

May 3, 2021

Public comments on the California Office of Environmental Health Hazard Assessment's Notice of Intent to list perfluorooctanoic acid as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65).

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) on the Notice of Intent to list perfluorooctanoic acid (PFOA) as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65). Our organizations strongly support OEHHA's determination to list PFOA as known to the state to cause cancer.

There is an expansive body of scientific literature reaching back more than three decades¹ that 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

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 (Hsd:Sprague Dawley® SD®) 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.

Thus, the NTP findings support the listing of PFOA as a carcinogen under California Proposition 65. The NTP is an authoritative body for carcinogens under Proposition 65 regulations. 27 Cal. Code Regs. § 25306(m). In addition, the NTP report formally identified PFOA as a carcinogen, and its conclusions meet the sufficiency criteria in the regulations, as outlined by OEHHA in its proposal. *Id.* §§ 25306 (d), (e)(2). Based on increased incidences of tumors, the report also concluded that there was some evidence of carcinogenic activity in female rats.

Considering this body of evidence, our organizations are deeply concerned about the ongoing uses of PFOA-related chemicals in popular consumer products – [such as liquid](#)

¹ Environmental Working Group. For decades, polluters knew PFAS chemicals were dangerous but hid risks from public. Available: <https://www.ewg.org/pfastimeline/>

² 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.

[foundation cosmetics products](#)³ – and the continued widescale persistence of PFOA in the environment. Despite the national effort to phase out production of PFOA and PFOA-related chemicals, these product and environmental exposures continue to affect the health and safety of California’s residents and people across the nation. Due to income and health disparities, low-income communities and communities of color are especially vulnerable to PFOA and broader PFAS exposure. Analysis published by the Union of Concerned scientists showed that low-income people and communities of color are also more likely to be living within 5 miles of PFAS-contaminated sites (e.g., chemical plants, defense bases, airports, and landfills) and drink water contaminated with PFAS.⁴

Managing PFAS as a class

Although listing PFOA as a chemical known to cause cancer is a crucial step forward for protecting public health, our organizations urge 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.⁵ This framework is necessary to avoid regrettable substitutions and manage a persistent, structurally similar class that includes thousands of chemicals.⁶ Further, other PFAS that have been studied, such as PFOS⁷ and the replacement chemical GenX,⁸ have shown evidence of carcinogenicity in two-year animal studies.

New Approach Methodologies as tools for carcinogenicity assessment

Although two-year animal studies are the standard, we would also like to point to the importance of New Approach Methodologies (NAMs) as tools for the future in determining carcinogenicity and regulatory decision-making. There is a great need to develop new tools to rapidly fill data gaps and increase the capacity to efficiently test and identify potential

³ Notices of Violation of the Safe Drinking Water and Toxic Enforcement Act (Proposition 65) filed by the Center for Environmental Health. AG Numbers 2020-03499, 2020-00823, 2019-00771, and 2019-00713. Available: <https://oag.ca.gov/prop65/60-day-notice-search>

⁴ Genna Reed. PFAS Contamination is an Equity Issue, and President Trumps’ EPA is Failing to Fix it. Union of Concerned Scientists. Available: <https://blog.ucsusa.org/genna-reed/pfas-contamination-is-an-equity-issue-president-trumps-epa-is-failing-to-fix-it>

⁵ 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.

⁶ 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.

⁷ 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.

⁸ 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.

threats to human health. For example, ToxCast program high-throughput screening data provides evidence of carcinogenic mechanisms. Chui et al. found that ToxCast assays assessed five of 10 key characteristics of carcinogens that support literature evidence of “induces oxidative stress,” “alters cell proliferation, cell death or nutrient supply,” and “receptor mediated effects” for PFOA.⁹

Recently, a team of scientists from the Environmental Working Group and Indiana University published a study that assessed the key characteristics of carcinogens of 26 types of PFAS, including PFOA.¹⁰ The key characteristics of carcinogens framework was developed to facilitate the organization and characterization of mechanistic data for cancer hazard identification. These characteristics aid in cancer hazard classification through parallel evaluation with human and animal evidence of carcinogenicity, which continue to be necessary to develop NAMs and to verify they can predict toxicity as precisely as human and animal studies. This framework includes evaluations of evidence from molecular epidemiology, animal toxicity and high-throughput assay screening studies.

The study by Temkin et al. found strong evidence that multiple PFAS induce oxidative stress, suppress the immune system, and modulate receptor-mediated effects. It also found suggestive evidence indicating that some PFAS can induce epigenetic alterations and influence cell proliferation. Experimental data indicate that PFAS are not genotoxic and generally do not undergo metabolic activation. Overall, the key characteristics analysis found in vitro and animal bioassay studies supporting “receptor mediated effects” and “alteration of cell proliferation, cell death or nutrient supply” for PFOA, along with studies supporting 21 and seven other PFAS, respectively. For PFOA, the associations for additional key characteristics were noted for “chronic inflammation,” “immunosuppression,” and “epigenetic alterations,”

In conclusion, our organizations support the listing of PFOA as a chemical known to cause cancer and strongly encourage OEHHA to assess the risk of health harms for the entire class of PFAS. We also urge OEHHA to establish the most protective safe harbor levels consistent with Proposition 65.

Sincerely,

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⁹ Chiu WA, Guyton KZ, Martin MT, Reif DM, Rusyn I. Use of high-throughput in vitro toxicity screening data in cancer hazard evaluations by IARC Monograph Working Groups. *ALTEX*. 2018;35(1):51-64.

¹⁰ Temkin AM, Hocesvar BA, Andrews DQ, Naidenko OV, Kamendulis LM. Application of the Key Characteristics of Carcinogens to Per and Polyfluoroalkyl Substances. *International Journal of Environmental Research and Public Health*. 2020;17(5).

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