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Working Group • Science and Environmental Health Network**

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*Via Federal Express and E-mail*

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*Re: Objections to American Chemistry Council (“ACC”) Petition to Rescind Authoritative  
Body Designation*

Dear Drs. Denton and Burk:

We write to register our strong objections to the ACC’s poorly disguised attempt to slow the process of the listing of Bisphenol A (BPA) under Proposition 65 by petitioning for the removal of the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction (“NTP-CERHR”) from the list of Proposition 65 authoritative bodies. The petition is a last ditch attempt to delay the listing that must follow from the NTP-CERHR’s monograph on BPA. The petition has no legal merit and should be dismissed. And in no circumstances should OEHHA postpone the listing of BPA under the authoritative bodies mechanism.

## **OEHHA Has No Basis for Postponing the Listing of BPA Under the Authoritative Bodies Mechanism**

Contrary to ACC's request, OEHHA has no basis for postponing the proposed listing of BPA. Under Proposition 65, OEHHA must revise and republish the Proposition 65 list of chemicals *at least annually*. Cal. Health & Saf. Code § 25249.8(a). The NTP-CERHR is an authoritative body recognized in the regulations, and OEHHA has a ministerial duty to list a substance identified by an authoritative body as a reproductive toxicant, as it has acknowledged. Cal. Code Regs. § 25306; *see* Final Statement of Reasons accompanying Section 25306, at 8. The authoritative bodies mechanism *requires* listing by OEHHA if the chemical has "been formally identified by an authoritative body as causing . . . reproductive toxicity." *Id.* § 25306(c). The NTP-CERHR's Monograph on BPA was finalized in September 2008, two years ago. Thus, pursuant to Proposition 65, OEHHA had an obligation to update the Proposition 65 list to include BPA by no later than September 2009. The listing of BPA has therefore already been delayed by at least a year. Further delay is unwarranted and unreasonable.

ACC has pointed to no authority supporting a postponement of the listing process. Contrary to ACC's efforts to confuse the two mechanisms, the authoritative body mechanism is independent of the state's qualified experts mechanism, as OEHHA has repeatedly acknowledged.<sup>1</sup> Whether or not a chemical has or has not been previously considered by the DART Identification Committee is irrelevant to whether the chemical meets the independent listing requirement of having been formally identified by an authoritative body as causing reproductive and developmental harm pursuant to Section 25306. Additionally, although the regulations provide for a referral to the DART Identification Committee, if OEHHA has determined that a chemical does *not* meet the requirements of Section 25306, 27 Cal. Code Regs. § 23506(i), that limited circumstance has nothing to do with OEHHA's responsibility to make the initial determination.

The NTP-CERHR is an authoritative body recognized in the regulations, Cal. Code Regs. § 25306(l). More importantly, it was recognized as an authoritative body in September 2008 when it released the final monograph on BPA. OEHHA should move forward expeditiously to list BPA pursuant to the findings in the NTP-CERHR monograph.

## **OEHHA and the DART Committee Have No Legal Basis for Removing NTP-CERHR as an Authoritative Body**

There is no legal justification for the removal of the NTP-CERHR as an authoritative body. Pursuant to the statute, a chemical may be listed if it is identified as a reproductive toxicant by a

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<sup>1</sup> Memorandum from Colleen Murphy, OEHHA Chief Counsel, to Members of the Carcinogen Identification Committee and DART Committee (July 20, 1998), at [http://oehha.ca.gov/prop65/public\\_meetings/cicdart2.html](http://oehha.ca.gov/prop65/public_meetings/cicdart2.html); OEHHA, Request for Relevant Information on a Chemical Being Considered for Listing by the Authoritative Bodies Mechanism: Bisphenol-A, February 12, 2010, at [http://oehha.ca.gov/prop65/CRNR\\_notices/admin\\_listing/requests\\_info/callinBPA021210.html](http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/callinBPA021210.html); *see* OEHHA, Mechanisms for Listing and Delisting Chemicals Under Proposition 65, May 15, 2007, at [http://www.oehha.ca.gov/prop65/policy\\_procedure/listde051007.html](http://www.oehha.ca.gov/prop65/policy_procedure/listde051007.html).

body considered to be “authoritative” by the state’s qualified experts, i.e. the DART Identification Committee. Health & Saf. Code § 25249.8(b). The DART Identification Committee may “identify bodies which are considered to be authoritative and which have formally identified chemicals as causing reproductive toxicity.” Cal. Code Regs. § 25305(b)(2). To be considered authoritative, the body must use one of the methods outlined in the rule and must be identified as having expertise by the DART Identification Committee. *Id.* The Committee may revoke the designation of a body as authoritative if it “no longer considers the body to have expertise in the identification of chemicals as causing . . . reproductive toxicity.” *Id.* at 25306(b). Contrary to the ACC’s statement that “there is no limitation on the grounds on which the DART-IC may be revoked or rescinded a designation,” the statutes and regulations place a clear limit on the DART Identification Committee’s decision-making: the Committee must determine that it no longer considers the body to be “authoritative” or to have “expertise” in identifying chemicals that cause reproductive toxicity. As the Statement of Reasons for the rule makes clear, an additional criteria for de-listing authoritative bodies, namely the authoritative body’s failure to keep using methods outlined in the rule, was considered and rejected as a basis for revoking an authoritative body listing; the Committee chose to limit the basis for de-listing to the authoritative body “no longer” having “expertise,” and that remains the sole criteria identified in the regulation. Statement of Reasons, at 7. The Committee must therefore not only have support for the proposition that the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction is not “authoritative” or have “expertise” in identifying chemicals that cause reproductive toxicity, it would also have to explain a change in NTP-CERHR’s qualifications that led the Committee to conclude that it “no longer” considers NTP-CERHR an authoritative body where it had before.

*ACC Previously Endorsed the Designation of NTP-CERHR as an Authoritative Body*

We note that ACC’s own representative endorsed the designation of NTP-CERHR as an authoritative body when the designation was before the DART Identification Committee in 2002. Meeting of the Science Advisory Boards Developmental and Reproductive Toxicant (DART) Identification Committee, Dec. 4, 2002 (hereinafter “Transcript”), at 108, 110, 111. For instance, the ACC representative stated that “the [ACC] Phthalates Esters Panel believes that the CERHR . . . is the appropriate entity to be named under the authoritative bodies regulation.” *Id.* at 110. She also went on to explain that “[o]ne of the reasons we feel that it’s critical that the CERHR themselves, and not the expert panel, be named as the authoritative body is that significant comments on the expert panel’s reports are very – the comments submitted are a very important part of the review process.” *Id.* at 111. ACC’s attempt to remove NTP-CERHR now is therefore somewhat curious.

*The DART Identification Committee Unanimously Approved NTP-CERHR as an Authoritative Body and Accepted Its Expertise*

The DART Identification Committee unanimously listed NTP-CERHR as an authoritative body, *id.* at 136, and NTP-CERHR's expertise was accepted without disagreement, *see id.* at 125-128 (Chairperson Miller: "My appreciation is that this expert panel and the documents that they produce are quite expert. I have no problems at all with the composition of the committees. It's [sic] seems they have assembled some excellent people to review these chemicals."; Dr. Burk; "I agree . . . that the panel reports are excellent."). The only discussion raising questions about the listing centered on how the NTP-CERHR reports presented their findings and whether the presentation explicitly addressed Proposition 65 requirements, the same issues raised by ACC in its petition under the guise of "expertise." As Dr. Donald of OEHHA stated then, "None of [the authoritative bodies] are operating specifically to address the requirements of Proposition 65, so we are always in the position of having to interpret any conclusions they draw in the context of Proposition 65." *Id.* at 128. In fact, the Chairperson of the DART Identification Committee explained the process, which was then confirmed by OEHHA: "[W]e do actually look at these reports to see that they fulfill our regulatory criteria, so that it is not like it is automatically – when they come from NTP-CERHR, that they are automatically accepted. They have to fulfill our regulatory criteria." *Id.* at 125.

*ACC Has No Basis for Its Argument that NTP-CERHR Does Not Possess the Requisite Expertise*

Even now ACC cannot generate any new arguments to support its proposition that the NTP-CERHR does not meet the expertise criteria outlined in the regulations. This is evident in the fact that none of ACC's arguments speaks at all to the NTP-CERHR's "expertise" or authority in decisions relating to whether a chemical is a reproductive toxin, for it is an argument it can hardly make. Rather, ACC relies exclusively on arguments that focus on the form of the NTP-CERHR's monographs, arguments considered and discarded by the DART Identification Committee in 2002, and not on the NTP-CERHR's expertise. *See* ACC Letter at 6-9. Its arguments boil down to a complaint that the NTP-CERHR's monographs do not use the same criteria as the DART Identification Committee and use criteria beyond those that are strictly relevant to a Proposition 65 listing, that the monographs do not express the NTP-CERHR's conclusions in the same terms as those used by Proposition 65, and that this might lead to confusion. *Id.*

However, the authoritative body report need not discuss the Proposition 65 criteria. *Exxon Mobil v. OEHHA* ("Exxon's notion that an authoritative body's document must discuss the regulation 25306(g) criteria is inconsistent with the [Proposition 65] regulation's clear statement that a 'list' suffices."). OEHHA may and continues to determine whether Proposition 65 criteria have been met by reviewing the reports of authoritative bodies and the supporting materials reviewed by the bodies even if the reports express their findings in terms different than Proposition 65 or the

implementing regulations, or use criteria in addition to those required for Proposition 65. Cal. Code Regs. § 25306(c) (“The lead agency shall determine which chemicals have been formally identified by an authoritative body as causing cancer or reproductive toxicity.”); *Exxon Mobil v. OEHHA* (“So long as OEHHA can conclude, on the basis of the entire record before it, that the authoritative body made the regulation 25306(g) findings, it may list a chemical pursuant to the authoritative body provision of the statute.”). This process does not render that authoritative body less expert or authoritative on the subject, the only criteria of relevance to a revocation of authoritative body status. These arguments about form were considered and set aside during the DART Identification Committee’s proceedings during which NTP-CERHR was listed, Transcript at 125-136, and OEHHA has successfully and repeatedly assessed and extracted the relevant Proposition 65 information from prior NTP-CERHR monographs.

ACC’s professed concerns and its petition are designed to delay a legally required listing of BPA. We urge OEHHA to dismiss the petition on its complete lack of legal merit and move ahead expeditiously on the listing of BPA under the authoritative bodies mechanism.

Sincerely,



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