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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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.¹

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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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. This framework is necessary to avoid regrettable substitutions and manage a persistent, structurally similar class that includes thousands of chemicals. Further, other PFAS that have been studied, beyond PFOA and PFOS, such as the replacement chemical GenX, 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


8 Bálan, 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.


Hazard Index for 4 additional PFAS (PFBS, GenX, PFNA, and PFHxS). 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.

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, including up to 22 million Californians, could have PFAS-contaminated drinking water. Analysis has also identified more than 57,000 presumptive contamination sites across the nation. 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. For instance, GenX

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and PFBS have been linked to health effects similar to those caused by the chemicals they have replaced (PFOA and PFOS, respectively). 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. 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. 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.

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.

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20 ibid.

Sincerely,

Anna Reade, PhD  
Senior Scientist  
and  
Katie Pelch, PhD  
Scientist  
Natural Resources Defense Council

Andria Ventura  
Legislative and Policy Director  
Clean Water Action

Erick Orellana  
Policy Advocate  
Community Water Center

Nancy Buermeyer  
Senior Policy Strategist  
Breast Cancer Prevention Partners

Lenny Siegel  
Executive Director  
Center for Public Environmental Oversight

Jenn Engstrom  
State Director  
CALPIRG

Robert W. Bowcock  
Managing Director  
Integrated Resource Management, Inc.

Erin Brockovich  
Founder  
Erin Brockovich Foundation

Heidi Sanborn  
Executive Director  
National Stewardship Action Council

Jamie McConnell  
Deputy Director  
Women’s Voices for the Earth
Michael Claiborne  
Directing Attorney  
Leadership Counsel for Justice and Accountability

Arlene Blum, PhD  
Executive Director  
Green Science Policy Institute

Bill Allayaud  
Vice President, California Government Affairs  
and  
Tasha Stoiber, PhD  
Senior Scientist  
Environmental Working Group

Charlie Pizarro  
Interim CEO  
Center for Environmental Health

Alicia Culver  
Executive Director  
Responsible Purchasing Network

Katherine Pease,  
Director of Science & Policy,  
Heal the Bay

Mindi Messmer, MS, PG, CG  
New Hampshire Safe Water Alliance  
NH Science and Public Health