# More Prop 65 Regulation Of PFAS Means More Risks For Cos.

By **Brett Winters, Graham Ansell and Will Wagner** (October 21, 2021)

Brett Winters

Graham Ansell

Will Wagner

California's Office of Environmental Health Hazard Assessment recently announced its intention to expand the regulation of the class of chemicals known as per- and polyfluoroalkyl substances under Proposition 65. PFAS are a broad class of human-made fluorinated chemicals.

In late September, OEHHA announced that perfluorooctane sulfonic acid, or PFOS, including its salts and transformation and/or degradation precursors, will be considered for possible listing as a carcinogen by the Carcinogen Identification Committee, or CIC.[1]

Shortly thereafter, OEHHA announced the Developmental and Reproductive Toxicant Identification Committee, or DARTIC, will meet to consider perfluorononanoic acid, or PFNA, and perfluorodecanoic acid, or PFDA, for possible listing as reproductive toxicants.[2]

These announcements, in conjunction with OEHHA's notice of intent, issued in March, to list perfluorooctanoic acid, or PFOA, as a carcinogen, illustrate the agency's intention to considerably expand the regulation of PFAS under Proposition 65.[3]

As detailed below, these listings would have a considerable impact on Proposition 65 requirements for products and drinking water discharges containing the chemicals.

The potential listing of PFOS precursors based on PFOS data is of particular note, as it may result in the novel regulation of additional chemicals under Proposition 65 based on information related to the parent chemical alone.

These developments will likely increase litigation and enforcement risks for California companies. Businesses should continue to closely follow PFAS regulatory developments in California, and consider providing public comments to OEHHA for the upcoming CIC and DARTIC meetings.

**Cancer Identification Committee Evaluation of PFOS**

On Sept. 24, OEHHA announced that the CIC will meet on Dec. 6 to consider PFOS, including its salts and transformation and/or degradation precursors, for possible listing as a carcinogen under Proposition 65. PFOS is currently listed under Proposition 65 as a developmental toxicant, but not as a carcinogen.

The CIC's focus on PFOS as a high-priority candidate for possible listing was decided on Nov. 17, 2020, at a virtual public meeting.[4] The consideration of PFOS and PFOS precursors for possible listing as a carcinogen at the upcoming CIC meeting is one of the final steps in the listing process under the "state's qualified experts" listing mechanism.[5]

Historically, PFOS and its precursors were used in certain consumer products such as textiles and carpets, and, most notably, in aqueous film forming foam.[6] PFOS is no longer

produced in the U.S., and its production and use worldwide was significantly curtailed in 2009 when it was added to Annex B under the Stockholm Convention on Persistent Organic Pollutants.[7] However, it may be present in certain imported consumer products, and persists in the environment.

The CIC will vote at the Dec. 6 meeting on whether or not PFOS and PFOS precursors have "been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer."[8] The CIC will base its decision primarily on study data assembled by OEHHA, including a single cancer bioassay, epidemiological studies, genotoxicity testing, and data on pharmacokinetics and biochemical and physiological processes.[9]

OEHHA has also heavily relied on purported "similarities in chemical structure and biological activity between PFOS and PFOA" to justify evaluating PFOS as a carcinogen in recent PFOS drinking water values.[10]

The CIC will consider listing PFOS precursors — longer-chain PFAS that can degrade to form PFOS — as carcinogens in conjunction with PFOS and its salts. Examples of possible PFOS precursors include N-EtFOSA, N-EtFOSE, EtFOSAA and PFOSA.

Classification of PFOS precursors as carcinogens based on PFOS studies would be noteworthy, as there is little precedent for such an approach at either a state or federal level.

OEHHA is accepting written public comments through Nov. 8 on the PFOS and PFOS precursors hazard identification materials assembled for the CIC's review.

**Evaluation of PFNA and PFDA as Reproductive Toxicants**

On Oct. 1, OEHHA announced that DARTIC will meet to consider listing PFNA and its salts, and PFDA and its salts, as reproductive toxicants under Proposition 65. Both PFNA and PFDA are long-chain PFAS that are no longer manufactured in the U.S.

While PFDA was produced in the U.S., it was never intentionally manufactured in any considerable volume. However, both PFNA and PFDA may be present in certain imported products, due to their continued use overseas. Both compounds may also be found in the environment at legacy aqueous film forming foam sites.

Neither chemical is currently listed under Proposition 65. To facilitate DARTIC's review, OEHHA compiled a summary document that discusses serum concentrations and detection frequencies in California residents, epidemiological findings, available animal studies, and mechanistic or in vitro data for both chemicals.[11]

Public comments on the hazard identification materials will be accepted by OEHHA until Nov. 15, and the DARTIC meeting will be held Dec. 14.

**Notice of Intent to list PFOA as a Carcinogen**

OEHHA is also in the final steps of listing PFOA as a carcinogen under Proposition 65. In March, OEHHA published a notice of intent to list PFOA as a carcinogen through the "authoritative bodies" mechanism.

The agency cited a 2020 National Toxicology Program study as the basis for the notice of

intent. Currently, PFOA is only listed under Proposition 65 as a developmental toxicant.

While the public comment period on the notice of intent closed on May 3, it is not clear where OEHHA is in the process of finalizing the listing.

**Lack of Standardized Analytical Methods for Quantifying PFAS in Consumer Products**

There is currently no standardized analytical method for quantification of PFAS in consumer products. Existing standardized methods are limited to U.S. Environmental Protection Agency drinking water methods 537.1 and 533. However, some analytical laboratories have modified these analytical methods to identify PFAS in consumer products.

An analytical screening method termed "total organic fluorine" has been suggested as an analytical approach to identify PFAS precursors in products and matrices.

While this method may provide some insight into the presence of PFAS precursors, it cannot be used to determine whether a product or matrix contains a specific precursor. Further analysis would be required to determine which PFOS precursor is present, and at what concentration.

**Legal and Warning Implications**

When a chemical is listed under Proposition 65, all exposures to that chemical occurring within the first 12 months of the listing are deemed to be exempt from Proposition 65's warning requirement. This exemption, however, does not consider when a product is manufactured or labeled, but only when an exposure to a person in California occurs.

Therefore, in reality, companies that sell products potentially containing the referenced PFAS should closely monitor these potential listings, and promptly consider product formulation and warning strategy, as product sell-through times often exceed the 12-month grace period.

Because PFOS and PFOA have been listed under Proposition 65 as reproductive toxicants without exposure safe harbors since 2017, the PFOS and PFOA carcinogenicity listings may not lead to significant additional enforcement activity. To date, there have only been six PFOA notices of violation and no PFOS notices of violation.

This lack of enforcement may be due to the fact that most of today's products are unlikely to contain PFOA or PFOS, since companies reformulated their products and processes from legacy long-chain PFAS, like PFOA and PFOS, to shorter-chain or other PFAS before their listing under Proposition 65. Analytical testing issues described above may also contribute to the low enforcement activity noted thus far.

However, the potential listing of PFOS precursors as carcinogens, and PFNA and PFDA as reproductive toxicants, may raise more significant issues.

Notably, it is unclear whether OEHHA has the authority to regulate chemical precursors — where data do not support the precursors themselves as reproductive toxicants or carcinogens — under Proposition 65. The Proposition 65 statutes only regulate "chemical[s] known to the state to cause cancer or reproductive toxicity."

The potential listing of PFNA and PFDA may be important for the regulated community, as

neither chemical has been previously listed under Proposition 65. While only time will tell, it is possible we will see significant PFNA and PFDA enforcement in coming years, if these chemicals are listed under Proposition 65.

**What to Watch**

The announcement to bring PFOS and PFOS precursors to the CIC for possible listing as a carcinogen, the notice of intent to list PFOA as a carcinogen, and the announcement that PFNA and PFDA may be listed as reproductive toxicants are just a few of the recent instances of California's expanding regulation of PFAS.

OEHHA also recently released draft public health goals of 0.007 and 1 parts per trillion for PFOA and PFOS in drinking water, respectively, based on purported cancer risk. The listing of PFOS as a carcinogen under Proposition 65 would eliminate contradictions in OEHHA's regulatory approach to PFOS between Proposition 65 and the recent draft PFOS public health goals, which is based on a carcinogenic endpoint.

The California Department of Toxic Substances Control has also recently expanded its oversight of PFAS, through its Safer Consumer Products program. In July, the department adopted carpets or rugs containing PFAS as a priority product under the program.[12]

More recently, the department proposed classifying food packaging containing PFAS and treatments for use on textiles or leather containing PFAS as priority products.[13] Additionally, the California governor recently signed two new bills regarding PFAS:

- The California Safer Food Packaging and Cookware Act of 2021, which prohibits the use of PFAS above certain levels in paper-based food packaging, and requires disclosure of certain chemicals in cookware; and

- The Product Safety — Juvenile Products: Chemicals: Perfluoroalkyl and Polyfluoroalkyl Substances bill, which prohibits the use of PFAS in certain child products, like bassinets, booster seats and crib mattresses.[14]

As noted earlier, these developments will likely increase litigation risk for businesses in California. Companies should continue to closely follow the regulatory developments discussed above, and can consider providing written public comments to OEHHA on the hazard identification materials that will be utilized in the upcoming PFAS state's qualified experts decisions.

If OEHHA moves forward with these listings, companies will have to promptly evaluate product formulations, and consider reformulations or warnings where appropriate.

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*Brett Winters, Ph.D., is a toxicologist and certified industrial hygienist at GSI Environmental Inc.*

*Graham Ansell, Ph.D., is a principal chemist at GSI Environmental.*

*Will Wagner is a senior associate at Arnold & Porter.*



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[8] California Health & Safety Code § 25249.8(b).

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[12] California Environmental Protection Agency, Department of Toxic Substances Control, Safer Consumer Products Regulations — Listing Carpets and Rugs Containing Perfluoroalkyl or Polyfluoroalkyl Substances as a Priority Product (April 2021), https://dtsc.ca.gov/wp-content/uploads/sites/31/2021/06/14_PFAS-CR_Final-Statement-of-Reasons.pdf.

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