

Office of Environmental Health Hazard Assessment



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Edmund G. Brown Jr.
Governor

January 22, 2013

David Rothman, DDS
President
Paur Reggiardo, DDS
Public Policy Advocate
California Society of Pediatric Dentistry
P.O. Box 221608
Carmel, California 93922

Dear Drs. Rothman and Reggiardo:

Thank you for your letter of May 11, 2010, on behalf of the California Society of Pediatric Dentistry, responding to the Request for Relevant Information on the possible listing of bisphenol A (BPA) under Proposition 65.¹ BPA is a candidate for listing as known to cause reproductive toxicity. The potential listing would be by the authoritative bodies provision² of Proposition 65 and based on findings by the National Toxicology Program (NTP). NTP made its findings in a report³ by the NTP Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) that BPA causes developmental toxicity at “high” doses.

After review of all the submissions received in response to the Request for Relevant Information, OEHHA has determined that BPA meets the criteria for listing under the authoritative bodies provision of Proposition 65. Accordingly, a Notice of Intent to List BPA will be published in the near future. Following its publication, there will be a 30-day period for submission of public comments regarding the possible listing. Comments should focus on whether or not the criteria for listing have been met.⁴ In the event that OEHHA finds the criteria have not been met after review of the comments,

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, California Health and Safety Code section 25249.5 et seq.

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

³ National Toxicology Program – Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR, 2008). *NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A*. NIH Publication No. 08 – 5994.

⁴ Title 27, Cal. Code of Regs., section 25306.

California Environmental Protection Agency

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the chemical will be referred to the Developmental and Reproductive Toxicant Identification Committee for its consideration as required by regulation.⁵

Your comments do not address the basis for listing BPA under Proposition 65, but do express concerns about the potential impact of the listing on the dental health of young children such as kindergarteners and first-graders. You also discuss the absence of BPA as an ingredient in dental sealants, that intraoral exposure to BPA that occurs in the sealant process is a byproduct of the degradation of other components of sealant materials, and that levels of exposure resulting from application of sealants is likely to be very low.

If BPA is added to the Proposition 65 list, you should be aware of the following:

- Proposition 65 expressly exempts businesses with fewer than 10 employees from its requirements, including the warning requirement.⁶ Many pediatric dentists may fall within this exemption.
- Proposition 65 provides an exemption to the warning requirement if the exposure is not significant.⁷ In cases where the average use of a product by the average consumer does not result in exposure to a listed chemical that exceeds a maximum allowable dose level (MADL)⁸, no warning is required. OEHHA can assist interested parties by providing a MADL.

OEHHA's general practice, when feasible, is to propose a MADL within one year of the listing of a chemical. In many cases, we have been able to finalize a MADL at or near the time the warning requirement for a newly listed chemical takes effect. If OEHHA makes a final determination to add BPA to the Proposition 65 list, we will consider whether it is feasible to release a draft MADL concurrent with the listing. At a minimum, we would make it a priority to develop and adopt a MADL for BPA at the earliest possible date following the chemical's listing. As you may be aware, Proposition 65 provides a "grace period" of 12 months after the chemical is listed before any interested party can sue for alleged violations of the Act. During that time, product manufacturers can evaluate their product exposures against the MADL and determine whether or not a warning is necessary.

Your letter indicates that BPA is not an ingredient in dental sealants but that some intraoral exposure to BPA occurs due to the degradation of other components in dental sealants. If your association would find it helpful, you may request that OEHHA provide

⁵ Title 27, Cal. Code of Regs., section 25306(i).

⁶ Health and Safety Code section 25249.11(b).

⁷ Health and Safety Code section 25249.10(c) and Title 27, Cal. Code of Regs., section 25821(c)(2).

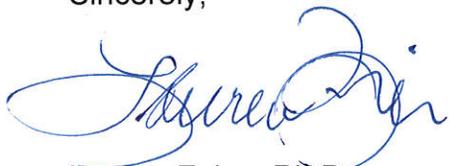
⁸ Title 27, Cal. Code of Regs., section 25801.

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assistance to you on evaluating whether the level released and nature of exposure would require warning, if BPA were listed.

Thank you for your interest in Proposition 65. If you have any questions or concerns, please contact me at (916) 322-6325 or by email at Lauren.Zeise@oehha.ca.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Lauren Zeise". The signature is fluid and cursive, with a large initial "L" and "Z".

Lauren Zeise, Ph.D.
Deputy Director for Scientific Affairs