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September 27, 2021

Administrator Michael Regan
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, N.W.
Washington, DC 20460-0001

Re: Docket Nos. EPA-HQ-OPPT-2020-0549, EPA-HQ-OW-2018-0594; Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, and Drinking Water Contaminant Candidate List 5-Draft

Dear Administrator Regan,

The undersigned are scientists with expertise in per- and polyfluoroalkyl substances ("PFAS") chemistry and toxicity. We are dedicated to better understanding the use and impacts of PFAS and deriving solutions to reduce serious adverse human and environmental health outcomes as a result of PFAS exposure.

We submit these comments in response to two recent actions proposed by the United States Environmental Protection Agency ("EPA" or the "Agency"): (1) a proposed rule under section 8(a)(7) of the Toxic Substances Control Act ("TSCA"),[1] which would require reporting and recordkeeping for PFAS chemicals manufactured in (including imported into) the United States since 2011, and (2) a listing of PFAS on the Safe Drinking Water Act ("SDWA") Draft Contaminant Candidate List 5 ("Draft CCL 5"), which is the first step in the screening and evaluation of chemicals that may warrant future regulation under the SDWA.[2] We support EPA's efforts to acquire detailed information on PFAS and its initial steps toward greater regulation of PFAS in drinking water.

One of the strengths of both proposals is that they apply a class-based approach to addressing PFAS. However, in both proposed agency actions, EPA employs a "working definition"[3] of PFAS that is inconsistent with the commonly accepted definition recently adopted by the Organisation for Economic Co-operation and Development ("OECD")[4] and used in most

[1] TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33,926 (proposed June 28, 2021) (to be codified at 40 C.F.R. pt. 705).
[2] Drinking Water Contaminant Candidate List 5 – Draft, 86 Fed. Reg. 37,948 (proposed July 19, 2021) (to be codified at 40 C.F.R. pt. 141).
[3] TSCA Section 8(a) Reporting, 86 Fed Reg. at 33,929; Drinking Water Contaminant Candidate List 5, 86 Fed. Reg. at 37,962.
[4] OECD. (2021). *Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance*.

U.S. legislation. This overly narrow definition would exclude many PFAS of known concern, undercutting the benefits of the Agency's actions.[5] For the reasons set forth below, we urge EPA to instead use the PFAS definition recently adopted by the OECD ("OECD definition"), which is scientifically sound and consistent with definitions that have been included in federal and state laws regulating PFAS.

I. EPA's Definition of PFAS in the Proposed TSCA Section 8(a)(7) Rule and SDWA Draft CCL 5 Does Not Include All PFAS.

PFAS as a class pose dangers to human and environmental health. Due to the presence of the highly stable, fully fluorinated carbon moieties, PFAS are either extremely resistant to environmental degradation—or transform into other highly persistent PFAS. Studies have shown that some PFAS take thousands of years to fully degrade. Their highly persistent nature further enables PFAS to accumulate in the environment, including in water, sediment, soil, and plants.[6] Multiple lines of scientific evidence suggest that many PFAS can contribute to a wide range of adverse health outcomes, including cancer, endocrine disruption, reproductive harm, and immunosuppression.[7]

Due to these shared characteristics, many of us co-authored a scientific review of the studied human and environmental health harms posed by PFAS in which we recommend wide adoption of a "class-based approach to managing the human and environmental risks associated with all PFAS, including polymers."[8] When regulatory agencies use a class-based approach to regulate and/or gather data on PFAS, they should use a consistent and comprehensive definition of PFAS to ensure that they gather information on all PFAS and avoid missing key data on unknown or newer PFAS, as well as PFAS breakdown- or by-products. EPA's PFAS definition used in both the TSCA section 8(a)(7) proposed rule and the proposed SDWA Draft CCL 5 listing, copied below, is scientifically unsupported, does not include all PFAS, and denies the Agency critical information about PFAS:

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https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf.

[5] Working definition from both TSCA and SDWA proposed agency actions: "[T]he structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R") can be hydrogen." TSCA Section 8(a) Reporting, 86 Fed Reg. at 33,929; Drinking Water Contaminant Candidate List 5, 86 Fed. Reg. at 37,962.

[6] Kwiatkowski, C. F., Andrews, D. Q., Birnbaum, L. S., Bruton, T. A., DeWitt, J. C., Knappe, D. R. U., Maffini, M. V., Miller, M. F., Pelch, K. E., Reade, A. Soehl, A., Trier, X., Venier, M., Wagner, C. C., Wang, Z., & Blum, A. (2020). Scientific Basis for Managing PFAS as a Chemical Class. *Environmental Science & Technology Letters, 7*(8), 523–543. https://doi.org/10.1021/acs.estlett.0c00255.

[7] Pelch, K. E., Reade, A., Kwiatkowski, C., Schultz, K., Varshavsky, J., Cavalier, H., Merced-Nieves, F., & Wolffe, T. (2021, June 7). *PFAS Health Database: A Systematic Evidence Map.* OSF. Retrieved September 15, 2021, from https://osf.io/f9upx/; Kwiatkowski et al., *supra* note 6.

[8] Kwiatkowski et al., *supra* note 6, at 537.

> **[T]he structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R''. Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen.[9]**

EPA did not identify any scientific support for this definition in the TSCA section 8(a)(7) proposed rule, and the only support cited in the proposed SDWA Draft CCL 5 listing was a cite back to the TSCA section 8(a)(7) proposed rule.

It is particularly concerning that EPA's definition excludes many high production volume PFAS due to its unduly narrow requirement for the presence of at least two *adjacent* fluorinated carbons. For example, polyvinylidene fluoride ("PVDF"), a fluoropolymer that EPA has previously identified as a PFAS[10] and that is widely used to line plastic shipping containers,[11] does not meet EPA's definition due to its alternating fully fluorinated carbon structure.

EPA's definition also excludes other high production volume fluorinated chemicals, such as many hydrofluorocarbon ("HFC") and hydrofluoroolefin ("HFO") refrigerant compounds, even though they have been categorized as PFAS by at least five European countries.[12] This concern is compounded by the fact that the exclusion of HFCs and HFOs from the definition makes it harder (if not impossible) to track their environmental breakdown products, particularly those that are PFAS themselves and also fall outside of the definition. For example, trifluoroacetic acid ("TFA") is a common HFC and HFO degradation product that poses risk to human and ecological receptors[13] and has been widely recognized as a PFAS by the California Department of Toxic

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[9] TSCA Section 8(a) Reporting, 86 Fed Reg. at 33,929; Drinking Water Contaminant Candidate List 5, 86 Fed. Reg. at 37,962.

[10] EPA. (2018, June 1). *EPA Activities on Per- and Polyfluoroalkyl Substances (PFAS)* [PowerPoint slides]. https://yosemite.epa.gov/sab/sabproduct.nsf/708FDD305E55DC7E8525829C005F9EB4/$File/PFAS+Presentation+SAB.pdf; Phelps, L.P. (2020, August 4). *Understanding Per- and Polyfluoroalkyl Substances (PFAS) in Air* [PowerPoint slides]. EPA. https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=541095&Lab=CEMM.

[11] Currently, PVDF is not reportable under the Toxics Release Inventory under the Emergency Planning and Community Right-to-Know Act.

[12] European Chemicals Agency. (n.d.). *Registry of restriction intentions until outcome.* Retrieved September 15, 2021, from https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b.

[13] Several of us have co-authored a rebuttal to industry comments in which we highlighted health concerns posed by TFA, and we refer readers to that rebuttal for the details of these concerns: Kwiatkowski, C. F., Andrews, D. Q., Birnbaum, L. S., Bruton, T. A., DeWitt, J. C., Knappe, D. R. U., Maffini, M. V., Miller, M. F., Pelch, K. E., Reade, A. Soehl, A., Trier, X., Venier, M., Wagner, C. C., Wang, Z., & Blum, A. (2021). Response to "Comment on Scientific Basis for Managing PFAS as a Chemical Class". *Environmental Science & Technology Letters 8*(2), 195–197. https://doi.org/10.1021/acs.estlett.1c00049.

Substances Control and others,[14] but it falls outside of EPA's definition because it only possesses one fully fluorinated carbon. Like other PFAS, TFA is highly persistent and mobile in the environment, and has also been linked to adverse health outcomes like skin and eye damage and harm to aquatic life.[15] Without accurate and robust reporting and recordkeeping of HFCs and HFOs, accurate environmental tracking of PFAS breakdown products like TFA is not possible.

In addition, EPA's overly narrow definition creates opportunity and incentive for the chemical industry to evade future regulatory requirements by manufacturing chemicals that possess the characteristics associated with PFAS but fall outside of EPA's narrow definition. DuPont, one of the leading manufacturers of PFAS in the United States, has been studying such compounds for nearly a decade.[16] The chemical industry has a long history of tweaking PFAS chemistry to evade regulation, including the recent manufacturing shift from long-chain PFAS (like PFOA[17] and PFOS[18]) to shorter-chain "replacement" PFAS that were erroneously assumed to be less problematic and now pose widespread environmental contamination issues, threatening human and ecological health.[19]

II. EPA Should Adopt the OECD Definition of PFAS and Use this Definition in All EPA Rulemakings.

Rather than use the PFAS definition in the proposed TSCA and SDWA actions, we recommend that EPA adopt the PFAS definition recently published by OECD, in which PFAS are defined as**:**

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[14] Safer Consumer Products, Department of Toxic Substances Control, & California Environmental Protection Agency. (2019). *Product – Chemical Profile for Treatments Containing Perfluoroalkyl and Polyfluoroalkyl Substances for Use on Converted Textiles or Leathers.* https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/11/Product-Chemical-Profile-for-Treatments-with-PFASs.pdf.

[15] Kwiatkowski et al., *supra* note 13.

[16] Peng, S., & Hung, M. (2012). Fluorinated sulfonate surfactants. *Journal of Fluorine Chemistry 133*, 77–85. https://doi.org/10.1016/j.jfluchem.2011.10.007; Coope, T., Moloy, K., Yake, A., Petrov, V., Taylor, C., Hung, M., & Peng, S. (2014). Fluorinated sulfamido amphoteric surfactants. *Journal of Fluorine Chemistry 161*, 41–50. https://doi.org/10.1016/j.jfluchem.2014.01.022.

[17] PFOA is an abbreviation for perfluorooctanoic acid.

[18] PFOS is an abbreviation for perfluorooctanesulfonic acid.

[19] Sun, M., Arevalo, E., Strynar, M., Lindstrom, A., Richardson, M., Kearns, B., Pickett, A., Smith, C., & Knappe, D. R. U. (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://doi.org/10.1021/acs.estlett.6b00398; Zhang, X., Lohmann, R., Dassuncao, C., Hu, X. C., Weber, A. K., Vecitis, C. D., & Sunderland, E. M. (2016). Source Attribution of Poly- and Perfluoroalkyl Substances (PFASs) in Surface Waters from Rhode Island and the New York Metropolitan Area. *Environmental Science & Technology Letters 3*(9), 316–321. https://doi.org/10.1021/acs.estlett.6b00255.

fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it).[20]

As stated in the report supporting this definition, "the intention of the revision of the PFAS definition is not to expand the PFAS universe, but to comprehensively reflect it. More concretely, the rationale behind the revision is to have a general PFAS definition that is coherent and consistent across compounds from the chemical structure point of view and is easily implementable for distinguishing between PFASs and non-PFASs, also by non-experts."[21] The OECD definition is scientifically sound and comprehensive; indeed, EPA scientists were members of the OECD group that prepared this definition.[22]

The OECD definition offers several benefits over the EPA definition, as detailed below.

First, the OECD definition covers all fluorinated chemicals that share common characteristics of PFAS, including persistence in the environment. Applying this definition across all EPA rulemakings in a uniform and consistent manner will help to avoid confusion about which chemicals are considered PFAS, and it will eliminate potential loopholes that incentivize the production of chemicals that fall outside of regulatory definitions but that still possess physicochemical characteristics of PFAS and behave like PFAS in the environment.

Second, using the broader OECD definition in the context of regulations that require submission of information will expand the data EPA receives about use of, and exposures to, PFAS in the United States. EPA's Comptox Database now indicates that there are over 9,000 PFAS,[23] and only 175 of these are subject to recordkeeping and reporting requirements under the Toxics Release Inventory;[24] PVDF and HFCs are not among the 175 PFAS subject to these reporting requirements. Adopting OECD's PFAS definition in both the TSCA and SDWA proposed agency actions would enable information gathering for PFAS (like PVDF and HFCs) that currently fall through regulatory cracks and could pose widespread exposure risks to humans.

Third, several federal and state laws have already employed definitions of PFAS that are consistent with the OECD definition. For example, the National Defense Authorization Act for Fiscal Year 2020 defined PFAS as "perfluoroalkyl and polyfluoroalkyl substances that are man-made chemicals with at least one fully fluorinated carbon atom."[25] Since 2019, eight states have passed laws using similar, broad definitions of PFAS that are consistent with OECD's, including

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[20] OECD, *supra* note 4, at 23.
[21] *Id.* at 23.
[22] *Id.* at 5.
[23] EPA. (n.d.). *PFAS Master List of PFAS Substances (Version 2).* Retrieved September 15, 2021, from https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster.
[24] EPA. (2021). *Chemicals Added to the Toxics Release Inventory Pursuant to Section 7321 of the National Defense Authorization Act.* https://www.epa.gov/sites/default/files/2021-01/documents/tri_non-cbi_pfas_list_1_8_2021_final.pdf.
[25] National Defense Authorization Act for Fiscal Year 2020, Pub. L. No. 116-92, § 332(c)(3), 133 Stat. 1198, 1314 (2019).

California,[26] Colorado,[27] Maine,[28] Vermont,[29] and Washington.[30] It would create needless confusion if EPA's new regulatory actions adopted different definitions of PFAS than those already in place in federal and state laws.

III. Conclusion

For the reasons set forth above, EPA should apply the OECD definition in all PFAS-related actions the Agency takes across programs, including in the proposed agency actions under TSCA and SDWA discussed here. The TSCA section 8(a)(7) proposed rule presents an important opportunity for EPA to obtain much-needed information about all PFAS in commerce in the United States over the last decade. And the SDWA Draft CCL 5 listing is a critical first step toward regulating PFAS in drinking water. For these actions to be as consequential as possible, we strongly urge EPA to consistently use a definition of PFAS that is comprehensive and scientifically sound, such as the OECD definition. If EPA finalizes the TSCA section 8(a)(7) rule with the narrower definition it proposed, it will deny the Agency—and the public—much-needed information about PFAS, and it will create inconsistencies with federal and state laws that are already in place. Moreover, a narrower definition of PFAS in the SDWA Draft CCL 5 listing will limit EPA's ability to adopt primary drinking water regulations for PFAS in the future, undermining the Agency's promise of ensuring safe drinking water for all. Accordingly, we urge EPA to adopt the scientifically supported OECD definition of PFAS in all of its rulemakings pertaining to PFAS across programs.

If you have any questions about these comments, please contact Rashmi Joglekar, Earthjustice, at rjoglekar@earthjustice.org.

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[26] S. 1044, 2019 Leg., Reg. Sess. (Cal. 2020).
[27] H.R. 19-1279, 72nd Gen. Assemb., Reg. Sess. (Colo. 2019).
[28] H.R. 1043, 129th Leg., Reg. Sess. (Me. 2019).
[29] S. 20, 2021 Gen. Assemb., Reg. Sess. (Vt. 2021).
[30] S. 5135, 66th Leg., Reg. Sess. (Wash. 2019).

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