Office of Environmental Health Hazard Assessment

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Secretary for
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January 22, 2013

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Environmental Working Group
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Dear Mr. Kar, Dr. Janssen, and Ms. Sharp:

Thank you for your letter of May 13, 2010, responding to the Request for Relevant Information on the possible listing of bisphenol A (BPA) as known to cause reproductive toxicity under Proposition 65 (California Health and Safety Code section 25249.5 et seq.). The potential listing would be by the authoritative bodies' provision of Proposition 65 (Health and Safety Code section 25249.8(b)), based on findings in a report by the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) that BPA causes developmental toxicity at "high" doses (NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A. NIH Publication No. 08 – 5994).

You commented that the state's qualified expert and authoritative body listing mechanisms are completely independent and cited documents to support the statement. OEHHA agrees with this conclusion and the documentation cited in the comments to support it. You indicated that other chemicals have been listed under Proposition 65 via the authoritative bodies mechanism based on NTP findings in NTP-CERHR reports. OEHHA agrees with this observation.

You also state that other entities "designate BPA as a reproductive and developmental toxicant." You name classifications and designations by the European Chemicals Bureau, the Canadian government and the U.S. Environmental Protection Agency (U.S. EPA). While the findings of the European and Canadian institutions are noteworthy, these entities are not Proposition 65 authoritative bodies as designated in Title 27, California Code of Regulations, section 25306(l)[1] and so their findings are not directly relevant to adding BPA to the Proposition 65 list based on the NTP formal identification.

You also cite U.S. EPA's 2010 Action Plan.[2] U.S. EPA conducted a "screening level review" of hazard and exposure information for the Action Plan. That review refers to the chemical as a developmental and reproductive toxicant in animal studies, and generally concurs with the NTP findings, and discusses the uncertainties regarding low dose effects. These findings are also reflected in U.S. EPA's Advance Notice of Proposed Rulemaking [3] to develop data under section 4(a) of the Toxic Substances Control Act. While U.S. EPA is an authoritative body, the Action Plan states that it "does not constitute a final Agency determination or other final Agency action"; thus, this document does not meet the criteria for formal identification specified in Section 25306(d) and cannot serve as a basis for listing BPA.

You noted that since the NTP-CERHR report was published, there have been additional studies published which support the conclusions of the report that there is "some concern" for the impacts of low dose exposure to BPA on brain and behavior. The proposed authoritative body listing is based on NTP conclusions regarding clear evidence of developmental toxicity at "high" doses of BPA. We acknowledge your concern for low dose effects, and that there have been a number of studies generated since the release of the NTP report. Since NTP did not consider this evidence, however, OEHHA has not reviewed it in support of the listing since it falls outside of the administrative record for the action by the authoritative body.

You also assert that "[h]uman exposure to BPA is widespread." While this topic is not directly related to the authoritative body listing of BPA, OEHHA acknowledges the information provided.

You commented that BPA meets the listing requirements under the authoritative bodies mechanism**.** 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

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[1] All further citations are to Title 27, Cal. Code of Regs., unless otherwise indicated.
[2] US Environmental Protection Agency, Bisphenol A Action Plan (CAS 80-05-7), Office of Pollution Prevention and Toxics, March 29, 2010.
[3] US Environmental Protection Agency, Advance Notice of Proposed Rulemaking, Testing Bisphenol A, Federal Register 76(143):44535-44546, available online at http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/BPA_ANPRM_76_FR_44535_2011-07-26.pdf.

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.

Comments should focus on whether or not the criteria for listing the chemical under Proposition 65 have been met (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 (Section 25306 (i)).

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