

September 27, 2010

Steven G. Hentges, Ph.D.  
Polycarbonate/BPA Global Group  
American Chemistry Council  
1300 Wilson Boulevard  
Arlington, Virginia 22209

Dear Dr. Hentges:

Thank you for your letter of August 5, 2010, transmitting a petition from the Polycarbonate/BPA Global Group of the American Chemistry Council to rescind the designation of the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) as an authoritative body under Proposition 65.

The petition makes three specific requests that:

1. The Director place the petition to rescind the designation of NTP-CERHR as a Proposition 65 authoritative body for reproductive toxicity on the agenda of the next Developmental and Reproductive Toxicant Identification Committee (DART IC) meeting.
2. The DART IC rescind the designation of NTP-CERHR as an authoritative body.
3. The Office of Environmental Health Hazard Assessment (OEHHA) not proceed with consideration for listing, issuing a notice of intent to list, or listing of any chemicals under the authoritative body mechanism on the basis of the NTP-CERHR monographs pending disposition of the petition.

In regard to your first two points, the agenda for the DART IC meeting is set by the Chairperson, Dr. Dorothy Burk, in consultation with the Director of OEHHA. After consulting with her, Dr. Burk has decided to include your petition as a discussion item on the agenda for the next meeting of the DART IC. This will allow the committee members to express their interest in re-considering the designation of NTP-CERHR as an authoritative body. A copy of your petition and this letter will be provided to the members of the DART IC prior to their October 21, 2010 meeting.

If the committee expresses sufficient interest in revisiting the NTP-CERHR designation, an action item will be included in the agenda of a subsequent committee meeting (most likely in Spring 2011). All interested stakeholders and OEHHA will then have an opportunity to present written comments to the committee and there will be sufficient time set aside on the agenda for a full discussion and decision on the question.

If the committee declines at its October 21 meeting to reconsider the designation of NTP-CERHR as an authoritative body, no further action will be taken on your petition.

Steven G. Hentges, Ph.D.  
September 27, 2010  
Page 2

As to your third request, until such time as NTP-CERHR is no longer designated as an authoritative body under Proposition 65, OEHHA remains responsible for implementing the statute and current regulations as they pertain to listing chemicals. This includes the authoritative bodies' mechanism and those listings that are based on final reports from NTP-CERHR.

Enclosed is a summary of the main arguments made in your petition, along with OEHHA's general responses. In the event the committee decides to reconsider the designation of the NTP-CERHR as an authoritative body at a future meeting, OEHHA will provide additional background materials to the committee and the public prior to that meeting.

Thank you for your continuing interest in Proposition 65. If you have any questions or would like to discuss this matter further, please call me at (916) 322-6325.

Sincerely,

Joan E. Denton, Ph.D.  
Director

Enclosure

cc: Allan Hirsch  
Chief Deputy Director  
Office of Environmental Health Hazard Assessment

Dorothy Burk, Ph.D.  
(Committee Chairperson)  
Department of Anatomy  
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Steven G. Hentges, Ph.D.

September 27, 2010

Page 3

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## ATTACHMENT 1

- *The petition reviews part of the history of the designation of the NTP as a Proposition 65 authoritative body for reproductive toxicity, and characterizes that history as controversial.*

In 1989, the Proposition 65 Scientific Advisory Panel designated the National Toxicology Program (NTP) as an authoritative body. However, at that time, the committee did not specify whether NTP was designated for purposes of identifying reproductive toxicity, carcinogenicity or both. In 1998, the Developmental and Reproductive Toxicant Identification Committee (DART IC) (a subcommittee of the Scientific Advisory Panel) rescinded the designation of NTP as an authoritative body for identifying reproductive toxicants. The committee was concerned that the NTP documents available at that time only presented the result of NTP-conducted studies, and did not include a weight-of-evidence evaluation of other relevant data. However, the DART IC indicated that the designation of NTP as an authoritative body should be reconsidered once the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) program was established.

In 2002, the DART IC unanimously designated NTP-CERHR as an authoritative body, solely as to final reports of the NTP-CERHR. Transcripts of the committee's discussion at the 1998 and 2002 meetings will be provided to the DART IC in the event it decides to reconsider the designation of NTP-CERHR as an authoritative body.

- *The petition focuses on the NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Bisphenol A. It discusses the five-level scale of "concern" included in the document and the levels of concern identified for specific issues. The petition subsequently argues that the levels of concerns identified in the NTP-CERHR Monograph are inherently inconsistent with the criteria for identifying chemicals as known to cause reproductive toxicity under Proposition 65.*

We agree with the petitioner that NTP-CERHR's levels of "concern" are inconsistent with the criteria for identifying chemicals as known to cause reproductive toxicity under Proposition 65. In fact, the "level of concern" expressed by NTP-CERHR represent "risk characterization" of an identified reproductive toxicant based on the known or anticipated level of exposure to the chemical in human populations. Because Proposition 65 does not allow known or anticipated levels of exposure to be considered in the decision of whether or not to list a chemical, these levels of "concern" have never been used by the Office of Environmental Health Hazard Assessment (OEHHA) as a basis for concluding that NTP-CERHR has formally identified a chemical as causing reproductive toxicity.

Instead, OEHHA uses the NTP-CERHR's findings concerning the **weight of the evidence** regarding a chemical's potential to cause reproductive toxicity. NTP-CERHR

uses a seven-point scale to evaluate the weight of evidence that a chemical causes reproductive or developmental toxicity in humans and/or laboratory animals:

- Clear evidence of adverse effects
- Some evidence of adverse effects
- Limited evidence of adverse effects
- Insufficient evidence of adverse effects
- Limited evidence of no adverse effects
- Some evidence of no adverse effects
- Clear evidence of no adverse effects

The basis for an OEHHA determination that a chemical has been identified by the NTP-CERHR as a reproductive toxicant is NTP-CERHR's conclusion that there is "clear evidence of adverse effects" for developmental, male reproductive and/or female reproductive endpoints. This kind of conclusion represents "hazard identification", the first of the four fundamental stages of risk assessment. Therefore, the *level of evidence* identified by NTP-CERHR, not the level of concern, is the relevant finding that forms the basis for listings under the authoritative bodies mechanism.

In the case of bisphenol A, NTP-CERHR said there is "clear evidence of adverse developmental effects in laboratory animals at high levels of exposure." Based on NTP-CERHR's finding of "clear evidence" of adverse effects, OEHHA stated in its February 2010 Request for Relevant Information on bisphenol A that the chemical appears to meet the regulatory listing criteria.

- *The petition states that NTP-CERHR's evaluation of adverse effects attributable to post-natal exposure makes it unsuitable as an authoritative body.*

This argument is not specific to NTP-CERHR as an authoritative body, but would apply to all of the authoritative bodies designated by the DART IC.

The regulation governing the authoritative bodies process provides that "the lead agency [OEHHA] shall determine which chemicals have been formally identified by an authoritative body as causing...reproductive toxicity" (Title 27, Cal. Code of Regs., section 25306(c)<sup>1</sup>). In applying the criteria specified in Section 25306(g) that define "as causing reproductive toxicity," OEHHA takes into account whether prenatal exposures, post-natal exposures, or both are identified as resulting in developmental toxicity. In some cases, OEHHA has not proceeded with listing a chemical that was formally identified by an authoritative body because developmental toxicity resulted entirely or predominantly from post-natal exposures.

For chemicals identified by NTP-CERHR as having clear evidence of developmental toxicity, none were identified based entirely or predominantly on effects resulting from post-natal exposures.

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<sup>1</sup> All further references are to sections of Title 27 of the California Code of Regulations.

The petition cites Section 25306(g) as stating that “developmental toxicity under Proposition 65 is confined to effects that are attributable solely to pre-natal exposure.” No such statement appears in the regulation. The lead agency’s long-standing interpretation of the statute has been that consideration of developmental toxicity is limited to effects that are entirely or predominantly attributable to pre-natal exposure, but that practice is not articulated in Section 25306 or elsewhere in the regulations.

- *The petition argues that use of the NTP-CERHR evaluations as the basis of authoritative body listings distorts the standard for sufficiency of data to support a finding under Proposition 65. The argument is based on the petitioner’s interpretation of Section 25306(g) and the Final Statement of Reasons for that regulation. The petitioner states that the authoritative bodies listing mechanism should result in listing only chemicals that the State’s Qualified Experts (SQE) would list, based on their scientific criteria. The petition notes that the DART-IC unanimously concluded that bisphenol A did not satisfy the SQE listing criteria.*

It has long been established that the authoritative bodies’ criteria set out in Section 25306 are not necessarily the same as the criteria the DART IC committee uses when it determines *de novo* whether a given chemical has been “clearly shown” to cause reproductive or developmental effects. The standard OEHHA applies under Section 25306 is well described in the *Western Crop Protection v Davis*<sup>2</sup> case, which addressed the standards used for listing chemicals under the authoritative bodies mechanism. The court determined that OEHHA must apply the criteria contained in Section 25306 to the scientific evidence *relied on by the authoritative body in making its identification of a chemical as a developmental toxicant* to determine if listing the chemical under Proposition 65 is required.

OEHHA should not and does not apply the DART IC’s criteria. The DART IC conducts a *de novo* review of the evidence for or against listing a particular chemical. Under the authoritative bodies’ process, OEHHA is not allowed to engage in a *de novo* review but instead simply applies the criteria in the regulation to the authoritative body’s document. The two listing processes are separate and distinct from each other, and arguments to the contrary have been consistently rejected by the courts.

Further, the final statement of reasons for Section 25306 makes it clear that by designating any authoritative body, the DART IC determines that the authoritative body’s chemical hazard identification process is sufficiently similar to their own criteria for identifying chemical hazards. The statement of reasons also notes that a given authoritative body’s processes need not be the same, but may be “substantially similar” to those employed by the DART IC. In this case, the DART IC determined in 2002 that the NTP-CERHR’s criteria are the same or substantially similar to its own when it designated NTP-CERHR as an authoritative body.

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<sup>2</sup> *Western Crop Protection v Davis* (2000), 80 Cal. App 4th 741.

The above discussion is not presented as an argument for or against the ultimate question of whether the DART-IC should rescind the designation of NTP-CERHR as an authoritative body for Proposition 65. It is being provided to you and the members of the committee to provide background information and clarification of the issues set out in the petition.