

**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,

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