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By Electronic Mail & Federal Express

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

RE: *Petition to Rescind Designation of NTP-CERHR as An Authoritative Body*

Dear Dr. Burk and Committee Members:

We, the undersigned attorneys and consultants, are writing on behalf of the Polycarbonate/BPA Global Group of the American Chemistry Council (hereinafter, "ACC") regarding its Petition to Rescind Designation of NTP-CERHR as an Authoritative Body for Purposes of Proposition 65 (hereinafter, "Petition"). We understand that the Petition has been included as a discussion item on the agenda for the next public meeting of the DART-IC on October 21, 2010, in order that the Committee may discuss and decide how to proceed with the Petition, but that no vote will be taken on the merits of the Petition. Accordingly, we are confining the scope of this letter to the preliminary issues of whether the Committee should entertain the Petition and, if so, how the Committee should proceed. We are doing so with the understanding that parties with an interest in the issues raised by the Petition will be provided opportunities to address the merits of the Petition at a later time, assuming that the Committee decides to entertain it.¹

REASONS WHY THE PETITION SHOULD BE HEARD

There are at least six reasons why the Committee should entertain the Petition. We address each separately below.

1. The Petition raises an important question that is fundamental to the implementation of Proposition 65. The importance of selecting authoritative bodies requires no

¹ When ACC submitted the Petition to OEHHA on August 5, 2010, OEHHA informed us that the relief requested under the Petition was a matter exclusively within the province of the Committee, and that we should submit the Petition directly to Dr. Burk as the Chair. With that same understanding, and to save time in the re-transmission of this letter, we are distributing copies of this letter directly to all members of the Committee, in order that they may review the letter fully prior to the October 21 meeting. We are submitting copies of this letter simultaneously to OEHHA, as indicated on the distribution list.

extrinsic proof. Rather it is clear on the face of the statute and regulations themselves. Section 25249.8(b) of the Statute identifies what has come to be known as the “authoritative bodies listing mechanism” as one of the principal (though not the primary) bases for listing chemicals as carcinogens or reproductive toxins. Section 25306 of the regulations reinforces that importance by providing that any chemical that is “formally identified” by a designated authoritative body as a carcinogen or reproductive toxin shall be listed. And the Committee is surely aware that hundreds of the chemicals designated as “known to the State” to cause cancer or reproductive toxicity were listed by this mechanism. The determination whether any agency should be designated as an “authoritative body” thus has profound consequences. The corollary question, whether the designation of any authoritative body should be rescinded, is equally important to the implementation of this Act.

Looking beyond that generality, the determination whether the “final reports” of NTP-CERHR,² in particular, should continue to serve that function is important to decisions that will arise in the not-too-distant future regarding a number of chemicals for which NTP-CERHR Monographs have been published and others for which Monographs are being drafted now. These chemicals include not only bisphenol A, which we addressed in the Petition as an example, but also acrylamide, genistein, soy infant formula and methanol, all of which raise profound collateral issues regarding the foods that Californians produce, distribute and consume.³

By raising these examples, we do not raise the issue now whether any of these chemicals (other than BPA) merits listing under Proposition 65, or whether listing would occur if these chemicals were evaluated by the Committee under the State’s Qualified Experts mechanism. Rather we raise them to point out that the chemicals that NTP-CERHR addresses are chemicals for which the consequences of listing are extremely important and complex, and for which the process by which listing decisions are made should be as comprehensive and transparent as possible, and which allows the decision-making body (*i.e.*, the Committee) to examine the relevant data fully and independently, consistently with the objectives of Proposition 65.

² For reasons to be discussed further when the merits of the Petition are addressed, NTP was designated as an authoritative body “only as to final reports of the . . . Center for Evaluation of Risks to Human Reproduction.” Cal. Code Regs., *tit.* 27, § 25306(l). The “final reports” issued by this agency are referred to as NTP Monographs, each of which includes the document referred to as an Expert Panel Report and an NTP Brief. Without intending to ignore that fine point, we have referred to the authoritative body simply as “NTP-CERHR.”

³ We note the claims of a collection of parties in their September 27, 2010 letter to the Committee, opposing the Petition on grounds that it is nothing more than a “poorly disguised attempt to slow the listing process” for BPA. While we acknowledge that a decision to grant the Petition may affect the outcome of *their* petition to list BPA (filed immediately after the Committee concluded that BPA should not be listed, but obviously prepared well before-hand with strategic goals in mind), the Petition raises valid questions as to whether the designation of NTP-CERHR as an authoritative body should be rescinded, for which BPA is only an example, many of which were raised by the Committee itself when its members decided to designate NTP-CERHR as an authoritative body in 2002, after that designation for NTP was rescinded in 1998.

2. *The Committee is the only body with authority to grant or deny the Petition.* To be blunt, we urge you to entertain the Petition because you are the only persons with authority under Proposition 65 and the regulations to decide it. We believe that ACC has raised important and valid questions regarding the appropriateness of NTP-CERHR as an authoritative body and, consistent with the limited purpose of this letter, will not argue those points now. We do point out, however, that other well-respected organizations within the regulated community, including the California League of Food Processors, the Infant Formula Council, the American Beverage Association and the Can Manufacturers Institute all have joined in the Petition. These organizations have a right, every bit as important as the proponents of listing, to be heard. With due respect to the Committee, we believe it is your obligation to hear them out.

In this regard, we assure the Committee that it *does* have authority under Proposition 65 and the regulations not only to hear the Petition, but also to grant the Petition, as a matter of its judgment and sound discretion. In this regard, we note that OEHHA, which found it appropriate to draft a “summary” of the Petition and to provide you with the Agency’s responses, has not told you otherwise. That is because it is clear from the regulations, and clearly expressed in the Statement of Reasons, that “implicit in authority to designate authoritative bodies is the power to revoke or rescind such a designation.”⁴

The argument that such authority is restricted to situations where the Committee “no longer considers [NTP-CERHR] to have expertise,” citing Section 25306(b) of the regulations, is plainly incorrect. In legal terminology, this regulation is referred to as a *grant of authority*, and not a *prohibition*. The quoted regulation indicates that the Committee has authority to rescind the designation of an authoritative body on that ground, but does not limit the Committee’s inherent authority to rescind such designations on other grounds. The final sentence of the regulation explicitly says that: “Nothing in this section shall be construed to limit or otherwise interfere with such authority.” Cal. Code Regs., *tit.* 27, § 25306(b).

Indeed, common sense itself leads to this conclusion. Should the regulations be read to require that any agency designated as an “authoritative body” must remain one forever? Even if the State’s Qualified Experts (*i.e.*, the Committee) were to disagree with its conclusions? Or if the Committee were to conclude that the documents that the authoritative body produced were confusing, or for some other reason no longer suited to making determinations under Proposition 65? Would the Committee have to determine not only that the agency’s documents were not useful, but *also* that the agency had no “expertise”? Bearing in mind that the term “expertise” is not defined, could the Committee determine that “expertise” must include a proven record of publishing written determinations that are useful for purposes of Proposition 65? Or could the

⁴ Final Statement of Reasons at 7-8. The complete quote reads as follows: “Implicit in the power to designate authoritative bodies is the power to revoke or rescind such a designation. The final sentence of subsection (b) makes this power explicit by specifying that the Panel shall have the authority to revoke or rescind any determination by it that a body is authoritative, *and* that this section shall not be construed to limit or otherwise interfere with that authority.” (emphasis added).

Committee simply determine that in order to serve as an authoritative body the agency must translate its analytical expertise into written determinations that are useful for purposes of Proposition 65? The answer, of course, is yes, because, as the State indicated in its official interpretation of the statute and regulations (*i.e.*, the Final Statement of Reasons), the Committee has implicit authority to revoke or rescind. That authority is not limited by the regulation.

For all of these reasons, the Committee does have authority to hear and to grant the Petition. Regardless of whether you decide to grant the Petition, you should hear it.

3. *The Petition is not an attack on NTP-CERHR.* Given the language of the regulation above and the argument asserted by opponents of the Petition, we hasten to add that the Committee's decision to hear (and potentially to grant) the Petition does not imply any criticism of NTP-CERHR or its Monographs. Rather it would be a recognition that NTP-CERHR has its own mission as the research arm of a federal agency, imposed by federal statutes, which does not include the obligation to express conclusions that are consistent with or amenable to Proposition 65.

In this instance, as we asserted in the Petition, the NTP-CERHR Monographs simply do not reach or express conclusions that lend themselves to authoritative body determinations. We do believe, however (and likewise assert in the Petition) that the Monographs do provide excellent summaries and analyses of data that are relevant to Proposition 65 determinations. If the Petition is granted, then the Monographs should be used as a complement or as an alternative to the Hazard Identification Materials that OEHHA prepares to support evaluations by the State's Qualified Experts.

4. *The Petition is not an attack on the OEHHA staff.* Nor should the Committee be concerned that a decision to grant the Petition would be a slight to OEHHA or its staff.

In the Petition, we emphasized the obvious incongruity between the Committee's unanimous July 2009 determination that BPA is not "clearly shown" to cause reproductive toxicity and OEHHA's February 2010 determination that BPA appears to meet the criteria for listing under the authoritative body mechanism, with both contradictory determinations based on a review of studies and statements in the same NTP-CERHR Monograph. In doing so, we are not trying to pit the Committee against the staff or compel the Committee to overrule the staff. Granted, we believe OEHHA is incorrect in its determination, and have filed extensive comments with the agency to demonstrate why its determination is incorrect, both factually and legally. As noted above, the issue presently before the Committee is whether to *hear* the Petition, and not whether to *grant* it. Thus, we will refrain from addressing those legal and scientific arguments now. Rather, we emphasize that the Committee should hear the Petition in order that these issues can be fully and fairly aired together with an analysis of the NTP-CERHR Monographs, which we will provide.

5. *Rescinding the designation of NTP-CERHR as an authoritative body will not unduly burden the Committee or the OEHHA staff in their duties to evaluate chemicals reviewed by NTP-CERHR.* As we pointed out in the Petition, the authoritative bodies listing mechanism was intended as an administrative convenience that would ease the burden on the Committee to evaluate chemicals one-by-one, yet still result in listing only of chemicals that the Committee itself would have listed. In this context, the Committee might be concerned that a decision to grant the Petition would overburden the Committee, if it were required to evaluate the chemicals currently reviewed by NTP-CERHR.

Given the relatively small number of chemicals that NTP-CERHR reviews, we do not believe that is a serious concern. As noted in the Petition, NTP-CERHR has issued only twenty Monographs in the twelve years of its existence. At this pace, NTP-CERHR chemicals can be absorbed conveniently into the State's Qualified Expert mechanism, especially if the NTP-CERHR Monographs are used as a complement or alternative to OEHHA Hazard Identification Materials, as suggested above.

6. *Fundamental fairness requires that all parties with an interest in the outcome of the Petition (and not just those who oppose it) be afforded an opportunity to express their views as to whether the Petition should be granted.* As noted above, a number of respected members of the regulated community have requested that this Petition be heard. For reasons unknown to us, however, the opportunity to submit written comments on the merits of the Petition has been restricted to a number of NGOs who oppose the Petition and urge that it should not even be heard.

To explain, we submitted the Petition to OEHHA and the Committee on August 5, 2010. OEHHA published notice of the Petition only on October 8, 2010, indicating that the Petition would be included on the agenda for the Committee's October 21, 2010 public meeting, as an item for discussion. In the interim, it appears that the Petition was distributed to various NGOs, which predictably (and vehemently) oppose the Petition and have used that opportunity to submit comments on the merits. At this point, however, neither ACC nor any others who support the Petition have had that opportunity. Indeed, many parties who may support (or oppose) the Petition learned of it only by virtue of the October 8 public notice, and have not had an opportunity to submit comments on the Petition at all.

In submitting the Petition, we expressly requested that it be published and that public comments be solicited timely so that the Petition could be considered at the October 21 meeting. We have no objection to its consideration as a discussion item at this meeting, with public comment and its consideration deferred until the next public meeting. We are very concerned, however, that the distribution of the Petition to only *some* parties, particularly to those who have opposed it on the merits by written comments, and not to the public at large, has created an unfairness or at the least an appearance of unfairness. We suggest that this unfairness can be obviated only by allowing all interested parties an opportunity to address the Petition with written comments, whether in favor of the Petition or opposed, and by allowing the Petition to be heard on its merits at the next public meeting of the Committee.

SUGGESTIONS AS TO HOW THE COMMITTEE SHOULD PROCEED

We understand from the inclusion of the Petition as a discussion item on the agenda for the October 21 public meeting that the Committee will entertain suggestions as to how it should proceed, assuming that the Committee decides to entertain the Petition. Recognizing that the Petition presents a very important issue, not only for ACC but for other parties that may support or oppose the Petition, we have two concerns: (1) the process should be designed to provide the Committee with the best and most complete information on which to base its decision, whether to grant or deny the Petition, and (2) all parties with a legitimate interest in the outcome of the Petition should be afforded a reasonable opportunity to submit comments. On these premises, our suggestions follow.

1. *Written Comments in Support of the Petition.* It should be clear from the face of the Petition that it includes only a brief summary of the reasons that the Petition should be granted. We believe it would benefit the Committee and all parties with an interest in the Petition, if ACC were afforded the opportunity to state the grounds for the Petition in full and to submit supporting documents at that time. Any other parties supporting the Petition should be required to file their comments at the same time as the petitioner. We do not believe this will result in excessive submissions. Rather, we anticipate that parties who favor the Petition likely will coordinate with ACC. Any comments in favor of the Petition by parties other than ACC likely will be brief.

2. *Written Comments in Opposition to the Petition.* With grounds in favor of the Petition fully articulated, any parties who oppose the Petition then should have a full and fair opportunity to respond.

3. *Rebuttal Comments in Support of the Petition.* Given our proposal to solicit comments in opposition to the Petition after the grounds in support are fully stated, it would only be fair to allow the Petitioner to respond to any opposing arguments. If the Committee agrees with this proposal, we would agree to a reasonable page limitation, and (consistent with the rules in most courts) would raise arguments only in response to those raised in opposition to the Petition. (In other words, we would not raise new arguments in support of the Petition for the first time in our rebuttal comments.)

4. *Oral Presentations Before the Committee.* One substantial advantage in soliciting responsive written comments, as above, would be to economize on time required for oral comments at the public meeting. The principal purpose of oral presentations would be to allow the Committee to raise questions, and for the Parties to respond. We propose that proponents and opponents of the Petition be allotted thirty minutes each, collectively. The proponents should be allowed to allot a portion of their time for rebuttal, at their option.

5. *Suspension of the Status of NTP-CERHR as an Authoritative Body Pending Resolution of the Petition.* In its response to the Petition, OEHHA indicated that the law does not allow the agency to suspend the *process* for authoritative bodies listings on the basis of NTP-

CERHR findings pending resolution of the Petition. Without debating that proposition (and noting that there is precedent for designating US EPA as an authoritative body on a *provisional* basis) we believe the Committee, should suspend the *status* of NTP-CERHR as an authoritative body pending resolution if it decides to entertain the Petition. This would be reasonable, because a decision to entertain the Petition on the basis of comments submitted for and against the Petition thus far would be a *de facto* recognition that there is good cause to consider the Petition and the relief it requests. This is somewhat akin to a preliminary injunction in legal matters. If the Petition is ultimately granted, then any unwarranted listings would be avoided. If the Petition is denied, then the suspension would have no significant consequences, and any pending potential listings could proceed.

CONCLUSION

In summary, and on behalf of our client, we thank the Committee for its decision to consider the Petition at the upcoming public meeting, if only as a discussion item. We look forward to the opportunity to discuss the Petition and the contents of this letter with you on October 21.

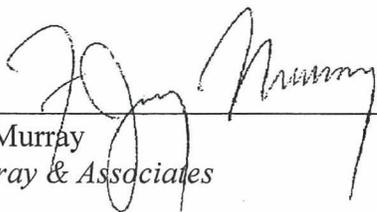
Respectfully submitted,



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