

July 8, 2011

VIA ELECTRONIC MAIL

Dorothy Burk, Ph.D., Chairperson
Developmental and Reproductive Toxicant Identification Committee

**Re: *Proposal to Designate National Toxicology Program
As Authoritative Body For Purposes of Proposition 65***

Dear Dr. Burke and Members of the Committee:

We write regarding item V on your agenda: "Consideration of the designation of the National Toxicology program (NTP) as an authoritative body" and, specifically, what appears to be a proposal to reconsider the designation of NTP-CERHR (Center for the Evaluation of Risks to Human Reproduction) as an authoritative body for purposes of identifying reproductive toxins. For reasons that we explain below, we request that the Committee hear the presentations on the agenda, solicit *written comment from the public, and vote on the proposal at the Committee's next public meeting, not at this one.*

We write as individuals who have appeared before you frequently on behalf of stakeholders vitally interested in and affected by the decisions of this Committee. We believe that this important issue deserves advance notice to the public and the opportunity for the Committee to receive input from the public and scientists outside OEHHA.

Background and Discussion

On approximately June 24, 2011, OEHHA published on its website a "tentative agenda" for the July 12-13 DART IC meeting. The tentative agenda includes the item below:

"V. CONSIDERATION OF THE DESIGNATION OF THE NATIONAL TOXICOLOGY PROGRAM (NTP) AS AN AUTHORITATIVE BODY

- Staff presentation
- Presentation by Dr. Kris Thayer, National Toxicology Program
[Follow this link for the Editorial in Environmental Health Perspectives¹](#)
- Committee consideration of identification of NTP as an authoritative body *and* consideration of the Petition filed on August 5, 2010 on behalf of the Polycarbonate/BPA Global Group of the American Chemistry Council to reconsider the designation of NTP-CERHR (Center for the Evaluation of Risks

¹ The link referred to above is included here:
<http://ehp03.niehs.nih.gov/article/fetchArticle.action?articleURI=info%3Adoi/10.1289/ehp.1103645>

to Human Reproduction) as an authoritative body for purposes of identifying reproductive toxins

- Public comments
- Committee discussion and decision”

It is not clear from the last point above, “Committee discussion and decision,” whether the DART IC intends to reach a decision on the “identification of NTP as an authoritative body,” or on the “Petition filed on August 5, 2010 on behalf of the American Chemistry Council . . .” (which was discussed at the last DART IC meeting, on October 21 2010), or on both.

To our knowledge, the listing of this matter as an agenda item is the first notice that such a proposal has been made. We have not seen a copy of the proposal in any written form or any documents associated with it. If the DART IC does indeed intend to consider designating NTP as an authoritative body at the July 12-13 meeting, then we would be concerned that this proposal would be voted on with little notice to the public.

Even with more notice, it would be somewhat precipitous for the Committee to vote on such a proposal at the July 12-13 meeting, if this is the first time the proposal is being presented to the Committee. The designation of *any* entity as an authoritative body is a matter of considerable consequence, on which serious and thoughtful public input should be solicited.

A brief history of how the NTP-CERHR came to be designated as an authoritative body demonstrates how much deliberation is appropriate. The NTP was one of five entities that were designated as authoritative bodies as a group in 1987, shortly after Proposition 65 was enacted. The Committee rescinded that designation with respect to reproductive toxicity at a public meeting in 1998 (although the Carcinogen Identification Committee kept its designation in place for carcinogenicity), but expressed an interest in revisiting the issue at such time as the CERHR (only then recently established), might be “up and running.”

During a public meeting on December 17, 2001, the Committee considered a proposal to “re-designate” NTP as an authoritative body for reproductive toxicity. The Committee heard a brief presentation on the subject and deferred further consideration to the next meeting, “after further work of the CERHR became available.”

At the next public meeting on December 4, 2002, the Committee heard substantive presentations from a number of parties, directed at determining whether the CERHR would satisfy the criteria for designation as an authoritative body under Section 25306(b),² including whether the Committee may wish to limit or condition the designation and specify such limitations or conditions in the designation. The Committee had the opportunity to review ten reports prepared by Expert Panels for review by the NTP-CERHR. With these reports in hand, many members of the public were able to comment knowledgeably on the

² Then, Section 12306(b).

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critical issues under Section 25306, and there was a full and fair discussion. Written comments were submitted and considered. Presentations were delivered. After deliberation, the Committee refined the proposal before it to a motion to “designate NTP as an authoritative body, but only as to the final reports of the CERHR.” That motion was approved.

Committee precedent and practice thus demonstrates that considerable due diligence and deliberation in the designation of an authoritative body is appropriate. The Committee’s step-by-step review was appropriate then and remains appropriate now.

The document posted with this agenda item on the OEHHA website indicates that NTP-CERHR no longer exists as an entity. NTP-CERHR was dissolved or otherwise merged into a new NTP organization, identified as the Office of Health Assessment and Translation (“OHAT”). It is not clear from the tentative agenda whether the OHAT is being nominated, as opposed to NTP. The designation of either entity as an authoritative body requires, at a minimum, a determination whether all of the criteria set forth at Sections 25305 and 25306 are satisfied.

Section 25305 provides, at subsection (b), that the “DART Identification Committee may undertake the following activities: . . . (2) Identify bodies which are considered to be authoritative and which have formally identified chemicals as causing reproductive toxicity.” (emphasis added). Section 25306, also at subsection (b), defines an authoritative body as “an agency or formally organized program or group which utilizes one of the methods set forth in subsection (d), for the identification of chemicals, and which . . . the DART Identification Committee has identified as having expertise in the identification of chemicals as causing reproductive toxicity.”

As noted above, we have not seen any proposal in written form or any analyses of this proposal. We therefore have no basis to comment as to how these criteria would be satisfied in the designation of NTP or the new NTP OHAT. We strongly suggest, however, as the history of designating NTP-CERHR indicates, that documentation is appropriate.

The DART IC was careful in 2002 to designate NTP-CERHR, not NTP, as the authoritative body, and with certain restrictions. This reflected the Committee’s consensus that not all organizations operating under the NTP umbrella could be regarded as “authoritative” on the subject of reproductive toxicity, no matter how highly regarded their expertise might be in other fields. Either way, there is no indication of whether the methods used by the NTP or the OHAT will satisfy the requirements of Section 25306(d). Above all, there are no samples of the NTP’s or the OHAT’s work for the Committee or the public to review.

This leads to a practical consideration. With no documents available, neither we nor any of our clients who may be interested have been able to review the proposal in order to determine whether they are interested or, if so, what comments they may have. With such little notice, few, if any, of our clients can attend the July 12-13 meeting or arrange to be represented there. For that matter, at least one of us is unable to attend the meeting due to previous commitments.

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Conclusion and Request

For all of these reasons, we believe it would be inappropriate for the Committee to designate NTP (or OHAT) as an authoritative body at the July 12-13 meeting. For clarity, we emphasize that there is no pre-disposition to oppose the designation of either entity. Rather, we believe that "consideration" of this topic at the July 12-13 meeting should be only the first step in a more deliberative review. We therefore request that the Committee not vote on the proposal at the July 12-13 meeting, but instead defer the decision to a future scheduled meeting of the Committee, with more notice to the public.

Sincerely,


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Greenberg Traurig, LLP


Trenton H. Norris
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cc: Cynthia Oshita
Office of Environmental Health Hazard Assessment