

**CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT  
SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT OF 1986  
(PROPOSITION 65)**

**NOTICE OF INTENT TO LIST CHEMICAL BY THE AUTHORITATIVE BODIES  
MECHANISM:  
PERFLUOROCTANOIC ACID**

**March 19, 2021**

The California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) intends to list *perfluorooctanoic acid (PFOA)* (CAS RN 335-67-1) as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65<sup>1</sup>). This action is being proposed pursuant to the "Authoritative Bodies" listing mechanism<sup>2</sup>. According to the National Toxicology Program (NTP 2020), PFOA was widely used in manufacturing of a variety of consumer products that included many nonstick applications, such as for clothing and cookware. PFOA is no longer produced in the US and its production and use worldwide was significantly curtailed with the 2019 ban of the compound under the Stockholm Convention on Persistent Organic Pollutants<sup>3</sup>. However, its persistence in the environment and breakdown of certain other per- and polyfluoroalkyl substances result in continued PFOA exposure.

**Background on listing by the Authoritative Bodies mechanism:** A chemical must be listed under the Proposition 65 regulations when two conditions are met:

- 1) An authoritative body formally identifies the chemical as causing cancer (Section 25306(d)<sup>4</sup>).
- 2) The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(e)).

However, the chemical is not listed if scientifically valid data which were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306(f)).

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<sup>1</sup> Health and Safety Code section 25249.5 *et seq.*

<sup>2</sup> Health and Safety Code section 25249.8(b) and Title 27, Cal. Code of Regs., section 25306.

<sup>3</sup> The new POPs under the Stockholm Convention.

<http://www.pops.int/TheConvention/ThePOPs/TheNewPOPs/tabid/2511/Default.aspx> (Accessed on 2/18/2021); Text of the Convention.

<http://chm.pops.int/Convention/ConventionText/tabid/2232/Default.aspx> (Accessed on 2/18/2021)

<sup>4</sup> All referenced sections are from Title 27 of the Cal. Code of Regulations.

NTP is one of several institutions designated as authoritative for the identification of chemicals as causing cancer (Section 25306(m)).

OEHHA is the lead agency for Proposition 65 implementation. After an authoritative body has made a determination about a chemical, OEHHA evaluates whether listing under Proposition 65 is required using the criteria contained in the regulations.

**OEHHA's determination:** PFOA meets the criteria for listing as known to the state to cause cancer under Proposition 65, based on findings of the NTP (2020).

**Formal identification and sufficiency of evidence for PFOA:** In 2020, NTP published a report, entitled *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*, that concludes that the chemical causes cancer (NTP, 2020). This report satisfies the formal identification and sufficiency of evidence criteria in the Proposition 65 regulations.

OEHHA is relying on the NTP's discussion of data and conclusions in the report that PFOA causes cancer. NTP (2020) states in the Conclusion section of the report's Abstract (page xviii):

“Under the conditions of these 2-year feed studies, there was *clear evidence of carcinogenic activity*...of PFOA in male Hsd:Sprague Dawley® SD® rats based on the increased incidence of hepatocellular neoplasms (predominately hepatocellular adenomas) and increased incidence of acinar cell neoplasms (predominately acinar cell adenomas) of the pancreas. The additional effect of perinatal exposure in combination with postnatal exposure was uncertain and limited to the observation of hepatocellular carcinomas.” (Emphasis in original)

The NTP (2020) report states in the main body of the report (pages 88 and 89, respectively):

“In males, the incidences of hepatocellular adenomas were increased in the 40 and 80 ppm groups with and without perinatal exposure and exceeded the historical control range. In addition, hepatocellular carcinomas, a rare neoplasm (0/340 historical control), occurred in the 300/80 group.”

“Increased incidences of pancreatic acinar cell adenomas and adenocarcinomas were observed in exposed males, as was the combined incidence of these neoplasms. Significantly increased incidences of adenomas in all postweaning exposed groups (36–64%) were higher than the historical control range for adenomas in males (45/340 historical control; range 0–28%) and the occurrence

of rare adenocarcinomas (2/340 historical control; range 0–2%) were observed in all postweaning exposure groups (20, 40, and 80 ppm).”

Thus, NTP (2020) found that PFOA causes increased incidences of combined malignant and benign tumors at two sites (liver and pancreas) and increased the incidences of rare malignant tumors (hepatocellular carcinoma and pancreatic acinar cell adenocarcinoma) in male rats<sup>5</sup>.

**Request for comments:** OEHHA is requesting comments as to whether PFOA meets the criteria set forth in the Proposition 65 regulations for authoritative bodies listings. In order to be considered, **OEHHA must receive comments by May 3, 2021**. This comment period has been extended an additional by 15 days due to the COVID-19 Emergency.

Because of limited in-office staffing during the COVID-19 emergency, OEHHA strongly recommends that comments be submitted electronically through our website at <https://oehha.ca.gov/comments>, rather than in paper form.

Comments submitted in paper form may still be mailed or delivered in person to the address below. Please be aware that the CalEPA and OEHHA employees are working remotely due to the COVID-19 emergency, so receipt of materials that are mailed or delivered in person will be delayed.

All non-electronic submissions should be directed to:

Tyler Saechao  
Office of Environmental Health Hazard Assessment  
1001 I Street  
P.O. Box 4010, MS-12B  
Sacramento, California 95812-4010

Telephone: 916-445-6900

Comments received during the public comment period will be posted on the OEHHA website after the close of the comment period.

OEHHA encourages all commenters to submit their comments in a format compliant with the accessibility requirements of the Americans with Disabilities Act, so that they

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<sup>5</sup> The hepatocellular adenomas observed in male rats in NTP (2020) are also rare in NTP historical controls (2/340; range 0-2%) (NTP 2019a) and (2/489; range 0-2%) (NTP 2019b).

can be read using screen reader technology and those with visual impairments are able to listen to them.

OEHHA is subject to the California Public Records Act and other laws that require the release of certain information upon request. If you provide comments, please be aware that your name, address and e-mail may be available to third parties.

If you have any questions, please contact Tyler Saechao at [Tyler.Saechao@OEHHA.ca.gov](mailto:Tyler.Saechao@OEHHA.ca.gov) or at (916) 445-6900.

## References

National Toxicology Program (NTP 2019a). NTP Historical Controls Report, All Routes and Vehicles, Harlan Sprague-Dawley Rats. Version April 2019. US Department of Health and Human Services, NTP, Research Triangle Park, NC. Available from: [https://ntp.niehs.nih.gov/ntp/historical\\_controls/ntp2000\\_2019/r\\_hcrpt\\_allrte20190400.pdf](https://ntp.niehs.nih.gov/ntp/historical_controls/ntp2000_2019/r_hcrpt_allrte20190400.pdf)

National Toxicology Program (NTP 2019b). NTP Historical Controls Report, All Routes and Vehicles, Harlan Sprague-Dawley Rats. Version November 2019. US Department of Health and Human Services, NTP, Research Triangle Park, NC. Available from: [https://ntp.niehs.nih.gov/ntp/historical\\_controls/ntp2000\\_2019/r\\_hcrpt\\_allrte20191100.pdf](https://ntp.niehs.nih.gov/ntp/historical_controls/ntp2000_2019/r_hcrpt_allrte20191100.pdf)

National Toxicology Program (NTP 2020). 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. Technical Report Series No. 598. US Department of Health and Human Services, NTP, Research Triangle Park, NC. Available from URL: [https://ntp.niehs.nih.gov/ntp/htdocs/lt\\_rpts/tr598\\_508.pdf](https://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr598_508.pdf).