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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

Submitted via electronic docket at https://oehha.ca.gov/comments

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 perfluorooctance sulfonic acid (PFOS) in drinking water.

In the public review draft published on July 22, 2021, OEHHA presented the following public health goals: 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 level of a drinking water contaminant at which adverse health effects are not expected to occur from a lifetime of exposure.

To date, the state of California has notification levels for PFOA, PFOS 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 the scientific analysis and offer suggestions for improvement to further protect human health.

- 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 that a safe level of exposure to PFOA or PFOS is likely 1 ppt or lower, and significantly below the current EPA health advisory of 70 ppt.
- We support the evaluation and use of human epidemiological evidence of harm for both the PFOA and PFOS assessments.
- We suggest that OEHHA use the most health protective study in setting the public health goal for PFOA.
- We suggest to the State Water Resources Control Board 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 a safe level of exposure to PFOA or PFOS is likely 1 ppt or lower

The scientific review and analysis, along with the resulting draft public health goal values published by OEHHA, provides additional credence to the extreme toxicity of PFAS. Although the U.S. Environmental Protection Agency's published health advisory established a value of 70 ppt for the combined exposure to PFOA and PFOS in 2016, most states that have subsequently reviewed the scientific evidence in setting a drinking water standard have calculated a much lower safe exposure limit.[1]

The proposed public health goal 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 public health goals 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 public health goals are non-enforceable, they will serve as the goal concentrations when developing maximum contaminant limits.

We support the use of human epidemiological data in both the PFOA and PFOS assessments

An expansive body of scientific literature reaching back more than three decades[2] 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.[3,4]

We strongly support the use of human epidemiological data that links PFOA to kidney cancer as the basis for the public health goal. This is similar to OEHHA's development of the public health goal for arsenic using human exposure data. These assessments are in accordance with the EPA's Guidelines for Carcinogenic Risk Assessment:

> 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.[5]

Both human epidemiological studies used in OEHHA's dose response analysis had large numbers of participants with representative exposure levels of the general population. 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

1 Post, Gloria. Recent US State and Federal Drinking Water Guidelines for Per- and Polyfluoroalkyl Substances. 2020. Available: setac.onlinelibrary.wiley.com/doi/10.1002/etc.4863
2 Environmental Working Group. For decades, polluters knew PFAS chemicals were dangerous but hid risks from public. Available:https://www.ewg.org/pfastimeline/
3 Barry V, Winquist A, Steenland K. Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. Environ Health Perspect. 2013 Nov-Dec;121(11-12):1313-8.
4 Verónica M. Vieira, 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. Environ Health Perspect. 2013. 121:3.
5 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

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.[6,7]

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 under California Proposition 65, as previously determined by OEHHA this year.[8]

We support the use of animal studies to develop the public health goal for PFOS, as no large sample-size epidemiology studies were identified to rigorously calculate human cancer risk. However, epidemiological studies were used to calculate non-cancer risk based on findings from the C8 study and the association of increased risk of elevated cholesterol. Recently Li et al. also found causal association of serum levels of PFOA, PFOS and PFHxS and elevated cholesterol.[9]

We suggest that OEHHA use the most health protective study in setting the public health goal for PFOA

In setting the proposed public health goal value for PFOA based on increased kidney cancer risk, OEHHA averaged the results from two different studies that found increased risk in the general population. As OEHHA noted in its analysis of biases in the epidemiologic studies, it was likely that problems related to participant recruitment and selection, categorizing exposure, and classification of those without kidney cancer all likely led to underestimates, not overestimates, of cancer risk. The justification for the use of the geometric mean as opposed to the most protective cancer slope factor is inadequate and described in the text as being used to "make maximum use of both these strong studies."

The most protective cancer slope factor should be used to calculate the public health goal so that it is designed to protect the most vulnerable populations, as required by statute, and the additional study or studies should be used as supporting evidence.

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6 Barry V, Winquist A, Steenland K. Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. *Environ Health Perspect*. 2013;121(11-12):1313-1318.

7 Steenland K, Woskie S. Cohort mortality study of workers exposed to perfluorooctanoic acid. Am J Epidemiol. 2012 Nov 15;176(10):909-17.

8 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-mechanism-perfluorooctanoic

9 Li Y, Barregard L, Xu Y, et al. Associations between perfluoroalkyl substances and serum lipids in a Swedish adult population with contaminated drinking water. *Environ Health*. 2020;19(1):33. 9

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 public health goals for PFOA and PFOS at the request of the State Water Resources Control Board, this only represents a small step toward protecting public health. Consequently, our organizations urge the State Water Board and OEHHA to prioritize review of PFAS beyond the long-chain PFAS compounds to include those still in widespread active use, and most comprehensively, 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. 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.[10] This framework is necessary to avoid regrettable substitutions and manage a persistent, structurally similar class that includes thousands of chemicals.[11] Further, other PFAS that have been studied, beyond PFOA and PFOS,[12] such as the replacement chemical GenX,[13] have shown evidence of carcinogenicity in two-year animal studies.

Our organizations are deeply concerned about the prevalence of all types of PFAS detected in drinking water and the continued widescale persistence in the environment. Analyzing state and federal data, it is estimated that more than 200 million Americans,[14] including up to 16 million Californians,[15] could have PFAS-contaminated drinking water. Analysis has also identified more than 40,000 industrial or municipal sites that are potential sources of PFAS contamination across the nation, as of July 2021.[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. A peer-reviewed study released in 2019 refutes claims by the chemical industry that the next generation of PFAS is safer than PFOA and PFOS.[17] For

10 Bălan Simona A, Mathrani Vivek C, Guo Dennis F, Algazi André M. Regulating PFAS as a Chemical Class under the California Safer Consumer Products Program. *Environmental Health Perspectives.* 2021;129(2):025001.

11 Kwiatkowski CF, Andrews DQ, Birnbaum LS, et al. Scientific Basis for Managing PFAS as a Chemical Class. *Environmental Science & Technology Letters.* 2020;7(8):532-543.

12 Butenhoff JL, Chang SC, Olsen GW, Thomford PJ. Chronic dietary toxicity and carcinogenicity study with potassium perfluorooctane sulfonate in Sprague Dawley rats. *Toxicology*. 2012;293, 1–15.

13 Caverly Rae, J.M.; Craig, L.; Slone, T.W.; Frame, S.R.; Buxton, L.W.; Kennedy, G.L. Evaluation of chronic toxicity and carcinogenicity of ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)-propanoate in Sprague-Dawley rats.*Toxicol. Rep*. 2015,2, 939–949.

14 David Q. Andrews and Olga V. Naidenko. Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States. *Environmental Science & Technology Letters* 2020 *7* (12), 931-936

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-water-environmental

16 Environmental Working Group. 2021. Suspected discharges of PFAS. Available at: https://www.ewg.org/interactive-maps/2021_suspected_industrial_discharges_of_pfas/map/

17 Fan Li, Jun Duan, Shuting Tian, Haodong Ji, Yangmo Zhu, Zongsu Wei, Dongye Zhao,

instance, GenX 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.[19] A recent 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. 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.[15]

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 will likely 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 public health goals for PFOA and PFOS at 0.007 ppt and 1 ppt, respectively, and strongly encourage OEHHA to use the most health protective studies to set PHGs and assess the risk of health harms for the entire class of PFAS.

Sincerely,

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Short-chain per- and polyfluoroalkyl substances in aquatic systems: Occurrence, impacts and treatment. 2020. Chemical Engineering Journal.,Volume 380,122506, ISSN 1385-8947.
18 USEPA (U.S. Environmental Protection Agency). 2018a. Public Review Draft: Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3). EPA 823P18001. U.S. Environmental Protection Agency, Washington, DC
19 Johnston J, Cushing L. Chemical Exposures, Health, and Environmental Justice in Communities Living on the Fenceline of Industry. *Curr Environ Health Rep*. 2020;7(1):48-57.

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