

Office of Environmental Health Hazard Assessment



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Edmund G. Brown Jr.
Governor

January, 2013

Mr. Thomas E. Tremble
Vice President, State Government Relations
Advanced Medical Technology Association
701 Pennsylvania Avenue, Suite 800
Washington, DC 20004-2654

Dear Mr. Tremble:

Thank you for your letter of May 12, 2010, on behalf of the Advanced Medical Technology Association, responding to the Request for Relevant Information on the possible listing of bisphenol A (BPA) under Proposition 65¹. 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, 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 proposed listing. Comments should focus on whether or not the criteria in OEHHA’s regulations for listing chemicals under Proposition 65 have been met.⁴ In the event that OEHHA finds the criteria have not been met after review of the comments, the chemical will be referred to

¹ The California 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 Regulations, 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 Regulations, section 25306.

California Environmental Protection Agency

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the Developmental and Reproductive Toxicant Identification Committee (DARTIC) for its consideration for possible listing as required by regulation.⁵

Your comments state that there is current scientific debate regarding the toxicity of BPA at low levels. It is important to note in this regard that the authoritative body, the NTP in the NTP-CERHR report, found that BPA causes developmental toxicity at “high” doses. The listing of BPA under Proposition 65 would be based on this high-dose finding. Your comments also note that the U.S. Food and Drug Administration has taken steps to reduce infants’ exposure but has not called for restriction of BPA use, and you urge that BPA’s availability not be limited. In this regard, the listing of a chemical under Proposition 65 does not ban or otherwise restrict its use. It simply requires that a warning be provided to Californians prior to their exposure to the chemical.

You also commented that, “the length and amount of exposure to affected populations is critical in light of the need to preserve patient access to needed therapies, particularly when there is a notable absence of demonstrably safer alternatives for medical applications.” While the listing process under Proposition 65 is concerned solely with identification of a reproductive hazard, there are other parts of the Proposition 65 process that address the level of exposure. For example, 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), the product is exempt from the warning requirement under Proposition 65 (Health and Safety Code section 25249.10(c)).

We acknowledge your concerns regarding the listing of BPA. If the chemical is listed, we will provide compliance assistance to businesses to reduce the likelihood of unnecessary litigation and warnings. OEHHA can assist interested parties by providing a MADL in regulation. 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 determine 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 Act. During that time, product manufacturers can evaluate their product exposures against the proposed MADL and determine whether or not a warning is necessary.

⁵ Title 27, Cal. Code of Regulations, sections 25306(h) and (i)

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OEHHA also can develop interpretive guidelines and, upon request, safe use determinations to provide further guidance to businesses and the public concerning the applicability of Proposition 65 to specific products or uses of a chemical. OEHHA would consider developing these materials as appropriate if BPA were listed. Our website at www.oehha.ca.gov has more information concerning these compliance assistance activities.

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,



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