



March 27, 2013

Via e-mail: "P65Public.Comments@oehha.ca.gov "

Ms. Cynthia Oshita
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Re: Prop 65 NOIL-Bisphenol A - GMA Comments

Dear Ms. Oshita:

Based in Washington, D.C., the Grocery Manufacturers Association (GMA)¹ is the voice of more than 300 leading food, beverage and consumer product companies that sustain and enhance the quality of life for hundreds of millions of people in the United States and around the globe. Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices and effective public policy solutions developed through a genuine partnership with policymakers and other stakeholders. In keeping with its founding principles, GMA helps its members produce safe products through a strong and ongoing commitment to scientific research, testing and evaluation and to providing consumers with the products, tools and information they need to achieve a healthy diet and an active lifestyle.

GMA is pleased to provide the following comments in response to OEHHA's January 25, 2013 notice of intent to list² bisphenol A (BPA) through Prop 65's authoritative bodies mechanism. GMA incorporates by reference comments submitted to OEHHA on May 13, 2010, by Morrison and Foerster³ on behalf of GMA regarding the February 12, 2010, OEHHA notice⁴ requesting public comments concerning whether

¹ GMA represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of 48 chief executive officers from the Association's member companies. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers and contributes over \$1 trillion in added value to the nation's economy.

² Notice of Intent to List: Bisphenol A [01/25/13]

(http://oehha.ca.gov/Prop65/CRNR_notices/admin_listing/intent_to_list/NOILABpkg42BPA.html)

³ May 13, 2010 MORRISON FOERSTER comments on behalf of GMA requesting a Public Hearing for Bisphenol-A (http://oehha.ca.gov/Prop65/CRNR_notices/admin_listing/requests_info/pdf/C15GMA_BPA.pdf)

⁴ OEHHA Request for Relevant Information on a Chemical Being Considered for Listing by the Authoritative Bodies Mechanism: Bisphenol-A [02/12/10] (http://oehha.ca.gov/Prop65/CRNR_notices/admin_listing/requests_info/callinBPA021210.html)

BPA meets the authoritative bodies listing criteria set forth in the Proposition 65 regulations in Title 27, Cal. Code of Regulations, section 25306⁵.

Based on the extensive scientific data available, GMA urges that BPA not be listed because:

- NTP-CERHR **did not** conclude that BPA causes selective reproductive toxicity. As referenced in the Polycarbonate/BPA Global Group of the American Chemistry Council comments⁶ submitted on May 13, 2010, Figure 2b in the Monograph,⁷ on which OEHHA relies to make its assertions, consolidates relevant studies and highlights “... *observations* about some of the animal data that NTP-CERHR considered.” NTP conclusions are actually captured in Figure 3 of the Monograph.⁹
- BPA is not a selective reproductive or developmental toxicant as outlined by Dr. Rochelle Tyl (RTI International)⁸, first author and study director of three of the studies (one-, two- and three-generation reproductive toxicity studies on BPA and estradiol) and co-author on another of the studies considered by NTP’s CERHR. “Reproductive or developmental effects occur only at very high BPA doses in the presence of profound maternal toxicity. At lower doses with less, but still significant, maternal toxicity, there are no reproductive or developmental effects. Based on other relevant studies, it is apparent that *maternal toxicity is most likely the critical determinant* of embryo-fetal/offspring toxicity observed at high doses of BPA. Consequently, BPA does not satisfy the criteria in Section § 25306 (g)(2) for listing under Proposition 65.”
- California’s own State’s Qualified Experts - the Proposition 65 Developmental and Reproductive Toxicant Identification Committee (DARTIC) - on July 15, 2009,⁹ voted unanimously not to list BPA as a reproductive toxicant. DARTIC considered the same pivotal studies in the 2008 NTP monograph¹⁰ on which OEHHA is now basing its decision to propose listing. DARTIC stated that there was inadequate evidence suggesting BPA caused reproductive toxicity in humans. Yet, they reminded the public that they may reconsider BPA should more compelling evidence become available, and urged that more scientific studies be conducted to continue studying the effects of BPA in humans. No new information has become available that would change DARTIC’s opinion.

⁵ Title 27, California Code of Regulations ARTICLE 3 (http://oehha.ca.gov/prop65/law/pdf_zip/RegsArt3.pdf)

⁶ American Chemistry Council (ACC) May 13, 2010 comments in response to Request for Relevant Information on Bisphenol A. (see pp. 17-18, http://oehha.ca.gov/Prop65/CRNR_notices/admin_listing/requests_info/pdf/C17accBPA.pdf); ACC comments submitted August 10, 2011 (http://oehha.ca.gov/Prop65/CRNR_notices/admin_listing/requests_info/pdf/C17aACCSupplementalDCI.pdf); ACC Comment submitted September 1, 2011 (http://oehha.ca.gov/Prop65/CRNR_notices/admin_listing/requests_info/pdf/C17bACCSupBPA.pdf).

⁷ NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A (see p.8, <http://ntp.niehs.nih.gov/ntp/ohat/bisphenol/bisphenol.pdf>)

⁸ RTI International May 12, 2010 Response to Request for Relevant Information on Bisphenol A (http://oehha.ca.gov/Prop65/CRNR_notices/admin_listing/requests_info/pdf/C7RTyBPA.pdf)

⁹ July 15, 2009 Meeting Synopsis and Slide Presentations Developmental and Reproductive Toxicant Identification Committee Meeting Held on July 15, 2009 [07/23/09] (http://www.oehha.ca.gov/prop65/public_meetings/dart071509synop.html)

¹⁰ NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A (<http://ntp.niehs.nih.gov/ntp/ohat/bisphenol/bisphenol.pdf>)

A chemical may be listed via the authoritative bodies mechanism under the Proposition 65 regulations only when both of the following criteria are met:

- The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(g))¹¹.
- An authoritative body formally identifies the chemical as causing reproductive toxicity (Section 25306(d)).

Because neither criterion has been met, BPA cannot be listed. Furthermore, a chemical may not be listed via the authoritative bodies mechanism “if scientifically valid data which were not considered by the authoritative body clearly establish that the chemical does not satisfy” the sufficiency criteria. Recently completed FDA studies¹² on BPA pharmacokinetics demonstrate:

- (i) efficient metabolism of oral exposure to BPA to biologically inactive metabolites (i.e., bisphenol A-glucuronide and bisphenol A-sulfate) primarily in mothers but also in developing fetus and then quickly eliminated from the body, and
- (ii) the inherent physiological differences between rodents and primates.

These studies underscore the lack of biological plausibility of potential adverse effect on reproduction and development from BPA exposure. Accordingly, BPA should not be listed for this reason as well.

Please do not hesitate to contact Dr. Emilia Lonardo, GMA VP of Consumer Product Safety and Science Policy (ELonardo@gmaonline.org, 202-639-5983) should you have any questions.

Thank you for taking these comments into consideration.

Sincerely,



Emilia Lonardo, Ph.D.
VP Consumer Product Safety and Science Policy

¹¹ Title 27, California Code of Regulations ARTICLE 3 § 25306. Chemicals Formally Identified by Authoritative Bodies – (g) For purposes of this section, “as causing reproductive toxicity” means that either of the following criteria have been satisfied:

(1) Studies in humans indicate that there is a causal relationship between the chemical and reproductive toxicity, or
(2) 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 biologically plausible.

¹² Doerge, D. R., Twaddle, N. C., Vanlandingham, M., and Fisher, J. W. 2010. Pharmacokinetics of bisphenol A in neonatal and adult Sprague-Dawley rats. *Toxicology and Applied Pharmacology*. 247(2):158-165. Available at <http://dx.doi.org/10.1016/j.taap.2010.06.008>.

Doerge, D. R., Vanlandingham, M., Twaddle, N. C., and Delclos, K. B. 2010. Lactational transfer of bisphenol A in Sprague-Dawley rats. *Toxicology Letters*. 199(3):372-376. Available at <http://dx.doi.org/10.1016/j.toxlet.2010.09.022>.

Doerge, D. R., Twaddle, N. C., Vanlandingham, M., Brown, R. P., and Fisher, J. W. 2011. Distribution of bisphenol A into tissues of adult, neonatal, and fetal Sprague-Dawley rats. *Toxicology and Applied Pharmacology*. Available at <http://dx.doi.org/10.1016/j.taap.2011.07.009>.

Doerge, D. R., Twaddle, N. C., Woodling, K. A., and Fisher, J. W. 2010. Pharmacokinetics of bisphenol A in neonatal and adult rhesus monkeys. *Toxicology and Applied Pharmacology*. 248(1):1-11. Available at <http://dx.doi.org/10.1016/j.taap.2010.07.009>.