technology leadership; onshoring key industries (including semiconductor manufacturing); and enabling American supply chain resiliency and security.

Prior to Chemours's formation, companies used perfluorooctanoic acid (PFOA) in a wide variety of uses and applications, including use by DuPont as a polymerization aid for producing certain fluoropolymers. In 2006, EPA invited DuPont and other major chemical companies to participate in a voluntary stewardship program, with the goal of reducing PFOA emissions and product content by 95% by 2010, and working towards total elimination by 2015. DuPont agreed to participate in the program and committed to—and then met—EPA's goals.

Pursuant to its stewardship commitments, DuPont undertook a research and development program to replace its use of PFOA as a polymerization aid. From those efforts, DuPont developed technology that relies on hexafluoropropylene oxide (HFPO) dimer acid and its ammonium salt. HFPO dimer acid and its ammonium salt are sometimes referred to collectively by the trade name "GenX" or "GenX technology," and they are collectively referred to here as "HFPO Dimer Acid." Based on extensive scientific studies, DuPont sought approval of the manufacture and use of HFPO

Dimer Acid as a polymerization aid under the Toxic Substances Control Act (TSCA).¹ While HFPO Dimer Acid was developed as a replacement for the use of PFOA as a polymerization aid, it importantly did *not* replace PFOA in PFOA’s wide variety of consumer-facing uses and applications, such as carpets, textiles, papers, or firefighting foams.

In January 2009, EPA issued a consent order approving DuPont’s request.² The order permitted DuPont to manufacture and use HFPO Dimer Acid as a polymerization aid subject to certain restrictions, including a requirement that DuPont complete and submit additional studies, which DuPont did. After Chemours was spun off from DuPont in 2015, Chemours assumed DuPont’s production and use of the HFPO Dimer Acid technology.

Years Later, EPA Issues a Deeply Flawed, Scientifically Unsound Toxicity Assessment

The agency action challenged here does not arise from the EPA stewardship program or the established TSCA consent order, but instead is based in substantial part on a 2021 EPA toxicity assessment entitled *Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known As “GenX Chemicals”* (Oct. 25, 2021) (Toxicity Assessment).³ The Toxicity Assessment set forth a so-called “reference dose” for HFPO Dimer Acid. The reference dose is intended to be an estimate of the amount that an individual can ingest over their lifetime and be “unlikely to [experience] noncancer

¹ Based on studies showing rapid elimination in rats, mice, and primates, among other studies, it is widely accepted that HFPO Dimer Acid is rapidly eliminated from peoples’ bodies. *See, e.g.,* Shawn A. Gannon et al., *Absorption, distribution, metabolism, excretion, and kinetics of 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoic acid ammonium salt following a single dose in rat, mouse, and cynomolgus monkey*, 340 *Toxicology* 1 (2016) (laboratory studies have confirmed that HFPO Dimer Acid is eliminated within a few days, which indicates that it is not persistent in the bodies of those test animals); Toxicity Assessment, *infra* note 3, at 21–26 (acknowledging the rapid elimination of HFPO Dimer Acid and citing several sources).

² *See* U.S. Env’t Prot. Agency, TSCA Consent Order P-08-508 & 509, <https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0565-0017>.

³ https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf; *see* U.S. Env’t Prot. Agency, *Human Health Toxicity Assessments for GenX Chemicals*, <https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals> (last updated Jan. 13, 2022).

health effects.” The Toxicity Assessment, which sets forth a reference dose *26 times lower* than what had been proposed by EPA only a few years earlier, contains major scientific flaws; fails to incorporate available peer-reviewed scientific literature highly relevant to the analysis; and significantly overstates the potential human risks associated with HFPO Dimer Acid.

EPA’s Toxicity Assessment (or reference dose) for HFPO Dimer Acid is arbitrary and capricious because, among other reasons:

- EPA relied upon a toxicological effect that occurs in rodents but is not relevant to humans;
- After admitting that its analysis “could be more relevant to rodents than humans,” EPA speculated, incorrectly, about other “modes of action” that would be relevant to humans. In so doing, EPA made several significant errors, including failing even to identify, much less evaluate, a critically important 2020 peer-reviewed study published on precisely this subject;⁴
- EPA invented a new toxicological concept—a so-called “constellation of effects”—to justify its reference dose. However, the constellation of effects concept is entirely unprecedented, and misapplies scientific principles normally used in a human health risk assessment; and
- In ways that are inconsistent with its own guidance and practice, EPA then used significantly inflated “uncertainty factors” to further ratchet down its reference dose for HFPO Dimer Acid.⁵

⁴ See Grace A. Chappell et al., *Assessment of the Mode of Action Underlying the Effects of GenX in Mouse Liver and Implications for Assessing Human Health Risks*, 48 *Toxicologic Pathology* 494 (2020).

⁵ Because of these and other serious scientific flaws, on March 18, 2022, Chemours filed a Request for Correction with EPA pursuant to the Information Quality Act. See Letter from Brian D. Israel to U.S. EPA, https://www.epa.gov/system/files/documents/2022-03/3.18.22-request-for-correction-letter-and-exhibits_0.pdf (“EPA’s Toxicity Assessment contains substantial scientific flaws; fails to incorporate available peer-reviewed scientific

To make matters worse, EPA did not provide any opportunity for public comment on the final reference dose and disregarded methodological criticism from nationally recognized experts. Even one of EPA’s own peer reviewers described EPA’s method of accounting for uncertainty in its reference dose calculation as “extreme” and “excessive.”⁶ And the American Chemistry Council criticized EPA’s methodology as “fundamentally flawed,” “a failure of the Agency to follow its accepted practice for ensuring the scientific integrity of its process,” and based on “significant changes to its interpretation of the science that were not subject to external review.”⁷

EPA Compounds Its Errors by Issuing an Unsupported Health Advisory

On June 15, 2022, EPA announced a Final HFPO Dimer Acid Health Advisory, based in substantial part on the flawed Toxicity Assessment, establishing a purported “safe” level of 10 parts per trillion.⁸ The Health Advisory was issued under the Safe Drinking Water Act (SDWA),⁹ which was established to protect the quality of drinking water in the United States. To protect drinking water, the SDWA authorizes EPA to establish national standards based on a detailed risk and cost assessment and the best available peer-reviewed science, and it requires all owners or operators of public water systems to comply with them. However, EPA did *not* use this rigorous

literature highly relevant to the analysis; and significantly overstates the potential human risks associated with HFPO-DA. Accordingly, EPA’s Toxicity Assessment does not comply with the IQA and should be corrected.”). On June 14—on the eve of announcing its Health Advisory—EPA rejected Chemours’s Request without correcting or adequately addressing any of these errors. Chemours respectfully requests that its Request for Correction and all supporting material be included in the Administrative Record for EPA’s Health Advisory.

⁶ U.S. Env’t Prot. Agency, EPA Doc. No. 822R-21-009, Response to Additional Focused External Peer Review of Draft Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (GenX Chemicals) at 18 (Oct. 2021), https://www.epa.gov/system/files/documents/2021-10/epa_2nd-response-to-peer-review_genx_508.pdf (comments of David A. Warren, MPH, Ph.D., Program Dir., Env’t Health Sci., Univ. of S.C. Beaufort).

⁷ Am. Chemistry Council, *ACC Comments on New EPA Health Advisories for Four Specific PFAS* (June 15, 2022), <https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2022/acc-comments-on-new-epa-health-advisories-for-four-specific-pfas>.

⁸ Health Advisory at 26.

⁹ 42 U.S.C. § 300f *et seq.*

regulatory process to establish a drinking water standard for HFPO Dimer Acid. Rather it used a supposedly non-regulatory approach—unconstrained by any Congressional guidance—to pronounce an “advisory” level which, among its other flaws: (i) did not utilize required rulemaking processes, such as public notice and comment; (ii) used a defective toxicity assessment; (iii) failed to consider the substantial costs to the American economy and other likely impacts and consequences of its action; and (iv) failed to acknowledge that the Health Advisory will have significant legal consequences,¹⁰ including mandatory incorporation into the laws of over 40% of the states in the country.¹¹

The Health Advisory compounds these flaws with profound scientific and methodological errors related to assumptions about exposure. To arrive at a level of 10 parts per trillion, EPA started with the reference dose announced in the Toxicity Assessment. EPA, using a long-obsolete

¹⁰ EPA itself relies on health advisory levels in numerous contexts impacting the American economy. For example, without limitation, EPA requires community water systems to monitor for certain contaminants, and then distribute annual Consumer Confidence Reports (CCRs) to customers. 40 C.F.R. § 141.151. As a part of this reporting, EPA “strongly encourages” community water systems to include “any results that indicate a health concern” and “EPA considers any detection above a proposed MCL or health advisory level to indicate concern.” U.S. Env’t Prot. Agency, EPA Doc. No. 816-R-09-011, Preparing Your Drinking Water Consumer Confidence Report at 19 (Apr. 2010), <https://nepis.epa.gov/exe/ZyPDF.cgi/P10072FC.PDF?Dockey=P10072FC.pdf>. State regulations for these CCR requirements include monitoring for contaminants with an EPA health advisory level. *See, e.g.*, Code Del. Regs. 4462-6.3.4 (requiring mandatory monitoring for “contaminants for which US EPA has developed and published a health advisory”). EPA also considers “available health assessment[s] to facilitate regulatory determinations” in selecting contaminants subject to its Unregulated Contaminant Monitoring Rule (UCMR). U.S. Env’t Prot. Agency, EPA Doc. No. 815-f-21-009, The Fifth Unregulated Contaminant Monitoring Rule (UCMR 5): Program Overview Fact Sheet at 3 (Dec. 2021), <https://www.epa.gov/system/files/documents/2022-02/ucmr5-factsheet.pdf>. EPA also includes health advisory levels as related “Health Information” in materials describing these UCMR contaminants. U.S. Env’t Prot. Agency, The Fifth Unregulated Contaminant Monitoring Rule (UCMR 5): March 2022 Meeting Presentations for Implementation (March 2022), <https://www.epa.gov/system/files/documents/2022-04/presentation-ucmr5-march-2022.pdf>.

¹¹ *See, e.g.*, Ala. Admin. Code § 335-6-15-.30(e) (setting the “correction action limit” for the “groundwater ingestion pathway” to equal U.S. EPA health advisories); Iowa Admin. Code r. 567-137.5(4) (using U.S. EPA health advisory levels as the “statewide standard for chemicals” in groundwater where no maximum contaminant level exists); N.C. Gen. Stat. Ann. § 143-215.2A (authorizing the state Department of Environmental Quality to require “permanent replacement water supplies” for any chemical for which U.S. EPA has issued a health advisory); Ohio Admin. Code § 3701-28-04 (setting “standards of chemical constituents for private water systems” to equal U.S. EPA health advisories); 35 Pa. Stat. Ann. § 6026.303 (authorizing the state Environmental Quality Board to set statewide health standards which “shall include” any existing U.S. EPA health advisory level); S.D. Admin. R. 74:54:01:05 (basing detection limits at “currently acceptable sampling and analytical techniques . . . until a maximum contaminant level (MCL) or health advisory level is set by the EPA”).

default assumption, then adjusted its reference dose by assuming that drinking water accounts for only 20% of a person's exposure to HFPO Dimer Acid.¹² In other words: in direct contradiction of a vast amount of data—all of which was available to EPA—EPA assumed that a person will be exposed to four times the amount of HFPO Dimer Acid from sources other than drinking water, such as food, dust, and soil.¹³ The unfounded assumption means that the Health Advisory is *five times less tolerant* of HFPO Dimer Acid in drinking water than the Toxicity Assessment—which itself was *26 times less tolerant* than EPA's earlier assessment. EPA also assumed—without basis and contrary to extensive data—that the public's exposure to HFPO Dimer Acid would be the same as that for PFOA, a chemical that is found in the environment throughout the United States and was used far more extensively than HFPO Dimer Acid.¹⁴ In sum, EPA issued a Health Advisory using data from the wrong chemical.

The fact that EPA's exposure assumption is arbitrary and capricious is further demonstrated by EPA's own statements. More than 20 years ago, EPA itself urged that “the need for using” “the 20 percent default . . . should be reduced” because it was a less-accurate method of evaluating exposure.¹⁵ Indeed, overwhelming data provided to EPA shows that its assumption of exposure from other sources is completely unfounded and contrary to the evidence and sound science.

¹² Health Advisory at 19, 26.

¹³ Weeks before the Health Advisory was published, Chemours submitted to EPA twenty-two independent reports containing exposure data for HFPO Dimer Acid from the U.S., Europe, and China. These data showed no significant exposure of HFPO Dimer Acid for the general population through food, dust, air, soil, sludge, biosolids, consumer products, or firefighting foams. *See* Letter from Sheryl Telford to Elizabeth Behl, U.S. EPA (May 31, 2022). Chemours respectfully requests that this letter and all attachments be included in the Administrative Record for EPA's Health Advisory.

¹⁴ Health Advisory at 4.

¹⁵ U.S. Env't Prot. Agency, EPA Doc. No. 822-B-00-004, Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health at 4-6 (2000), <https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=20003D2R.txt>.

Chemours Seeks Judicial Review of EPA’s Health Advisory

Chemours seeks judicial review of the Health Advisory, which is legally defective and will have unnecessary and adverse consequences—not only for Chemours, but for the public as well.

Chemours intends to advance (among others) the following claims:

The Health Advisory’s Reference Dose is Arbitrary and Capricious

The reference dose in the Health Advisory is unsupported by substantial evidence and is arbitrary and capricious, in violation of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). EPA is required to use “the best available, peer-reviewed science” in its decision-making.¹⁶ But in calculating the HFPO Dimer Acid reference dose, EPA deviated from its own standard toxicity-assessment methods; and it disregarded contrary evidence and methodological criticism from experts. The resulting reference dose is scientifically flawed, utilizes arbitrary and capricious uncertainty factors, and grossly overstates the risk presented by HFPO Dimer Acid.

The Health Advisory’s Exposure Assumptions are Arbitrary and Capricious

The exposure assumptions (called the “relative source contribution”) used in the Health Advisory also are unsupported by substantial evidence and are arbitrary and capricious. EPA claimed that it had insufficient data to accurately calculate the relative source contribution, so it simply assumed that 80% of human exposure to HFPO Dimer Acid is from sources other than drinking water. EPA’s own guidance cautions that this assumption should only be used “infrequently,” as the minimum information necessary to calculate relative source contribution “should be available in most cases.”¹⁷ In this case, overwhelming data show that use of the 80% assumption is flawed. In addition, EPA assumed—again without basis and contrary to extensive

¹⁶ 42 U.S.C. § 300g-1(b)(3)(A).

¹⁷ U.S. Env’t Prot. Agency, EPA Doc. No. 822-B-00-004, Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health at 4-12 (2000), <https://nepis.epa.gov/Exec/zyPURL.cgi?Dockey=20003D2R.txt>.

data—that the public’s exposure to HFPO Dimer Acid would be the same as that for PFOA, a chemical that is found in the environment throughout the United States and was used far more extensively than HFPO Dimer Acid. EPA’s blanket assumption that “since GenX chemicals are substitutes for PFOA, products (*e.g.*, some nonstick coatings, aqueous film-forming foam [AFFF]) that were previously made using PFOA may now rely on GenX chemicals” shows that EPA fundamentally misunderstands how HFPO Dimer Acid is used as a polymerization aid, as set forth in EPA’s own TSCA consent order.¹⁸

EPA Did Not Follow Proper Procedure and Required Due Process

EPA failed to follow required public notice-and-comment procedures in issuing the Health Advisory. That process allows individuals, organizations, agencies, and businesses to provide written input on proposed environmental decisions that can have far-reaching effects. By failing to allow for such input here, EPA has taken a final action with substantial adverse consequences based on an incomplete and non-public record, and its flawed process contributed to a deeply flawed advisory level. EPA also failed to follow proper procedure in other respects, including failing to take into account costs and benefits of its actions, the consequences of its actions on the broader American economy, and the ability of the United States to ensure that critical technologies remain available.

EPA Issued the Health Advisory in Excess of its Statutory Authority

The Safe Drinking Water Act gives EPA’s Administrator the authority to “publish health advisories” for “contaminants” that are not otherwise the subject of regulation. 42 U.S.C. § 300g-1(b)(1)(F). But it limits the definition of “contaminant” to “any physical, chemical, biological, or radiological substance or matter *in water*.” *Id.* § 300f(6) (emphasis added). The statute thus limits

¹⁸ Health Advisory at 4.

EPA's authority in issuing health advisories to addressing substances or matter "in water." Yet the Health Advisory's assumption of a 20% relative source contribution, and the resulting level of 10 parts per trillion, are based on hypothesized exposures to HFPO Dimer Acid *outside* of water, such as through the consumption of food. EPA thus lacks statutory authority—not to mention a factual basis—for relying on this assumption.

EPA's Publication of the Health Advisory Violates Constitutional Requirements

Although the Safe Drinking Water Act gives EPA's Administrator authority to "publish health advisories (which are not regulations) or take other appropriate actions for contaminants not subject to any national primary drinking water regulation," 42 U.S.C. § 300g-1(b)(1)(F), there is nothing in the statute that tells the Administrator how to exercise that power. Indeed, Congress failed to provide EPA with *any* guidance or constraints at all regarding the purpose, content, methodology, or application of health advisories. Moreover, EPA has not promulgated through guidance or regulation any limiting principles for its authority, which it appears to believe (given its issuance of the Health Advisory) provides it with unfettered discretion to issue advisories whenever and however it wants, and irrespective of the consequences. Finally, EPA health advisories are in fact regulatory in nature because they have significant legal consequences in numerous contexts including use by EPA and mandatory adoption in over 20 states.

The Safe Drinking Water Act's delegation of authority to EPA to issue health advisories is therefore unconstitutional because, among other things, it violates the constitutional nondelegation doctrine. The Constitution vests "All legislative Powers" in Congress alone. U.S. Const. art. I, § 1. Although Congress may delegate *administrative* authority to executive agencies to carry out statutory policy, it may do so only if Congress provides an "intelligible principle" by which the agency can exercise such authority. Congress did not do so in creating the authority to issue health advisories, nor has EPA acknowledged any limitations in exercising that authority.

For these reasons, as well as others that will be discussed in future briefing, EPA's Health Advisory is unlawful and should be vacated.

Date: July 13, 2022

Respectfully submitted,

/s/ Allon Kedem

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DRAFT: ATTACHMENT TO JULY 13, 2022 LETTER TO DEQ

«TodaysDate»

«RecipientName»

«RecipientAddressStreet»

«RecipientAddressCity», «RecipientAddressState» «RecipientAddressZip»

Re: Drinking Water for «ResidentAddressStreet»

Dear Owner/Resident/Tenant:

As you have previously been informed, since early September 2017, Chemours—in consultation and cooperation with the North Carolina Department of Environmental Quality (NCDEQ)—has been conducting a well sampling program in the vicinity of the Fayetteville Works facility. Chemours has entered into a Consent Order with the NCDEQ and Cape Fear River Watch, which was approved by the Superior Court for Bladen County on February 25, 2019. Pursuant to that Consent Order, Chemours has agreed to provide permanent replacement drinking water to residences, businesses, and public organizations with a drinking water well found to have concentrations of HFPO Dimer Acid (commonly known as GenX) at or above 140 parts per trillion (ppt), which is North Carolina’s provisional health goal, or any applicable health advisory, whichever is lower. For these residences, businesses, or public organizations, the permanent replacement drinking water may be established by a connection to a public water supply (if feasible), installation of a whole building granulated activated carbon (GAC) system, or installation of reverse osmosis (RO) systems at every kitchen and bathroom sink. Until permanent replacement drinking water is provided, Chemours will provide bottled water.

On June 15, 2022, the United States Environmental Protection Agency (US EPA) issued a drinking water health advisory for HFPO Dimer Acid of 10 ppt. Testing of your drinking water showed levels of HFPO Dimer Acid between 10 ppt and 140 ppt. **If Chemours has been providing bottled water to your residence, your residence will continue to qualify for bottled water until permanent replacement drinking water is provided. If Chemours has installed one or more reverse osmosis systems in your residence, Chemours will continue to maintain those systems unless and until a different permanent replacement drinking water is selected and provided.**

Chemours has commenced litigation in federal court seeking review of US EPA’s health advisory and reserves its rights in connection with that litigation. Nonetheless, and to be responsive to concerns of NCDEQ and the impacted community, Chemours is moving forward now, and while that litigation is pending, with the extension of permanent replacement drinking water options to properties that have tested above 10 ppt for HFPO Dimer Acid.

Because testing of your drinking water shows levels of HFPO Dimer Acid between 10 ppt and 140 ppt, we are writing to inform you that you now qualify (subject to Chemours’s reservation of rights, as noted above) for one of the following three options:

1. a connection to a public water supply (if feasible);
2. installation and maintenance of a whole house GAC system; or
3. installation and maintenance of RO systems at every kitchen and bathroom sink.

If a public water connection were to be available and you were to select it, Chemours would facilitate connecting to such system and reimburse your monthly water bill up to a maximum of \$75 per month (subject to upward adjustment) for a period of 20 years. Because NCDEQ still needs to determine, based on further analysis being conducted by Chemours, the locations where connection to a public water supply would be feasible, and NCDEQ has not yet made a determination about your location, we are unable to offer you this option at this time, and **you need not make a selection yet regarding your permanent replacement drinking water.** Further information as to the availability and likely timing of public water connection will be provided to you once it becomes available, at which point a selection among the available options will need to be made. (If your property is located in an area where public water is readily available, Chemours may have reached out to you for connecting to such public water and will continue to offer that option.) **In the meantime, please be assured that if you are currently receiving bottled water, we will continue to provide you with bottled water either through scheduled deliveries or provision of a voucher that you can use to purchase bottled water. If Chemours has installed one or more reverse osmosis systems in your residence, Chemours will continue to maintain those systems unless and until a different permanent replacement drinking water is selected and provided.**

Nonetheless, if you have already determined that you would not want your residence to be connected to public water even if it were available, you may select now between the other two permanent replacement drinking water options (GAC or RO). If you select either GAC or RO, you would not be able to seek a public water connection or a different filtration option from Chemours in the future.

If you would like to select GAC or RO now, or if you have any questions about this letter, please call and leave a message at 910-678-1101 and leave your name and contact information. A representative will return your call as soon as possible.

For additional information, please see the Chemours website: <https://www.chemours.com/en/about-chemours/global-reach/fayetteville-works>.

Sincerely,

Dawn M. Hughes, Plant Manager
Chemours – Fayetteville Works

Attachments:

GenX Fact Sheet

PFAS Fact Sheet

Drinking Water Program Overview

Granular Activated Carbon Treatment System Overview

Reverse Osmosis Treatment System Overview