Office of Environmental Health Hazard Assessment



Lauren Zeise, Ph.D., Director
Headquarters • 1001 I Street • Sacramento, California 95814
Mailing Address: P.O. Box 4010 • Sacramento, California 95812-4010
Oakland Office • Mailing Address: 1515 Clay Street, 16th Floor • Oakland, California 94612



MEMORANDUM

TO:

Darrin Polhemus

Deputy Director, Division of Drinking Water State Water Resources Control Board

FROM:

Lauren Zeise

Director

DATE:

June 26, 2018

SUBJECT:

RECOMMENDATION FOR INTERIM NOTIFICATION LEVELS FOR

PERFLUOROOCTANOIC ACID (PFOA) AND PERFLUOROOCTANE

SULFONATE (PFOS)

The Office of Environmental Health Hazard Assessment (OEHHA) is recommending an interim notification level (NL) of 14 parts per trillion (ppt) for perfluorooctanoic acid (PFOA) and 13 ppt for perfluorooctane sulfonate (PFOS) in drinking water. These values, based on a review of currently available health-based advisory levels and standards and supporting documentation, were identified by OEHHA in response to a request by the State Water Resources Control Board (SWRCB). We are recommending that these NLs be used on an interim basis, while OEHHA completes its derivation of a final recommendation for NLs for these compounds.

PFOA and PFOS are environmentally persistent, and are readily absorbed but not readily eliminated from the human body. Effects associated with exposure to PFOA and PFOS include:

- Developmental toxicity: PFOA and PFOS were listed as developmental toxicants under California's Proposition 65 in November 2017.¹
- Immunotoxicity: The National Toxicology Program in September 2016² released a comprehensive and systematic review of the literature that concluded that PFOA and PFOS are "presumed to be an immune hazard to humans" based on evidence from human and animal studies.

¹ California Regulatory Notice Register, No. 45-Z, page 1714, November 10, 2017.

² NTP (National Toxicology Program). 2016. Monograph on Immunotoxicity Associated with Exposure to Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Research Triangle Park, NC: National Toxicology Program. https://ntp.niehs.nih.gov/ntp/ohat/pfoa pfos/pfoa pfosmonograph 508.pdf

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- Cancer: The World Health Organization's International Agency for Research on Cancer (IARC) has classified PFOA as possibly carcinogenic to humans.³
 A positive association was observed between testicular and kidney cancers in humans, and testicular tumors in multiple animal studies have been observed. Liver and pancreatic tumors were also observed in animal studies.
- Liver toxicity: A number of animal and human studies in the scientific literature show these chemicals are toxic to the liver.

Dose-response data on these endpoints have been reviewed by several states and the federal government for the purpose of deriving drinking water health advisory (HA) levels or standards for these compounds. The US Environmental Protection Agency (US EPA) in 2016 developed HA levels of 70 ppt for PFOA⁴ and for PFOS⁵ based on developmental effects observed in animal toxicity studies.

The most recent comprehensive reviews that resulted in water advisory levels or standards for these chemicals were published by the State of New Jersey. It considered the sensitive endpoints described above. For PFOS,⁶ New Jersey in June 2018 found the most sensitive endpoints were associated with immunotoxicity and that 13 ppt was protective against this endpoint. For PFOA, New Jersey in March 2017 estimated that a water concentration of 14 ppt was associated with a 10⁻⁶ risk of cancer.⁷ New Jersey found this same level to be protective against liver toxicity.

OEHHA has reviewed the documents and process used by New Jersey to derive these numbers and finds both to be rigorous and sufficient for establishing interim NLs for these compounds.

³ IARC. 2017. Some Chemicals Used as Solvents and in Polymer Manufacture. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 110. International Agency for Research on Cancer, World Health Organization, Lyon, France.

⁴ US EPA. 2016. Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA). EPA 822-R-16-005. Office of Water, United States Environmental Protection Agency, Washington DC; US EPA. 2016. Office of Water. Health Effects Support Document for Perfluorooctanoic Acid (PFOA). EPA 822-R-16-003, May 2016, 322 pages.

⁵ US EPA. 2016. Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS). EPA 822-R-16-004. Office of Water, United States Environmental Protection Agency, Washington DC. US EPA. 2016. Office of Water. Health Effects Support Document for Perfluorooctane Sulfonate (PFOS). EPA 822-R-16-002, May 2016, 245 pages.

⁶ State of New Jersey, New Jersey Drinking Water Quality Institute, Maximum Contaminant Level Recommendation for Perfluorooctane Sulfonate in Drinking Water, Appendix A. Health-Based Maximum Contaminant Level Support Document: Perfluoroctane Sulfonate (PFOS), New Jersey Drinking Water Quality Institute Health Effects Subcommittee, June 5, 2018, 1102 pages.

⁷ State of New Jersey, New Jersey Drinking Water Quality Institute, Maximum Contaminant Level Recommendation for Perfluorooctanoic Acid in Drinking Water, Appendix A. Health-Based Maximum Contaminant Level Support Document: Perfluoroctanoic Acid (PFOA), New Jersey Drinking Water Quality Institute Health Effects Subcommittee, February 15, 2017, 458 pages.

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OEHHA also notes that the New Jersey values are similar to water concentrations that can be derived from a public draft report released this month by the US Agency for Toxic Substances and Disease Registry (ATSDR): *Toxicological Profile for Perfluoroalkyls*.⁸ ATSDR's draft minimal risk level (MRL) of 3 × 10⁻⁶ milligrams per kilogram of body weight per day (mg/kg-day) for PFOA and 2 × 10⁻⁶ mg/kg-day for PFOS are based on developmental effects observed in animal toxicity studies. Applying OEHHA's public health goal methodology to these MRLs would result in drinking water advisory levels of 13 ppt for PFOA and 9 ppt for PFOS.

Therefore, based on an initial review of the currently available health-based advisory levels and regulatory standards for PFOA and PFOS, OEHHA recommends that the SWRCB adopt the values of 14 ppt for PFOA and 13 ppt for PFOS, developed by New Jersey, as interim NLs as OEHHA completes its own derivation of recommended drinking water NLs for these chemicals. OEHHA expects this to occur later this year.

cc: Julie Henderson

Deputy Secretary for Health and Public Policy California Environmental Protection Agency

⁸ ATSDR (2018). Toxicological Profile for Perfluoroalkyls - Draft for Public Comment. Agency for Toxic Substances and Disease Registry, United States Department of Health and Human Services, Atlanta, Georgia.