Office of Environmental Health Hazard Assessment

Joan E. Denton, Ph.D., Director
Headquarters • 1001 I Street • Sacramento, California 95814
Mailing Address: P.O. Box 4010 • Sacramento, California 95812-4010
Oakland Office • Mailing Address: 1515 Clay Street, 16th Floor • Oakland, California 94612

Linda S. Adams
Secretary for Environmental Protection

Arnold Schwarzenegger
Governor

April 13, 2007

Clerk of the Board
Air Resources Board
1001 I Street, 23rd Floor
Sacramento, California 95814

RE: Staff Report Regarding the Air Resources Board's Proposed Airborne Toxic Control Measure for Formaldehyde from Composite Wood Products

Dear Clerk of the Board,

The Office of Environmental Health hazard Assessment (OEHHA) is responsible for providing risk managers in State and local government agencies, including the Air Resources Board (ARB), with toxicological and medical information relevant to decisions involving public health. The purpose of this letter is to underscore the health effects of formaldehyde summarized in the ARB staff report (see Chapter VII, Sections 2a through 2c, pp 133-155, which was written by OEHHA staff), and to respond to public comments which you have received in this regard.

The original health effects analysis for formaldehyde was provided in the 1992 staff report (Part B Health Effects Assessment of Formaldehyde) conducted as part of the identification of formaldehyde as a Toxic Air Contaminant (TAC) by the Board in 1992. At that time there were definitive findings of nasal carcinomas in rodents and suggestive findings in humans of lung and upper respiratory tract cancers. OEHHA concluded that no threshold for the carcinogenic dose-response was expected, and a unit risk factor of 6×10^{-6} $(\mu g/m^3)^{-1}$ was calculated using a model which considered both the dose of formaldehyde received by the affected tissues in rodents and the effects of cell proliferation. The 1992 staff report was peer reviewed by the Scientific Review Panel on Toxic Air Contaminants (SRP), as mandated by the Health and Safety Code as part of the Toxic Air Contaminant identification process.

OEHHA has continued to follow the literature on the cancer and noncancer health effects of formaldehyde since that time. OEHHA developed Reference Exposure Levels (RELs) based on acute and chronic non-cancer effects involving respiratory irritation, which are used in the Air Toxics Hot Spots Program as indicative of a level that would not produce noncancer health effects. Formaldehyde was evaluated during the prioritization of TACs for the Children's Environmental Health Protection Act (SB 25), which was undertaken in 2001. OEHHA concluded that formaldehyde presents a relatively high level of concern for possible

differential health impacts on infants and children, based not only on its carcinogenicity but also its respiratory effects, including irritation of the nose and upper respiratory tract, decreased lung function, and a likely propensity to exacerbate asthma.

At the public workshop in March 2007, a consultant for the Formaldehyde Council presented the opinion that OEHHA's risk assessment was overly conservative and that the benefits projected by ARB from its proposed control measure are therefore overestimated. The comment was based on a petition received in 2002 from the Formaldehyde Council to re-examine the unit risk factor for formaldehyde. The principal basis of this petition was an analysis by scientists at the Chemical Industries Institute for Toxicology (CIIT), which used a more complex analysis of the likely carcinogenic dose-response based on analysis of deposition of formaldehyde in the rodent nasal cavity, and the role of DNA damage and cell proliferation. This model suggested that the cancer unit risk would be high (comparable to that predicted by OEHHA and U.S. EPA) at doses of several parts per million or above, but much lower (although not actually zero) at lower concentrations likely to be present in the general environment. OEHHA reviewed the materials submitted by the petitioner and presented our conclusions to the Scientific Review Panel (SRP). The SRP discussed the petition and formaldehyde research at two meetings. The SRP sent a letter to the Board in September, 2005 declining to recommend reconsideration of OEHHA's 1992 formaldehyde unit risk factor. This was largely due to the uncertainties in the model surrounding the formaldehyde concentration at which, according to the CIIT model, the unit risk "switched" from low to high. This modeled inflection point could vary considerably depending on the choice of some poorly characterized input parameters, and might reasonably be low enough that environmental and indoor exposures were in the "high potency" range. Also, it became apparent during the course of the discussions that several important epidemiological studies were about to be published, which might add considerably to the evidence of human carcinogenicity.

Since that time OEHHA has continued to monitor developments in the scientific understanding of formaldehyde toxicity, regarding both its carcinogenicity, and its non-cancer effects. Concern for the carcinogenicity of formaldehyde has increased. The International Agency for Research on Cancer (IARC) held a meeting in June 2004 at which evidence for formaldehyde carcinogenicity was reviewed and the conclusions and classification were updated; this review has just appeared in print in IARC Monographs Vol 88 (December 2006). Formaldehyde was upgraded from its previous (Monographs Volume 62, 1995) status of *probably carcinogenic to humans* (Group 2A) to *carcinogenic to humans* (Group 1), based on the determination that the evidence of carcinogenicity in humans (from epidemiological studies) is now *sufficient*. OEHHA concurs with this evaluation. It should be noted that IARC determined that there is sufficient evidence for nasal carcinoma in humans and now strong evidence of an association of formaldehyde with leukemia. Thus, our concerns with the reliability and

applicability of the CIIT model, which is not relevant to leukemia in particular, have increased rather than decreased since 2005.

Finally, OEHHA reviewed and agrees with the risk assessment of formaldehyde exposure presented in the composite wood ATCM staff report, which utilizes OEHHA's unit risk factor. The risk assessment in the staff report reflects current science on formaldehyde exposure and risk from composite wood products.

Sincerely,

M. Marty for George Alexeeff

George V. Alexeeff, Ph.D.
Deputy Director for Scientific Affairs

cc: Dr. Melanie A. Marty, Ph.D., Chief
Air Toxicology and Epidemiology Branch
1515 Clay Street, 16th Floor
Oakland, California 94612