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Public comments on the California Office of Environmental Health Hazard Assessment's Proposed Public Health Goals for Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid in Drinking Water (Second Public Review Draft)

Our organizations submit these comments to the California Office of Environmental Health Hazard Assessment (OEHHA) in support of the proposed public health goals for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water.

On July 14, 2023, OEHHA published in the California Regulatory Notice Register a notice announcing the availability of the second draft technical support document for the proposed Public Health Goals (PHGs) for PFOA and PFOS. The proposed PHGs for PFOA and PFOS remain unchanged from the first draft (published July 30, 2021): 0.007 parts per trillion (ppt) for PFOA based on kidney cancer in humans and 1 ppt for PFOS based on tumors in animal studies. These public health goals correspond to the OEHHA-calculated one-in-a-million risk values and represent the levels of these contaminants in drinking water that would "pose no significant health risk to individuals consuming the water on a daily basis over a lifetime."

To date, the state of California has notification levels for PFOA, PFOS, PFHxS, and PFBS, but no maximum contaminant levels (MCLs) have been set for any PFAS or the class of PFAS combined. Although the development of public health goals for PFOA and PFOS is important, addressing all PFAS as a class is critically needed to protect Californians from contaminated drinking water.

Our organizations support OEHHA's scientific analysis and urge OEHHA to quickly finalize these PHGs so that the State Water Resources Control Board (SWRCB) can establish health-protective MCLs for PFOA and PFOS as soon as possible. Further, we urge OEHHA and the SWRCB to more efficiently protect public health by addressing all chemicals within the PFAS class.

- We support OEHHA's analysis of the most recent science and its use of the best available data and most current principles to arrive at the conclusion PFOA and PFOS can cause harm at extremely low levels (below current reporting limits), and
- We support the use of the best available science, including human epidemiological data, in both the PFOA and PFOS assessments, and
- We suggest to the SWRCB that PFAS be evaluated as a class and support establishing a class-based public health goal for PFAS.

We support the public health goal analysis and conclusion that PFOA and PFOS can cause harm at extremely low levels (below current reporting limits).

The scientific review and analysis, along with the resulting draft PHGs published by OEHHA, provides additional credence to the extreme toxicity of PFAS and is in alignment with current analyses by the United States Environmental Protection Agency (US EPA). In March 2023, US EPA proposed maximum contaminant level goals (MCLGs) for PFOA and PFOS of 0 ppt based on the conclusion that both chemicals are "likely carcinogenic." US EPA's policy is to set MCLGs at zero for any non-threshold carcinogens. While OEHHA's approach to setting PHGs for carcinogens is slightly different, relying on cancer slope factors, the practical implications of both approaches and conclusions are that PFOA and PFOS can cause health harms, including cancer, and need to be strictly regulated to protect public health.

The proposed PHG analysis indicates that PFAS are potentially impacting numerous different health endpoints at low parts per trillion levels, including increased risk of kidney cancer, liver damage, increased cholesterol and immunotoxicity. Setting stringent PHGs is imperative for protecting against the increased risk of cancer, as well as the numerous other adverse health harms associated with PFOA and PFOS. Although PHGs are non-enforceable, they are a critical step in the development of MCLs, by establishing the goal level which should be aspired to in order to protect public health.

We support the use of the best available science, including human epidemiological data, in both the PFOA and PFOS assessments.

An expansive body of scientific literature reaching back more than three decades[1] links increased PFOA exposure to increased rates of cancer. These findings are drawn from studies in animals and workers, and of exposed communities. In 2012, the C8 Science Panel study of nearly 70,000 exposed community members living near the Parkersburg, W.V., DuPont facility found a probable link between PFOA exposure and testicular and kidney cancer.[2]

We strongly support the use of human epidemiological data that links PFOA to kidney cancer as the basis for the PHG. These assessments are in accordance with the EPA's Guidelines for Carcinogenic Risk Assessment:

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[1] Environmental Working Group. "For Decades, Polluters Knew PFAS Chemicals Were Dangerous but Hid Risks from Public," August 29, 2019, https://www.ewg.org/pfastimeline/; Gaber, Nadia, Lisa Bero, and Tracey J. Woodruff. "The Devil They Knew: Chemical Documents Analysis of Industry Influence on PFAS Science." *Annals of Global Health* 89, no. 1 (June 1, 2023): 37. https://doi.org/10.5334/aogh.4013.

[2] Barry, Vaughn, Andrea Winquist, and Kyle Steenland. "Perfluorooctanoic Acid (PFOA) Exposures and Incident Cancers among Adults Living Near a Chemical Plant." *Environmental Health Perspectives* 121, no. 11–12 (January 2013): 1313–18. https://doi.org/10.1289/ehp.1306615; Vieira, Verónica M., Kate Hoffman, Hyeong-Moo Shin, Janice M. Weinberg, Thomas F. Webster, and Tony Fletcher. "Perfluorooctanoic Acid Exposure and Cancer Outcomes in a Contaminated Community: A Geographic Analysis." *Environmental Health Perspectives* 121, no. 3 (March 2013): 318–23. https://doi.org/10.1289/ehp.1205829.

> Epidemiologic data are extremely valuable in risk assessment because they provide direct evidence on whether a substance is likely to produce cancer in humans…When human data of high quality and adequate statistical power are available, they are generally preferable over animal data and should be given greater weight in hazard characterization and dose-response assessment, although both can be used.[3]

Both human epidemiological studies used in OEHHA's dose response analysis had large numbers of participants with representative exposure levels of the general population.[4] The study by Shearer et al. included renal cell carcinoma cases identified from a randomized screening trial of 150,000 adults, and Viera et al. identified cases from 13 counties in Ohio and West Virginia from an estimated population study area of 500,000. PFOA exposure was assessed directly using measured serum levels of individuals (Shearer et al.), a good indicator of long-term exposure, and Viera et al. estimated PFOA levels using a validated exposure model. Both studies showed evidence of a dose-response relationship. The findings of these studies are also consistent with two other human studies that show a strong association between PFOA and kidney cancer.[5]

We agree that studies in animals also support the carcinogenicity of PFOA to humans. The National Toxicology Program's 2020 report "NTP Technical Report on the Toxicology and Carcinogenesis Studies of Perfluorooctanoic Acid (CASRN 335-67-1) Administered in Feed to Sprague Dawley Rats" concluded, following two-year feeding studies, that PFOA causes cancer in male rats. The NTP study found "clear evidence of carcinogenic activity" and that PFOA exposure increased the incidence of tumors in liver and pancreas in male rats. The NTP findings supported the proposed listing of PFOA as a carcinogen in the first draft PHG document and under California Proposition 65 (Prop65).[6]

Epidemiological studies were informative in evaluating the non-cancer risk of PFOS, including in particular the increased cholesterol levels observed in the C8 study.[7] In the absence of a large

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[3] U.S. EPA. Guidelines for Cancer Risk Assessment. 2005. EPA/630/P-03/001F. Available at: https://www.epa.gov/sites/default/files/2013-09/documents/cancer_guidelines_final_3-25-05.pdf

[4] Shearer, Joseph J, Catherine L Callahan, Antonia M Calafat, Wen-Yi Huang, Rena R Jones, Venkata S Sabbisetti, Neal D Freedman, et al. "Serum Concentrations of Per- and Polyfluoroalkyl Substances and Risk of Renal Cell Carcinoma." *JNCI: Journal of the National Cancer Institute* 113, no. 5 (May 1, 2021): 580–87. https://doi.org/10.1093/jnci/djaa143; Vieira, Verónica M., Kate Hoffman, Hyeong-Moo Shin, Janice M. Weinberg, Thomas F. Webster, and Tony Fletcher. "Perfluorooctanoic Acid Exposure and Cancer Outcomes in a Contaminated Community: A Geographic Analysis." *Environmental Health Perspectives* 121, no. 3 (March 2013): 318–23. https://doi.org/10.1289/ehp.1205829.

[5] Barry, Vaughn, Andrea Winquist, and Kyle Steenland. "Perfluorooctanoic Acid (PFOA) Exposures and Incident Cancers among Adults Living Near a Chemical Plant." *Environmental Health Perspectives* 121, no. 11–12 (January 2013): 1313–18. https://doi.org/10.1289/ehp.1306615; Steenland, K., and S. Woskie. "Cohort Mortality Study of Workers Exposed to Perfluorooctanoic Acid." *American Journal of Epidemiology* 176, no. 10 (November 15, 2012): 909–17. https://doi.org/10.1093/aje/kws171.

[6] California Office of Environmental Health Hazard Assessment. Notice Of Intent To List Chemical By The Authoritative Bodies Mechanism: Perfluorooctanoic Acid. 2021. Available at: https://oehha.ca.gov/proposition-65/crnr/notice-intent-list-chemical-authoritative-bodies-mechanismperfluorooctanoic

[7] Steenland, K., S. Tinker, S. Frisbee, A. Ducatman, and V. Vaccarino. "Association of Perfluorooctanoic Acid and Perfluorooctane Sulfonate With Serum Lipids Among Adults Living Near a Chemical Plant."

sample-size epidemiological study evaluating cancer endpoints, OEHHA used the Key Characteristics of Carcinogens Framework to evaluate and conclude that PFOS is carcinogenic. We continue to support his approach and note that it is in agreement with the findings of the Carcinogen Identification Committee's State Qualified Experts, which listed PFOS as a carcinogen under Prop65 in December 2021.

PFAS should be evaluated as a class, and California should consider establishing a class based public health goal.

Although we understand that OEHHA developed the proposed PHGs for PFOA and PFOS at the request of the SWRCB, this only represents a small step toward protecting public health. Consequently, our organizations urge the SWRCB and OEHHA to prioritize review of PFAS beyond the long chain PFAS compounds to include the entire class of chemicals. California's Environmental Contaminant Biomonitoring Program lists the entire class of PFAS as priority chemicals for measuring it in the blood and urine of Californians, and has proposed to expand this class to include all carbon-fluorine bond containing substances. This is in part due to the persistence conferred to chemicals containing carbon-fluorine bonds and that it is a resource efficient approach, facilitating the use of non-targeted laboratory screening methods for chemicals with carbon-fluorine bonds. The Department of Toxic Substances Control also applies the class approach to prioritizing chemicals within the Safer Consumer Products program and supports extending this approach to other regulatory agencies to focus on this entire class of chemicals with similar hazard traits.[8] This framework is necessary to avoid regrettable substitutions and manage a persistent, structurally similar class that includes thousands of chemicals.[9] Further, other PFAS that have been studied, beyond PFOA and PFOS,[10] such as the replacement chemical GenX,[11] have shown evidence of carcinogenicity in two-year animal studies.

US EPA has taken the first steps towards a class-based approach for addressing PFAS in drinking water. In March 2023 US EPA proposed MCLs for PFOA and PFOS as well as a

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American Journal of Epidemiology 170, no. 10 (November 15, 2009): 1268–78. https://doi.org/10.1093/aje/kwp279.

[8] Bălan, Simona Andreea, Vivek Chander Mathrani, Dennis Fengmao Guo, and André Maurice Algazi. "Regulating PFAS as a Chemical Class under the California Safer Consumer Products Program." *Environmental Health Perspectives* 129, no. 2 (February 2021): 025001. https://doi.org/10.1289/EHP7431.

[9] Kwiatkowski, Carol F., David Q. Andrews, Linda S. Birnbaum, Thomas A. Bruton, Jamie C. DeWitt, Detlef R. U. Knappe, Maricel V. Maffini, et al. "Scientific Basis for Managing PFAS as a Chemical Class." *Environmental Science & Technology Letters* 7, no. 8 (August 11, 2020): 532–43. https://doi.org/10.1021/acs.estlett.0c00255.

[10] Pelch, Katherine E., Anna Reade, Carol F. Kwiatkowski, Francheska M. Merced-Nieves, Haleigh Cavalier, Kim Schultz, Taylor Wolffe, and Julia Varshavsky. "The PFAS-Tox Database: A Systematic Evidence Map of Health Studies on 29 per- and Polyfluoroalkyl Substances." *Environment International* 167 (September 1, 2022): 107408. https://doi.org/10.1016/j.envint.2022.107408.

[11] Caverly Rae, J.M., Lisa Craig, Theodore W. Slone, Steven R. Frame, L.William Buxton, and Gerald L. Kennedy. "Evaluation of Chronic Toxicity and Carcinogenicity of Ammonium 2,3,3,3-Tetrafluoro-2-(Heptafluoropropoxy)-Propanoate in Sprague–Dawley Rats." *Toxicology Reports* 2 (2015): 939–49. https://doi.org/10.1016/j.toxrep.2015.06.001.

Hazard Index for 4 additional PFAS (PFBS, GenX, PFNA, and PFHxS).[12] While we are pleased with the acknowledgment that exposure to multiple PFAS can have an additive effect, we urge OEHHA and the SCRWB to address PFAS in drinking water more comprehensively. Such actions are necessary because of the large fraction of unknown PFAS in drinking water sources, which will continue to be an issue as long as PFAS are in production and use.[13]

Our organizations are deeply concerned about the prevalence of all types of PFAS detected in drinking water and the continued wide scale contamination in the environment. Analyzing state and federal data, it is estimated that more than 200 million Americans,[14] including up to 22 million Californians,[15] could have PFAS-contaminated drinking water. Analysis has also identified more than 57,000 presumptive contamination sites across the nation.[16] In addition to the environmental exposures to PFOA and PFOS that continue to affect the health and safety of California's residents despite their phase-out, there is growing evidence that the replacement chemicals that continue to be approved for use are just as harmful to human health and the environment. Multiple toxicity assessments of other PFAS have been performed by EPA, all documenting a range of health effects associated with PFAS exposure.[17] For instance, GenX

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[12] US EPA. "PFAS National Primary Drinking Water Regulation Rulemaking." *Federal Register*, Proposed Rules, 88, no. 60 (March 29, 2023): 18638.

[13] Perkins, Tom. "Revealed: US Water Likely Contains More 'Forever Chemicals' than EPA Tests Show." *The Guardian*, July 6, 2022, sec. US news. https://www.theguardian.com/us-news/2022/jul/06/us-drinking-water-pfas-toxic-forever-chemicals-epa-tests.

[14] Andrews, David Q., and Olga V. Naidenko. "Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States." *Environmental Science & Technology Letters* 7, no. 12 (December 8, 2020): 931–36. https://doi.org/10.1021/acs.estlett.0c00713.

[15] Natural Resources Defense Council. 2021 Dirty Water: Toxic "Forever" PFAS Chemicals Are Prevalent in the Drinking Water of Environmental Justice Communities. Available at: https://www.nrdc.org/resources/dirty-water-toxic-forever-pfas-chemicals-are-prevalent-drinking-waterenvironmental. Most recent estimate of the number of Californians served by public water systems with PFAS contamination is from Q3 2022 to Q2 2023. Data from: California Water Board. "GeoTracker PFAS Map," 2022. https://geotracker.waterboards.ca.gov/map/pfas_map.

[16] Salvatore, Derrick, Kira Mok, Kimberly K. Garrett, Grace Poudrier, Phil Brown, Linda S. Birnbaum, Gretta Goldenman, et al. "Presumptive Contamination: A New Approach to PFAS Contamination Based on Likely Sources." *Environmental Science & Technology Letters*, October 12, 2022. https://doi.org/10.1021/acs.estlett.2c00502.

[17] US EPA. "ORD Human Health Toxicity Value for Lithium Bis[(Trifluoromethyl)Sulfonyl]Azanide (HQ-115) (CASRN 90076-65-6│DTXSID8044468)," July 2023. https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=547108&Lab=CPHEA; US EPA. "Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as 'GenX Chemicals.'" Final, October 2021. https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf; US EPA. "ORD Human Health Toxicity Value for Perfluoropropanoic Acid (CASRN 422-64-0│DTXSID8059970)," July 2023. https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=547109&Lab=CPHEA; US EPA. "IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA, CASRN 375-22-4) and Related Salts." Final, December 2022. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0701tr.pdf; US EPA. "IRIS Toxicological Review of Perfluorohexanoic Acid [PFHxA, CASRN 307-24-4] and Related Salts." Final, April 2023. https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0704tr.pdf; US EPA. "IRIS Toxicological Review of Perfluorodecanoic Acid (PFDA) and Related Salts (Public Comment and External Review Draft)," April 2023. https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=354408;

and PFBS have been linked to health effects similar to those caused by the chemicals they have replaced (PFOA and PFOS, respectively).[18]
Due to income and health disparities, low-income communities and communities of color are especially vulnerable to PFOA, PFOS and broader PFAS exposure, although few studies have been conducted to characterize disparities. A report analyzing California's PFAS drinking water monitoring data revealed that PFAS pollution in California is widespread throughout the state, but more intense in communities already overburdened by multiple sources of pollution and by other factors that make them more sensitive to pollution, putting those vulnerable communities at greater risk of harm from PFAS exposure.[19] At least 69 percent of state-identified disadvantaged communities have PFAS contamination in their public water systems. Almost a quarter of these communities face the highest levels of PFAS contamination in the state.[20] A more recent study using monitoring data from 18 states found that communities of color are more likely to be exposed to harmful levels of PFAS in their water supplies than people living in other communities.[21]

Finally, by focusing only on two chemicals, both of which are long-chain PFAS, water systems are likely to invest in treatment that will not be optimized to treat short-chain PFAS that are similarly toxic. As a result, systems may have to spend additional money to address these other PFAS chemicals, placing a tremendous economic burden on ratepayers and potentially limiting actions that could be taken against PFAS manufacturers to recoup treatment costs. California's limited approach is, therefore, shortsighted and fails to consider the overall health and fiscal impacts of PFAS on communities.

In conclusion, our organizations support the development of PHGs for PFOA and PFOS at 0.007 ppt and 1 ppt, respectively, and strongly encourage OEHHA to finalize these PHGs quickly so that efforts can be focused on addressing the risk of health harms for the entire class of PFAS.

US EPA. "Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3)." Final, April 2021. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=350888; US EPA. "IRIS Toxicological Review of Perfluorohexanesulfonic Acid (PFHxS, CASRN 335-46-4) and Related Salts." External Review Draft, July 24, 2023.

[18] US EPA. "Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as 'GenX Chemicals.'" Final, October 2021. https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf; US EPA. "Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3)." Final, April 2021. https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=350888.

[19] Kar, Avinash, Anna Reade, and Susan Lee. "Dirty Water: Toxic 'Forever' PFAS Chemicals Are Prevalent in the Drinking Water of Environmental Justice Communities." NRDC, August 18, 2021. https://www.nrdc.org/resources/dirty-water-toxic-forever-pfas-chemicals-are-prevalent-drinking-water-environmental.

[20] ibid.

[21] Liddie, Jahred M., Laurel A. Schaider, and Elsie M. Sunderland. "Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems." *Environmental Science & Technology* 57, no. 21 (May 30, 2023): 7902–12. https://doi.org/10.1021/acs.est.2c07255.

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