



November 16, 2016

Via E-Mail (P65Public.Comments@oehha.ca.gov)

Michelle Ramirez

Office of Environmental Health Hazard Assessment

P.O. Box 4010, MS-12B

Sacramento, CA 95812-4010

Re: Notice of Intent to List: Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Dear Ms. Ramirez:

The American Chemistry Council (ACC) appreciates the opportunity to comment on the Office of Environmental Health Hazard Assessment's (OEHHA) notice of intent to list perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS) pursuant to the Safe Drinking Water and Toxic Enforcement Act of 1986, also known as Proposition 65, as a chemical known to the State to cause developmental toxicity. OEHHA bases the proposed listing on drinking water health advisories and health effects support documents issued by the U.S. Environmental Protection Agency (EPA) for PFOA and PFOS in 2016. Since these EPA documents are non-regulatory technical guidance and subject to revision, and, therefore, do not represent a "conclusion" or "final action" of the Agency, they do not meet the requirements of the authoritative bodies listing mechanism.

To list a chemical pursuant to the authoritative bodies mechanism, OEHHA must establish that two conditions are met:

1. An authoritative body must formally identify the chemical as causing reproductive toxicity pursuant to Cal. Code Regs. tit. 27, § 25306(d); and
2. The evidence considered by the authoritative body must meet the sufficiency criteria contained in Cal. Code Regs. tit. 27 § 25306(g).

EPA, the authoritative body in this case, has not formally identified either PFOA or PFOS as causing reproductive toxicity. OEHHA's regulations provide, in pertinent part, that a chemical is "formally identified" by an authoritative body if:

the chemical has been included on a list of chemicals causing ... reproductive toxicity issued by the authoritative body; or is the subject of a report which is published by the authoritative body and which concludes that the chemical causes ... reproductive toxicity; or has otherwise been identified as causing ... reproductive toxicity by the



authoritative body in a document that indicates that such identification is a final action....¹

OEHHA claims that the EPA documents meet the criteria of § 25306(d)(1) because PFOA and PFOS are each “subject of a report which is published by the authoritative body and which concludes that the chemical causes ... reproductive toxicity” and have “otherwise been identified as causing ... reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action.” OEHHA contends that the second criterion is satisfied because EPA developed a lifetime drinking water health advisory for each substance based on a reference dose (RfD) derived from animal studies.

According to EPA, however, “EPA’s health advisories are *non-enforceable* and *non-regulatory* and provide technical information to state agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination.”² Moreover, EPA states “[a]s science on health effects of these chemicals evolves, EPA will continue to evaluate new evidence.”³ Thus, it is evident that EPA does not *conclude* that either PFOA or PFOS *cause* reproductive toxicity as required by § 25306(d)(1). In addition, EPA is clear that the RfDs derived for purposes of the health advisories are not a final action by the Agency, as required by § 25306(d)(1), because they are subject to ongoing review and revision.

In conclusion, the EPA documents are non-regulatory technical guidance and are subject to revision, and, therefore, do not meet the criteria of § 25306(d)(1). Since EPA has not “formally identified” either PFOA or PFOS as causing reproductive toxicity, they should not be listed on Proposition 65 pursuant to the authoritative bodies mechanism.

ACC appreciates OEHHA’s consideration of our comments. Should you have questions, please feel free to contact me at (916) 448-2581 or Tim_Shestek@americanchemistry.com.

Sincerely,



Tim Shestek
Senior Director

¹ Cal. Code Regs. tit. 27, § 25306(d)(1).

² <https://www.epa.gov/ground-water-and-drinking-water/drinking-water-health-advisories-pfoa-and-pfos> (emphasis added).

³ *Id.*; see also EPA, Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA) (May 2016), at 11 (“The HA value is not a legally enforceable federal standard and is subject to change as new information becomes available.”); EPA, Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS) (May 2016), at 12 (same).

