

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Comments on Certain New Chemicals: Receipt and Status Information for July 2019

84 Fed. Reg. 46,723 (September 5, 2019)

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Earthjustice \* Alaska Community Action on Toxics \* Buxmont Coalition for Safer Water \*
Clean Cape Fear \* Environmental Defense Fund \* Environmental Health Strategy Center \*
Environmental Justice Task Force – Tucson \* Environmental Working Group \* GreenCAPE \*
Merrimack Citizens for Clean Water \* National PFAS Contamination Coalition \* Natural
Resources Defense Council \* Newburgh Clean Water Project \* PFOAProjectNY \* Sierra Club \*
Testing for Pease \* Toxics Action Center \* Waterkeeper Alliance \* Westfield Residents
Advocating For Themselves \* Whidbey Water Keepers \* Your Turnout Gear and PFOA

The undersigned organizations submit the following comments regarding the
premanufacture notices (“PMNs”) for three per- and polyfluoroalkyl substances (“PFAS”)
identified in Certain New Chemicals; Receipt and Status Information for July 2019, 84 Fed. Reg.
46,723 (Sept. 5, 2019). Our organizations include community groups in areas affected by PFAS
contamination, a national coalition of impacted communities, and local and national
organizations advocating for strengthened protections against the risks posed by existing and
new PFAS. The three chemicals addressed in these comments (the “PMN chemicals” or “PMN
PFAS”) are:

Table with 5 columns: PMN Number, Chemical Identity (Generic), Date Received, Submitter, Use (Generic). Rows include P-19-0138, P-19-0139, and P-19-0140.

For the reasons below, we strongly urge EPA to prohibit commercialization of all three
PMN chemicals — P-19-0138, P-19-0139 and P-19-0140 — to protect public health and the
environment. To the extent that any commercialization of any of the PMN chemicals is
permitted, EPA must impose prohibitions and restrictions that prevent unreasonable risk of
injury to health or the environment, including to potentially exposed or susceptible
subpopulations.

## I. Introduction

PFAS are a “large, complex, and ever-expanding” class of more than 4,000 synthetic chemicals that contain fluorine atoms bonded to a carbon chain.<sup>1</sup> The carbon-fluorine bond is “one of the strongest ever created by man,” making PFAS extremely persistent in the environment, and difficult to break down or remediate.<sup>2</sup> Government and independent academic research, including large epidemiological studies of human PFAS exposure, has shown that many PFAS bioaccumulate in the bodies of living organisms and are highly toxic; exposure to even relatively low levels of PFAS is associated with liver damage, high cholesterol, thyroid disease, decreased antibody response to vaccines, asthma, decreased fertility, and decreased birth weight.<sup>3</sup> Importantly, data suggest that PFAS may also affect the growth, learning, and immune response of infants and older children.<sup>4</sup>

Less than a century after they were first created, PFAS are now ubiquitous in people, the environment, and wildlife.<sup>5</sup> Unlike other persistent compounds such as PCBs, many PFAS are highly mobile and, as a result, widespread in groundwater. As of July 2019, over 700 known locations in nearly every state have been affected by PFAS contamination, including at least 446 communities where PFAS have been detected in drinking water.<sup>6</sup> An estimated six million

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<sup>1</sup> *Examining the Federal Response to the Risks Associated with Per- and Polyfluoroalkyl Substances (PFAS): Hearing Before the S. Comm. on Env't & Pub. Works*, 116th Cong. (Mar. 28, 2019) (Testimony of Linda S. Birnbaum, Director, Nat'l Inst. of Env'tl. Health Sci. & Nat'l Toxicology Program, Nat'l Insts. of Health), [https://www.epw.senate.gov/public/index.cfm/hearings?Id=918A6066-C1F1-4D81-A5A0-F08BBE06D40B&Statement\\_id=D2255C99-7544-42CA-B9DC-0D4F11CCB964](https://www.epw.senate.gov/public/index.cfm/hearings?Id=918A6066-C1F1-4D81-A5A0-F08BBE06D40B&Statement_id=D2255C99-7544-42CA-B9DC-0D4F11CCB964). For convenience, a copy of Dr. Birnbaum's testimony is attached hereto as **Exhibit A**. See also Buck, R. C., Franklin, J., Berger, U., Conder, J. M., Cousins, I. T., De Voogt, P., ... & van Leeuwen, S. P. (2011). Perfluoroalkyl and polyfluoroalkyl substances in the environment: terminology, classification, and origins. *Integrated Environmental Assessment and Management*, 7(4), 513-541, <https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.258>

<sup>2</sup> Testimony of Linda Birnbaum, *supra* note 1, at 2.

<sup>3</sup> See Agency for Toxic Substances & Disease Registry (“ATSDR”), Toxicological Profile for Perfluoroalkyls (Draft for Public Comment), at 5–6 (June 2018) (“ATSDR Toxicological Profile”), <https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf>

<sup>4</sup> Rappazzo, K., Coffman, E., & Hines, E. (2017). Exposure to perfluorinated alkyl substances and health outcomes in children: a systematic review of the epidemiologic literature. *International Journal of Environmental Research and Public Health*, 14(7), 691, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5551129/>

<sup>5</sup> See, e.g., Sun, M., Arevalo, E., Strynar, M., Lindstrom, A., Richardson, M., Kearns, B., ... & Knappe, D. R. (2016). Legacy and emerging perfluoroalkyl substances are important drinking water contaminants in the Cape Fear River Watershed of North Carolina. *Environmental Science & Technology Letters*, 3(12), 415-419, <https://pubs.acs.org/doi/abs/10.1021/acs.estlett.6b00398>; Graber, J. M., Alexander, C., Laumbach, R. J., Black, K., Strickland, P. O., Georgopoulos, P. G., ... & Mascari, M. (2019). Per and polyfluoroalkyl substances (PFAS) blood levels after contamination of a community water supply and comparison with 2013–2014 NHANES. *Journal of Exposure Science & Environmental Epidemiology*, 29(2), 172, <https://www.nature.com/articles/s41370-018-0096-z.pdf>.

<sup>6</sup> Env'tl. Working Grp., *Mapping the PFAS Contamination Crisis: New Data Show 712 Sites in 49 States* (July 2019), [https://www.ewg.org/interactive-maps/2019\\_pfas\\_contamination/](https://www.ewg.org/interactive-maps/2019_pfas_contamination/); see also Env'tl. Working Grp., *Mapping the PFAS Contamination Crisis: New Data Show 610 Sites in 43 States* (Mar. 2019),

Americans drink water containing PFAS levels exceeding EPA’s lifetime health advisory for perfluorooctanoic acid (“PFOA”) and perfluorooctane sulfonate (“PFOS”), two widespread and highly toxic PFAS,<sup>7</sup> and some states, such as Michigan and New Jersey, are setting their own, more stringent standards. Moreover, nearly 99 percent of Americans have PFAS in their blood.<sup>8</sup> For these reasons, the director of the Center for Disease Control and Prevention’s National Center for Environmental Health stated that the presence and concentrations of PFAS in U.S. drinking water is “one of the most seminal public health challenges for the next decades.”<sup>9</sup>

Yet, EPA continues to approve new PFAS under the Toxics Substances Control Act (“TSCA”), even when it lacks sufficient information to find that the new chemicals are not likely to present unreasonable risks to health or the environment. EPA has approved over 400 PFAS through the TSCA new chemicals program, of which *less than half* included human toxicity, ecotoxicity and environmental fate data.<sup>10</sup> The three PMN chemicals are merely the latest examples<sup>11</sup> of new PFAS submitted for EPA approval without the studies and data required to evaluate their effects on human health and the environment and therefore without the information needed to support a determination that they are unlikely to pose unreasonable risk.

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<https://www.ewg.org/news-and-analysis/2019/04/mapping-pfas-contamination-crisis-new-data-show-610-sites-43-states>.

<sup>7</sup> Hu, X. C., Andrews, D. Q., Lindstrom, A. B., Bruton, T. A., Schaidler, L. A., Grandjean, P., ... & Higgins, C. P. (2016). Detection of poly-and perfluoroalkyl substances (PFASs) in US drinking water linked to industrial sites, military fire training areas, and wastewater treatment plants. *Environmental Science & Technology Letters*, 3(10), 344-350,

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5062567/>.

<sup>8</sup> Calafat, A. M., Wong, L. Y., Kuklennyik, Z., Reidy, J. A., & Needham, L. L. (2007). Polyfluoroalkyl chemicals in the US population: data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and comparisons with NHANES 1999–2000. *Environmental Health Perspectives*, 115(11), 1596-1602. See also ATSDR, An Overview of Perfluoroalkyl and Polyfluoroalkyl Substances and Interim Guidance for Clinicians Responding to Patient Exposure Concerns (2018),

[https://www.atsdr.cdc.gov/pfas/docs/pfas\\_clinician\\_fact\\_sheet\\_508.pdf](https://www.atsdr.cdc.gov/pfas/docs/pfas_clinician_fact_sheet_508.pdf).

<sup>9</sup> Pat Rizzuto et al., *CDC Sounds Alarm on Chemical Contamination in Drinking Water*, Bloomberg Env’t. (Oct. 17, 2017), <https://news.bloombergenvironment.com/environment-and-energy/cdc-sounds-alarm-on-chemical-contamination-in-drinking-water>.

<sup>10</sup> See Tala R. Henry, EPA, Presentation at the Progress Implementing Changes to the New Chemicals Review Program Under the Amended TSCA Public Meeting, at 8 (Dec. 6, 2017), [https://www.epa.gov/sites/production/files/2017-12/documents/presentation\\_4\\_and\\_5\\_-\\_categories\\_sustainable\\_futures\\_december\\_6th\\_pub.pdf](https://www.epa.gov/sites/production/files/2017-12/documents/presentation_4_and_5_-_categories_sustainable_futures_december_6th_pub.pdf) (noting that EPA has approved “approximately 400 [perfluorinated] chemicals in several structural categories....Data (health tox, eco tox, fate) for < half”).

<sup>11</sup> Since 2002, EPA has issued more than 200 consent orders for new PFAS it has approved, most of which note that the new chemical “may present an unreasonable risk of injury to human health and the environment” and that there may be “significant (or substantial) human exposure to the substance and its degradation products.” See Sharon Lerner, *EPA Allowed Companies to Make 40 New PFAS Chemicals Despite Serious Risks*, The Intercept (Sept. 19, 2019), <https://theintercept.com/2019/09/19/epa-new-pfas-chemicals/>.

## II. TSCA Section 5 – Legal Framework

Under TSCA, EPA must assess the safety of every new chemical submitted via the PMN process. EPA’s safety review must be risk-based, without consideration of costs or other non-risk factors. Chemicals can enter commerce unrestricted only if EPA determines that the substance “is not likely to present an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use.”<sup>12</sup> In order to make a “not likely to present an unreasonable risk” finding for a new chemical, EPA must have sufficient data to assess a new chemical’s risks. TSCA requires “sufficient” information and this information must address all relevant endpoints. Given what is known about PFAS, EPA cannot make a “not likely” finding for chemicals in this class in the absence of results from standard tests for carcinogenicity, subchronic toxicity, reproductive/developmental effects, immunotoxicity, metabolism, pharmacokinetics and fate, transport and biodegradation, at a minimum. Under the amended TSCA, the burden of producing adequate information to support a finding that a chemical is “not likely to present unreasonable risk” rests with the manufacturer. As stated by senators in a statement on June 7, 2016 regarding the amendment, “this affirmative approach to better ensuring the safety of new chemicals entering the market is essential to restoring the public’s confidence in our chemical safety system.”<sup>13</sup>

If, on the other hand, EPA determines that the new chemical “presents an unreasonable risk of injury to health or the environment,”<sup>14</sup> it must regulate the chemical under TSCA section 5(f). Section 5(f) requires EPA to issue either: i) a proposed rule, limiting the volume of the substance that may be manufactured, processed, or distributed in commerce, or imposing any, or several, of the conditions set forth in TSCA section 6(a); or ii) an order to prohibit or limit the manufacture, processing, or distribution in commerce of the substance.<sup>15</sup>

If EPA can neither make a “not likely” finding nor determine that the substance “presents an unreasonable risk,” it must regulate the chemical pursuant to a TSCA section 5(e) order. Under TSCA, EPA cannot make either a “not likely” or a “presents” finding: i) where “the information available to [EPA] is insufficient to permit a reasoned evaluation of the health and environmental effects” of the chemical,<sup>16</sup> or ii) where “in the absence of sufficient information to permit [EPA] to make such an evaluation,” the chemical “*may present* an unreasonable risk of injury to health or the environment.”<sup>17</sup> If EPA issues a section 5(e) order based on the criteria in TSCA section 5(a)(3)(B), that order must “prohibit or limit the manufacture, processing,

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<sup>12</sup> 15 U.S.C. § 2604(a)(3)(C).

<sup>13</sup> 162 Cong. Rec. S3516 (daily ed. June 7, 2016), <https://www.congress.gov/congressional-record/2016/06/07/senate-section/article/S3511-1>.

<sup>14</sup> 15 U.S.C. § 2604(a)(3)(A)

<sup>15</sup> *Id.* § 2604(f).

<sup>16</sup> *Id.* § 2604(a)(3)(B)(i).

<sup>17</sup> *Id.* § 2604(a)(3)(B)(ii)(I) (emphasis added). TSCA also requires a 5(e) order if the substance “is or will be produced in substantial quantities,” and either will or may “enter the environment in substantial quantities” or will or may result in “significant or substantial human exposure.” *Id.* § 2604(a)(3)(B)(ii)(II).

distribution in commerce, use, or disposal of such substance or ... any combination of such activities to the extent necessary to protect against an unreasonable risk of injury.”<sup>18</sup>

### **III. EPA cannot find that any of the three PMN substances are not likely to present unreasonable risk.**

#### **A. EPA cannot make a “not likely to present” determination for any of the PMN substances because, as PFAS, they pose and will contribute to unreasonable risks.**

EPA cannot make a “not likely to present unreasonable risk” determination for the PMN chemicals because PFAS chemicals, by virtue of their shared and inherent properties, present unreasonable risks that have not been addressed in the PMN submissions. Despite some structural differences from compound to compound, PFAS share a set of “unique physical and chemical characteristics imparted by the fluorinated region of the molecule.”<sup>19</sup>

Moreover, recent research has shown that these harmful properties are shared both by “long-chain” PFAS such as PFOA and PFOS, which have been largely phased out due to widely-acknowledged known risks, and by “short-chain” PFAS like perfluorobutane sulfonate (“PFBS”) and GenX chemicals that have been introduced as replacements for their long-chain counterparts.<sup>20</sup> In a decision recommending the elimination of approximately 150 PFAS chemicals, the United Nations Persistent Organic Pollutants Review Committee affirmed that “a transition to the use of short-chain per- and polyfluoroalkyl substances (PFASs) for dispersive applications such as fire-fighting foams is not a suitable option from an environmental and human health point of view.”<sup>21</sup>

While the chemical structures of the three PMN chemicals under review have been redacted, the strength of the carbon-fluorine bonds makes those chemicals, as well as the ultimate products, a high concern for human and ecological health. The departing director of the National Institute for Environmental Health Science, in testimony before the Senate Environment and Public Works Committee on March 28, 2019, has advised that “[a]pproaching PFAS as a

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<sup>18</sup> *Id.* § 2604(e).

<sup>19</sup> Lindstrom, A.B., M.J. Strynar, and E.L. Libelo. (2011). Polyfluorinated Compounds: Past, Present, and Future. *Environmental Science & Technology*, 45(19), 7954-7961, <https://pubs.acs.org/doi/abs/10.1021/es2011622>.

<sup>20</sup> See, e.g., EPA, EPA-823-P-18-001, Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt: Public Comment Draft (Nov. 2018), [https://www.epa.gov/sites/production/files/2018-11/documents/genx\\_public\\_comment\\_draft\\_toxicity\\_assessment\\_nov2018-508.pdf](https://www.epa.gov/sites/production/files/2018-11/documents/genx_public_comment_draft_toxicity_assessment_nov2018-508.pdf). The “long-chain” and “short-chain” distinction, which refers to the number of fluorinated carbon molecules in the chemical, itself involves arbitrary divisions with no scientific basis. These is a continuum of PFAS chain lengths, not two distinct classes, and common properties that apply to a broad range of PFAS across that continuum.

<sup>21</sup> Persistent Organic Pollutants Review Comm., UNEP, Decision POPRC-14/2: Perfluorooctanoic Acid (PFOA), Its Salts and PFOA-Related Compounds (2018), <http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC14/Overview/tabid/7398/ctl/Download/mid/21545/Default.aspx?id=17&ObjID=26011>.

class for assessing exposure and biological impact is the most prudent approach to protect public health,”<sup>22</sup> and a 2015 statement signed by over 200 international scientists and experts called for action to “prevent the[] replacement” of long-chain PFAS with hazardous fluorinated alternatives.<sup>23</sup>

ATSDR recently reported, based on existing epidemiological data, that human exposure to many different PFAS is associated with pre-eclampsia, liver damage, high cholesterol, risk of thyroid disease, decreased antibody response to vaccines, increased risk of asthma, increased risk of decreased fertility, and decreased birth weight.<sup>24</sup> Notably, in a survey of different PFAS chemicals of varying structures and chain lengths, ATSDR found a number of common health effects, summarized below.

### Summary of ATSDR’s Findings on Health Effects from PFAS Exposure

	Immune e.g. decreased antibody response, decreased response to vaccines, increased risk of asthma diagnosis	Developmental & Reproductive e.g. pregnancy-induced hypertension/pre-eclampsia, decreased fertility, small decreases in birth weight, developmental toxicity	Lipids e.g. increases in serum lipids, particularly total cholesterol and low-density lipoprotein	Liver e.g. increases in serum enzymes and decreases in serum bilirubin levels	Endocrine e.g. increased risk of thyroid disease, endocrine disruption	Body Weight e.g. decreased body weight	Blood e.g. decreased red blood cell count, decreased hemoglobin and hematocrit levels
PFOA	×	×	×	×	×	×	×
PFOS	×	×	×	×	×	×	×
PFHxS	×	×		×	×		×
PFNA	×	×	×	×	×	×	
PFDeA	×	×	×	×	×	×	
PFDoA	×	×		×		×	
PFUA	×	×		×		×	×
PFHxA		×		×			×
PFBA		×		×	×		×
PFBS				×			×

*This table, prepared by the Natural Resources Defense Council, summarizes ATSDR’s findings on the associations between PFAS exposure and health outcomes in human and animal studies (not an exhaustive list of chemicals or health outcomes; includes both “serious” and “less serious” effects, as defined by ATSDR). Note x’s in black represent PFAS for which ATSDR considers their liver effects to be specific to animals.*<sup>25</sup>

<sup>22</sup> Testimony of Linda S. Birnbaum, *supra* note 1, at 13.

<sup>23</sup> Blum, A., Balan, S. A., Scheringer, M., Trier, X., Goldenman, G., Cousins, I. T., ... & Peaslee, G. (2015). The Madrid statement on poly-and perfluoroalkyl substances (PFASs). *Environmental Health Perspectives*, 123(5), A107-A111, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4421777/>. For convenience, a copy of the Madrid Statement is attached hereto as **Exhibit B**.

<sup>24</sup> ATSDR Toxicological Profile, *supra* note 3, at 5–6.

<sup>25</sup> A prior version of the table is available in Anna Reade et al., NRDC, *Scientific and Policy Assessment for Addressing Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* 17 (Apr. 2019),

An epidemiological study of Mid-Ohio Valley residents near a chemical plant found significant associations between PFOA exposure and kidney and testicular cancers.<sup>26</sup> In animal studies, exposure to many PFAS has been shown to induce liver toxicity, developmental toxicity, and immune toxicity, among other effects.<sup>27</sup> Moreover, while long-chain PFAS have been more extensively studied, recent research has found that the short-chain replacement PFAS are associated with similar health effects.<sup>28</sup>

Because of the strength of the carbon-fluorine bond, PFAS are also “very persistent.”<sup>29</sup> Often known as “forever chemicals,” PFAS persist in the environment for “years, decades, or longer.”<sup>30</sup> According to EPA, “[s]hort-chain PFAS are as persistent in the environment as their longer-chain analogues.”<sup>31</sup> PFAS, and in particular short-chain PFAS, are also highly mobile.<sup>32</sup> In fact, replacement PFAS compounds may be equally, if not more, mobile in an aqueous environmental medium, resulting in widespread soil and groundwater contamination that is particularly difficult to capture and treat.<sup>33</sup> As a result, even small releases of PFAS have had significant and long-lasting effects.

PFAS can also accumulate in people and other biological organisms, such that even small exposures over an extended period of time can result in significant cumulative effects. While EPA has claimed that short-chain PFAS “are generally less bioaccumulative,”<sup>34</sup> recent research involving short-chain PFAS have found that such chemicals are more bioaccumulative than

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[https://www.nrdc.org/sites/default/files/media-uploads/nrdc\\_pfas\\_report.pdf](https://www.nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf). For convenience, a copy of this report is attached hereto as **Exhibit C**.

<sup>26</sup> Barry, V., Winquist, A., & Steenland, K. (2013). Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. *Environmental Health Perspectives*, 121(11-12), 1313-1318, <https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.1306615>.

<sup>27</sup> ATSDR Toxicological Profile at 6.

<sup>28</sup> Cheryl Hogue, *Short-Chain and Long-Chain PFAS Show Similar Toxicity, US National Toxicology Program Says*, Chem. & Eng’g News (Aug. 24, 2019), <https://cen.acs.org/environment/persistent-pollutants/Short-chain-long-chain-PFAS/97/i33>; Conley, J. M., Lambright, C. S., Evans, N., Strynar, M. J., McCord, J., McIntyre, B. S., ... & Wilson, V. S. (2019). Adverse Maternal, Fetal, and Postnatal Effects of Hexafluoropropylene Oxide Dimer Acid (GenX) from Oral Gestational Exposure in Sprague-Dawley Rats. *Environmental Health Perspectives*, 127(3), 037008, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6768323/>.

<sup>29</sup> EPA, EPA-823-R1-8004, Per- and Polyfluoroalkyl Substances (PFAS) Action Plan 9 (Feb. 2019) (“PFAS Action Plan”), [https://www.epa.gov/sites/production/files/2019-02/documents/pfas\\_action\\_plan\\_021319\\_508compliant\\_1.pdf](https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf).

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* at 13.

<sup>32</sup> Kotthoff, M., & Bücking, M. (2018). Four chemical trends will shape the next decade's Directions in perfluoroalkyl and polyfluoroalkyl substances research. *Frontiers in Chemistry*, 6, 103, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5895726/>.

<sup>33</sup> Brendel, S., Fetter, É., Staude, C., Vierke, L., & Biegel-Engler, A. (2018). Short-chain perfluoroalkyl acids: environmental concerns and a regulatory strategy under REACH. *Environmental Sciences Europe*, 30(1), 9, at 4, <https://enveurope.springeropen.com/articles/10.1186/s12302-018-0134-4>.

<sup>34</sup> EPA, PFAS Action Plan at 11.

previously believed and that the bio-persistence of short-chain PFAS and their breakdown products has not been correctly measured in earlier studies.<sup>35</sup>

EPA's failure to consider the common risks posed by PFAS has allowed industry to substitute the most-studied PFAS, like PFOA and PFOS, with less-studied but similarly dangerous alternatives. These new PFAS include substances that are associated with reproductive harm, neurotoxicity, development defects, and other serious health effects.<sup>36</sup> Rather than repeat those serious public health mistakes, EPA should not conclude that any new PFAS are "not likely to present an unreasonable risk" unless EPA receives conclusive, chemical-specific evidence—involving all endpoints relevant to PFAS—to the contrary.

**B. The structural similarities between the PMN chemicals and GenX provide additional evidence of unreasonable risk.**

Not only are the new chemical substances PFAS, but their generic names indicate structural similarities to GenX chemicals ("GenX"), a group of chemicals that EPA has already found to present serious health threats. While the chemical structure of each PMN chemical has been withheld as confidential business information ("CBI"), their names indicate that they are all perfluorinated, as opposed to polyfluorinated, chemicals. The use of "dioxa-" and "trioxa-" in the generic names indicate the presence of multiple ether groups (oxygen molecules bonded to two carbons) in the PFAS chain. The use of "alkanoyl" indicates the likely presence of an organic acid, and the use of "fluoride" in two of the chemical names indicates that fluorine is attached to the organic acid. These chemical structures, to the extent they may be discerned from the limited information made available in the PMNs, resemble those of GenX chemicals, which similarly have an ether and an organic acid group, with ammonia attached to the organic acid instead of fluorine.

According to EPA, GenX has caused harm to prenatal development, the immune system, liver, kidney, and thyroid in animal studies.<sup>37</sup> These studies also have found GenX to cause cancer, and the European Chemicals Agency classified GenX as a substance of "very high concern" based on its "high potential to cause effects in wildlife and in humans ... due to its very

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<sup>35</sup> See, e.g., Wang, Z., Cousins, I. T., Scheringer, M., & Hungerbuehler, K. (2015). Hazard assessment of fluorinated alternatives to long-chain perfluoroalkyl acids (PFAAs) and their precursors: status quo, ongoing challenges and possible solutions. *Environment international*, 75, 172-179, <https://www.ncbi.nlm.nih.gov/pubmed/25461427>; Kabadi, S. V., Fisher, J., Aungst, J., & Rice, P. (2018). Internal exposure-based pharmacokinetic evaluation of potential for biopersistence of 6: 2 fluorotelomer alcohol (FTOH) and its metabolites. *Food and Chemical Toxicology*, 112, 375-382, <https://www.ncbi.nlm.nih.gov/pubmed/29331735>; Pérez, F., Nadal, M., Navarro-Ortega, A., Fàbrega, F., Domingo, J. L., Barceló, D., & Farré, M. (2013). Accumulation of perfluoroalkyl substances in human tissues. *Environment International*, 59, 354-362, <https://doi.org/10.1016/j.envint.2013.06.004>.

<sup>36</sup> See Sharon Lerner, *EPA Allowed Companies to Make 40 New PFAS Chemicals Despite Serious Risks*, The Intercept (Sept. 19, 2019), <https://theintercept.com/2019/09/19/epa-new-pfas-chemicals/>.

<sup>37</sup> EPA, EPA-823-P-18-001, Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt: Public Comment Draft (Nov. 2018), [https://www.epa.gov/sites/production/files/2018-11/documents/genx\\_public\\_comment\\_draft\\_toxicity\\_assessment\\_nov2018-508.pdf](https://www.epa.gov/sites/production/files/2018-11/documents/genx_public_comment_draft_toxicity_assessment_nov2018-508.pdf).

high persistence, mobility in water, potential for long-range transport, accumulation in plants[,] and observed effects on human health and the environment.”<sup>38</sup> Because EPA approved the GenX PMN without adequate controls, GenX has been detected in the Cape Fear River and in public drinking water wells. Particularly given the lack of testing data on the PMN chemicals, the structural similarities to GenX provide an independent basis to find that they present or may present unreasonable risk.

C. For two of the new chemicals, the limited information provided in the PMN submissions establishes a strong likelihood of unreasonable risk.

In addition to the presumption of risk from PFAS, the limited information available for at least two of the PMN chemicals further precludes a “not likely” finding. The limited health hazard information submitted to EPA for P-19-0138 and P-19-0139, and available on ChemView, raises significant concerns regarding the safety of these substances, as detailed below.

1. *Safety Data Sheets indicate severe hazards.*

The PMN submissions for both substances include heavily-redacted chemical Safety Data Sheets (“SDS”), which indicate the chemicals’ Hazardous Materials Identification System IV (HMIS IV) health rating.<sup>39</sup> The rating system is intended to inform employers and workers about hazards of chemicals in the workplace under normal conditions of use, and covers both acute and chronic health hazards.

- P-19-0138 was rated as a 3 out of 4 on the HMIS IV scale. A HMIS IV health rating of 3 characterizes chemicals “that are likely to cause major injury unless prompt action is taken and/or medical treatment is given. This includes ‘suspect’ or ‘potential’ carcinogens, chemicals that are severely irritating and/or corrosive to the skin, and chemicals that are corrosive to the eye or cause irreversible eye damage.”<sup>40</sup>
- P-19-0139 was rated as a maximum 4 out of 4 on the HMIS IV scale, representing a “severe health hazard.” A HMIS IV rating of 4 characterizes chemicals that “may cause life-threatening, permanent, or major injury from a

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<sup>38</sup> Press Release, Eur. Chems. Agency, MSC Unanimously Agrees that HFPO-DA Is a Substance of Very High Concern (June 27, 2019), <https://echa.europa.eu/fr/-/msc-unanimously-agrees-that-hfpo-da-is-a-substance-of-very-high-concern>.

<sup>39</sup> The Hazardous Materials Identification System (HMIS) is a voluntary hazard rating scheme developed by American Coating Association (ACA) to help employers comply with workplace labeling requirements of the U.S. Occupational Safety and Health Administration's (OSHA) revised Hazard Communication Standard (HCS). See Am. Coatings Ass’n., *HMIS*®, <https://www.paint.org/advocacy/occupational-health-and-safety/hmis/> (last visited Oct. 4, 2019). For convenience, a copy of the HMIS rating system criteria is attached hereto as **Exhibit D**.

<sup>40</sup> See Nat’l Inst. of Env’tl. Health Scis., Hazardous Materials Identification System HMIS, at 3, [https://tools.niehs.nih.gov/wetp/public/Course\\_download2.cfm?trandid=1483](https://tools.niehs.nih.gov/wetp/public/Course_download2.cfm?trandid=1483) (last visited Oct. 4, 2019).

single exposure or repeated exposures. Irreversible injury may result from brief contact. This includes carcinogens, reproductive toxins, and chemicals that are respiratory sensitizers.”<sup>41</sup>

The chemical SDSs also indicate that the National Fire Protection Association 704 health hazard ratings for both chemicals are the highest possible, rated at 4 out of 4.<sup>42</sup> Given the health hazard information contained in the SDS documents, the known persistence, mobility, and bioaccumulative nature of PFAS chemicals, and therefore the fact that some human and/or ecological exposure is reasonably foreseen, EPA cannot make a “not likely” finding for P-19-0138 and P-19-0139.

2. *Safety Data Sheets include acute toxicity warnings based on limited studies.*

The SDS for P-19-0138 indicates that the chemical is “fatal if inhaled,” citing a 4-hour inhalation exposure study from 1974. The acute lethal concentration was estimated to be equivalent to 234.7 ppm, which the study concluded was “considered moderately toxic.”

The SDS for P-19-0139 indicates that the substance is “toxic if swallowed” and “fatal if inhaled.” These findings reference an acute oral toxicity estimate of 167 mg/kg (LD50) based on OECD Test Guideline 401 testing methodology, and an acute inhalation toxicity estimate of 62 ppm (LC50, 4-hour exposure) based on OECD Test Guideline 403 testing methodology. We note that the supporting test data for these estimates were *not included* with the PMN submission for P-19-0139. According to EPA’s “Low-Concern Criteria for Human Health and Environmental Fate and Effects,” an oral LD50 of 167 mg/kg falls within the “**High**” hazard threshold for human health (>50-300 mg/kg acute mammalian toxicity).<sup>43</sup> Because the molecular weight of P-19-0139 is not publicly available, it is not possible to compare the acute inhalation toxicity value with EPA’s human health criteria.

The limited toxicity information on P-19-0138 and P-19-0139 suggests that the chemicals pose potentially significant, and even fatal, adverse health risks. Because ingestion and inhalation are listed as potential routes of exposure on the substances’ SDSs, EPA cannot reasonably make an affirmative “not likely” finding based on this information alone. We also urge EPA to classify the SDS’ acute inhalation toxicity estimates for the two substances by comparing them to the agency’s criteria for acute inhalation toxicity.

D. EPA does not have sufficient data to support a not likely finding.

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<sup>41</sup> *Id.*

<sup>42</sup> The purpose of the NFPA 704 standard is to “address the health, flammability, instability, and related hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies.” See Nat’l Fire Prot. Ass’n, *NFPA 704: Standard System for the Identification of the Hazards of Materials for Emergency Response* (2017), <https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=704>.

<sup>43</sup> *Id.*

1. *The PMN submission lacks test data and information for health endpoints known to be sensitive to PFAS.*

Extensive research has identified human health endpoints that are sensitive to exposure to PFAS chemicals. As described above, ATSDR's 2018 Draft Toxicological Profile for Perfluoroalkyls found associated adverse developmental and reproductive health effects from exposure to nearly all of the fourteen PFAS studied.<sup>44</sup> Animal studies have demonstrated that many PFAS induce hepatotoxicity (showing effects on endpoints such as liver weight and fatty acid  $\beta$ -oxidation activity), immunotoxicity, and cancer.<sup>45</sup> Both short-chain and long-chain PFAS are toxic to the liver, thyroid, and other organs.<sup>46</sup>

The limited test information available for the three PMN chemicals, however, does not address these health effects associated with PFAS exposure. The test data available for P-19-0138 and P-19-0139 appear to only address acute toxicity. The PMN submissions for P-19-0140 only includes one acute toxicity study and one mutagenicity study, with additional ocular irritation and skin sensitization information. Without assessing health data specifically for the well-studied PFAS toxicity endpoints, EPA does not have enough evidence to make an affirmative finding that the PMN PFAS are not likely to present an unreasonable risk.

2. *The submitter for P-19-0139 failed to include acute oral and inhalation toxicity studies with PMN submission.*

Under TSCA section 5, any person submitting a PMN for review is legally obligated to also submit any "information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance... on health or the environment."<sup>47</sup> The premanufacture notice shall include "all existing information concerning the environmental and health effects" of the substance,<sup>48</sup> pursuant to TSCA sections 5(d)(1)(A) and 8(a)(2), "insofar as known to the person submitting the notice or insofar as reasonably ascertainable."<sup>49</sup> EPA's TSCA regulations also state that "each [PMN] must contain all test data in the submitter's possession or control which are related to the effects on health or the environment of any manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance or any mixture or article containing the new chemical substance, or any combination of such activities."<sup>50</sup>

In apparent violation of these requirements, the ChemView file for P-19-0139 contains no health and safety studies, despite the fact that studies of acute oral toxicity and acute

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<sup>44</sup> ATSDR Toxicological Profile at 5–6.

<sup>45</sup> *Id.* at 6–15.

<sup>46</sup> Cheryl Hogue, *Short-Chain and Long-Chain PFAS Show Similar Toxicity, US National Toxicology Program Says*, Chem. & Eng'g News (Aug. 24, 2019), <https://cen.acs.org/environment/persistent-pollutants/Short-chain-long-chain-PFAS/97/i33>.

<sup>47</sup> 15 U.S.C. § 2604(d)(1)(B).

<sup>48</sup> *Id.* § 2607(a)(2)(E).

<sup>49</sup> *Id.* § 2604(d)(1)(A).

<sup>50</sup> 40 C.F.R. § 720.50(a).

inhalation toxicity are referenced in the unredacted portions of the chemical's SDS. Moreover, in the primary PMN form for P-19-0139, the PMN submitter marked that it did not submit any test data regarding environmental fate, health effects, or environmental effects.<sup>51</sup> However, the unredacted portion of P-19-0139's SDS indicates that the substance is "toxic if swallowed" and "fatal if inhaled." **The test information supporting these toxicity estimates appears not to have been submitted along with the PMN notice.** These referenced studies are test data and cannot be withheld as confidential under TSCA section 14.

We note that the acute lethal concentration by inhalation at 62 ppm (LD50) for P-19-0139 is nearly four times lower – and thus more concerning – than that of P-19-0138 (235 ppm), for which the associated inhalation toxicity study is available. EPA cannot make a determination that the chemical is unlikely to pose an unreasonable risk in the absence of these crucial health data. EPA must demand the production of those studies, immediately publish them on ChemView, provide an opportunity for the public to review and comment on them, and withhold a final determination on this PMN until after that comment period is closed.

3. *EPA lacks sufficient data on the PMN chemicals' ecotoxicity.*

EPA has the legal obligation to evaluate whether a new chemical presents an unreasonable risk of injury to the environment, in addition to human health. It cannot do so in absence of ecotoxicity information. The SDSs for both P-19-0138 and P-19-0139 indicate that "toxic effects cannot be excluded" for acute and chronic aquatic toxicity, yet no studies or test data relevant to this statement were submitted for either chemical. There are no data available for persistence, degradability, bioaccumulative potential, or mobility in soil for these two chemicals. For substance P-19-0140, the 48-hour acute toxicity test with *Daphnia* determined that the lowest concentration causing 100% immobility was 10 mg/L. As with the health data, we urge EPA to compare the toxicity estimates against the agency's hazard classification criteria to characterize the extent of hazard.

4. *EPA lacks sufficient data on the PMN chemicals' exposures and releases.*

Based on the publicly available PMN submissions, it does not appear that the submitter provided any studies or supporting data measuring or estimating exposures to or releases of the PMN chemicals. Moreover, all of the descriptions of exposure and releases in the PMN forms themselves are redacted as CBI. Exposure and release information is a critical component of any PMN review, but particularly for chemicals such as PFAS where even small exposures and releases can be persistent in the environment and accumulate in living organisms, resulting in lasting harm. The SDSs for all three chemicals indicate that "likely routes of exposure" include inhalation, skin contact, ingestion, and eye contact. The acute oral toxicity study submitted for P-19-0140 specifically states that the "oral route was selected as it is a possible route of human exposure during manufacture, handling or use of the test item." However, no further information was provided about expected exposure concentrations or release amounts.

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<sup>51</sup> Sanitized PMN for P-19-0139 at 2.

To the extent that release and exposure data are available, they cannot be withheld as CBI, as section 14 of TSCA provides that health and safety studies—a term the statute defines broadly to include, for example “studies of occupational exposure to a chemical substance”—are “not protected from disclosure.”<sup>52</sup> If such information exists but has not been submitted, EPA must demand it.

5. *EPA cannot assume that an identified use as an intermediate results in negligible release or exposure.*

The use identified for each of the PFAS PMN substances is exceedingly generic: “intermediate.” For a number of reasons, use as an intermediate should *not* lead to an assumption of low exposure in the absence of strong evidence.

First, the chemical may remain in downstream reaction products or in the final product as a residual due, for example, to incomplete reactions.<sup>53</sup> These residuals can be present in significant amounts in certain cases and there can be variation in the extent to which they are present over time, in different batches, or among different producers and processors. This variability should also be considered when evaluating potential risk.

In addition, intermediates must still be manufactured as well as typically stored, transferred, or distributed, all of which are activities that can lead to exposures – including to workers, whom TSCA expressly identifies as a “potential exposed or susceptible subpopulation.”

Moreover, even if the primary use of a certain chemical is as an intermediate, there are often other uses of such chemicals, especially if the producer makes them commercially available to other entities. It is therefore reasonably foreseen that these PMN chemicals will have uses other than as an intermediate, likely resulting in greater exposure and harm to health and the environment. It is notable that many PFAS previously approved as “intermediates” –

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<sup>52</sup> 15 U.S.C. §§ 2602(8), 2613(b)(2).

<sup>53</sup> See e.g., Cal. Dep’t of Toxic Substances Control, Safer Consumer Products Regulations – Listing Spray Polyurethane Foam Systems With Unreacted Methylene Diphenyl Diisocyanates as a Priority Product: Initial Statement of Reasons (Mar. 2017), [https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/07/SPF\\_ISOR.pdf](https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/07/SPF_ISOR.pdf); Am. Coatings Ass’n, Comment on the Designation of PV29 for TSCA Risk Evaluation, at 2 (Mar. 15, 2017), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0725-0008>.

including GenX and a by-product of a Nafion intermediate<sup>54</sup> – have since been released and detected in the environment and in human blood.<sup>55</sup>

Finally, while companies often claim that intermediate chemicals are handled exclusively in “closed systems,” this term is often loosely used and needs to be rigorously defined and supported by clear evidence establishing the absence of possible exposures and releases. At a minimum, worker exposures should be assumed barring evidence to the contrary.

6. *EPA must conduct additional testing of the PMN substances pursuant to the Agency’s PBT policy.*

As described above, many PFAS chemicals share persistent, bioaccumulative, and toxic (“PBT”) properties, and PFAS should be presumed to be PBT in the absence of strong evidence to the contrary.<sup>56</sup> As such, the PMN chemicals should also be reviewed under EPA’s PBT Policy, which calls for toxicity testing beyond that provided with the PMN submissions.<sup>57</sup>

EPA developed the PBT Policy in order to “alert[] potential PMN submitters to possible assessment or regulatory issues associated with PBT new chemicals review” and “provide[] a vehicle by which the Agency may gauge the flow of PBT chemical substances through the TSCA New Chemicals Program ...”<sup>58</sup> Of particular relevance is tier 3 of the PBT Policy, which states that: “[h]uman health hazards should be determined in the combined repeated dose oral toxicity with the reproductive/developmental toxicity screening test ...”<sup>59</sup> The PBT policy further states, “tier 3 testing will normally be required” if the “measured biodegradation half-life is > 60 days and measured BCF is > 1,000.”<sup>60</sup>

The PMN chemicals should be subject to tier 3 testing requirements. PFAS substances routinely persist in the environment for years or decades, with environmental half-lives far

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<sup>54</sup> Nafion by-product 2 (CAS 749836-20-2) is a byproduct of Nafion copolymer precursor (CAS 4089-58-1), which is listed on the TSCA Inventory and is reported by Chemours on the 2016 Chemical Data Reporting as an intermediate. Nafion by-product 2 has been detected in the Cape Fear River, and in 99% of tested blood samples of North Carolina residents. *See* Strynar, M., Dagnino, S., McMahan, R., Liang, S., Lindstrom, A., Andersen, E., ... & Ball, C. (2015). Identification of novel perfluoroalkyl ether carboxylic acids (PFECAs) and sulfonic acids (PFESAs) in natural waters using accurate mass time-of-flight mass spectrometry (TOFMS). *Environmental Science & Technology*, 49(19), 11622-11630, <https://pubs.acs.org/doi/abs/10.1021/acs.est.5b01215>; <https://cen.acs.org/environment/persistent-pollutants/hunt-GenX-chemicals-people/97/i14>

<sup>55</sup> Sun, M., Arevalo, E., Strynar, M., Lindstrom, A., Richardson, M., Kearns, B., ... & Knappe, D. R. (2016). Legacy and emerging perfluoroalkyl substances are important drinking water contaminants in the Cape Fear River Watershed of North Carolina. *Environmental Science & Technology letters*, 3(12), 415-419, <https://pubs.acs.org/doi/full/10.1021/acs.estlett.6b00398>.

<sup>56</sup> *See* Point III.A *infra*.

<sup>57</sup> Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances, 64 Fed. Reg. 60,194-02 (Nov. 4, 1999).

<sup>58</sup> *Id.* at 60,196.

<sup>59</sup> *Id.* at 60,203.

<sup>60</sup> *Id.*

longer than two months. According to Dr. Linda Birnbaum, former head of the National Institute of Environmental Health Sciences, “PFAS remain in the environment for so long that scientists are unable to estimate an environmental half-life.”<sup>61</sup> While the PMN submissions do not provide a bioconcentration factor (BCF) or bioaccumulation factor (BAF), PFAS chemicals are known to bioaccumulate in the blood, which traditional BCFs and BAFs do not account for, as they assess accumulation of a chemical in fat tissue. A BCF or BAF is thus a poor measure of the potential bioaccumulation of PFAS chemicals.

Despite their PBT status, the PMN submitters have not provided the testing called for under EPA’s PBT policy. EPA should require such testing and, consistent with the PBT Policy, should also impose a “ban on commercial production until data are submitted which allow the Agency to determine that the level of risk can be appropriately addressed by less restrictive measures.”<sup>62</sup> Past experience demonstrates that once PFAS chemicals enter commerce and are released to the environment, they are often highly toxic, mobile, and difficult to treat or remediate. EPA should thus exercise its TSCA authority and follow its own policy to prohibit production until sufficient data has been submitted to fully evaluate the risks posed by the PMN chemicals.

#### **IV. EPA has unlawfully redacted and withheld information about the PMN chemicals.**

TSCA requires EPA to make PMN submissions and supporting studies publicly available for review and comment. As acknowledged by EPA, “public participation [in the PMN review process] cannot be effective unless meaningful information is made available to interested persons.”<sup>63</sup> For the PMN chemicals, however, EPA has failed to provide the information required by TSCA and EPA’s implementing regulations, leaving the public unable to fully evaluate them.

##### **A. The Federal Register notice does not comply with TSCA’s publication deadlines or notice requirements.**

TSCA mandates that: “not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a [PMN] ..., [EPA] shall publish in the Federal Register a notice which—

- (A) identifies the chemical substance for which notice or information has been received;
- (B) lists the uses of such substance identified in the notice; and
- (C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any information which was

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<sup>61</sup> Kelly Lenox, Nat’l Inst. of Env’tl. Health Scis., *PFAS in the Spotlight Across the Globe*, Env’tl. Factor (Oct. 2018), <https://factor.niehs.nih.gov/2018/10/feature/1-feature-pfas/index.htm>.

<sup>62</sup> 64 Fed. Reg. 60,203.

<sup>63</sup> Premanufacture Notice Requirements and Review Procedures, 48 Fed. Reg. 21,722, 21,737 (May 13, 1983).

developed pursuant to subsection (b) or a rule, order, or consent agreement under [section 4].”<sup>64</sup>

Thus, when a person submits a PMN for a chemical substance pursuant to 15 U.S.C. § 2604(a), EPA “shall” publish notice of receipt of the PMN in the Federal Register within five business days and the notice of receipt “shall...describe[]” certain tests submitted with the PMN.<sup>65</sup> Here EPA should have published the notice of receipt for these PMNs no later than August 5, 2019, but EPA only published those notices on September 5, 2019—a month late.<sup>66</sup>

This lapse in time is significant. EPA is given only 90 days to review new chemical notices; therefore, by the time EPA has published notice of receipt in the Federal Register and the public is given an opportunity to comment, EPA’s evaluation of the chemical substance may well be almost over. The significance of the timing is illustrated well by these three PMNs. According to EPA’s statistics page, all three chemicals are in the *final* risk characterization stage, meaning EPA is about to make its final determination.<sup>67</sup> Compounding the effects of this delay, EPA still has not published sufficient information for the public to adequately review and comment on the PMN chemicals.<sup>68</sup>

In addition, the notices failed to list the test data received with the PMNs, in violation of EPA’s duties under TSCA section 5(d)(2)(C) and 40 C.F.R. § 720.70(b)(3). Specifically, a PMN submitter must include in the PMN “all test data in the submitter’s possession or control” relating to the health and environmental effects of the new chemical.<sup>69</sup> In the notice of receipt for the PMN in the Federal Register, EPA must publish “a list” of all such test data submitted with the PMN.<sup>70</sup> In addition, for information submitted with the PMN pursuant to section 5(b), the notice of receipt must also “describe[] the nature of the tests performed...and any information which was developed.”<sup>71</sup>

When EPA belatedly published the notices of receipt of these three PMNs in the Federal Register,<sup>72</sup> the agency did not publish a list or descriptions of the test data submitted with the PMNs, despite the fact that the PMN must include such test data to the extent it exists.<sup>73</sup> In the absence of such information, the public cannot determine what data EPA has on the PMN substances and what human health or environmental endpoints remain unstudied.

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<sup>64</sup> 15 U.S.C. § 2604(d)(2) (emphasis added).

<sup>65</sup> *Id.* § 2604(d)(2).

<sup>66</sup> See Certain New Chemicals; Receipt and Status Information for July 2019, 84 Fed. Reg. 46,723, 46,730 (Sept. 5, 2019).

<sup>67</sup> EPA, *Active New Chemical Cases in Risk Characterization Stage*, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/active-new-chemical-cases-risk-0> (last visited Oct. 1, 2019).

<sup>68</sup> See Points IV.B-IV.E *infra*.

<sup>69</sup> 40 C.F.R. § 720.50(a) (describing the test data that must be submitted); see also 15 U.S.C. § 2604(d)(1)(B).

<sup>70</sup> 40 C.F.R. § 720.70(b)(3).

<sup>71</sup> 15 U.S.C. § 2604(d)(2)(C).

<sup>72</sup> 84 Fed. Reg. 46,730.

<sup>73</sup> See 40 C.F.R. § 720.50(a) (a PMN “must contain all test data in the submitter’s possession or control”).

B. EPA has not made all of the health and safety studies referenced in the PMN submissions available for public review and comment.

TSCA mandates that a PMN “shall be made available...for examination by interested persons,” subject to limited protections against the release of confidential information under TSCA section 14.<sup>74</sup> To do so, EPA’s implementing regulations require that EPA place “[a]ll information submitted with a [PMN], including any health and safety study and other supporting documentation” in a “public file for that [PMN].”<sup>75</sup> Then, EPA must make the PMN’s public file available online and by request from the EPA Docket Center.<sup>76</sup>

As described above, the PMN submissions for P-19-0139 reference health and safety studies that have not yet been provided to EPA, much less made available in the public file. EPA must demand the submission of those studies, immediately publish them on ChemView, and provide an opportunity for the public to review and comment on them.

Also as discussed above, there are also key human health and environmental endpoints for which EPA lacks adequate data. To review the risks posed by the PMN chemicals, EPA must demand additional testing. When such studies are received, they too must be made available online, with a corresponding opportunity to comment.

C. The PMN public files available on ChemView are overly redacted in violation of TSCA section 14.

Much of the information that EPA has made available on ChemView, including the contents of the PMN forms and the SDS, is redacted as CBI. The redacted material, however, is not limited to CBI or authorized by TSCA. Instead, EPA has unlawfully withheld health and safety data and other information that must be disclosed under TSCA section 14.

1. *The publicly available files on ChemView redact health and safety information in violation of TSCA section 14(b)(2).*

TSCA section 14(b)(2) provides that health and safety information is information that EPA cannot conceal as confidential business information (with two narrow exceptions). In each of these public files, the documents EPA has made publicly available through ChemView redact extensive health and safety information in violation of TSCA section 14(b)(2). Specifically, for each PMN, the PMN indicates that the PMN submission included a lengthy document providing physical and chemical properties, but the public file contains only a single blank page instead of these documents. These physical and chemical property documents have been completely redacted. In addition, for each PMN, the PMN redacts all worker exposure information and the amount of the chemical released to the environment. Both types of data are health and safety information that cannot be concealed.

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<sup>74</sup> 15 U.S.C. § 2604(d) (emphasis added).

<sup>75</sup> 40 C.F.R. § 720.95; *see also id.* § 720.3(kk).

<sup>76</sup> 40 C.F.R. § 700.17(b)(1),(2); *id.* § 720.95.

Health and safety studies, and “any information” contained therein, are generally not confidential and thus not protected from disclosure.<sup>77</sup> Only in two narrowly defined circumstances can discrete information contained within a health and safety study be protected from disclosure. EPA is not authorized to disclose discrete “information” in a health and safety study that discloses: (1) “processes used in the manufacturing or processing of a chemical substance or mixture;” or (2) “in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.”<sup>78</sup>

Nevertheless, EPA has allowed extensive redactions of health and safety information that do not meet the narrow exceptions to the disclosure requirements of TSCA section 14(b)(2). Specifically, EPA allowed the submitters to completely redact their documents on physical chemical properties, and EPA also allowed them to redact worker exposure information and the amount of the chemical released to the environment. All of this information falls within TSCA’s capacious definition of health and safety study as “any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter.”<sup>79</sup> EPA’s own regulations clarify that health and safety studies include “studies of . . . chemical and physical properties,”<sup>80</sup> so there can be no question that the physical and chemical properties reported for these chemicals are health and safety information. Health and safety studies also include “[a]ssessments of human and environmental exposure, including workplace exposure,”<sup>81</sup> and therefore EPA should be disclosing the worker exposure information and information on the amount of the chemical released to the environment.

This denial of information on potential health impacts of the new chemicals also impedes the public’s ability to understand and meaningfully participate in EPA’s decision-making process.<sup>82</sup> Even if EPA did not have a mandatory duty to proactively make these studies available under TSCA sections 5(d)(1) and 14(b)(2) (which it does), the agency is still required to reject such confidentiality claims and disclose the studies under section 14. Under Section 14(f)(2)(B), EPA must review the confidentiality claims supporting the redactions of health and safety studies if EPA “has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section.”<sup>83</sup> As health and safety studies do not

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<sup>77</sup> See 15 U.S.C. § 2613(b)(2) (TSCA’s confidentiality protection “does not prohibit the disclosure of . . . any health and safety study which is submitted under this Act with respect to . . . any chemical substance or mixture . . . for which notification is required under section 2604. . . ; and any information reported to, or otherwise obtained by, [EPA] from a health and safety study.” (emphases added)).

<sup>78</sup> 15 U.S.C. § 2613(b)(2); see also 40 C.F.R. § 720.90(a) (mandating disclosure of health and safety information unless otherwise protected).

<sup>79</sup> 15 U.S.C. § 2602(8) (emphases added).

<sup>80</sup> 40 C.F.R. § 720.3(k),

<sup>81</sup> *Id.*

<sup>82</sup> See e.g. *Am. Radio Relay League, Inc. v. F.C.C.*, 524 F.3d 227, 237 (D.C. Cir. 2008) (“It . . . [is] a fairly obvious proposition that studies upon which an agency relies . . . must be made available . . . in order to afford interested persons meaningful notice and an opportunity for comment.”).

<sup>83</sup> 15 U.S.C. § 2613(f)(2)(B).

qualify for protection under section 14(b)(2), EPA “shall” review and reject these confidentiality claims under Section 14(f)(2)(B). Failure to reject these confidentiality claims also violates Section 14(e)(1)(B)(ii)(II), which mandates that EPA cease protecting information once “the Administrator becomes aware that the information does not qualify for protection from disclosure.”

2. *The redactions of the PMN chemicals’ SDSs violate the requirements of TSCA section 14.*

For each of the PMN chemicals, EPA provides through ChemView a heavily redacted Safety Data Sheet. These redactions violate the requirements of TSCA section 14 because safety data sheets: (1) do not meet the requirements for confidentiality established in Section 14(c)(1)(B); and (2) contain information from health and safety studies that cannot be withheld as confidential.

Pursuant to the Occupational Safety and Health Act, the manufacturer of a new chemical substance must develop a safety data sheet for the chemical if the chemical poses any “physical hazard” or “health hazard.”<sup>84</sup> The safety data sheet must then be widely distributed, going to any “employer,” meaning any person who operates a “business where chemicals are either used, distributed, or are produced for use or distribution, including a contractor or subcontractor.”<sup>85</sup> In turn, these employers must make the safety data sheet readily accessible to all employees and to the employees’ designated representatives, such as a union agent.<sup>86</sup> And the Emergency Planning and Community Right-to-Know Act requires “any facility which is required to prepare or have available a material safety data sheet” to submit those safety data sheets or the hazard information contained within them to the appropriate local emergency planning committee, the State emergency response commission, and the fire department.<sup>87</sup> In turn, that information must be “made available to the general public.”<sup>88</sup>

Given the wide distribution required of safety data sheets, safety data sheets *per se* cannot satisfy the requirements for confidentiality under TSCA. A submitter cannot reasonably claim that it has “taken reasonable measures to protect the confidentiality” of the safety data sheet,<sup>89</sup> given that the safety data sheet must be shared with all companies that use, distribute, or process the chemical, all employees of said companies, and any designated representatives of said employees.<sup>90</sup> Given the breadth of individuals to whom the safety data sheet must be disclosed, the submitter also cannot reasonably certify that the safety data sheet “is not required to be disclosed or otherwise made available to the public under any other Federal law.”<sup>91</sup>

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<sup>84</sup> See 29 C.F.R. §§ 1910.1200(c), (g).

<sup>85</sup> See 29 C.F.R. §§ 1910.1200(c), (g).

<sup>86</sup> *Id.* §§ 1910.1200(g)(8), (11).

<sup>87</sup> 42 U.S.C. § 11021(a).

<sup>88</sup> *Id.* § 11044(a).

<sup>89</sup> 15 U.S.C. § 2613(c)(1)(B)(i).

<sup>90</sup> 29 C.F.R. § 1910.1200(g).

<sup>91</sup> 15 U.S.C. § 2613(c)(1)(B)(ii).

Accordingly, because such information “is required to be made public under [another] provision of Federal law” EPA must disclose it as part of the public file for a PMN.<sup>92</sup>

These safety data sheets also include information from health and safety studies, e.g., physical and chemical property information,<sup>93</sup> which cannot be withheld under 15 U.S.C. § 2613(b)(2), as explained above.

3. *The PMN submissions rely on inapplicable exemptions to CBI substantiation requirements.*

When a PMN submitter withholds information as CBI, TSCA requires the submitter to substantiate the basis for its confidentiality assertion.<sup>94</sup> This substantiation requirement is subject only to limited exceptions in section 14(c)(2).<sup>95</sup> Here, the PMN submissions invoke substantiation exemptions that are not provided in that section, depriving EPA of the information that it needs to review the CBI assertions.

In all three PMNs, information about the chemicals’ impurities and byproducts has been withheld without substantiation. The PMN submissions assert that such information is exempt from substantiation under TSCA section 14(c)(2)(A), which covers “[s]pecific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.”<sup>96</sup> However, a list of impurities and byproducts is not a description of anything; it is merely an identification of other chemicals that may either be present in the PMN chemical or be created during its production. Even if a person could infer some information about the chemicals’ manufacturing or processing from a list of impurities and byproducts, section 14(c)(2)(A) does not exempt all process-related information from substantiation. Instead, that section provides a narrow exemption for descriptions of “the processes used in manufacture or processing of a chemical substance, mixture, or article.”<sup>97</sup> As lists of impurities and byproducts do not fall within the scope of that statutory exemption, EPA must require substantiation for those CBI assertions.

The PMN submissions also assert that any pollution prevention information provided on the PMN is exempt from CBI substantiation as “specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.”<sup>98</sup> This exemption is wholly inapplicable; pollution prevention information is not “specific information regarding the use, function, or application of a chemical substance,” but rather describes “efforts to reduce or minimize potential risks associated with activities surrounding manufacturing,

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<sup>92</sup> *Id.* § 2613(d)(8).

<sup>93</sup> 29 C.F.R. § 1900.1200(g)(2).

<sup>94</sup> 15 U.S.C. § 2613(c)(3).

<sup>95</sup> *Id.* § 2613(c)(2).

<sup>96</sup> *Id.* § 2613(c)(2)(A).

<sup>97</sup> *Id.*

<sup>98</sup> *Id.* § 2613(c)(2)(E).

processing, use and disposal of the PMN.”<sup>99</sup> Regardless of whether the foregoing information may ultimately warrant withholding as CBI, it is not exempt from substantiation under TSCA. EPA must therefore require such substantiation and reject any CBI claims that are inadequately substantiated or unauthorized by TSCA.

**D. EPA failed to make correspondence related to PMNs available for examination by interested persons.**

EPA also has a duty to include in the public files all correspondence related to the PMN. Given EPA’s duty to make every PMN and all supporting documentation, including correspondence, available for public examination, EPA must provide all correspondence related to the PMN in the public file.<sup>100</sup> Yet, the public files included on ChemView do not include any correspondence between the PMN submitter and EPA. Of course, we cannot determine whether any correspondence has taken place between EPA and the submitter because EPA is not publishing the correspondence. Nonetheless, there is almost certainly correspondence for these PMNs, because these PMNs are now at the risk characterization stage of the PMN process,<sup>101</sup> meaning that EPA has already sent the submitter its interim decision and the submitter has likely responded.

**V. EPA must regulate all three PMN chemicals to protect against unreasonable risk to public health and the environment.**

Based on the information presented above, EPA should find that the three PFAS PMNs “present an unreasonable risk,” triggering EPA’s regulatory obligations under TSCA section 5(f).<sup>102</sup> This provision requires EPA to “take . . . action . . . to the extent necessary to protect against [unreasonable] risk.”<sup>103</sup> Using its Section 5(f) authority, EPA should issue an order to prohibit the manufacture, processing, and distribution of the three PFAS PMNs because no other restriction would avert unreasonable risk.<sup>104</sup>

At a minimum, because EPA cannot make the “not likely to present an unreasonable risk of injury” finding with respect to any of the three PFAS PMNs, these substances cannot enter commerce without restrictions under section 5(e) that “prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or . . . any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to

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<sup>99</sup> EPA, Form 7710-25 (Rev. 6-09), Premanufacture Notice for New Chemical Substances, at 16, <https://www.epa.gov/sites/production/files/2018-07/documents/pmnviewonly11-30-18.pdf> (last visited Oct. 4, 2019).

<sup>100</sup> See 40 C.F.R. § 720.40(d)(1); *id.* § 720.95; *id.* § 720.3(kk) (“Support documents means material and information submitted to EPA in support of a TSCA section 5 notice, including but not limited to, correspondence . . . .” (emphasis added)).

<sup>101</sup> See EPA, *Active New Chemical Cases in Risk Characterization Stage*, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/active-new-chemical-cases-risk-0> (last visited Oct. 1, 2019).

<sup>102</sup> See Point III *supra*.

<sup>103</sup> 15 U.S.C. § 2604(f)(1).

<sup>104</sup> *Id.* § 2604(f)(3)(A).

health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use.”<sup>105</sup>

If EPA issues a 5(e) order on the ground that it lacks information sufficient to permit a reasoned evaluation of the health and environmental effects of the three PMN chemicals, or “in the absence of sufficient information to make such an evaluation” the substances “may present” unreasonable risk, it must order that a full array of tests be conducted, covering acute, chronic and subchronic toxicity and ecotoxicity. This includes, but is not limited to, tests for carcinogenicity, reproductive/developmental effects, immunotoxicity, metabolism, pharmacokinetics, and fate, transport, persistence and biodegradation.

To prevent unreasonable risk of injury, the results of this testing must be submitted to EPA, and analyzed by EPA up front, *before* EPA makes a final decision on whether the chemicals may enter commerce and, if so, on what terms. For many new PFAS chemicals that have already entered commerce under a section 5(e) order since 2002,<sup>106</sup> EPA has specified the need for certain testing, but not required the testing to be conducted unless and until the chemical is produced over a certain volume. That “trigger volume” is almost always withheld by EPA as CBI (so the public cannot ascertain compliance). This approach would not be permissible for any of the three PMN chemicals both because they are PFAS, and based on what is known about their hazard profile. In sum, EPA cannot comport with the mandate of section 5(e)—to “prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance ...to the extent necessary to protect against an unreasonable risk of injury”—if it allows manufacture, processing, or use prior to additional testing and review of the test results.

To protect against human and environmental exposure, any Section 5(e) order or Section 5(f) order or rule must provide that if any of these three PMN chemicals enters commerce, the PMN submitter must “capture,” “recover” or “destroy” at least 99.99999 percent of any and all releases (including surface water discharges, wastewater effluent and air emissions). Given the persistence and mobility of these substances, as well as their toxicity and bioaccumulative qualities, this type of limit is necessary to protect against unreasonable risk.

In addition, in any Section 5 order or rule, EPA must include language that protects against PFAS contamination resulting from disposal—requiring that any method of disposal result in complete destruction of the PFAS (to 99.99999 percent) or permanent containment.

Moreover, if EPA issues any orders or rules under TSCA sections 5(e) or (f), it should ensure that they are free from the loopholes and exceptions that have made prior TSCA consent

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<sup>105</sup> *Id.* § 2604(e)(1)(A).

<sup>106</sup> *See, e.g.*, Consent Order for P-06-0388, -0389, and -0390, Perfluoroalkyl ethyl methacrylate copolymers (July 3, 2006), [https://chemview.epa.gov/chemview/proxy?filename=sanitized\\_consent\\_order\\_p\\_06\\_0388c.pdf](https://chemview.epa.gov/chemview/proxy?filename=sanitized_consent_order_p_06_0388c.pdf); TSCA Section 5 Order for P-11-0543, Polyfluorinated alkyl quaternary ammonium chloride (Oct. 30, 2014), <https://chemview.epa.gov/chemview/chemicaldata.do?sourceId=16&chemicalDataId=37162552&chemicalId=15641358>.

orders for PFAS ineffective.<sup>107</sup> Thus, for example, any restrictions on releases and disposal must apply to these substances whether they are manufactured or processed intentionally or are present as byproducts. In addition, any restrictions must apply irrespective of whether the chemical is part of an article, or not, and irrespective of whether its primary intended use is as an intermediate or in an enclosed system. Any orders or rules under TSCA sections 5(e) or (f) should require the manufacturer to develop and provide EPA with an analytical standard for the substance, so that EPA and other regulators can test to determine whether it is getting into water bodies or drinking water as a result of manufacturing, processing, distribution, use, or disposal.

If EPA issues any Section 5(e) or 5(f) order that allows some commercial use with restrictions, that order must take into account that personal protective equipment is not sufficient to protect workers from health effects that are known to be associated with even low exposures to PFAS. As a result, EPA should require implementation of a hierarchy of controls approach in any workplaces where the three PMN chemicals are manufactured or processed, so that appropriate engineering and administrative controls are used as a first resort for worker protection, similar to the requirements in OSHA standards at 29 C.F.R. § 1910.134(a)(1) and guidance in Appendix B to subpart I of 29 C.F.R. § 1910.<sup>108</sup> Alternatively, EPA must include provisions in any Section 5(e) or (f) order or rule specifying what protections are needed to ensure that workers exposed to these PMN substances do not face unreasonable risk, including the precise level of PPE that is required to protect workers. Moreover, EPA should specify that the substances can only be used in a fully enclosed environment.

Finally, after any 5(e) or 5(f) order or rule issues, EPA must promptly issue a Significant New Use Rule (“SNUR”) to ensure that the protections apply to potential manufacturers, processors and users in addition to the PMN submitters.<sup>109</sup> Such a SNUR should include all of the protections against unreasonable risk that apply to the PMN submitter, including making it a significant new use not to implement a hierarchy of controls to protect workers.

Thank you for your consideration.

Submitted by:

Earthjustice

Alaska Community Action on Toxics  
Buxmont Coalition for Safer Water  
Clean Cape Fear

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<sup>107</sup> See, e.g., Vaughn Hagerty, *Regulators Prepare Crackdown on Air and Water Emissions of GenX*, N.C. Health News (Oct. 8, 2018) (noting that GenX chemical discharged into river was a byproduct and the restrictions in the TSCA consent order included an exception for byproducts), <https://www.northcarolinahealthnews.org/2018/10/08/regulators-prepare-crackdown-dupont-chemours-genx/>

<sup>108</sup> See Significant New Uses of Chemical Substances; Updates to the Hazard Communication Program and Regulatory Framework; Minor Amendments to Reporting Requirements for Premanufacture Notices, 81 Fed. Reg. 49,598 (July 28, 2016).

<sup>109</sup> Cf. 15 U.S.C. § 2604(f)(4).

Environmental Defense Fund  
Environmental Health Strategy Center  
Environmental Justice Task Force – Tucson  
Environmental Working Group  
GreenCAPE  
Merrimack Citizens for Clean Water  
National PFAS Contamination Coalition  
Natural Resources Defense Council  
Newburgh Clean Water Project  
PFOAProjectNY  
Sierra Club  
Testing for Pease  
Toxics Action Center  
Waterkeeper Alliance  
Westfield Residents Advocating For Themselves  
Whidbey Water Keepers  
Your Turnout Gear and PFOA