

# Office of Environmental Health Hazard Assessment



Matthew Rodriguez  
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Edmund G. Brown Jr.  
Governor

January 22, 2013

Gene Livingston  
Greenberg Traurig LLP  
1201 K Street, Suite 1100  
Sacramento, California 95814

Dear Mr. Livingston:

This is in response to a letter of May 12, 2010 from Ms. Lisa Halko on behalf of the California Dental Association (CDA) and the CDA Foundation, responding to the Request for Relevant Information on the possible listing of bisphenol A (BPA) under Proposition 65.<sup>1</sup> We are addressing this to you since we understand that Ms. Halko is no longer with your firm.

BPA is a candidate for listing as known to cause reproductive toxicity. The potential listing would be by the authoritative bodies provision<sup>2</sup> of Proposition 65 and based on findings by the National Toxicology Program (NTP). NTP made its findings in a report<sup>3</sup> 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 public comment period regarding the possible listing. Comments should focus on whether or not the regulatory criteria for listing have been met.<sup>4</sup> In the event that OEHHA finds the criteria have not been met after review of the comments, the chemical

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

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

<sup>3</sup> 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.

<sup>4</sup> Title 27, Cal. Code of Regs., section 25306.

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

Ms. Halko's comments were submitted in opposition to the possible Proposition 65 listing of BPA, and stated that dental sealants are no longer made with BPA and do not cause exposures that require a warning. She further commented that it is rare for dental sealants to cause any exposure to BPA, and indicated concern that a Proposition 65 listing of BPA could discourage use of dental sealants in children. Ms. Halko is correct that where there is no exposure or insignificant exposure to BPA, a warning is not required. Regarding the current lack of use of BPA in dental sealants, OEHHA will not indicate in future notices that BPA is used in making dental sealants. We appreciate the clarification.

Ms. Halko also predicted that a listing of BPA would likely lead dentists and other oral health professionals to use warnings to avoid baseless litigation, and that that result would be inconsistent with the Court of Appeal decision in *Nicole-Wagner vs. Deukmejian*.

Proposition 65<sup>6</sup> expressly exempts businesses with fewer than 10 employees from its requirements. Many dentists and oral health professionals may fall within this exemption, reducing the likelihood that they would be the targets of litigation. For all other businesses, warnings would only be required if exposures to BPA were sufficiently high.<sup>7</sup> You gave a number of reasons why you thought this would be very unlikely. If the chemical is listed, we will provide compliance assistance to businesses to reduce the likelihood of unnecessary litigation and warnings. For example, where the average use of a product by the average consumer does not result in an exposure to a listed chemical that exceeds a maximum allowable dose level (MADL), 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. In some instances, OEHHA has been able to propose MADLs concurrent with or even prior to the listing of a chemical. 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 will 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 warning requirement. During that time, product manufacturers can evaluate their

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<sup>5</sup> Title 27, Cal. Code of Regs., sections 25306(i).

<sup>6</sup> Health and Safety Code section 25249.11(b).

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

product exposures against the MADL and determine whether or not a warning is necessary.

OEHHA also can develop interpretive guidelines<sup>8</sup> and safe use determinations<sup>9</sup> to provide further guidance to businesses and the public concerning the applicability of Proposition 65 to specific products or uses of a chemical. This type of guidance might be especially helpful in deterring unnecessary litigation against dentists and oral-health professionals. OEHHA would consider developing these materials as appropriate if BPA is listed.

Ms. Halko's comments also included arguments concerning the formal identification of BPA as causing reproductive toxicity. These comments incorrectly identify the statements in the NTP-CERHR document used by OEHHA as the basis of formal identification. As stated in the Request for Relevant Information, OEHHA relied on the conclusion by NTP that there is clear evidence of developmental toxicity in laboratory animals at "high" doses. These developmental effects include fetal death and reduced litter size in rats and mice exposed prenatally. The text that Ms. Halko cited refers to NTP's conclusion about a level of concern for human populations taking into account what is known about current human exposures. It is important to note that Proposition 65's listing process is based exclusively on hazard identification. Anticipated human exposure is taken into account later in the Proposition 65 process. It is not considered during the listing phase. The statute and implementing regulations focus on whether or not the authoritative body identifies the chemical as posing a reproductive toxicity hazard. Under Proposition 65, listing is based solely on hazard identification resulting from scientific studies in either animals or humans. Thus, the risk characterization conclusions related to "level of concern" were not used in OEHHA's determination that BPA has been formally identified by NTP as causing reproductive toxicity.

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](mailto:Lauren.Zeise@oehha.ca.gov).

Sincerely,



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

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<sup>8</sup> Title 27, Cal Code of Regulations, section 25203.

<sup>9</sup> Title 27, Cal Code of Regulations, section 25204.