Comment from the Environmental Working Group on

"Announcement of Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List"

Docket ID: EPA-HQ-OW-2019-0583

For too long, the Environmental Protection Agency has ignored the risks of per- and polyfluoroalkyl substances (PFAS). For decades, chemical manufacturers, chemical users and product manufactures as well as the Department of Defense have been able to discharge PFAS chemicals with impunity, contaminating the air, water, and soil – and by extension our food and drinking water. PFAS chemicals are "forever chemicals"[1] that never break down in the environment and can linger for decades in the human body, where they are known and suspected to cause a host of human health harms. Despite the widely recognized health risks from PFAS chemical exposure, they remain virtually unregulated under nearly every environmental statute.

This must change. Although there are many things that the EPA must do to address the PFAS crisis, finalizing a regulatory determination under the Safe Drinking Water Act (SDWA) and setting a health-protective drinking water limit would be important first steps toward reducing Americans' exposure through drinking water.

The PFAS Action Plan states that "the EPA will make a final determination for PFOA and PFOS, and as appropriate, other PFAS and take the appropriate next regulatory steps under the SDWA."[2] The EPA must fulfill that commitment and act quickly to finalize the regulatory determination and begin the next regulatory steps under the SDWA. However, to adequately protect Americans from PFAS in drinking water, EPA must broaden the finalized regulatory determination beyond PFOA and PFOS. The best approach would be to regulate PFAS as a class, as it has done for haloacetic acids, polychlorinated biphenyls (PCBs), total trihalomethanes (TTHM), and total coliform bacteria. As a transition toward using a class approach, the EPA should consider regulating groups of PFAS compounds.[3] At a minimum, the EPA should include in the regulatory determination all PFAS chemicals that have toxicity values established by any federal or state government agency; PFAS chemicals with final or proposed regulations by the states; and PFAS chemicals commonly found at military bases. Any national primary drinking water standard set by the EPA should protect vulnerable and disadvantaged populations. To be truly health protective, a Maximum Contaminant Level (MCL) of one part per trillion, or ppt, for total PFAS is appropriate.

[1] Joseph G. Allen, *These Toxic Chemicals are Everywhere – Even in Your Body. And They Won't Ever Go Away*, Wash. Post (Jan. 2, 2018), https://www.washingtonpost.com/opinions/these-toxic-chemicals-are-everywhere-and-they-wont-ever-go-away/2018/01/02/82e7e48a-e4ee-11e7-a65d-1ac0fd7f097e_story.html
[2] Envtl. Prot. Agency, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* 23 (Feb. 2019), www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.
[3] Ian T. Cousins et al., *Strategies for Grouping Per- and Polyfluoroalkyl Substances (PFAS) to Protect Human and Environmental Health*, 22 Envtl. Sci: Processes & Impacts, advance article (June 04, 2020), https://pubs.rsc.org/en/content/articlelanding/2020/EM/D0EM00147C#!divAbstract.

Action under the Safe Drinking Water Act is long overdue

The EPA has been aware of the risks from PFAS since at least 1998, when 3M alerted it that PFOS build up in blood[4] and the agency began an audit of 3M studies.[5] In 2001, private attorney Rob Bilott provided the EPA with a trove of documents obtained through legal discovery documenting the risks from PFOA.[6] The same year, the EPA warned the Department of Defense about risks from PFAS in aqueous film-forming foam, or AFFF, but failed to take any regulatory action within its own jurisdiction.[7] The EPA understood the risks well enough to broker a voluntary agreement with eight companies to phase out the use of PFOA in 2006[8] but failed nonetheless to take regulatory action. The EPA has still not finalized the significant new use rule intended to formalize this phaseout, and comments on the EPA's most recent proposal indicate some of those long-chain PFAS are still being used.[9] PFOA and PFOS have been on the SDWA candidate chemical list since 2009. Since then, the EPA has released two PFAS action plans[10] and two health advisories for PFOA and PFOS,[11] and conducted monitoring for six PFAS chemicals under the Unregulated Contaminant Monitoring Rule 3. And yet, remarkably, there are no federal enforceable limits on how much PFAS can be present in drinking water.

PFOA, PFOS, and other PFAS chemicals meet the statutory criteria for a positive regulatory determination under the Safe Drinking Water Act

Section 1412(b)(1)(A) of the SDWA creates a three-part test for a determination to regulate a contaminant in drinking water. Under that test, EPA should make a positive determination when:

(a) the contaminant may have an adverse effect on the health of persons;
(b) the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

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[4] Letter from 3M to Envtl. Prot. Agency, Re: TSCA Section 8(e) – Perfluorooctane Sulfonate – Docket Numbers 8EHQ-1180-374; 8EHQ-0381-0394 (May 16, 1998), https://static.ewg.org/reports/2020/pfas-epa-timeline/1998_3M-Alerts-EPA.pdf?_ga=2.244955904.447577099.1591500990-1525964376.1554386940.

[5] Letter from Kathy M. Clark, Envtl. Prot. Agency Office of Enforcement and Compliance Assurance, to Julia Hatcher, Attorney, Latham &Watkins (Oct. 9, 2001), https://static.ewg.org/reports/2020/pfas-epa-timeline/2001_EPA-3M-AuditResponse.pdf?_ga=2.244955904.447577099.1591500990-1525964376.1554386940.

[6] Memorandum from Granta Y. Nakayam, Assistant Administrator, EPA Office of Enforcement and Compliance Assurance, to the Envtl. Appeals Bd. (Dec. 14, 2005), https://static.ewg.org/reports/2020/pfas-epa-timeline/2001_Bilott-Submits-to-EPA.pdf?_ga=2.54747054.447577099.1591500990-1525964376.1554386940.

[7] Presentation of Mary F. Dominiak, *EPA Activities/Issues on Fluorosurfactants*, DOD AFFF Workshop (March 16, 2001), https://www.documentcloud.org/documents/4358461-2001-EPA-DoD-Meeting-on-AFFF.html

[8] Envtl. Prot. Agency, Fact Sheet: 2010/2015 PFOA Stewardship Program, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/fact-sheet-20102015-pfoa-stewardship-program (last accessed June 09, 2020).

[9] Pat Rizzuto, *Older PFAS That EPA Thought Obsolete Still Used, Agency Told*, Bloomberg Law (April 30, 2020), https://news.bloomberglaw.com/environment-and-energy/older-pfas-that-epa-thought-obsolete-still-used-agency-told.

[10] Envtl. Prot. Agency, Long-Chain Perfluorinated Chemicals (PFCs) Action Plan (Dec. 30, 2009), https://www.epa.gov/sites/production/files/2016-01/documents/pfcs_action_plan1230_09.pdf; Envtl. Prot. Agency, PFAS Action Plan (Feb. 14, 2019), https://www.epa.gov/pfas/epas-pfas-action-plan.

[11] Envtl. Prot. Agency, Drinking Water Health Advisories for PFOA and PFOS, https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos.

(c) in the sole judgment of the administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems. [12]

PFOA, PFOS, and other PFAS chemicals currently meet all three of these criteria, and the list of applicable compounds may lengthen with increased monitoring.

Statutory Criterion 1: PFAS chemicals have adverse effects on the human health system.

PFOA and PFOS meet this statutory criterion

EWG supports the EPA's finding that PFOA and PFOS have adverse health effects on the human health system.[13] PFAS chemical are associated with serious health harms, even at very low doses.[14] PFOA and PFOS are the PFAS chemicals with the most well-established health risks. One of the largest epidemiological studies in history[15] found probable links between PFOA and six diseases: kidney and testicular cancer, ulcerative colitis, preeclampsia, thyroid disease and high cholesterol. PFOS exposure is also associated with toxicity to the liver, thyroid, heart, lung, and kidneys.[16] Other significant health effects associated with PFOA and PFOS exposure include reproductive and developmental harms[17] and reduced effectiveness of vaccines.[18]

The EPA's analysis relies largely on the summary of the adverse health effects provided in the 2016 lifetime health advisory health effects support documents for PFOA and PFOS. EPA also uses 0.07 µg/L (70 ppt) as a health reference level (HRL) for the regulatory determination, based on the 2016 lifetime health advisory (LHA).[19] EPA should use a lower HRL for the final regulatory determination. The 2016 LHA failed to give enough weight to human evidence of

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[12] 42 U.S.C. §300g-1(b)(1)(A).

[13] 85 Fed. Reg. 14115.

[14] Impacts to mammary gland development have been associated with low-level doses of PFOA. *See, e.g.*, Deirdre K. Tucker et al., *The Mammary Gland is a Sensitive Pubertal Target in CD-1 and C57Bl/6 Mice Following Perinatal Perfluorooctanoic Acid (PFOA) Exposure*, 54 Reprod. Toxicology 26 (2015), https://www.ncbi.nlm.nih.gov/pubmed/25499722; Madisa B. Macon et al., *Prenatal Perfluoroocyanoic Acid Exposure in CD-1 Mice: Low Dose Developmental Effects and Internal Dosimetry*, 122 Toxicological Sci. 131 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3143465/; and Sally S. White et al., *Gestational and Chronic Low-Dose PFOA Exposures and Mammary Gland Growth and Differentiation in Three Generations of CD-1 mice*, 119 Envtl. Health Perspectives 1070 (2011), https://www.ncbi.nlm.nih.gov/pubmed/21501981. PFOA, PFOS, PFHxS, and PFDeA are also associated with reduced effectiveness of vaccines, even at low doses. *See* Anna Reade, Tracy Quinn, & Judith S. Schreiber, *Scientific & Policy Assessment for Per- and Polyfluoroalkyl Substances in Drinking Water*, Natural Resources Defense Council (April 12, 2019), https://www.nrdc.org/sites/default/files/media-uploads/nrdc_pfas_report.pdf.

[15] C8 Sci. Panel, *C8 Probable Link Reports*, http://www.c8sciencepanel.org/prob_link.html (last visited June 09, 2020).

[16] Zhuotong Zeng et al., *Assessing the Human Health Risks of Perfluorooctane Sulfonate by In Vivo and In Vitro Studies*, 126 Envtl. Int'l 598 (2019), https://www.sciencedirect.com/science/article/pii/S0160412018331507.

[17] Alexis Temkin, *PFAS and Developmental and Reproductive Toxicity: An EWG Fact Sheet*, Envtl. Working Grp. (Sept. 19, 2019), https://www.ewg.org/news-and-analysis/2019/09/pfas-and-developmental-and-reproductive-toxicity-ewg-fact-sheet.

[18] Tasha Stoiber, *PFAS Chemicals Harm the Immune System, Decrease Response to Vaccines, New EWG Review Finds*, Envtl. Working Grp. (June 21, 2019), https://www.ewg.org/news-and-analysis/2019/06/pfas-chemicals-harm-immune-system-decrease-response-vaccines-new-ewg.

[19] 85 Fed. Reg. 14115.

health harms, including immunotoxicity, or sensitive health endpoints, like reproductive harms. Based on these more sensitive health endpoints, EWG believes that one part per trillion would be a more appropriate HRL.[20]

Additional PFAS chemicals also meet this statutory criterion

All other PFAS chemicals likely also meet this statutory criterion. The SDWA does not require a definitive showing that a chemical is harmful, only that it "*may* have an adverse effect on the health of persons."[21]

An emerging body of evidence shows that many, and likely all PFAS, *may* cause adverse effects on the human health system. All PFAS persist in the environment, and many PFAS build up in the blood and organs. Since 1999, the Centers for Disease Control and Prevention has monitored 14 different PFAS chemicals in blood through the National Health and Nutrition Examination Survey.[22] A 2013 study analyzed the concentrations of 21 different PFAS in autopsy samples from brain, liver, lung, bone, and kidney tissue and found PFAS in all human tissues.[23] A March 2020 analysis, led by EWG researchers, applied the Key Characteristics of Carcinogens framework for cancer hazard identification to 26 different PFAS and found that each PFAS chemical displayed at least one of the key characteristics.[24]

The Agency for Toxic Substances and Disease Registry conducted a comprehensive study of 14 PFAS in 2018 and found several health effects associated with various PFAS. The ATSDR also developed minimum risk levels for four PFAS: PFOA, PFOS, PFNA, and PFHxS.[25] The EPA has identified health impacts and developed draft toxicity values for GenX and PFBS[26] and is in the process of developing draft toxicity values for PFBA, PFHxA, PFHxS, PFNA, and PFDA.[27]

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[20] *See* Philippe Grandjean & Esben Budtz-Jørgensen, *Immunotoxicity of perfluorinated alkylates: calculation of benchmark doses based on serum concentrations in children*, 12 Envtl. Health 35 (2013), https://ehjournal.biomedcentral.com/articles/10.1186/1476-069X-12-35; Sharon Lerner, *Teflon Toxin Safety Level Should Be 700 Times Lower Than Current EPA Guideline*, The Intercept (June 18, 2019) https://theintercept.com/2019/06/18/pfoa-pfas-teflon-epa-limit/; David Andrews, *EWG Proposes PFAS Standards that Fully Protect Children's Health*, Envtl. Working Grp. (May 06, 2019), https://www.ewg.org/research/ewg-proposes-pfas-standards-fully-protect-children-s-health.

[21] 42 U.S.C. § 300g-1(b)(1)(A)(i) (emphasis added).

[22] Ctrs. for Disease Control and Prevention, Nat'l Biomonitoring Program, Per- and Polyfluorinated Substances (PFAS) Factsheet, https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html (last updated April 7, 2017).

[23] Francisca Perez et al., *Accumulation of Perfluoroalkyl Substances in Human Tissues*, 59 Env't Int'l 354 (2013), https://pubmed.ncbi.nlm.nih.gov/23892228/

[24] Alexis M. Temkin et al., *Application of Key Characteristics of Carcinogens to Per and Polyfluoroalkyl Substances,* 17 Int'l Journal of Envtl. Research & Public Health 1668 (2020), https://pubmed.ncbi.nlm.nih.gov/32143379/.

[25] Agency for Toxic Substances and Disease Registry, Toxicological Profile for Perfluoroalkyls (2018), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.

[26] Envtl. Prot. Agency, GenX and PFBS Draft Toxicity Assessments, https://www.epa.gov/pfas/genx-and-pfbs-draft-toxicity-assessments (last visited June 09, 2020).

[27] Envtl. Prot. Agency, Systematic Review Protocol for the PFAS IRIS Assessments, https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=345065 (last visited June 09, 2020).

More than a dozen states have determined that there is adequate health information to initiate regulations or develop health guidelines for various PFAS in drinking water, including PFOA, PFOS, GenX, PFBA, PFBS, PFHpA, PFHxS, PFHxA, PFNA, and PFDA.[28]

Recent studies by the National Toxicology Program show that many short-chain PFAS chemicals created to replace their long-chain predecessors are associated with the same or similar toxic effects.[29] For example, the EPA's draft toxicological profile of PFBS found connections to thyroid and kidney effects, asthma and other pulmonary disorders, elevated serum cholesterol, and high-density lipoproteins levels in animal studies.[30] PFBS has also been associated with cardiovascular disease,[31] a decline in semen mobility,[32] preeclampsia,[33] and potential neurotoxicity.[34] The draft toxicological profile for Gen X, released at the same time as the profile for PFBS, found health effects, in animal studies, in the kidney, blood, immune system, developing fetus, and the liver.[35] The state of Minnesota has found that PFBA exposure is associated with thyroid and liver effects in animal studies.[36]

Other legacy long-chain PFAS chemicals also have documented health effects. Epidemiological studies suggest that PFHxS causes liver damage, decreases antibody response to vaccines, increases the risk of early menopause, increases the risk of osteoporosis, and disrupts endocrine (hormone) function.[37]Animal studies show that PFHxS is associated with thyroid hormone levels

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[28] Am. Water Works Ass'n (AWWA), *Per- and Polyfluoroalkyl Substances (PFAS): Summary of State Policies to Protect Drinking Water* (May 2020), https://www.awwa.org/LinkClick.aspx?fileticket=nCRhtmGcA3k%3D&portalid=0.

[29] Nat'l Toxicology Program, Per- and Polyfluoroalkyl Substances (PFAS), https://ntp.niehs.nih.gov/whatwestudy/topics/pfas/index.html (last visited April 22, 2020); *See also* Cheryl Hogue, *Short-Chain and Long-Chain PFAS Show Similar Toxicity, US National Toxicology Program Say,* Chemical & Engineering News (Aug. 24, 2019), https://cen.acs.org/environment/persistent-pollutants/Short-chain-long-chain-PFAS/97/i33.

[30] Envtl. Prot. Agency, *Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3)* (Nov. 2018), https://www.epa.gov/sites/production/files/2018-11/documents/pfbs_public_comment_draft_toxicity_assessment_nov2018-508.pdf.

[31] Memgmeng Huang et al., *Serum Polyfluoroalkyl Chemicals are Associated with Risk of Cardiovascular Diseases in National US Population*, 199 Env't Int'l 37 (2018), https://www.ncbi.nlm.nih.gov/pubmed/29933236.

[32] Xiaofei Song et al., *Biomonitoring PFAAs in Blood and Semen Samples: Investigation of a Potential Link between PFAAs Exposure and Semen Mobility in China,* 113 Env't Int'l 50 (2018), https://www.ncbi.nlm.nih.gov/pubmed/29421407.

[33] Rong Huang et al., *Prenatal Exposure to Perfluoroalkyl and Polyfluoroalkyl Substances and the Risk of Hypertensive Disorders of Pregnancy*, 18 Envtl. Health 5 (2019), https://ehjournal.biomedcentral.com/articles/10.1186/s12940-018-0445-3#citeas.

[34] Qian Zhang et al., *Effects of Perfluorooctane Sulfonate and its Alternatives on Long-Term Potentiation in the Hippocampus CA1 Region of Adult Rats In Vivo*, 5 Toxicology Research 539 (2016), https://pubs.rsc.org/en/content/articlelanding/2016/tx/c5tx00184f#!divAbstract.

[35] Envtl. Prot. Agency, *Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3)* (Nov. 2018), https://www.epa.gov/sites/production/files/2018-11/documents/genx_public_comment_draft_toxicity_assessment_nov2018-508.pdf.

[36] Minnesota Dep't of Health, *PFBA and Drinking Water* (August 2017), https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfbainfo.pdf.

[37] *See* ATSDR, *supra* note 25, at 197, 282, 335, 148, and 445.

and reduced immune response.[38] Studies also associate PFHxS with reproductive harms[39] and potential neurotoxicity.[40] PFDA is associated with increases in serum lipids, including total cholesterol and low-density lipoprotein (LDL), decreased antibody response to vaccines, decreases in body weight and growth,[41] and increased risk of preterm birth.[42] PFNA is associated with increases in serum lipids – total cholesterol and low-density lipoprotein (LDL), immune effects and developmental effects,[43] preterm birth,[44] and reduced sperm quality.[45] These effects, in part, led the state of New Jersey to set the first-in-nation MCL for a PFAS chemical, in 2018, limiting PFNA to 13 ppt.[46]

The EPA has a significant amount of data on health effects from various PFAS. As the EPA points out in the preliminary regulatory determination, it has studies on 33 different PFAS in its Health and Environmental Research Online database.[47] A search of Chemview shows that industry has submitted TSCA 8(e) substantial risk reports on 127 different PFAS chemicals, 99 of which are on the TSCA active inventory.[48] The FY2020 National Defense Authorization Act, passed by Congress in December 2019, requires the EPA to complete a data call-in from manufacturers by 2023. The EPA should initiate this call-in immediately and use the data collected to further inform its analysis on adverse health effects and occurrence.

Given the documented health effects of many PFAS, the EPA should add additional PFAS to the regulatory determination and strongly consider regulating PFAS as a class.

Statutory criterion 2: PFAS are known to occur, or there is a substantial likelihood that PFAS will occur, in public water systems with a frequency and at levels of public health concern.

EWG agrees with the EPA's determination that PFOA and PFOS occur with a frequency and at levels of public health concern in public water systems, and therefore meet the second statutory

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[38] *See* Minnesota Dep't of Health, *PFHxS and Groundwater* (April 2019), https://www.health.state.mn.us/communities/environment/risk/docs/guidance/gw/pfhxsinfo.pdf.
[39] Yan Wang et al., *Association Between Maternal Serum Perfluoroalkyl Substances During Pregnancy and Maternal and Cord Thyroid Hormones: Taiwan Maternal and Infant Cohort Study*, 122 Envtl. Health Perspectives 529 (2014), https://www.ncbi.nlm.nih.gov/pubmed/24577800.
[40] Zhang et al., *supra* note 34.
[41] *See* ATSDR, *supra* note 25, at 25, 199, 289, 119.
[42] Qi Meng et al, *Prenatal Exposure to Perfluoroalkyl Substances and Birth Outcomes; An Updated Analysis from the Danish National Birth Cohort*, 15 Int'l Journal of Environmental Research & Public Health 1832 (2018), https://www.mdpi.com/1660-4601/15/9/1832.
[43] Gloria B. Post, *Technical Support Document: Interim Specific Ground Water Criterion for Perfluorononanoic Acid (PFNA, C9) (CAS# 375-95-1; Chemical Structure: $CF_3(CF_2)_7COOH$)*, New Jersey Dep't of Envtl. Prot., Office of Science (June 2015), https://www.nj.gov/dep/dsr/supportdocs/PFNA_TSD.pdf.
[44] *See* Meng et al., *supra* note 42.
[45] Germaine M. Buck Louis et al., *Perfluorochemicals and Human Semen Quality: The LIFE Study*, 123 Envtl. Health Perspectives 57 (2015), https://ehp.niehs.nih.gov/doi/10.1289/ehp.1307621.
[46] New Jersey Dep't of Envtl. Prot., Site Remediation Program, Contaminants of Emerging Concern, https://www.nj.gov/dep/srp/emerging-contaminants/; *see also* New Jersey Drinking Water Standards by Constituent, https://www.nj.gov/dep/standards/drinking water.pdf (last visited June 08, 2020).
[47] 85 Fed. Reg. 14121.
[48] Envtl. Prot. Agency, ChemView, https://chemview.epa.gov/chemview (searched June 8, 2020).

criterion.[49] However, the EPA vastly undercounts the likely occurrence by relying on unnecessarily high reporting limits in Unregulated Contaminant Monitoring Rule 3, and failing to include data from various state monitoring programs. The UCMR 3 and state monitoring data document widespread occurrence from additional PFAS as well. The EPA also underestimates occurrence by using an HRL of 70 ppt to define "levels of public health concern."

In addition to ample data about where PFAS are *known* to occur, there is also significant evidence of where there is a *substantial likelihood* that PFAS will occur in public drinking water systems at levels of public health concern.

The UCMR 3 data undercounts the occurrence of PFAS in public water systems

The EPA relies primarily on data from the UCMR 3 to make its determination that PFOA and PFOS meet criterion 2. Under the UCMR 3, the EPA collected data on the occurrence of six PFAS chemicals in public water systems from 2013 to 2015.[50] The minimum reporting levels (MRLs) for PFOA and PFOS were 0.02 µg/L (20 ppt) and 0.04 µg/L (40 ppt) respectively.[51] The EPA also reported combined PFOA and PFOS levels in samples by simply calculating the sum of the two measurements. However, these combined PFOA and PFOS measurements also undercount occurrence. As the EPA points out in the preliminary determination, "Concentrations of PFOS or PFOA below their respective MRLs were set equal to 0 µg/L when calculating the total PFOS/PFOA concentration for the sample."[52] That means that if a sample measured 20 ppt of PFOA and 39 ppt of PFOS, only 20 ppt would be reported as the total concentration of PFOS and PFOA, even though the actual measurement was 59 ppt.

Based on the data made publicly available under the UCMR 3, one analysis found that the drinking water for six million people exceeded EPA's lifetime health advisory for PFOA and PFOS.[53] EPA also acknowledges monitoring for four other PFAS under the UCMR 3: PFNA, PFHxS, and PFBS. MRLs for these PFAS ranged from 10 ppt to 90 ppt. EPA found public water systems serving 16 million people reported results for one or more of the six PFAS measured at or above their respective MRL.[54]

However, far more public water systems had detectable PFAS than is revealed by the public UCMR 3 data. Euronfins Eaton Analytical, a private lab that analyzed one-third of the UCMR 3 data, reported that 28 percent of the water systems it tested had PFAS at over five ppt, and nearly double that percentage had PFAS at concentrations over 2.5 ppt. An EWG analysis of that summary data estimated that water systems serving nearly 110 million Americans are likely

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[49] 85 Fed. Reg. 14117.
[50] Envtl. Prot. Agency, Third Unregulated Contaminant Monitoring Rule, https://www.epa.gov/dwucmr/third-unregulated-contaminant-monitoring-rule (last visited April 22, 2020).
[51] 85 Fed. Reg. 14117.
[52] *Id.*
[53] Xindi C. Hu et al., *Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants,* 3 Envt'l Sci. & Tech. Letters 344 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5062567/.
[54] 85 Fed. Reg. 14120.

impacted at levels of 2.5 ppt or higher.[55] Some of these water systems may have had high measurements of combined PFAS but were reported as non-detects because individual measurements fell below the MRLs.

Recent tests commissioned by EWG found widespread PFAS contamination in water supplies that reported non-detects in the UCMR 3 results.[56] Tap water samples collected between May and December 2019 from 44 places in 31 states found that all but one location[57] had detectable levels of PFAS. All but three samples had PFAS above one ppt. Thirty-four of the places where EWG found PFAS had not previously reported detections under EPA or state monitoring.[58] Data also shows that PFAS contamination in rainwater is widespread, suggesting that all water systems served by surface water likely have at least some PFAS contamination.[59]

EPA undercounts occurrence data by relying on monitoring data from only four states

In the preliminary determination, EPA relies on state monitoring data for PFOA and PFOS from Colorado, Michigan, New Hampshire, and New Jersey, in addition to the UCMR 3 data.[60] EPA indicates that it relies on these states because they have data on *summed* PFOA and PFOS, not just PFOA and PFOS individually. EPA also notes that all four states had at least one summed PFOA and PFOS concentration above 70 ppt. [61] EPA does not disclose whether it is considering only state occurrence data that includes some samples exceeding the LHA. The EPA should not limit its analysis to states with summed PFOA and PFOS calculations or states reporting concentrations above the LHA. To do so would vastly underreport occurrence of PFAS.

The EPA acknowledges that some other states have monitoring data, namely California, Illinois, North Carolina, Pennsylvania, Vermont, and Washington, but declines to use that data in its occurrence analysis.[62] The EPA should take into consideration occurrence data from all states that have it, even if sampling is still ongoing or targeted. This includes Alaska,[63] California,[64]

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[55] David Andrews, *Report: Up to 110 Million Americans Could Have PFAS-Contaminated Drinking Water*, Envtl. Working Grp. (May 22, 2018), https://www.ewg.org/research/report-110-million-americans-could-have-pfas-contaminated-drinking-water.

[56] Sydney Evans et al., *PFAS Contamination in Drinking Water Far More Prevalent than Previously Reported*, Envtl. Working Grp. (Jan. 22, 2020), https://www.ewg.org/research/national-pfas-testing/#:~:text=WEDNESDAY%2C%20JANUARY%2022%2C%202020&text=Based%20on%20our%20tests%20and,all%20that%20use%20surface%20water.

[57] The only location without detectable PFAS was Meridian, Miss., which draws its drinking water from wells more than 700 feet deep. *Id.*

[58] *Id.*

[59] Marie Zhuikov, *Sea Grant Research Addresses the Growing Crisis of PFAS Exposure, Finds PFAS in Rainwater* (Apr. 28, 2019), https://www.seagrant.wisc.edu/news/sea-grant-research-addresses-the-growing-crisis-of-pfas-exposure-finds-pfas-in-rainwater/.

[60] 85 Fed. Reg. 14117.

[61] 85 Fed. Reg. 14118.

[62] 85 Fed. Reg. 14112, 14117-18.

[63] State of Alaska, Division of Spill Prevention & Response, Per- and Polyfluoroalkyl Substances, Drinking Water Sample Results, https://dec.alaska.gov/spar/csp/pfas/sample-results/ (last visited June 09, 2020).

[64] State of California Water Bds., State Water Res. Control Bd., Per- and Polyfluoroalkyl Substances, https://www.waterboards.ca.gov/pfas/ (last updated June 08, 2020).

Kentucky,[65] Ohio,[66] Pennsylvania,[67] Vermont,[68] and more.[69] The EPA should actively seek out this data from states rather than relying only on what it receives through public comment. It should consider occurrence from *all* the PFAS that are being measured, not just PFOA and PFOS. Because state monitoring could continue for some time, and some monitoring programs have been put on hold due to the COVID-19 pandemic,[70] EPA *should not* wait until monitoring is complete to finalize the regulatory determination.

The EPA must lower what it considers to be occurrence at a "level of public health concern"

In the preliminary determination, the EPA discusses the occurrence of summed PFOA and PFOS that exceeds the 70 ppt combined HRL, based on the lifetime health advisory for PFOA and PFOS.[71] It's unclear whether the HRL is also what the EPA defines as occurrence "at levels of public health concern." EWG strongly recommends that the EPA consider all PFAS detections above one ppt in considering occurrence.

States and public health experts have advocated for regulation of PFAS at levels orders of magnitude lower than the LHA. Since the EPA release the LHA in 2016, three states have adopted MCLs significantly lower than 70 ppt. In May 2019, Vermont finalized an MCL of 20 ppt for 5 combined PFAS, including PFOA and PFOS.[72] In September 2019, New Hampshire finalized MCLs of 12 and 15 ppt for PFOA and PFOS, respectively.[73] On June 1, 2020, New Jersey finalized MCLs of 14 ppt for PFOA and 13 ppt for PFOS.[74] Over a dozen states have either proposed MCLs or released health guidelines lower than 70 ppt. Leading experts have asserted that an MCL of one ppt is necessary to be health protective.[75]

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[65] Kentucky Dep't of Envtl. Prot., *Evaluation of Kentucky Community Drinking Water for Per- and Polyfluoroalkyl Substances* (Nov. 18, 2019), https://eec.ky.gov/Documents%20for%20URLs/PFAS%20Drinking%20Water%20Report%20Final.pdf.

[66] Ohio Envtl. Prot. Agency, *Ohio PFAS Sampling* (Feb. 21, 2020), https://epa.ohio.gov/Portals/28/documents/pfas/2-21-2020-Webinar-Slides.pdf.

[67] Pennsylvania Dep't of Envtl. Protection, PFAS in Pennsylvania, https://www.dep.pa.gov/Citizens/My-Water/drinking_water/PFAS/Pages/default.aspx (last visited June 09, 2020).

[68] Vermont Agency of Natural Resources, *Per and Polyfluoroalkyl Substances (PFAS)*, https://dec.vermont.gov/water/drinking-water/water-quality-monitoring/pfas

[69] Not an exhaustive list. EPA should seek sampling data directly from states.

[70] *See, e.g.*, Ismail Turay Jr., *Ohio EPA Suspends Testing Drinking Water for 'Forever Chemicals' Amid COVID-19 Concerns*, Dayton Daily News (Apr. 02, 2020), https://www.daytondailynews.com/news/state--regional/ohio-epa-suspends-testing-drinking-water-for-forever-chemicals-amid-covid-concerns/sZT3gA8fg4iMldd2F90qWM/.

[71] 85 Fed. Reg. 14117.

[72] Nessa Horewitch Coppinger & Daniel M. Krainin, *Vermont Governor Signs Law Setting Strict PFAS Limits*, Lexology (May 17, 2019), https://www.lexology.com/library/detail.aspx?g=ff7f9a3a-1fe9-42a5-9424-007575fc2770.

[73] However, the New Hampshire Superior Court enjoined the enforcement of these PFAS MCLs in December 2019; as such, no enforceable PFAS MCLs currently exist. Jim Martin, *Update on New Hampshire PFAS Drinking Water Standards (MCLs)*, New Hampshire Dep't of Envtl. Services (Jan. 10, 2020), https://www4.des.state.nh.us/nh-pfas-investigation/?p=1185.

[74] Michael Sol Warren, *N.J. Gets Strict on Cancer-Causing 'Forever Chemicals' in Drinking Water,* NJ.com (June 01, 2020), https://www.nj.com/news/2020/06/nj-gets-strict-on-cancer-causing-forever-chemicals-in-drinking-water.html.

[75] *See* Grandjean & Budtz-Jørgensen; Lerner; Andrews, *supra* note 20.

There is also a substantial likelihood that PFAS will occur in public drinking water systems at levels of public health concern

Criterion 2 considers not only known occurrence but also data showing a *substantial likelihood* that PFAS will occur in public drinking water at levels of public health concern. In addition to the UCMR 3 data and state monitoring data, there is a wealth of data on PFAS contamination in surface and ground water. Many of these surface and ground water measurements are taken from or near sources of drinking water, making it likely that public drinking water systems are also contaminated. EWG maintains and regularly updates a map with more than 1,500 sites contaminated with PFAS.[76] EWG's map contains the UCMR 3 data but also sites identified through state monitoring and Department of Defense testing. The map tracks contamination not only from PFOA and PFOS but from all PFAS sampled. A recent EWG analysis found that groundwater at military installations is frequently contaminated with eight different kinds of PFAS: PFOA, PFOS, PFBS, PFHxS, PFHpA, PFHxA, PFDA, and PFNA, sometimes in very high concentrations.[77] EWG's analysis found, as of May 2020,[78] that there was:

- Perfluorooctanoic acid (PFOA) at 274 sites.
- Perfluorooctanesulfonic acid (PFOS) at 276 sites.
- Perfluorobutanesulfonic acid (PFBS) at 259 sites.
- Perfluorohexanesulfonic acid (PFHxS) at 216 sites.
- Perfluoroheptanoic acid (PFHpA) at 214 sites.
- Perfluorohexanoic acid (PFHxA) at 150 sites.
- Perfluorodecanoic acid (PFDA) at 130 sites
- Perfluorononanoic acid (PFNA) at 206 sites.

EWG also maintains a map of suspected dischargers of PFAS, which identifies 2,501 unique facilities in sectors that are known to produce or use PFAS.[79] That data is drawn from EPA's chemical data reporting rule, EPA's ECHO database, a 2017 survey by the New York Department of Environmental Conservation, and a 2017 internal EPA memorandum identifying different PFAS uses.[80] Without mandatory reporting data, it's difficult to know which of these facilities are discharging PFAS and at what volumes. However, researchers have found that the number of industrial sites manufacturing PFAS, military training centers, and wastewater treatment facilities are all significant predictors of PFAS detection frequencies and concentrations in public water supplies.[81]

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[76] Envtl. Working Grp. (EWG), *Mapping the PFAS Contamination Crisis: New Data Show 1,582 Sites in 49 States* (May 4, 2020), https://www.ewg.org/interactive-maps/pfas_contamination/.
[77] Melanie Benesh, *The Pentagon Should Address All Types of PFAS on Military Bases*, EWG (May 26, 2020), https://www.ewg.org/news-and-analysis/2020/05/pentagon-should-address-all-types-pfas-military-bases.
[78] Reflects the number of sites as of May 2020. DOD sampling is ongoing, so these numbers are likely to increase.
[79] Jared Hayes & Scott Faber, *UPDATE: Thousands of Industrial Facilities Likely Discharging Toxic 'Forever Chemicals' Into Air and Water*, EWG (April 09, 2020), https://www.ewg.org/news-and-analysis/2020/04/updated-thousands-industrial-facilities-likely-discharging-toxic-forever.
[80] *Id.*
[81] *See* Hu et al., *supra* note 53.

The EPA is also in the process of adding 172 PFAS chemicals to the Toxic Release Inventory.[82] Although reporting data from these facilities will likely not be available until after the regulatory determination is finalized, the EPA should use this data when setting a NPDWR to determine where there is a substantial likelihood that public water systems are contaminated.

Statutory criterion 3: Regulating PFAS chemicals offers a meaningful opportunity for health risk reduction

Although statutory criterion 3 is at the discretion of EPA, EWG agrees with EPA's conclusion that regulating PFAS would offer a meaningful opportunity for health risk reduction, particularly for vulnerable and disadvantaged populations. PFAS contaminate the blood and organs of nearly every living being, and experts estimate that 25 percent of Americans have elevated levels of PFAS in their blood serum.[83] PFAS chemicals have long half-lives, and many can stay in the human body for decades.[84] Americans also face dozens of new exposures to PFAS every day – through our food, water, and air, from indoor dust, carpets, clothing, and cosmetics. As documented above, PFAS exposure can lead to adverse health outcomes.

Drinking water is a major exposure pathway for PFAS chemicals. The drinking water LHA for PFOA and PFOS used uncertainty factors to estimate that around 20 percent of exposure comes from drinking water in the general population.[85] Next to contaminated sites, however, drinking water can account for as much as 75 percent of exposure.[86] Therefore, treating PFAS in drinking water presents a meaningful opportunity to reduce exposure and health risk. Various treatment technologies exist to remove or dramatically reduce the amount of PFAS in drinking water including granular activated carbon, ion exchange, and high-pressure membrane filtration.[87]

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[82] Envtl. Prot. Agency, Chemicals Added to the Toxics Release Inventory Pursuant to Section 7321 of the Nat'l Defense Authorization Act, https://www.epa.gov/sites/production/files/2020-04/documents/tri_non-cbi_pfas_list_2_19_2020_final_clean.pdf.

[83] *See* David Andrews, *Insight: The Case for Regulating All PFAS Chemicals as a Class*, Bloomberg Environment (May 20, 2019), https://news.bloombergenvironment.com/environment-and-energy/insight-the-case-for-regulating-all-pfas-chemicals-as-a-class/. Andrews determines that 25% of Americans have elevated blood serum levels of PFAS by comparing NHANES biomonitoring data with safe blood serum concentrations calculated by the German Environment Agency. *Compare* Ctrs. for Disease Control & Prevention, Nat'l Biomonitoring Program, Per- and Polyfluorinated Substances (PFAS) Factsheet, https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html (last updated April 7, 2017) *with* German Env't Agency, *HBM I Values for Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic acid (PFOS) in Blood Plasma* 59 Bundesgesundheitsbl 1364 (2016), https://link.springer.com/content/pdf/10.1007%2Fs00103-016-2437-1.pdf.

[84] Half-life estimates range from over two years from PFOA and PFNA to 5.4 years for PFOS to 8.5 years for PFHxS. *See* Reade et al., *supra* note 14, at 12.

[85] *See* Envtl. Prot. Agency, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)* at 10 (May 2016), https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final_508.pdf; Envtl. Prot. Agency, *Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS)* at 11 (May 2016); https://www.epa.gov/sites/production/files/2016-05/documents/pfos_health_advisory_final_508.pdf.

[86] *See* Elsie M. Sunderland et al., *A Review of the Pathways of Human Exposure to Poly- and Perfluoroalkyl Substances (PFASs) and Present Understanding of Health Effects*, 29 Journal of Exposure Sci. & Envtl. Epidemiology 131 (2018), https://pubmed.ncbi.nlm.nih.gov/30470793/.

[87] Though various factors will impact the efficacy of any given treatment system, including type of PFAS, co-occurring contaminants, and water chemistry. *See* Tasha Stoiber et al., *PFAS in Drinking Water: An Emergent Water Quality Threat*, 1 Water Solutions 40, 44 (2020); https://cdn3.ewg.org/sites/default/files/u352/WS_01_2020_Research_PFAS_Water_June8_2020.pdf?_ga=2.210400272.447577099.1591500990-1525964376.1554386940. *See also* Reade et al., *supra* note 14.

Epidemiological evidence shows that reducing PFAS in drinking water translates to lower blood levels. A 2017 analysis looked at PFOA blood serum levels over time in both Cincinnati and in a Northern Kentucky suburb. Both communities are downriver from the Washington Works Plant in Parkersburg, West Virginia and use the Ohio River as a drinking water source. In 1992, Cincinnati began treating its drinking water with granular activated carbon, but Northern Kentucky did not adopt any treatment technologies that would reduce PFAS levels in finished tap water. The researchers noted that PFOA levels in blood serum went down during the 1990s in Cincinnati but rose in Northern Kentucky. The researchers concluded that difference in blood serum levels was likely attributable to the water treatment technology adopted in Cincinnati.[88]

PFAS chemicals are contaminants that "present the greatest public health concern"

Importantly, regulating PFAS chemicals in drinking water will not only reduce health risk for the general population, but for susceptible and disadvantaged populations. Section1412(b)(1)(C) of SDWA requires EPA to prioritize regulation of contaminants that "present the greatest public health concern."[89] In determining which contaminants present the greatest public health concern, EPA must take into consideration "the effect of such contaminants on subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population."[90]

Children are particularly vulnerable to the risks from PFAS. As EPA notes, "PFOA and PFOS are known to be transmitted to the fetus via cord blood and to the newborn, infant, and child via breastmilk."[91] Studies show that children face a higher risk of multiple health impacts from PFAS, including immune effects, infection, asthma, cardio-metabolic, neurodevelopmental, thyroid, renal, and puberty onset.[92] Given the much higher exposure to PFAS through drinking water in communities near contaminated sites, those fenceline communities should also be considered among the most at risk.

EPA must apply the regulatory determination to more than just PFOA and PFOS

EPA seeks comment on whether it should include more than PFOA and PFOS in the regulatory determination.[93] EPA seeks comment on whether it should evaluate PFAS individually, using different grouping approaches, or through a treatment technique.[94] To protect public health, EPA must expand the regulatory determination beyond PFOA and PFOS. The best way to do so

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[88] Robert L. Herrick et al., *Polyfluoroalkyl Substance Exposure in the Mid-Ohio River Valley, 1991-2012,* 228 Envtl. Pollution 50 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5540235/.
[89] 42 U.S.C. § 300g-1(b)(1)(C).
[90] *Id.*
[91] 85 Fed. Reg. 14119.
[92] Kristen M. Rappazzo et al., *Exposure to Perfluorinated Alkyl Substances and Health Outcomes in Children: A Systematic Review of the Epidemiologic Literature*, 14 Int'l Journal of Envtl. Research & Pub. Health 691 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5551129/.
[93] 85 Fed. Reg. 14120.
[94] 85 Fed. Reg. 14122.

would be to regulate PFAS as a class. EWG would also support a treatment technique as an approach towards eliminating the class of PFAS in drinking water.

The bulk of PFOA and PFOS contamination in drinking water likely comes from legacy pollution. 3M ceased manufacturing PFOS in 2002.[95] The companies participating in the voluntary PFOA stewardship program agreed to phase out their use of PFOA and PFOA-related chemicals by 2015.[96] Although recent comments to a proposed supplemental significant new use rule under the Toxic Substances Control Act revealed that some manufacturers continue to use PFOA,[97] these uses likely account for a small fraction of ongoing discharges of PFAS in drinking water. Instead, most ongoing manufacturing discharges of PFAS are likely from the short-chain PFAS chemicals created to replace PFOA and PFOS. Limiting the regulatory determination to PFOA and PFOS will contribute to regrettable substitution and fail to protect Americans from newer forms of PFAS pollution that may be just as toxic.[98]

Moreover, PFOA and PFOS are often comingled with other PFAS chemicals at contaminated sites. PFAS chemicals are used in complex mixtures, can form as impurities, or break down from other PFAS chemicals. Aqueous film-forming foam and AFFF-impacted groundwater is thought to contain as many as 40 different *sub-classes* of PFAS with unknown number of constituent PFAS chemicals.[99] A lack of reporting requirements and confidential business protections make it difficult, if not impossible, to know how many PFAS are discharged into the environment from any given manufacturing site or remain in finished products.

Regulation on a chemical-by-chemical basis is untenable, unrealistic, and would fail to protect public health. EPA estimates that 602 PFAS have been used in the U.S. since June 2006,[100] but has only developed analytical methods to test for 29 of these chemicals in drinking water.[101] The last time EPA made a positive regulatory determination for a chemical was in 2011 for perchlorate.[102] Nine years later, EPA has yet to finalize a NPDWR, and reportedly may not do so at all.[103] Yet, EPA has reviewed more than 294 new PFAS chemicals since 2006.[104] The pace of regulation under SDWA cannot possibly keep up with the pace of innovation of new PFAS chemicals. Therefore, a broad approach is needed to protect public health.

EPA should regulate PFAS as class

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[95] Envtl. Prot. Agency, *supra* note 2, at 9.
[96] *See* Envtl. Prot. Agency, *supra* note 8.
[97] *See* Rizzuto, *supra* note 9.
[98] *See* Nat'l Toxicology Program, *supra* note 29.
[99] Krista A. Barzen-Hanson et al., *Discovery of 40 Classes of Per- and Polyfluoroalkyl Substances in Historical Aqueous Film-Forming Foams (AFFF) and AFFF-Impacted Groundwater*, 51 Env't Sci. & Tech. 2047 (2017), https://pubs.acs.org/doi/pdf/10.1021/acs.est.6b05843.
[100] Envtl. Prot. Agency, *supra* note 2, at 12.
[101] Envtl. Prot. Agency, EPA PFAS Drinking Water Laboratory Methods, https://www.epa.gov/pfas/epa-pfas-drinking-water-laboratory-methods (last updated April 27, 2020).
[102] 73 Fed. Reg. 60262 (Oct. 10, 2008).
[103] *See* Brady Dennis & Juliet Eilperin, *EPA Decides Against Limits on Drinking Water Pollutant Linked to Health Risks, Especially in Children*, Wash. Post (May 14, 2020), https://www.washingtonpost.com/climate-environment/2020/05/14/epa-decides-against-limits-drinking-water-pollutant-linked-health-effects/.
[104] Envtl. Prot. Agency, PFAS Laws and Regulations, https://www.epa.gov/pfas/pfas-laws-and-regulations (last updated on July 30, 2018).

The most health-protective approach would be to make a regulatory determination for PFAS as a class. More than 200 scientists determined in the 2014 Helsingør[105] and 2015 Madrid[106] Statements that the scientific literature identified the potential for harm associated with the entire class of PFAS. Linda Birnbaum, Director of the National Institute for Environmental Health Science at the time, testified before the Senate Environment and Public Works Committee in March 2019, that "[a]pproaching PFAS as a class for assessing exposure and biological impact is the most prudent approach to protect public health."[107]

EPA commonly regulates chemicals in classes or categories. There are already NPDWRs for nine classes of substances under the Safe Drinking Water Act.[108] The EPA regulates 26 categories of chemicals as toxic pollutants under the Clean Water Act.[109] The EPA regulates more than 30 categories of chemicals under the Clean Air Act.[110] There are 33 categories of chemicals that must be reported under the Toxic Release Inventory under the Emergency Planning and Community Right To Know Act.[111] There are more than 60 classes of chemicals that are considered hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act.[112] EPA has specific authority to regulate chemical classes under

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105 Martin Scheringer et al., *Helsingør Statement on Poly- and Perfluorinated Alkyl Substances (PFASs)*, 114 Chemosphere, 337 (2014), https://www.sciencedirect.com/science/article/pii/S004565351400678X.
106 Arlene Blum et al., *The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)*, 123 Envtl. Health Perspectives A107 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4421777/.
107 Testimony of Linda S. Birnbaum, *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., 13 (Mar. 28, 2019), https://www.epw.senate.gov/public/index.cfm/hearings?Id=918A6066-C1F1-4D81-A5A0-F08BBE06D40B&Statement_id=D2255C99-7544-42CA-B9DC-0D4F11CCB964.
108 Alpha/photon emitters, beta photon emitters, chloramines, chromium (total), haloacetic acids, PCBs, total coliforms, total trihalomethanes, xylenes (total). *See* Envtl. Prot. Agency, National Primary Drinking Water Standards, https://www.epa.gov/sites/production/files/2016-06/documents/npwdr_complete_table.pdf
109 Antimony and compounds, arsenic and compounds, beryllium and compounds, cadmium and compounds, chlorinated benzenes (other than di-chlorobenzenes), chlorinated ethanes, chloroalkyl ethers, chlorinated phenols, chromium and compounds, copper and compounds, cyanides, dichlorobenzenes, dichloroethylenes, haloethers, halomethanes, lead and compounds, mercury and compounds, nickel and compounds, nitrophenols, nitrosamines, phthalate esters, polychlorinated biphenyls, polynuclear aromatic hydrocarbons, selenium and compounds, silver and compounds, thallium and compounds, zinc and compounds. 40 C.F.R. § 401.15
110 For example, the following categories were included in the original hazardous air pollutant list published by Congress: antimony compounds, arsenic compounds, beryllium compounds, cadmium compounds, chromium compounds, cobalt compounds, cyanide compounds, glycol ethers, lead compounds, manganese compounds, mercury compounds, fine mineral fibers, nickel compounds, selenium compounds, polycyclic organic matter, radionuclides. 42 U.S.C. § 7412 (b)(1)
111 Antimony compounds, arsenic compounds, barium compounds, beryllium compounds, cadmium compounds, chlorophenols, chromium compounds, cobalt compounds, cyanide compounds, copper compounds, diisocyanates, dioxin and dioxin-like compounds, certain glycol esters, hexabromocyclododecane, lead compounds, manganese compounds, mercury compounds, nickel compounds, nicotine and salts, nitrate compounds, nonylphenol, nonylphenol ethoxylates (NPEs), polybrominated biphenyls (PBBs), PCBs, polychlorinated alkanes, polycyclic aromatic compounds (PACs), selenium compounds, silver compounds, strychnine and salts, thallium compounds, vanadium compounds, warfarin and salts, zinc compounds, ethylenebisdithiocarbamic acids/salts/esters (EBDCs). 40 C.F.R. § 372.65.
112 Aflatoxins, antimony compounds, arsenic compounds (two chemicals), barium compounds, beryllium compounds, cadmium compounds (more than three chemicals), carbamates and carboxylic acid hydrazines, chromium compounds, chlordane (alpha and gama isomers, technical mixture and metabolites), chlorinated aliphatic hydrocarbons, chlorinated benzenes (six chemicals), chlorinated ethers (three chemicals), chlorinated ethane (seven

TSCA,[113] and it has done so with new chemicals. For example, there are more than 300 PFAS chemicals that are already regulated as a class under two different TSCA significant new use rules.[114] EPA found a class approach was justified because the chemicals posed similar risks to human health and the environment, had persistent and bioaccumulative tendencies, and likely came from similar sources.[115]

EPA regulates classes of chemicals for various reasons, including shared traits, molecular makeup, similar sources of exposure, common health risks, and ease of reporting. For example, the EPA regulates mercury compounds as a class under the Clean Water Act because of their combined effect as a potent neurotoxin and tendency to bind with other chemicals.[116] When the EPA regulated a class of polybrominated diphenyl ethers, or PBDEs, in a TSCA SNUR, it looked at shared origins and similar sources of exposure, as well as similar health and environmental effects, as a basis for regulating as a class.[117]

PFAS chemicals co-occur, have common persistent and bioaccumulative tendencies, and share similar toxicity traits. As such, EPA should regulate them as a class. As a transition towards using a full class approach, EPA could consider regulating groups of PFAS compounds, as suggested in the preliminary determination.[118] EPA has explored regulating other drinking water contaminants in groups and subgroups. In 2010, EPA announced a new drinking water strategy, which focused, in part, on addressing "contaminants as groups rather than one at a time so that enhancement of drinking water protection can be achieved cost-effectively."[119] In 2011, EPA recommended establishing a single regulatory standard for a group of carcinogenic volatile

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chemicals), chlorinated fluorocarbons, chlorinated naphthalene, chlorinated phenols (four chemicals), chlorinated toluenes, chloroalkyl ethers, cobalt compounds, coke oven emissions, cyanides, cyanide compounds, cyanides (soluble salts and complexes not otherwise specified), copper compounds, creosote (three chemicals), cresylic acid, DDT and metabolites, dichlorobenzidine, diphenylhydrazine, endosulfan and metabolites, endrin and metabolites, ethylenebis dithiocarbamic (acid, salts, and esters), fine mineral fibers, fluoromethanes, glycol ethers, haloethers, halomethanes, heptachlor and metabolites (three chemicals), hexachlorocyclohexane (seven chemicals), lead compounds, manganese compounds, mercury compounds, methyl ethyl pyridines, nickel compounds, nitrate compounds, nitrogen mustard (two chemicals), nitrosamines (three chemicals), nitrophenols (other than chlorinated), phthalate esters, polychlorinated biphenyls (PCBs), polycyclic organic matter, polynuclear aromatic hydrocarbons (PAHs), radionuclides, selenium compounds, silver compounds, thallium compounds, zinc compounds, 1,2-ethanediylbis- salts and esters, 2,4-D salts and esters, 2,4,5-T (amines, esters, and salts), 2,4,5-TP esters, unlisted hazardous wastes characteristic of corrosivity, unlisted hazardous waste characteristic of ignitability, unlisted hazardous wastes characteristic of reactivity, unlisted hazardous wastes characteristic of toxicity. 40 C.F.R. § 302.4; 40 C.F.R. § 261 appendix viii; 40 C.F.R. § 261.33(f); 40 C.F.R. § 401.15.

[113] 15 U.S.C. § 2625(c) ("Any action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this chapter with respect to a category of chemical substances or mixtures, any reference in this chapter to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category").

[114] *See* 40 C.F.R. § 721.9582; 40 C.F.R. § 721.10536.

[115] 77 Fed. Reg. 48924.

[116] 82 Fed. Reg. 27154.

[117] 77 Fed. Reg. 19862.

[118] 85 Fed. Reg. 14122.

[119] Envtl. Prot. Agency, Drinking Water Strategy (March 2010), https://web.archive.org/web/20100327064231/http://www.epa.gov/safewater/sdwa/dwstrategy.html.

organic compounds (VOCs) as a first step towards that goal.[120] Just this month, a group of leading scientists published an advance peer-reviewed article on potential strategies for grouping PFAS chemicals that should inform the agency's thinking.[121] However, as noted below, any grouping should include a mix of chain lengths to ensure adequate treatment for both short and long chain PFAS.

At a minimum, EPA should expand the number of PFAS included in the regulatory determination

Although a class approach would be the best approach, at a minimum EPA should expand the PFAS included in the regulatory determination to include PFAS for which EPA or the ATSDR has developed a draft toxicity value, PFAS for which states have proposed or finalized ground or drinking water limits, and PFAS regularly detected in public water systems or groundwater through EPA, DOD, or USGS monitoring efforts. It is imperative that any PFAS grouping include mix of PFAS chain-lengths to ensure that adequate treatment technologies are adopted and maintained. Several technologies exist to remove PFAS from drinking water, but efficacy varies depending on the kind of PFAS being removed, among other factors. As EPA acknowledges, short chain PFAS are more mobile and more likely to break through some treatment technologies like granular activated carbon and anion exchange resins.[122] Adopting a National Primary Drinking Water Regulation (NPDWR) for PFOA and PFOS only could expose Americans to unsafe levels of other PFAS chemicals in their drinking water. Likewise, adopting an NPDWR for only long-chain PFAS chemicals would leave treatment systems vulnerable to breakthrough from short-chain PFAS, putting consumers' health at risk.

National Primary Drinking Water Recommendations

Any NPDWR must protect vulnerable and disadvantaged populations and consider sensitive health endpoints

Should the EPA elect to adopt an MCL as a NPDWR, it should ensure that it is protective not only for the general population but also for vulnerable populations like children, workers, the elderly, and people who live near contaminated sites. To protect vulnerable populations, the MCL should be lower than EPA's 2016 LHA of 70 ppt, which failed to consider vulnerable subpopulations adequately and sensitive health endpoints, such as mammary gland development and immunotoxicity. New Jersey, New Hampshire, and Vermont have already adopted MCLs for PFOA, PFOS, and other PFAS chemicals that take vulnerable populations into account, rely on sensitive health endpoints, and are much lower than 70 ppt.[123] More than a dozen other states

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[120] *See, e.g.*, Envtl. Prot. Agency, *Basic Questions and Answers for the Drinking Water Strategy Contaminant Groups Effort*. (Jan. 2011), nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100NRW9.TXT;
Water Research Foundation, C*arcinogenic VOCs Contaminant Group: Filling Critical Knowledge Gaps to Inform Meaningful Regulation* (June 05, 2019), https://www.waterrf.org/news/carcinogenic-vocs-contaminant-group-filling-critical-knowledge-gaps-inform-meaningful.

[121] Cousins et al., *supra* note 3.

[122] 85 Fed. Reg. 14120 ("there are limitations and uncertainties pertaining to these removal processes for PFAS. For example, the treatment efficacy of GAC and anion exchange resins is strongly dependent upon the type of PFAS present and the physio-chemical properties of the solution matrix.")

[123] *See* AWWA, *supra* note 28.

have proposed MCLs or health guidelines that are also much lower than 70 ppt, also taking into account vulnerable populations and sensitive health endpoints. Leading experts have suggested that a standard of one ppt is needed to protect public health.[124]

The EPA should consider adopting a treatment technique

The EPA should consider adopting a treatment technique in lieu of an MCL. Section 1412(b)(7)(A) of the SDWA authorizes that approach when "it is not economically or technologically feasible to ascertain the level of a contaminant." The EPA currently has analytical methods to test for 29 PFAS in drinking water under methods 537.1 and 533.[125] This is a small fraction of the PFAS chemicals that could be present in drinking water. However, the EPA has not yet developed or validated a method for total PFAS or total organic fluorine. For this reason, if the EPA elects to regulate PFAS chemicals as a class, it may not be technologically feasible to ascertain the level of total PFAS in finished tap water. Adopting a treatment technique would allow the EPA to mandate cleanup without developing an analytical method first. Reverse osmosis is currently the most effective treatment technique for removing both long- and short-chain PFAS and, over the long run, may also be the most cost-efficient technology.[126]

The final regulatory determination should consider and analyze environmental justice considerations

The EPA has committed to "integrate environmental justice into everything" it does to "help to make our vulnerable, environmentally burdened, and economically disadvantaged communities healthier, cleaner, and more sustainable places in which to live, work, play, and learn."[127] It claims that in preparation for the preliminary regulation determination, it gathered diverse perspectives through "direct engagement with impacted communities in five states, engagement with tribal partners, and roundtables conducted with community leaders near impacted sites."[128] The EPA has focused nearly all of its analysis on sensitive subpopulations on infants, children, and nursing mothers – but has failed to explicitly consider and account for disproportionately greater risk for all residents in environmental justice communities, and especially infants, children and nursing mothers in those communities. In the final regulatory determination, the EPA should expand its analysis to highlight the impact of PFAS contamination in environmental justice communities and articulate how regulation could meaningfully reduce health risks. As EPA moves to regulate PFAS under other statutory authorities, it should also integrate environmental justice considerations into those regulations.

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124 *See* Grandjean & Budtz-Jørgensen; Lerner; Andrews, *supra* note 20.
125 *See* Envtl. Prot. Agency, *supra* note 101.
126 *See* Stoiber et al., *supra* note 87. *See also* Reade et al., *supra* note 14.
127 Envtl. Prot. Agency, *EJ 2020 Action Agenda*, iii (Oct. 2016), https://www.epa.gov/sites/production/files/2016-05/documents/052216_ej_2020_strategic_plan_final_0.pdf.
128 85 Fed. Reg. 144119.

EPA must do more to protect Americans from PFAS chemicals

Removing PFAS from drinking water is just one of many steps the EPA must take to protect Americans from PFAS chemicals. In addition to finalizing the regulatory determination and quickly moving to set health-protective drinking water limits, the EPA should:

- Develop and validate analytical methods to detect all PFAS in drinking water.
- Establish effluent limitations, permit limits, pretreatment standards, and sewage sludge standards for PFAS under the Clean Water Act.
- Regulate PFAS as toxic pollutants under the Clean Water Act.
- Regulate PFAS as Hazardous Air Pollutants under the Clean Air Act.
- Designate PFAS as hazardous substances under CERCLA to jumpstart the cleanup process in contaminated communities.
- Stop approving new uses of PFAS under the Toxic Substances Control Act, and
- Require reporting of PFAS releases under the Emergency Planning and Community Right To Know Act, as required by the FY 2020 NDAA.

EWG appreciates the opportunity to comment on this preliminary determination. Should you have any questions regarding this comment or wish to discuss further, please contact Melanie Benesh, Legislative Attorney, at mbenesh@ewg.org.