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July 7, 2011

Via ELECTRONIC & U.S. MAIL

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

RE: *Request for Opportunity to Address Committee*

Dear Dr. Burke:

I am writing on behalf of our client, the American Chemistry Council Polycarbonate/BPA Global Group (“ACC”), to request the DART IC to allocate time at its upcoming July 12-13, 2011 public meeting for representatives of ACC to address the Committee regarding ACC’s Petition to Rescind Designation of NTP-CERHR as an Authoritative Body for Purposes of Proposition 65 (“Petition”). I regret the need to submit this request with such formality and frankness, but we are convinced by the circumstances below that the request must be made.

ACC’s Request to the DART IC

Specifically, we are requesting time to address the reasons that ACC filed the Petition, why the Petition has scientific and legal merit, and why granting the Petition would improve the implementation of Proposition 65, in addition to curing the anomalous proposal to list bisphenol A under the Authoritative Bodies listing mechanism, after your Committee voted unanimously not to list that chemical. Of course, we want to address questions from the Committee on these subjects, and respond to objections from any person who believes the Petition should not be granted.

Our comments would be delivered by three ACC representatives who co-authored the Petition, and would require no more than twenty minutes (aside from responding to questions). We request the opportunity to deliver our comments “before or during the [Committee’s] discussion or consideration” of the Petition, within the meaning of the Bagley-Keene Open Meeting Act.¹

Background for Request

ACC submitted the Petition to the Committee on August 5, 2010, over two months in advance of the Committee’s next scheduled meeting on October 21, 2010. OEHHA published the Petition promptly on its website, allowing for extensive public comment, and prepared a legal analysis of the Petition and provided it to the Committee with a letter dated September 27, 2010.

¹ Bagley-Keene Open Meeting Act of 2004 (“Open Meeting Act”), Cal. Govt. Code § 1112.5.7.

Nevertheless, the Committee declined to hear the Petition at the public meeting, electing instead to include the Petition on the agenda as an item for “discussion” only, allowing only OEHHA’s staff and Chief Counsel to address the Committee and prohibiting the public (even interested parties) from doing so.

It was evident from OEHHA’s extended discussion of the Petition with the Committee that there was a great deal of confusion regarding the basis for the Petition and its effect, if granted. One Committee member expressed concern that granting the Petition would result in the Committee’s being denied access to NTP-CERHR Monographs for its deliberations under the “State’s Qualified Experts” listing mechanism, which clearly would not occur.² OEHHA’s Chief Counsel responded that there appeared to be confusion about the different listing processes.³ Other Committee members appeared to indicate that they did not understand how the Authoritative Bodies and State’s Qualified Experts listing mechanisms were related.⁴

At that point, I, as counsel for ACC, requested the opportunity to address the Committee to explain these matters, but was prohibited from doing so.⁵ Without the opportunity to speak, we could only protest that the effective denial of the Petition without an opportunity to address the Committee was a denial of due process of law. Putting aside the question of whether prohibiting members of the public to address the Committee on this agenda item was consistent with the Open Meeting Act,⁶ we believe that our client deserves a reasonable opportunity to address the Committee at the July 12-13 meeting to discuss the items enumerated above, and further to address the Committee’s questions and concerns.

If we understand the agenda correctly, the DART IC has not allocated any time for ACC to address the Committee regarding its Petition, except insofar as ACC might be able to speak during the time designated for “Public Comments.” If that understanding is incorrect, then we trust that the Committee will clarify this misunderstanding in advance of the meeting and adjust the agenda

² Meeting of the Developmental and Reproductive Toxicant Identification Committee, October 21, 2010, Transcript at pp. 114-15.

³ *Id.* at 115.

⁴ *Id.* at 117-18.

⁵ *Id.* at 119-21.

⁶ The Bagley-Keene Open Meeting Act of 2004 (“Open Meeting Act”) provides in pertinent part as follows: (a) Except as otherwise provided in this section, *the [Committee] shall provide an opportunity for members of the public to directly address the state body on each agenda item before or during the [Committee’s] discussion or consideration of the item.*” Cal. Govt. Code § 1112.5.7(a) (emphasis added). None of the exceptions to this rule, (which relate to closed sessions, administrative adjudications, hearings conducted by the State Board of Control, or meetings of the Public Utilities Commission) allow the Committee to forbid the public from addressing the Committee on agenda items that are not “voting” items. Rather, *the law requires an opportunity for public input on any matter that the Committee “discusses” or “considers.”* We can find no authority that would allow a state body, such as the Committee, to prohibit public comment on an agenda item simply because the state body designates the agenda item for “discussion” and does not intend to take a vote. Indeed, such a process is contrary to the very purpose of the Open Meeting Act, which is to encourage and allow all members of the public to offer their comments, in the anticipation that such comments may inform the state body’s judgment.

to give ACC the requested twenty minutes to explain why we believe the Committee should take the action we have requested.

Our concern that ACC will not be allowed a meaningful opportunity to be heard is heightened by the Committee's discussion at its last meeting of a proposal to limit the right of the public to comment on agenda items at all DART IC meetings.⁷ Ironically, the Committee placed this proposal on its agenda "for committee discussion only" and prohibited any public comment on the issue, because the Committee was not "voting" on the proposal.^{8,9} Nevertheless, the Committee discussed the proposal extensively, and Committee members were requested to comment. When its deliberations were finished, the Committee appeared to be resolved to "keep the [public] comment period short,"¹⁰ to limit the opportunity for any person to comment to "three minutes" regardless of the number of persons who wish to comment,¹¹ and to prohibit commenters who share the same interest in an issue from sharing their individual time to coordinate their collective time into one coherent presentation.¹²

In this context, and after the Committee refused to allow ACC, through me, to offer any comment regarding the Petition, we must address our concerns that the DART IC does not intend to allow our client a meaningful opportunity to be heard at the July 12-13 meeting, either. We are convinced that the allocation of three minutes to ACC would be not be sufficient.

ACC Should Be Provided a Fair Opportunity to Present Its Petition to the Committee

It is self-evident that the Committee should provide ACC a fair opportunity to present its Petition to the Committee. The Petition is a request for action that is within the Committee's authority to take. In fact, *only* the Committee has that authority. ACC is affected by the Committee's actions. What better reasons could there be for the Committee to allocate a reasonable amount of time to hear what ACC, the petitioner, has to say? Especially where, according to the Agenda, it appears that OEHHA has been allocated time to analyze the Petition and present its views?

We are genuinely mystified why the Committee would not to allow ACC to address the obvious confusion and questions about the Petition at the October 21, 2010 meeting. We regret the need to say this, but it appeared to those in the regulated community that certain advocates, who felt aggrieved by the Committee's decision not to list Bisphenol A, had requested the Committee to impose rules to prevent companies whose products are regulated under Proposition 65 from

⁷ Meeting of the Developmental and Reproductive Toxicant Identification Committee, October 21, 2010, Transcript at pp. 86-107.

⁸ *Id.* at 91.

⁹ As indicated at n. 6 above, the Open Meeting Act requires all state bodies, including the Committee, to allow public comment on any item on its agenda that the state body "discusses" or "considers," and does not allow a state body to prohibit public comment on a proposal merely because it does not intend to vote on it.

¹⁰ Transcript at 102.

¹¹ *Id.* at 100-01.

¹² *Id.* at 103.

addressing the Committee in the future in any meaningful way, and the Committee acceded to their requests.

According to the transcript of the October 21, 2010 meeting, the proposal to limit public comments at DART IC meeting had its “origins” in a July 22, 2009 letter from certain non-governmental organizations to the former Director of OEHHA, criticizing OEHHA and the DART IC because the Committee had voted (unanimously) not to list Bisphenol A.¹³ According to the authors, the DART IC members lacked expertise to carry out their duties, it was unreasonable to expect the (unqualified) Committee to weigh conflicting opinions, certain Committee members dominated others who did not understand or were unprepared, and OEHHA staff should “step in” at public meetings “to correct” asserted “misunderstandings” regarding issues of science and regulation, apparently to guide the Committee to reach decisions more to their liking.¹⁴

In response to this letter, the former Director arranged for a meeting attended by her, a representative of those organizations, and you, as the Chair of the Committee. According to the transcript, the former Director asked you “to bring three specific items relating to meeting procedures” for “discussion” on the Committee’s agenda, which would “affect the Committee’s deliberations at future meetings.”¹⁵ The Committee put these proposals on its agenda, “discussed” them without the benefit of public comment, and appeared to reach resolution on them, exactly as the authors of the letter requested.

We do not understand why OEHHA and the Committee would give the above-described complaints so much dignity. Putting aside the insulting and warrantless attacks on your professional qualifications, the allegations that the Committee’s procedures were unfair to pro-listing advocates are simply untrue. The Committee held a special full-day meeting to address BPA, for the express purpose of allowing all interested persons to be heard. Given the broad public interest in BPA, we believe that was appropriate, and the Committee should be praised, rather than criticized, for bending over backward to allow all interested persons the opportunity to be heard, rather than closing the door.

For our part, I am pleased that ACC was able to present comments from nationally respected experts in their fields, including a former president of the Society of Teratology who actually conducted critical studies that were the subject of some of the reports before the Committee. As to the pro-listing advocates, we think it appropriate that they were able to present prominent scientists who represented their views. We would not inhibit their ability to do so.

In our experience, this is the way the Committee always has conducted public meetings on listing decisions. The system has worked fairly well for approximately twenty years. The Committee has recognized those with special expertise appropriately, allowing them time to speak commensurate to the information they have to offer, regardless of their pro-listing or anti-listing views. The Committee similarly has allowed lay persons or those who wish to offer anecdotal

¹³ *Id.* at 84.

¹⁴ July 22, 2009 letter to OEHHA, attached.

¹⁵ Transcript at 84.

information time to state their views. We can recall few, if any, meetings where there was not sufficient time for all interested persons to provide their comments, or where the Committee was not able to address all of the matters on its agenda. Indeed, many meetings (including the October 21, 2010 meeting) have adjourned early.

In other words, the measures proposed at the October 21, 2010 meeting are a solution in search of a problem. Worse, they give the appearance of a preemptory “gag rule” on persons whose products may be regulated by the Committee’s decisions, imposed at the behest of persons who always want the Committee to rule in favor of listing all candidate chemicals. It is difficult to imagine that experts will be persuaded to travel to California to appear before the Committee if they risk being limited arbitrarily in their ability to present comments, regardless of the credentials and information they may have. It is not difficult, however, to see whose agenda such a rule would favor.

The assertion that interested persons may offer comments in writing, while true, does not fully address the problem. Written materials may be the primary vehicle through which to offer informed comments, but oral presentations offer commenters the opportunity to determine whether written comments are understood, to clarify, and to ask and respond to questions. Indeed, some committee members have advised us to come to meetings prepared to make comprehensive oral comments, indicating that we cannot assume that written comments have been fully digested or understood. That is not a criticism of this Committee or any Committee member; rather, it is a recognition of the process, deadlines, and the fact that Committee members are busy professionals who lend their expertise to the process as volunteers.

The Committee should not be mistaken that its prior “discussion” of the above-described measures now compels the DART IC to limit public comment, whether to three minutes or any other arbitrary period. Although the Open Meeting Act *allows* the Committee to “adopt reasonable regulations” that “limit . . . the total amount of time allocated for public comment on particular issues and for each individual speaker,”¹⁶ the Committee has not adopted any such regulations.

Thus, the Committee remains free to act on its broad, inherent authority to conduct its meeting as it sees fit, except as constrained by fundamental notions of due process and the Open Meeting Act. As relevant here, the Open Meeting Act imposes only one absolute requirement: the Committee must provide an opportunity for the public to address the Committee directly “on each agenda item before or during [the Committee’s] discussion or consideration” of the item.¹⁷

There are compelling reasons that the DART IC should not impose the “three minute rule” that OEHHA proposed. We recognize that other state bodies, including legislative committees, sometimes do impose such a rule. The DART IC is different from those bodies in many ways. In stark contrast to the legislature, whose full-time employees are available in their offices year-round, and which holds many types of public hearings (some for investigations and fact-finding, some to demonstrate support before the taking of a vote), the DART IC meets only once or twice

¹⁶ Cal. Govt. Code § 1112.5.7(b).

¹⁷ Cal. Govt. Code § 1112.5.7(a).

Dorothy Burk, Ph.D., Chairperson
Developmental and Reproductive Toxicant Identification Committee
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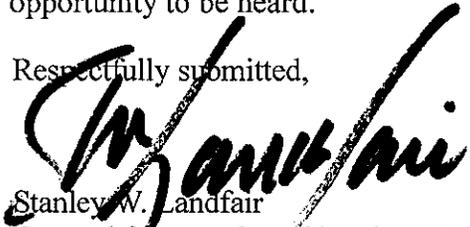
per year, and must make its listing decisions only in those public meetings. This is the only opportunity for persons affected by those decisions to address the Committee in person, and the only opportunity for Committee members to see and hear them. As noted above, the persons we have brought before the Committee are recognized experts in complex scientific disciplines. The purpose of their public comments is not simply to say "I'm for it," or "I'm against it," but to explain why science or policy supports or does not support a proposal to list, and thus to inform the Committee's judgments.

In closing, please note that I have referred often above to the "*opportunity to be heard.*" That is because the fundamental concept of due process of law, in its most basic formulation, consists of two elements: "notice" and "the opportunity to be heard." The promise of due process is not fulfilled if there is no meaningful opportunity to address a state body as it proceeds in a public meeting to make an important, potentially adverse decision. If fairness to those on all sides of an issue is a concern, the solution is to allow all sides the opportunity to be heard. That is all our client is requesting now: the opportunity to be heard.

Conclusion

For all of the reasons above, the DART IC should be willing to allocate twenty minutes at its July 12-13 meeting for our client to address the Committee regarding its Petition. ACC has raised a serious item of business for the Committee, which only the Committee has the authority to act upon. It is only fair to allow ACC a meaningful opportunity to be heard.

Respectfully submitted,



Stanley W. Landfair
Counsel for American Chemistry Council
Polycarbonate/BPA Global Group

SWL

cc: Members of the Developmental and Reproductive Toxicant Identification Committee
Cynthia Oshita, Proposition 65 Implementation, OEHHA
Carol-Monahan Cummings, Chief Counsel, OEHHA

ATTACHMENT

**Letter from NRDC, *et al.*
to OEHHA re asserted
unfairness of DART IC**

**Breast Cancer Fund • Clean Water Action • Environment California
Healthy Building Network • Natural Resources Defense Council
Science & Environmental Health Network**

July 22, 2009

Dear Dr. Denton,

We are writing to express our serious concerns about the conduct of the Developmental and Reproductive Toxicant Identification Committee on July 15, 2009. There were numerous ways in which we believe the meeting was mishandled by OEHHA and by the Chair, and these problems collectively gave the committee a biased view of the issue, and incorrect information on which to base their decision. Based on the concerns outlined below, we protest the conduct of the meeting and do not believe the decision of the panel reflects decisions intended by Proposition 65. We therefore request reconsideration of this listing decision.

- 1) *Lack of expertise of the committee.* There are no members of the panel with expertise in male reproductive toxicology, and no members of the panel have significant expertise in newer areas of toxicology such as neurobehavioral toxicology and endocrine disruption. Several members of the panel have essentially no relevant expertise at all. The committee members appeared to be unprepared for the meeting, and many seemed not to have read the materials. This poor level of background and preparation meant that the decision was not likely to be based on the weight of the scientific evidence.
- 2) *Staff presentations.* Presentations by OEHHA staff were difficult for the panel and the audience to hear and understand, making the presentations less effective. Furthermore they did not include any professional judgment or recommendation as to whether a listing is appropriate or a recommendation for (or against) listing. We are told this is intentional, that OEHHA staff intends not to “take sides” on the issue. This is inconsistent with practices in most scientific advisory panels, when the agency brings a proposal to the panel for review or approval.
- 3) *Structure of the meeting and allocation of time.* In an effort to develop a coherent and thorough case for listing, prior to the meeting, the NGO scientists and independent scientists repeatedly requested additional time for their presentations. We were repeatedly told that time would be strictly limited to 5-10 minutes per presenter. Immediately prior to the start of the meeting, Dr. Solomon asked Dr. Denton and the Chair this question one more time in regard to Dr. vom Saal’s presentation, and was given the same answer. As a result, we needed to have two speakers cede their full time to Dr. vom Saal, and to seriously shorten our presentation. In contrast, the industry panel contained only five speakers and was given a full 70 minutes to present (nearly 15 minutes per speaker). Using this process not only did they have more time per speaker, they were able to present

an organized case against listing. When they went over their allotted time, the Chair immediately offered their panel an additional 15 minutes without any protest. Since our lead scientists had already spoken, there was no chance for them to rebut industry's arguments. This structure results in no opportunity for a comprehensive presentation and rebuttal in favor of listing, and could explain in part why DARTIC lists so few chemicals using the "clearly shown" listing route.

- 4) *Failure to require financial disclosures.* Contrary to proper procedures, none of the industry presenters were required to disclose their financial conflicts of interest when they presented their testimony. After the meeting, one of us (GLS) spoke with two panel members (Dr. Jones and Dr. Hobel). Both of them stated their belief that industry had not been present at the meeting. They further stated that the American Chemistry Council is a non-profit group, with the implication apparently being that they are not an industry group. They also apparently believed that Dr. Tyl and Dr. Murray were independent scientists who had come to the meeting on their own time. Dr. Tyl contributed to this misunderstanding by stating that her institute receives 80% of its funding from government, without mentioning that the studies she was presenting on bisphenol A had been funded entirely by the American Plastics Council. Dr. Murray failed to make any disclosures at all. None of the industry panelists were asked for their disclosures, as they should have been. It is our understanding that it would be Dr. Denton's role on the panel to assure that this procedure is properly followed. The belief of some panelists that the industry presentation represented independent science rather than a commercial perspective may have made them more receptive and less critical of the arguments presented.
- 5) *Confusion about the charge.* After the meeting, in a conversation with one of us (GLS), two panel members, Dr. Jones and Dr. Hobel, stated that based on the science they had heard today, they had serious concerns about the use of bisphenol A in baby products. The Chair of the panel made similar comments in the media.¹ Yet these three panelists had just voted not to list the chemical under Prop. 65. These perspectives are at odds with one another. If the science presented at the meeting raised their concern to the level that they would be concerned about the trace amounts of BPA in baby bottles, surely that would mean the science was sufficiently strong to meet the actual "clearly shown" standard. Our review of presentations at past DARTIC meetings shows that industry persistently presents their view of the meaning of this legal standard, and urges on the committee members, all of whom are scientists without legal training, an incorrect standard of scientific certainty. Listening to the panel's deliberations made it quite clear that the panelists are confused about this issue, but OEHHA staff failed to clarify the distinction and educate the panel about their actual charge. We understand from informal conversations that OEHHA intentionally does not advise the panelists on the meaning of the "clearly shown" legal standard they are to apply, and leaves it up to them to decide what it means. It is not reasonable, however, to expect a panel of scientists to have an understanding of what standard of certainty

¹ <http://latimesblogs.latimes.com/greenspace/2009/07/bisphenol-a-california.html>

the law requires them to apply in making their decision. Nor is it reasonable to expect the committee to hear conflicting presentations by commenters and expect them to make the legally correct choice of standard. We believe this failure by OEHHA influenced the decision on BPA and perhaps other chemicals in the past. Additionally, after the panel was instructed that they were not to consider dose in their deliberations, dose was still mentioned as a factor in their decision. At this point, the director of OEHHA has the responsibility to remind the panel yet again about the role of dose in the process. This panel only meets twice per year and needs strong leadership from not only the OEHHA staff but from its director as well.

- 6) *Failure of scientific staff to correct panel members' misunderstandings.* During the panel's deliberations, numerous scientific points of confusion arose, and it was repeatedly clear that panelists did not understand the literature on various endpoints. At several points in the discussion, there were opportunities for OEHHA staff to clarify the science, and to correct misunderstandings. The staff repeatedly failed to make those necessary corrections and clarifications, and appeared to be either confused or unprepared to explain the studies. These points of confusion allowed several important endpoints to be disregarded or dismissed, when a correct understanding of the science could have resulted in a different outcome. It is the staff's responsibility to step in to correct misunderstandings and mischaracterizations of the science, both in the public comment, and during the panel's deliberations.
 - a. *For example, during the discussion of male reproductive toxicity, there was a discussion between committee members (Dr Jones) and staff about the prostate data.* Dr Jones was one of two committee members assigned to review the male reproductive toxicology data and in his initial remarks had not commented on the prostate data but led a general discussion about his opinion on the overall lack of sufficient evidence for male reproductive effects of BPA. When asked by the Chair to specifically comment on the prostate data, it was clear that Dr. Jones was not familiar with this data and he asked for clarification from OEHHA staff. Instead of immediately clarifying the question and pointing out the inaccuracies in the statements made by Dr. Jones when referring to a table in the draft OEHHA document, OEHHA staff made ambiguous remarks that seemed to further confuse Dr. Jones and committee members and led them to conclude this endpoint was not critical.
 - b. *A second example:* Committee members were confused and asked OEHHA staff to clarify whether or not it was appropriate for them to consider cancer endpoints in their evaluation. OEHHA legal staff was not able to clarify this for committee members other than to say they could consider endpoints that were "transplacental carcinogenesis" and it was up to them to determine whether or not the data supported this endpoint. In addition, scientific staff stated that they did not thoroughly evaluate this data, although it was presented in their draft document and both prostate and mammary cancer were identified as endpoints of concern by the NTP

when making their conclusions about the same scientific data. DART IC members also incorrectly stated that these effects only occurred at high doses, which was completely inaccurate as these effects occur within the range of current human exposure. This was another missed opportunity for staff to point out information about the neonatal exposures and cancer endpoints that were completely relevant and should have been effects to trigger a listing. Instead of being prepared to talk about the data that was already in their draft document, OEHHA staff offered to prepare more materials on these endpoints in the future and to bring them back to the committee at a later date. This effectively removed these endpoints from consideration for listing at this meeting.

As a result of these numerous irregularities in the conduct of the meeting on July 15, 2009, we are lodging a protest about the conduct of this meeting. We believe the results are not valid and should be reconsidered.

Sincerely,

Dr. Sarah Janssen, MD, PhD, MPH, Staff Scientist
Dr. Gina Solomon, MD, MPH, Senior Scientist
Natural Resources Defense Council

Gretchen Lee Salter, Policy Manager
Breast Cancer Fund

Andria Ventura, Program Manager
Clean Water Action

Pamela King Palitz, Environmental Health Advocate and Staff Attorney
Environment California

Julie Silas, Director, Health Care Projects
Healthy Building Network

Joseph H. Guth, JD, PhD, Legal Director
Science & Environmental Health Network