

Albany
Atlanta
Brussels
Denver
Los Angeles

**McKenna Long
& Aldridge**^{LLP}
Attorneys at Law

101 California Street • 41st Floor • San Francisco, CA 94111
Tel: 415.267.4000 • Fax: 415.267.4198
www.mckennalong.com

New York
Philadelphia
San Diego
San Francisco
Washington, D.C.

STANLEY W. LANDFAIR
(415) 267-4170
slandfair@mckennalong.com

CHRISTIAN VOLZ
(415) 267-4108
cvolz@mckennalong.com

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VIA U.S. MAIL AND EMAIL

George Alexeeff, Ph.D.
Acting Director
Office of Environmental Health
Hazard Assessment
1001 "I" Street
Post Office Box 4010
Sacramento, California 95812

RE: SUPPLEMENTAL RESPONSE TO REQUEST FOR
RELEVANT INFORMATION ON BISPHENOL A

Dear Dr. Alexeeff:

On behalf of our client the Polycarbonate/BPA Global Group of the American Chemistry Council ("ACC"), we are submitting this supplemental response to OEHHA's February 12, 2010 Request for Relevant Information on bisphenol A ("BPA"). This supplemental response should be considered together with ACC's detailed written submittals dated May 13, 2010 and September 15, 2009.

In the February 2010 Request for Relevant Information, OEHHA incorrectly stated that the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction ("NTP-CERHR") had "concluded" that there is clear evidence of adverse developmental effects in laboratory animals at 'high' levels of exposure. In both the Request for Relevant Information and in public meetings since that Request was issued, OEHHA has made it clear that this purported "conclusion" is based on "Figure 2b" of the NTP-CERHR "Brief" which is a component of the 2008 Monograph on BPA.

In both prior submittals, ACC presented multiple reasons why BPA should not be considered for listing, and does not meet the criteria for listing as a developmental or reproductive toxicant under Proposition 65's "authoritative bodies mechanism" based upon the conclusions stated in the September 2008 "Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A" published by the NTP-CERHR. Prominent among those

reasons, although by no means the only reason, was that NTP-CERHR Monographs evaluate risk in a way that is inconsistent with the hazard-based requirement for listing under Proposition 65. It is well established that Proposition 65 is purely a hazard-based system that does not take exposure or risk into account in listing decisions. From its beginning, though, NTP-CERHR's purpose was to reach qualitative risk-based conclusions that consider both hazard and exposure information and are expressed in the form of "levels of concern." These are very different approaches and the NTP-CERHR approach is incompatible with the strict Proposition 65 requirement to base listing decisions only on hazard considerations.¹

The distinction between NTP-CERHR's risk-based approach and the hazard-based approach under Proposition 65 was expressed clearly by NTP's leaders in a recent announcement of the formation of the new NTP Office of Health Assessment and Translation:

*"To our knowledge, CERHR was the only resource of its kind, producing evaluations that considered toxicity findings in the context of current human exposures to derive "level-of-concern" conclusions. This qualitative integration step is what distinguished CERHR documents from more traditional hazard evaluations prepared by other agencies."*²

The NTP-CERHR level-of-concern conclusions are expressed on a standardized five-level scale that ranges from "negligible" to "high concern." Following this approach, the NTP-CERHR Monograph on BPA reached seven level-of-concern conclusions that qualitatively characterize different combinations of exposure and reproductive or developmental toxicity end points. Notably, the most severe conclusion reached by NTP-CERHR was "some concern" for certain developmental effects, which is the midpoint on the level-of-concern scale. In addition to being a risk-based conclusion, which is inherently not suitable for Proposition 65 purposes, the equivocal nature of the conclusion does not satisfy Proposition 65's "clearly shown" standard.

As ACC has argued at length in both its prior submittals, it is invalid and unsupportable for OEHHA to ignore the actual – and equivocal – **conclusions** of the NTP-CERHR Monograph while relying upon Figure 2b, which is described in the Monograph itself not as NTP's "conclusions" but rather, as a summary of the "weight of evidence" in certain laboratory animal studies.³ We will not restate ACC's prior arguments here but, in this supplemental submission,

¹ As also discussed in our prior submittals, the Proposition 65 hazard considerations are restricted only to developmental effects that result from pre-natal exposure. In contrast, NTP-CERHR has no such restriction and their risk-based conclusions are based on all relevant studies with pre-natal exposure, post-natal exposure or both.

² See <http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info%3Adoi%2F10.1289%2Fehp.1103645> (emphasis added)

³ Figure 2b, at p. 8 in the NTP Brief is captioned "The **weight of evidence** that bisphenol A causes adverse developmental or reproductive effects in **laboratory animals**." (Emphasis added.) By contrast, Figure 3 on that

(footnote continued on next page)

we do want to draw OEHHA's attention to certain facts involved in NTP-CERHR's own peer-review process. In this process, NTP's "Board of Scientific Counselors" ("BSC") examines the qualitative risk-based level-of-concern conclusions in the draft Brief and then votes to accept, reject or modify these conclusions.⁴ Significantly, the BSC does not vote either on the entire draft Brief or on any other specific part of the draft Brief, nor does it otherwise endorse any specific parts of the draft Brief beyond the level-of-concern conclusions. This process confirms that NTP-CERHR's **conclusions** are unambiguously the level-of-concern conclusions that are voted on by the BSC.

The draft NTP Brief on BPA was released for public comment on April 15, 2008 (Minutes, June 11 – 12, 2008, at 5). On June 11, 2008, NTP's BSC met in Research Triangle Park, North Carolina to review the draft NTP Brief on BPA. NTP's charge to the BSC and additional *ad hoc* reviewers was:

To determine whether the scientific information cited in the draft NTP Brief on BPA is technically correct, clearly stated, and supports the NTP's **conclusions** regarding the potential for BPA to cause adverse reproductive and developmental effects in exposed humans (Minutes at 19; Peer Review Comments and NTP Response at 2) (emphasis added).

The June 11, 2008 BSC review of the draft NTP Brief on BPA began with an overview of the CERHR process and of the draft Brief itself, followed by general comments from the BSC and oral public comments. Next, Dr. Kristina Thayer of NIEHS presented the detailed scientific evidence supporting the NTP's (draft) **conclusion** on each of the topic areas covered in the draft Brief (Minutes at 5). Dr. Thayer's presentation included among other things a Figure summarizing the "weight of the evidence that BPA causes adverse developmental or reproductive effects in laboratory animals" that is essentially identical to Figure 2b in the final NTP Monograph. Dr. Thayer described the reasons for NTP's decision on assigning a weight of evidence for each endpoint. Following each section of her presentation, the *ad hoc* and BSC members discussed the topic of that section. Upon completion of the discussion of all topics, the BSC voted on the proposed **conclusions** of the draft Brief (Minutes at 16). See "Actions on the draft NTP Brief by the NTP Board of Scientific Counselors"; see also "Bisphenol A Peer Review Comments and NTP Response."

(footnote continued from previous page)

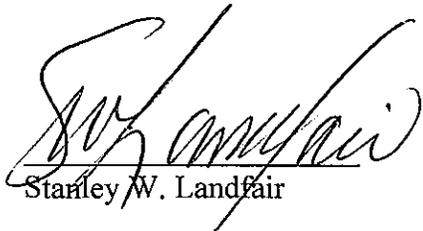
same page is captioned "NTP **conclusions** regarding the **possibilities** that **human** development or reproduction **might** be effected [sic] by exposure to bisphenol A." (Emphasis added). As noted above, Figure 3 states "levels of concern" and the highest level of concern indicated for bisphenol A is "some concern."

⁴ All the documents referred to in the following discussion can be found on NTP's website at this link: <http://ntp.niehs.nih.gov/?objectid=720164F2-BDB7-CEBA-F5C6A2E21851F0C4>.

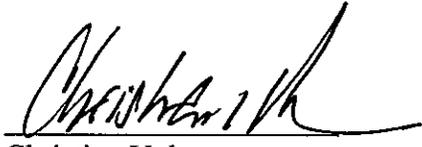
A review of the cited documents clearly demonstrates what ACC has consistently asserted: the **conclusions** of the NTP Brief are its “levels of concern” for each endpoint, the most serious of which was “some concern.” The scientific evidence relevant to each endpoint and decision on level of concern was considered by the BSC as they decided how to vote on each **conclusion**, but the evidence itself was not considered a “conclusion” and was not the subject of any votes. This specifically includes the predecessor version of Figure 2b in the final NTP Brief – it was presented, it was considered, but it was not an NTP “conclusion” requiring a vote and it was not the subject of a vote, in contrast to NTP’s actual level-of-concern **conclusions**.

In view of this additional documentary evidence that Figure 2b clearly was not considered a **conclusion** by NTP-CERHR itself – the authoritative body – or by the NTP BSC, which reviewed the draft NTP-CERHR Brief, we respectfully submit that OEHHA should reconsider its previously stated position on this point and agree that NTP-CERHR did not **conclude** that BPA is a developmental toxicant and thus, that the NTP-CERHR Brief does not “formally identify” BPA as a developmental toxicant.

Respectfully submitted,



Stanley W. Landfair



Christian Volz

SWL/CV/gmp

cc: Steven G. Hentges, Ph.D.
F. J. Murray, Ph.D.

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