

Office of Environmental Health Hazard Assessment



Matthew Rodriguez
Secretary for
Environmental Protection

George V. Alexeeff, Ph.D., D.A.B.T., Director
Headquarters • 1001 I Street • Sacramento, California 95814
Mailing Address: P.O. Box 4010 • Sacramento, California 95812-4010
Oakland Office • Mailing Address: 1515 Clay Street, 16th Floor • Oakland, California 94612



Edmund G. Brown Jr.
Governor

January 22, 2013

Hugh N. Tucker, Ph.D.
Distinguished Research Fellow
Global Research and Development
Mead Johnson Nutrition
2400 West Lloyd Expressway
Evansville, Indiana 47721-0001

Dear Dr. Tucker:

Thank you for your letter of May 13, 2010, on behalf of Mead Johnson Nutrition, 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 (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 on the OEHHA website at www.oehha.ca.gov and in the California Regulatory Notice Register in the near future. Following its publication, there will be a 30-day public comment period regarding the proposed listing. In order to be relevant to the listing process, comments should focus on whether or not the criteria for listing the chemical under Proposition 65 have been met (Title 27, Cal. Code of Regulations, section 25306). 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 (Title 27, Cal. Code of Regulations, section 25306(i)).

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.

California Environmental Protection Agency

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

Hugh N. Tucker, Ph.D.

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In your comments you object to the possible listing by stating that “the authoritative body listed in the petition has not determined that BPA is hazardous to health”. This statement is based on conclusions in the NTP-CERHR document regarding the “level of concern” for current human exposures to the chemical. NTP’s conclusions regarding level of concern for fetal exposures to BPA ranged from negligible concern to some concern, depending on the type of endpoints. However, it is important to note that Proposition 65’s listing process is based exclusively on hazard identification from scientific studies in animals or humans. The implementing regulations focus on whether or not the authoritative body identifies the chemical as posing a reproductive toxicity hazard. In contrast, NTP’s conclusions regarding “level of concern” are based in part on information regarding known human levels of exposure to BPA. Anticipated human exposure is taken into account later in the Proposition 65 processes, and is not considered during the listing phase.

The formal identification criteria in the Proposition 65 regulation are met by the NTP-CERHR’s report that concludes that there is clear evidence of adverse developmental effects in laboratory animals at “high” levels of exposure to BPA. These developmental effects include fetal death and reduced litter size in rats and mice exposed prenatally.

NTP’s conclusions regarding “weight of evidence” also meet the criteria for formal identification as provided in regulation because BPA “is the subject of a report which is published by the authoritative body and which concludes that the chemical causes cancer or reproductive toxicity; or has otherwise been identified as causing cancer or reproductive toxicity by the authoritative body in a document that indicates that such identification is a final action...” (Section 25306(d)(1)).

Your comments also list several international groups that have considered the safety of BPA, and also provide a quote from a U.S. Food and Drug Administration (FDA) representative at a press conference. While this information attests to the ongoing focus on BPA by government regulatory agencies, it does not provide a basis for withdrawing BPA from consideration for listing under Proposition 65. Several governmental bodies have expressed concern about BPA (e.g., the French Agency for Food, Environmental and Occupational Health & Safety, Health Canada), and some have taken steps to reduce human exposures.

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