CENTER FOR OCCUPATIONAL AND ENVIRONMENTAL HEALTH

UNIVERSITY OF CALIFORNIA, LOS ANGELES • SCHOOL OF PUBLIC HEALTH
650 CHARLES E. YOUNG DRIVE SOUTH, LOS ANGELES, CALIFORNIA 90095-1772
TELEPHONE 310-206-6920 • FAX 310-206-9903
DIRECTOR: JOHN R. FROINES, PHD.

September 12, 2005

Barbara Riordan
Interim Chairman
Air Resources Board
1001 I Street
P.O. Box 2815
Sacramento, California 95812

Dear Mrs. Riordan:

Please accept this letter as the response of the Scientific Review Panel (SRP) to the request in former ARB Chairman Allan C. Lloyd's letter of February 4, 2003 to review the original 1992 formaldehyde health risk assessment in order to respond to a petition received by the Air Resources Board (ARB) from the Formaldehyde Epidemiology, Toxicology and Environmental Group, Inc. (now the Formaldehyde Council). It is the Panel's conclusion and recommendation that there is not sufficient new scientific data supporting the petition to formally reopen the prior risk assessment on formaldehyde at this time. The SRP's deliberations, recommendation, and suggestions relating to the recommendation are described in detail below.

The original petition was submitted to the ARB in a letter dated April 11, 2002, according to a procedure instituted by the Panel in 1989 to determine whether new scientific information warrants review of an original risk assessment. The process requires the ARB and the Office of Environmental Health Hazard Assessment (OEHHA) review the new material before referring it to the Panel. The submittal must contain the following information:

1. The submittal must describe specifically what in the original risk assessment will be qualitatively and/or quantitatively changed. If new evidence is accepted, does it change the determination of health effects, the determination of a threshold, or the potency, and if so, how do they change?

2. The submittal must describe the importance of the new evidence as it relates to the scientific basis of the original risk assessment.

3. The new scientific information is required to be peer-reviewed.

The petition requested review of the original 1992 formaldehyde risk assessment based primarily on a cancer risk assessment model which was laid out in a report issued by the Chemical Industry Institute of Toxicology (CIIT) in 1999.

The OEHHA completed its initial evaluation and on November 21,2002, submitted to the ARB its recommendation that the petition be denied. The OEHHA recommendation was based on its conclusion that the evidence presented in the petition (1) did not change the determination that formaldehyde is a carcinogen; (2) presented information that considered the possibility of non-linear dose response relationships, but presented no clear grounds to review the original "no threshold" determination; and (3) did not provide any new epidemiology or bioassays supporting a change in potency. In addition, there was insufficient information to fully evaluate the CIIT model, issues such as model uncertainty were not adequately addressed, and there were concerns that a considerable amount of the supporting materials had not been peer reviewed.

On February 4, 2003, the ARB formally asked the Panel for its recommendation whether a new review of the original 1992 risk assessment is warranted based on the information contained in the petition. The Panel first considered and discussed the petition in detail in its June 20, 2003 meeting. In addition to the petition, the Panel also reviewed an evaluation of the petition from the OEHHA and a letter dated April 23, 2004, submitted to the Panel on behalf of the petitioner as a supplement to the original petition. At the time of the June 2003 meeting, however, it became known that several new health studies of occupational workers exposed to formaldehyde would be published later that year. The Panel postponed its final deliberations and recommendation pending its consideration of the new epidemiological health studies after their publication.

The Panel, in its May 19, 2004 meeting, returned to its deliberation of the petition and also discussed the new epidemiological studies. The Panel concluded that there was not sufficient new data to support the petition to review the formaldehyde risk assessment. In addition, the newly published studies represented relevant new information, but they did not allow determination of a causal relationship between formaldehyde exposure and leukemia. These studies deserve further evaluation over time given their potential importance.

During its deliberations, the Panel also discussed that while the CIIT model would not change the original conclusion that found formaldehyde to be a toxic air contaminant, the model does represent a new approach and does contain new information. However, that new information is not yet sufficiently developed, i.e., additional and extensive work is required of the petitioners. The Panel is aware that OEHHA is continuing to review toxic air contaminants as required by the Children's Environmental Health Protection Act (SB25, Escutia, chaptered 1999) for their impact on children's health. Formaldehyde was discussed during the preparation of OEHHA's initial October 2001 report under that program and may be reviewed in their next report. If

formaldehyde is reviewed, it would be appropriate to further consider the CIIT model at that time to the degree that it had had further development.

During the course of the SRP's deliberations the Panel was aided by the comments of Dr. Dale Hattis, Clark University, Worcester, MA who is a risk assessment expert with particular knowledge of formaldehyde. Dr. Hattis' input was considered highly relevant by the Panel. Dr. Hattis concluded that further work was required on the risk assessment models before they would be in acceptable form for consideration.

It is worth noting that the International Agency for Research on Cancer (IARC) held a meeting which included twenty-six scientists from ten countries in June, 2004 to assess the carcinogenic potential of formaldehyde and two other organic compounds. The IARC Working Group concluded that formaldehyde is *carcinogenic to humans (Group 1) on the basis of sufficient evidence in humans and sufficient evidence in experimental animals.* This represents a higher classification than previous IARC evaluations.

Thank you for requesting the Panel's recommendation. Should you have any questions about our recommendation, please let me know.

Sincerely,

John R. Froines

John R. Froines, Ph.D., Chairman
Scientific Review Panel

cc: Members, Scientific Review Panel
Joan Denton, Ph.D., Director
Office of Environmental Health Hazard Assessment