

Office of Environmental Health Hazard Assessment



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Edmund G. Brown Jr.
Governor

January 22, 2013

John M. Rost, Ph.D.
Chair
North American Metal Packaging Alliance, Inc.
1203 19th Street NW, Suite 300
Washington, DC 20036-2401

Dear Dr. Rost:

Thank you for your letter of May 13, 2010 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, based on findings by the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) that BPA causes developmental toxicity at “high” doses.³

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

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.

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

California Environmental Protection Agency

The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption.

Your comments discuss the decision by the DARTIC not to list BPA as an argument against authoritative body listing of the chemical. Proposition 65 identifies multiple methods for listing of chemicals but does not put in place a hierarchical or consensus structure, instead each listing mechanism functions independently.⁶ Thus, a decision not to list a chemical under one of the listing mechanisms does not preclude its consideration for listing via one of the other mechanisms.

On the issue of formal identification, your comments also note that NTP-CERHR states that its report is not a quantitative risk assessment and is not intended to supersede risk assessments conducted by regulatory agencies. You indicate that listing BPA would be inconsistent with NTP's advice and therefore inappropriate. Proposition 65 and the implementing regulations for the authoritative bodies mechanism require the listing of chemicals based solely on formal identification of a reproductive hazard by the authoritative body, and do not require a full risk assessment. Elements of risk assessment other than hazard identification (e.g., dose response assessment) are taken into account at future points in the Proposition 65 process but not at the listing stage. Listing does not depend on whether or not the authoritative body has completed all the steps in risk assessment, or whether or not the authoritative body contemplates the use of a document under Proposition 65.

Your comments state that a person would have to consume food or beverages from 14 million cans a day in order to achieve the BPA exposure of ≥ 50 mg/kg-d described by NTP-CERHR as a "high" dose. You indicate that this is not physically or biologically possible. Without endorsing or detracting from the calculations you provide, we note that this type of calculation is relevant to a different part of the Proposition 65 process, and not to the listing process. The matter you are addressing is relevant to the issue of whether a warning would be required if BPA were placed on the list. For information concerning calculating an exposure to a listed chemical that requires a warning, see Title 27 of the California Code of Regulations, section 25801 et seq.

The issue of whether an association between an adverse reproductive effect in humans and a chemical is "biologically plausible" is addressed in the Proposition 65 regulation for listing via the authoritative bodies mechanism:

"Studies in experimental animals indicate that there are sufficient data, taking into account the adequacy of the experimental design and other parameters such as, but not limited to, route of administration, frequency and duration of exposure, numbers of test animals, choice of species, choice of dosage levels, and consideration of maternal toxicity, indicating that an association between adverse reproductive effects in humans and the toxic agent in question is

⁶ Health and Safety Code section 25249.8.

biologically plausible.” (Title 27, Cal. Code of Regs., section 25306(g)(2), emphasis added.)

The “biologically plausible” phrase in this regulation does not pertain to actual levels of exposure that may be occurring in the human population from any given source. Rather, the phrase “biologically plausible” applies to extrapolation of findings from animal studies to humans in a biological framework. NTP found that there was clear evidence of developmental toxicity in animals from BPA at high doses, and specifically found that it is possible that BPA can affect human development.⁷ The data relied upon by the NTP in the NTP-CERHR report were reviewed by OEHHA against the sufficiency of evidence criteria cited above. OEHHA found they met the criteria in the regulation, including biological plausibility.

Elsewhere in your comments you refer to reviews by other bodies of the potential hazards posed by current uses of BPA. You note for example that the US Food and Drug Administration “clearly stated that BPA has not been proven to be harmful to children or adults in any of its current uses.” Under Proposition 65, even if current exposures have not been proven to cause reproductive or developmental harm in humans, the chemical must be listed if there are sufficient data in laboratory animals to support the formal identification by the authoritative body. That is the case for BPA.

You also describe new studies from the U.S. Environmental Protection Agency providing evidence that BPA at extremely low doses has no effect on female development and fertility. In this regard, we note that the proposed authoritative body listing of BPA is based on NTP-CERHR conclusions concerning evidence of developmental toxicity at “high” doses (greater than or equal to 50 mg/kg-d), and not at low doses.

Elsewhere in your comments you provide a summary of the use and value of BPA in the metal packaging industry, its use as an epoxy resin and the difficulties involved in replacing BPA. Please note that that listing of BPA under Proposition 65 would not prohibit use of BPA in any product and, consequently, would not require replacement of BPA in metal packaging. Rather, warnings about exposures caused by use of a product are required unless there would be no observable effect given an exposure 1,000 times greater than that resulting from use of the product by the average consumer.⁸ If levels of BPA exposure are sufficiently low, warnings would not be required. If the chemical is listed, we will provide compliance assistance to businesses to reduce the likelihood of unnecessary litigation and warnings. 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), no warning is required. OEHHA can assist interested parties by adopting a MADL.

⁷ NTP-CERHR Monograph pp. 6-8

⁸ HSC section 25249.10(c) and Title 27, Cal Code of Regs., section 25821(c)(2).

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 adopt the MADL at or near the time the warning requirement for a newly listed chemical takes effect.⁹ 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 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.

OEHHA also can develop interpretive guidelines¹⁰ and safe use determinations¹¹ 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 in the event BPA is 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,



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

⁹ Health and Safety Code section 25249.10(b).

¹⁰ Title 27, Cal Code of Regulations, section 25203.

¹¹ Title 27, Cal Code of Regulations, section 25204.