

Albany  
Atlanta  
Brussels  
Denver  
Los Angeles

**McKenna Long  
& Aldridge**<sup>LLP</sup>  
Attorneys at Law

101 California Street • 41st Floor • San Francisco, CA 94111  
Tel: 415.267.4000 • Fax: 415.267.4198  
www.mckennalong.com

New York  
Philadelphia  
Sacramento  
San Diego  
San Francisco  
Washington, D.C.

CHRISTIAN VOLZ  
(415) 267-4108  
cvolz@mckennalong.com

STANLEY W. LANDFAIR  
(415) 267-4170  
slandfair@mckennalong.com

October 15, 2010

***VIA EMAIL AND FEDERAL EXPRESS***

Joan E. Denton, Ph.D., Director  
OFFICE OF ENVIRONMENTAL HEALTH  
HAZARD ASSESSMENT  
1001 "I" Street  
Post Office Box 4010  
Sacramento, California 95812

***RE: DEVELOPMENTAL AND REPRODUCTIVE TOXICANT IDENTIFICATION  
COMMITTEE; COMMENTS ON PROCEDURES FOR PUBLIC COMMENTS,  
COMMITTEE DISCUSSIONS, AND COMMITTEE VOTES DURING MEETINGS***

Dear Dr. Denton:

On behalf of the Polycarbonate/BPA Global Group of the American Chemistry Council ("ACC"), we submit the following comments with respect to item IV on the agenda for the October 21, 2010 public meeting of the Developmental and Reproductive Toxicant Identification Committee ("DART-IC"). Item IV, identified on the agenda published on OEHHA's website on October 8, 2010 as "for Committee discussion only," is "Procedures for Presentation of Public Comments, Committee Discussions, and Committee Votes During Meetings."

Under the heading for agenda item IV, OEHHA published an NRDC letter dated July 22, 2009 and OEHHA's response to that NRDC letter dated September 1, 2010. We understand from these correspondence that the NRDC letter is the genesis of this agenda item and its purpose is principally to address NRDC's complaints about the public meeting that the DART-IC held on July 15, 1999 to decide whether the chemical bisphenol-A ("BPA") should be listed as a reproductive toxicant under Proposition 65, and that the purpose of placing this item on the agenda is to allow the Committee to "discuss any changes it feels may be appropriate to address the concerns raised in [the NRDC] letter . . . including: procedures used at the meetings for public comment periods, committee discussions and voting protocols."

Under these circumstances, we believe it is appropriate to point out that the Committee went to extraordinary measures in holding a special public meeting exclusively devoted to BPA.

We also cannot fail to note that public comments were not solicited on this topic, and that this issue appears to have been placed on the agenda solely to address NRDC's complaints.

For these reasons, *we request that this letter be forwarded formally to the DART-IC prior to the October 21, 2010 public meeting and posted as part of the public record* (immediately, if possible), so that the record may be corrected as to the following: contrary to NRDC's complaints, this all-day meeting was a model of completeness and fairness; the proponents and opponents of listing both made thorough and engaging presentations that addressed all relevant scientific, legal and other reasons they believed that BPA should or should not be listed; the Committee listened to all speakers and questioned many (demonstrating their familiarity with the written submissions); and the Committee went out of its way to accommodate any and all proponents of listing, in order that their views could be heard. In this regard, the Committee also went out of its way to consider grounds upon which BPA might be listed, in clear and obvious solicitude to the proponents of listing. Indeed, the Committee promised to remain open to listing if new evidence should develop at a later time. The verbatim transcript of the meeting reflects this.

Because this agenda item is intended to address the comments in NRDC's letter, we have responded below to each of NRDC's comments, in order. We have provided references to the transcript and to documents, where appropriate.

NRDC's first comment was:

*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.

ACC strongly disagrees with (1) the unwarranted and insulting comments about the professional qualifications of the DART-IC members, (2) the baseless allegation that the Committee members were unprepared and had not read relevant materials, and (3) the conclusion that DART-IC's decision was therefore "not likely to be based on the weight of the scientific evidence." It is impossible not to infer that this remarkable series of spiteful comments reflects primarily the partisanship of the commenters and their anger at the DART-IC's decision not to list BPA.

Every member of the Committee is a respected, accomplished professional, and all members have expertise in either developmental toxicology, teratology, gynecology and obstetrics, epidemiology or reproductive toxicology, satisfying the criteria set forth at Cal. Code Regs., tit. 27, § 25302(b)(2). The fact, if true, that none are specialists in the above-cited sub-

specialties does not mean that the Committee is unable to understand arguments and weigh evidence in those areas. The commenters appear simply disgruntled that the unconvincing arguments and unconventional studies presented by some of their speakers did not convince the Committee.

In contrast to NRDC, we observed a Committee that was engaged and attentive during the presentations. The transcript shows that many members of the Committee questioned the expert presenters. *See* Transcript (“Tr.”) at 54 - 56 (questions to Dr. Solomon); 73 - 76 (questions to Dr. Vom Saal); 82 - 84 (questions to Dr. Woodruff). The Committee’s hour-long deliberations, discussions and votes, all of which were conducted on the record, were thorough, organized and deliberative, and included extensive colloquies among the Committee members and the OEHHA staff. *See* Tr. at 209 - 253. The Committee members homed in directly on the crucial issues of study design and quality, route of administration, and maternal toxicity. Their assessments of the individual studies, and of the weight of evidence overall, were thoughtful and clearly articulated.

NRDC’s second comment was:

*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.

We disagree with the assertion that the OEHHA staff presentations were difficult to understand. Some oral presentations were challenging due to the accents of the speakers, but this should not be discouraged or criticized in a state as culturally diverse as California. We were able to understand each speaker, and found that any difficulty was compensated for by the written materials and PowerPoint slides. We do not agree that the DART-IC’s evaluation and decision processes would benefit from more adversarial presentations, or explicit listing recommendations by OEHHA staff.

NRDC’s third comment was:

*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.

This comment grossly distorts what actually occurred at the July 15, 2009 meeting. To begin with, the public meeting was the culmination, not the beginning of the hearing process. Opponents and proponents of listing all had the opportunity to submit unlimited written comments prior to the meeting, and took advantage of that. The comments of the Committee members during the meeting demonstrated that they had reviewed and were familiar with the comments, including the voluminous Hazard Identification Materials prepared by OEHHA and the NTP-CERHR Monograph.

As to the meeting itself, the Chair allotted each speaker (including proponents and opponents) up to ten minutes each, but acknowledged that some speakers from each side had requested to appear as groups. She encouraged them to do so, and indicated that members of groups would be allowed to cede time to each other in order to deliver coordinated or expanded presentations. Tr. at 49. It was clear throughout the presentations that the proponents and opponents of listing did organize themselves to present cohesive presentations, addressing scientific, legal and other factors in equal manner, and with the same comparative emphasis.

The actual allocation of time and subject of the speakers' presentations follows:

- 1) OEHHA staff presentations took 55 minutes, from 10:07 to 11:02 a.m., followed by seven minutes of Q&A with the Committee.
  
- 2) The NRDC team consisted of six speakers (Dr. Solomon, Ms. Sutton, Ms. Apatira, Dr. vom Saal, and Dr. Woodruff, and Ms. Forsyth). It is clear from the transcript that Dr. Solomon, who acknowledged that BPA presented a "difficult complicated decision," completed her prepared (and very cogent) remarks in full, and then was permitted to yield additional time to Dr. vom Saal. Tr. at 50-56. Ms. Sutton (a research scientist) and Ms. Apatira (a medical student) joined in Dr. Solomon's comments and yielded their time to Dr. vom Saal, presented by some as the world's most foremost authority on BPA. Tr. at 56. Dr. vom Saal then delivered a prepared presentation. The transcript shows that he delivered a fulsome presentation (20 full pages), including 44 PowerPoint slides. Tr. 56-76.

Dr. Woodruff (Director of the Program on Reproductive Health at UCSF Medical School) then delivered a prepared presentation, which also included PowerPoint slides. Tr. at 76-84. Ms. Forsyth then delivered her entire presentation, which consisted of a personal plea that the Committee list BPA. Tr. at 84-85. Notwithstanding their allotment of sixty minutes, the entire team spoke for only 48 minutes, from 11:24 to 12:12, including nine minutes of Q&A with the Committee. If we need to reduce the issue to minutes, the team had twelve minutes yet to speak. The transcript shows that no speaker's comments were abridged. Each completed his or her presentation.

- 3) A lunch break was taken from 12:12 to 1:05.
- 4) The opposition to listing consisted of only seven speakers (Ms. Silveira, for the California Grocer's Association, the ACC team (consisting of Mr. Landfair, Dr. Hentges, Dr. Tyl, Dr. Murray and Dr. Lawyer), and Dr. Hoyle, for the North American Packaging Alliance). They were allotted 70 minutes. Tr. at 87.
- 5) Ms. Silveira spoke for four minutes, from 1:05 to 1:09.
- 6) Mr. Landfair introduced the ACC team at 1:09. His oral presentation and his PowerPoint slides clearly identified Drs. Hentges, Tyl, and Murray as representing ACC. Their entire presentation took 66 minutes from 1:09 to 2:15, including ten minutes of Q&A with the Committee. The presentation was interrupted, however, by telephone calls from technicians broadcasting the meeting to the speaker's lectern (Tr. at 90, 98), a "time-out" to correct technical problems with the broadcast equipment (Tr. at 97, 111), and discussion regarding the amount of time allowed (Tr. at 129-30). Because of these interruptions and extensive questions from the Committee members to the speakers, the opponents of listing were allotted an additional few minutes, extending their time to 2:25. Even then, in order to stay within the time limits, Dr. Lawyer (who co-prepared ACC's written submission) elected not to speak. Dr. Hoyle spoke for ten minutes, from 2:15 to 2:25. Although Mr. Landfair interrupted Dr. Hoyle when it appeared that he would exceed his time, the transcript shows that he still was within his allotment and thus was permitted to complete his remarks. Tr. at 145.
- 7) Following the opponents to listing, sixteen additional NGO speakers then spoke for 73 minutes, from 2:37 to 3:59, to make a variety of arguments and comments in favor of listing BPA. The speakers included representatives of the Environmental Working Group, Coalition for Clean Air, Center for Environmental Health, Environment California, Association of Reproductive Health Professionals, two representatives of the Breast Cancer Fund, another

representative of NRDC, the Breast Cancer Fund and other organizations, as well as any individual who desired to speak. Every speaker presenting scientific evidence spoke at length. Some read from letters or other documents already submitted to the Committee. Regarding NRDC's complaints about the supposedly "confusing" standard for listing, a lawyer/scientist proponent of listing opined at considerable length regarding the "clearly shown" standard, and why that should compel listing. *See* Tr. at 189-93. Importantly, no one who desired to speak was denied the opportunity. Although some speakers may have perceived themselves rushed, the transcript shows that each speaker was permitted to get his/her point across.

8) The DART-IC members then discussed the evidence for 63 minutes, from 4:00 to 5:03. The voting process began at 5:03.

In summary, and contrary to NRDC's claims that they were shortchanged in the allocation of time and deprived of the opportunity for rebuttal, the facts are: (1) the NGOs in favor of listing BPA spoke first, with a consolidated allotment of 60 minutes and spoke for only 48 minutes; and (2) the seven opponents of listing only slightly exceeded their collective allotment of 70 minutes by only five minutes, which the Committee appropriately allowed due to interruptions and questions; (3) following ACC's presentations against listing, the NGOs spoke last, with 16 additional speakers taking an additional 73 minutes. Several of the speakers who followed ACC's presentations made rebuttal arguments ranging from public policy to scientific merits to simply *ad hominem* arguments, to testimonials and personal pleas. The total speaking time for NRDC and other NGOs in favor of listing was 121 minutes. The total speaking time for ACC and two industry associations opposed to listing was 75 minutes. Thus, pro-listing speakers took nearly two-thirds of the speaking time and had approximately 60% more time than those opposed, and had the advantages of speaking both first and last.

It is simply untrue that on July 15, 2009 NRDC, *et al.* were given "no opportunity for a comprehensive presentation and rebuttal in favor of listing . . ." Rather, they enjoyed both. It is true that ACC was "able to present an organized case against listing," but so were the proponents of listing. And that simply means that both the proponents of listing and the opponents were afforded due process – a salutary result in our view, although NRDC appears to disagree.

NRDC's fourth comment was:

*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.

These comments are unpersuasive and self-contradictory. NRDC has complained that the "industry panel" was given 70 minutes to "present an organized case against listing," yet here they seem to be arguing that Drs. Tyl and Murray, two of the four members of the "industry panel," misled the DART-IC regarding their affiliation with industry. We submit that nobody in the room, and certainly no member of the DART-IC, failed to understand that Drs. Tyl and Murray were part of the ACC team, particularly after Mr. Landfair introduced them both orally and with a PowerPoint slide as members of the ACC Team. Unlike NRDC, Drs. Jones and Hobel (and the other Committee members) showed professional respect for the expertise and integrity of Drs. Tyl and Murray "despite" their financial connections to industry. There is no reason to think the DART-IC's deliberations or decision were influenced by a lack of formal financial disclosures. Nor was there any lack of opportunity for NRDC to bring this up at the meeting, if they believed it to be an issue.

NRDC's fifth comment was:

*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. 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 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.

We disagree that the DART-IC members were confused about or somehow unable to understand the applicable “clearly shown” standard. As OEHHA notes in its response, the Committee has written guidance documents that provide very detailed criteria to assist them in evaluating the weight of relevant human and animal data, judging the quality of individual studies, and assessing the “weight of evidence.” ACC did in fact, at the meeting, make explicit references to those very DART-IC guidance documents, but that was hardly “urg[ing] an incorrect standard of scientific certainty.” Indeed, this whole discussion tends to ignore that OEHHA and the DART-IC authored those documents, and that the ACC team basically read the standards from those documents back to the Committee. Moreover, the “clearly shown” standard is set in the Act itself; in essence, NRDC’s complaint is that it would prefer a lower standard.

As for the off-the-record comments attributed to Drs. Jones, Burk, and Hodel, assuming they are accurately portrayed, there is clearly no contradiction between expressing “concerns” about possible risks (including risks of adverse effects having nothing to do with reproductive toxicity), and the Committee’s decision that the weight of evidence did not “clearly show” that BPA causes developmental or reproductive toxicity. All people, including members of the Committee, are entitled to be ultra cautious in their personal lives and choices, and to avoid the “slightest risk,” or “any possible risk.”

NRDC’s sixth comment was:

*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. [Examples omitted.]

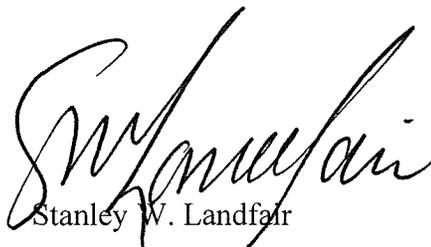
We disagree that the referenced discussion about obscure endpoints reflected any serious confusion on the part of the Committee or any failure of diligence or responsiveness on the part of OEHHA staff. We also strongly disagree that the weight of scientific evidence indicates that BPA causes prostate or mammary cancer.

In conclusion, ACC believes the DART-IC meeting on July 15, 2009 was well conducted and that the Committee exercised sound judgment in soliciting public comment, in allocating time among commenters, and in its subsequent deliberations and decisions. NRDC's complaints and criticisms regarding the Committee's expertise and procedures are unwarranted.

Very truly yours,



Christian Volz



Stanley W. Landfair

CV/gmp

cc: Dorothy Burk, Chairperson, Developmental and Reproductive Toxicant Identification Committee (By Federal Express and e-mail)  
Committee Members (By Federal Express)  
Carol Monahan-Cummings, Chief Counsel (OEHHA) (By Federal Express)  
Cindy Tuck, Undersecretary, Cal/EPA (By U.S. Mail)