

Office of Environmental Health Hazard Assessment



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Secretary for Environmental Protection

Arnold Schwarzenegger
Governor

September 1, 2010

Dr. Sarah Janssen
Natural Resources Defense Council

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, Ph.D., Legal Director
Science & Environment Health Network

Dear Drs. Janssen, Solomon, Guth and Ms. Salter, Ventura, King-Palitz and Silas:

Thank you for your letter of July 22, 2009 in which you discussed your concerns about the July 15, 2009 meeting of the Prop 65 Developmental and Reproductive Toxicant Identification Committee (DART-IC). At that meeting, the DART-IC considered and rejected the listing of Bisphenol-A (BPA) as a reproductive or developmental toxicant for purposes of Proposition 65.¹

Your letter sets out a number of concerns about how the July 2009 meeting was conducted. In response, staff from the Office of Environmental Health Hazard Assessment (OEHHA), including myself, and Dr. Dorothy Burk, the DART-IC chairperson, met with you on April 8, 2010 to discuss these concerns. Although we do not agree with everything in your letter, we appreciate your candid remarks. Below is a brief response to each of the six issues identified in your letter.

¹ The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code section 25249.5 et seq., commonly known as Proposition 65.

California Environmental Protection Agency

The energy challenge facing California is real. Every Californian needs to take immediate action to reduce energy consumption.

1. Lack of expertise of the committee – OEHHA agrees that the appointment of additional members to the committee with backgrounds in areas such as male reproductive hazards would benefit the committee's overall review of certain chemicals for possible listing. OEHHA will continue to support appointments that enhance the knowledge base of the committee. In addition, OEHHA will encourage the committee members to leverage the significant expertise of the staff scientists at OEHHA who are responsible for collecting the hazard identification materials for the chemicals presented for listing decisions and are, therefore well-versed in the details and issues likely to come up on chemicals they have evaluated. These scientists are available at the meetings to answer questions any of the members may have concerning the technical aspects and interpretation of the data being presented.
2. Staff presentations – As a general practice, OEHHA staff avoid making specific arguments for or against the listing of any given chemical since this decision is entirely within the purview of the expert committees. However, in future meetings we intend to organize our written and oral presentations in such a way as to focus separately on each endpoint of concern and to identify those studies that OEHHA staff feels are most important to the committee's evaluation of the chemical. As noted above, OEHHA will also encourage the committee members to take advantage of the scientific expertise of our staff to help answer questions, provide perspective and clarify misunderstandings or misstatements concerning the data being discussed.
3. Structure of the meeting and allocation of time – Dr. Burk has requested that this item be included on the agenda of the next DART-IC meeting to be held on October 20, 2010. The committee will discuss any changes it feels may be appropriate to address the concerns raised in your letter and our subsequent meeting including: procedures used at the meetings for public comment periods, committee discussions and voting protocols.
4. Failure to require financial disclosure – As we discussed at our meeting with you in April, our general practice at the meetings has been to ask speakers to identify the organizations, if any, that they are representing at the meeting. To the extent that committee members have questions about the source of funding for the research or other materials a speaker is presenting, the committee members are free to ask the speaker to disclose the funding source. We are constrained by the California Open Meeting Act from requiring individuals to disclose such information² so they may legitimately decline to do so if asked by a committee member.
5. Confusion about the charge – We agree that the 'clearly shown' standard in the statute and regulations has become the subject of much debate in public

² Government Code section 11124

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comments in recent years. This standard is not a legal determination; it is instead a scientific judgment in which the state's qualified experts are expected to apply their own knowledge and expertise to determine if a chemical has been "clearly shown by scientifically valid testing according to generally accepted principals to cause reproductive toxicity." As you know, the DART-IC and the Carcinogen Identification Committee have developed guidance documents concerning how to evaluate the evidence that is presented to them when making this scientific judgment. OEHHA will provide copies of this guidance to each committee member prior to the committee meeting and will provide a brief statement concerning this issue at each meeting, prior to listing decision items. In addition, legal staff is always available at the meetings to answer any questions committee members may have concerning statutory or regulatory issues.

6. Failure of scientific staff to correct panel members' misunderstandings – To the extent that it is appropriate to do so, OEHHA's staff provides factual information to the committee members where it appears a misunderstanding among one or more of them exists. OEHHA staff does not comment concerning the exercise of any member's scientific judgment or otherwise interfere with the deliberations of the committee, whether or not they agree or disagree with the committee members reasoning or conclusions. However, as discussed under item number two, we will encourage committee members to utilize the scientific expertise of OEHHA staff during their deliberations.

Thank you for providing us with your concerns regarding the July 15, 2009 DART-IC meeting. We continue to be open to constructive criticism of our efforts to implement the Proposition 65 program.

Sincerely,



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Director

cc: Dorothy T. Burk, Ph.D.
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