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November 17, 1996

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RE: Report of November 15 Public Workshop Sponsored by
CalEPA's Office of Environmental Health Hazard
Assessment

At the request of the Vinyl Institute I attended the November 15, 1996 public workshop sponsored by the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHHA) on the "Revised Draft Procedure for Prioritizing Candidate Chemicals for Consideration Under Proposition 65 by the State's Qualified Experts". This workshop also served as a public forum to receive any preliminary comments on the draft prioritized candidate chemicals under consideration for carcinogenicity and/or reproductive toxicity evaluation.

The majority of time was devoted to a review of the document by staff and discussion with the audience participants (approximately 55) on recommended changes or problems, with a lesser amount of time and staff focus to specific chemicals. Staff repeatedly stated that they would be relying heavily on the written comments (due November 20). In fact, most of those who did speak to specific chemical issues (highlights of which are included below) noted that comments were preliminary and that written comments were being prepared for submission.

Dr. Lauren Zeise (chief of the OEHHHA's Reproductive and Cancer Hazard Assessment Section), gave a detailed review of the draft procedure document. I am assuming that the recipients of this report are familiar with the contents of the October 1996 draft and have not, therefore, summarized its contents or repeated her presentation. Dr. Zeise and Dr. Richard Becker, Director of OEHHHA, responded to most of the questions concerning the prioritization process and seem very open to specific changes but are not interested in

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making wholesale changes to the approach embodied in the October draft. It is OEHHA's stated intention to have refinements to the proposed prioritization document (based on discussions at this workshop meeting and the written comments received) ready for the December 4 meeting of the Science Advisory Board's Developmental and Reproductive Toxicant Identification Committee, with the procedure finalized and released in early 1997.

The agency noted that at this time it does not anticipate changing the rankings for chemicals in the medium area at the conclusion of the comment period December 4. As you know, vinyl chloride is in this medium category. Rather, the agency will focus its attention on those chemicals in the high and medium-high level first.

Review of General Issues Relative to the October 1996 Draft Procedure Document Discussed During Workshop -- Additional Written Input Being Sought by OEHHA:

While the draft version of the VI comments does not specifically call for recommended changes in the procedure document, several of the points made about vinyl (such as ongoing epidemiological and toxicological studies, filling of data gaps, consideration of mechanistic data, etc.), might be expanded to some general suggestions. It is not critical that this be done, but if there is time, it might be useful to add some general discussion to the VI comments. Given the shortness of time between the end of the comment period and the DART meeting, the structure of the process as spelled out in the draft will likely be finalized without much change unless the OEHHA receives targeted comments. Listed below are some of the topics discussed:

1. Review by "World Class" Science Groups: There are some chemicals listed that are currently undergoing risk assessments by "world class" scientific groups (ex. IARC). Is there a way to procedurally include such types of review activity without the review being a delaying tactic.

2. Stigmatization of Being a Listed Chemical: There was considerable discussion on the issue of a chemical being stigmatized by its inclusion on a state list of carcinogens. The agency understands industry's sensitivity on this issue and is willing to examine some neutral nomenclature.

3. Controversy Regarding Use of Random Selection: There is not agreement that random selection is an appropriate component of this process; the Environmental Defense Fund believes that the use of random selection is nothing more than a way to defer/delay action and finds this approach unacceptable. The agency has taken the view that use of random selection will still allow the chemicals with high and medium-high developmental/reproductive toxicity

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concerns to proceed first to the outside science experts for review, while removing some of the political pressure that could result from the agency making selections among the 800 chemicals. The activist community will likely continue to focus its comments on removal of random selection.

4. No Time Frames Specified for Actions: Specific time frames for each step of the process were reportedly part of the initial OEHHA document. Specific time slots are not included in this draft; the EDF spokesperson is unhappy with this change.

5. Exiting Listing: There was discussion on whether there should/can be a mechanism by which a chemical can "exit" the process following its random selection and review. This topic was raised by Paul Kronenberg of the California CIC and others. As the process now exists, a chemical would remain assigned to category II if it received anything other than a "high ranking (i.e., medium-high, medium, low, and postponed). Items receiving a "high ranking would be listed on the Candidate list and a Hazard Identification Document would be prepared. The Agency agreed that they have not clearly spelled out exactly what would happen to those chemicals in category II and they understand the need for the process to be more specific as to the path forward.

6. Consideration of Other Data Input: The document does not specifically include consideration of mechanistic data (John O'Donohue representing a CMA panel on hydroquinone noted that his panel is submitting such data but it is not clear how this data will be considered or reviewed).

7. Filling of Data Gaps: The agency, in responding to questions by the audience, said it is relying on outside interests to identify potential gaps. Several participants stated that they believed the Agency should identify places where they believe data is needed to make a determination regarding the proper priority. The staff will be discussing this issue. I don't anticipate changes in this area.

Highlights of Chemical Specific Comments by Participants:
(Please forgive misspellings of names -- there were no name tags and individuals were not asked to spell their names)

1. Grocery Manufacturer's Association: While a good portion of James Coughlin's (sp?) comments focused on issues such as random selection, consideration of mechanistic data, he also specifically discussed the issue of essential trace elements such as chromium and copper sulfate. He talked about activities underway within respected scientific bodies (the Institute of Medicine's Food and Nutrition Board and

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the World Health Organization) that will be discussed in detail in GMA's comments.

2. Environmental Defense Fund (Bill Pease): While a majority of his comments dealt with the procedural issues (and he spoke at quite some length), he expressed outrage that styrene was dropped off the list with no explanation other than what he believes must be a purely political decision. No one on the staff responded on this item.

3. Murray Associates (Jay Murray): He is a former member of the SAB and spoke on behalf of several different groups on general topics as well as chemical specific items. He suggested that in addition to considering mechanistic data that the agency might also consider pharmacokinetic data. He noted that relative to carbaryl (for which he was representing Rhone Poulenc) a lower ranking should be received. He stated that it was reviewed by EPA in 1994 and it received a Group C designation.

4. Halogenated Solvents Industry Alliance (Michael Neale): He spoke to trichlorethylene and methylene chloride and noted that some of the flawed studies included in the chemical drafts have already been reviewed by the U.S. Agency for Toxic Substances and Disease Registry.

5. Lonza Chemicals (Bill Thomas): He spoke about formaldehyde and challenged its ranking. Jay Murray also addressed formaldehyde on behalf of an independent resin producers group and noted that CARB, OSHA, and the CPSC have all considered pieces of the issue being considered.

6. CMA Hydroquinone Panel (John O'Donohue): He was the individual who first raised the data gap issue. He noted that CMA members are willing to collect data to fill identified gaps, but noted that there doesn't seem to be a way to find out what the agency believes they are.

7. Baker Performance Products (Arthur Lawyer): He spoke to acrolein and stated that Baker wants the status lowered as there are new events since the original comments to the State were submitted.

8. Monsanto (Ron Hogue): Spoke about butyl benzyl phthalate, for which they are the only U.S. producer and noted that in 1995 the USEPA deleted BBT from its SARA 313 listing. He further noted that four studies by NTP have all indicated that BBT should be listed as of "no immediate concern." He also referenced biodegradation studies and stated that in only one of 54 samples taken was there a measurement and it was less than 1 ppb per liter of California water. He noted that it is used as a plasticizer in PVC as part of a flooring matrix.

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If you have any questions on the above, please let me know.
I can be reached at 408/531-0356 PST.

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