



February 15, 2008

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

Submitted via: <http://www.arb.ca.gov/lispub/comm/bclist.php>

Re: Proposed Airborne Toxic Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products; Modified Text and Additional Document (Release date January 31, 2008)

Dear Clerk:

The Formaldehyde Council, Inc. (FCI) appreciates the opportunity to submit comments to the Air Resources Board on the Proposed Airborne Toxic Control Measure to Reduce Formaldehyde Emissions from Composite Wood Products.¹ The revised materials released on January 31, 2008, propose modifications for compliance testing, certification, and labeling of composite wood products.

FCI submitted detailed comments on the lack of scientific support for the proposed rule in April 2007, and, together with other experts, summarized these deficiencies at the ARB hearing. While FCI appreciates the refinements that ARB endeavors to achieve in the implementation of the rule, ARB has failed to address the deficiencies in the foundation for the rule itself.

The rationale for the rule rests in large part on a 1992 estimated cancer potency for formaldehyde by the Office of Environmental Health Hazard Assessment (OEHHA). OEHHA performed a conservative cancer risk assessment, designed to estimate the cancer risk to humans at low exposure levels of formaldehyde by extrapolating the results of cancer in laboratory rats at higher levels of exposure. If OEHHA's estimates were accurate, the proposed reductions in formaldehyde emissions would have a small (but not insignificant) benefit. Notably, OEHHA's estimates are at odds with more realistic risk assessments by other respected agencies. Since OEHHA conducted its risk assessment in 1992, new and relevant scientific data on formaldehyde has been published, which has not been incorporated in OEHHA's risk assessment despite requests to re-open the risk assessment process. Using this information, a

¹ The Formaldehyde Council, Inc. ("FCI") is a nonprofit trade association that represents the leading producers and users of formaldehyde in the United States that is dedicated to promoting the responsible use of formaldehyde. FCI members continue to invest considerable resources to advance the scientific understanding of formaldehyde. Since its founding, FCI has become recognized as an expert resource in the science of formaldehyde toxicology and applicable risk assessment models. FCI members manufacture the majority of the U.S. production volume of formaldehyde. FCI is committed to advancing the state of scientific understanding on potential toxicology, epidemiology, and environmental effects related to formaldehyde, as well as providing accurate technical and scientific information relating to potential exposures, uses and effects of formaldehyde or formaldehyde-based products. For more information about the FCI, including a list of members, visit www.formaldehyde.org.

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robust, biologically-based approach to estimating the potential cancer risk of formaldehyde to humans was developed and published. Importantly, this approach to assessing the potential cancer risk of formaldehyde has been embraced and adopted by regulatory agencies in the US and internationally, including US EPA (2006)², Health Canada (2001)³, the World Health Organization (WHO, 2002)⁴, and the Australian Government (2006)⁵.

Table 1 compares the estimated cancer risks of formaldehyde exposure in California using the cancer potency estimates (i.e., the inhalation unit risk per $\mu\text{g}/\text{m}^3$) for formaldehyde adopted by OEHHA and the other agencies. The cancer potency estimates in Table 1 are all based on the same study of formaldehyde in rats. With the exception of the choice of the cancer potency factor, all assumptions and calculations were exactly the same as those used by OEHHA. So, the only reason for the difference in the results in Table 1 is the different estimates of the cancer potency of formaldehyde.

Table 1. Comparison of Estimated Cancer Risk of Formaldehyde in California using OEHHA Methodology and the Cancer Potency Factors of Various Organizations

Organization	Inhalation unit risk per g/m^3	Cancer Risk per Million for Adult (current average exposure)	Cancer Cases Reduced per Million post Phase 2	California Cancers Prevented per Year post Phase 2
US EPA (1988)	13×10^{-6}	186	76	39
OEHHA (1992)	6×10^{-6}	86	35	18
US EPA (1992) proposed according to OEHHA (1992)	2×10^{-6} 0.2×10^{-6}	28 3	12 1.2	6 0.6
Health Canada (2001)	0.00017×10^{-6}	0.002	0.001	0.0005
WHO (2002)	0.00019×10^{-6}	0.002	0.001	0.0005
Australia (2006)	0.0024×10^{-6}	0.03	0.014	0.007
US EPA (2006)	0.0027×10^{-6}	0.04	0.016	0.008

As noted above, based on OEHHA's estimates of formaldehyde's cancer potency and the average exposure to formaldehyde in California, the implementation of Phase 2 is estimated by

² US EPA (2006) National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products; List of Hazardous Air Pollutants, Lesser Quantity Designations, Source Category List. 71 Fed. Reg. 8348-49 (Feb. 16, 2006).

³ Health Canada (2001) Priority Substances List Assessment Report: Formaldehyde. February, 2001.

⁴ WHO (2002) Concise International Chemical Assessment Document 40: Formaldehyde. Geneva.

⁵ Australian Government Department of Health and Ageing (2006) Priority Existing Chemical Assessment Report No. 28. Formaldehyde. National Industrial Chemicals Notification and Assessment Scheme. November, 2006.

OEHHA to prevent 35 cancer cases per million people. In contrast, the other agencies' cancer potency factors, combined with OEHHA's estimates of average exposure to formaldehyde in California, produce an estimated reduction of cancer cases much smaller than one in a million. For example, only 0.001 cancer cases per million people (or one cancer case per *billion* people) would be prevented using the cancer potency factors adopted by Health Canada and WHO (Table 1). Similarly, US EPA's (2006) cancer potency factor predicts a reduction of only 0.016 cancer cases per million people.

Based on an estimated population of 35 million people in California and OEHHA's estimate of a reduction of 35 cancer cases per million people over a 70-year lifetime, OEHHA's estimated number of cancer cases prevented per year in California is 18.⁶ In contrast, using the cancer potency factors of the Other Agencies, the estimated number of cancer cases prevented per year in California ranges from 0.0005 to 0.008 (Table 1). In other words, the estimated time required to prevent *one* case of cancer in the entire population of California after implementing Phase 2 ranges from *125 to 2000 years*.

OEHHA's estimated cancer potency for formaldehyde is 2,250 to 36,000 times greater than that of the other agencies. Either OEHHA has greatly overestimated the risk or US EPA, Health Canada, WHO, and Australia all have greatly underestimated the risk. These other agencies have expressed a strong preference for using the risk assessment methodology of Conolly et al. (1999), such as USEPA's decision to use this risk assessment model for formaldehyde when it established emission standards for plywood and composite wood products.

In the case of formaldehyde, we have determined that the cancer potency derived using the approach developed by [Conolly et al., 1999] and peer-reviewed by an independent expert peer review panel sponsored by EPA and the Canadian government represents an appropriate alternative to EPA's current IRIS URE for formaldehyde, and is therefore the best available peer-reviewed science at this time."⁷

The cancer risk assessment of formaldehyde by OEHHA does not rely on what US EPA calls "the best available peer-reviewed science at this time." In fact, the OEHHA risk assessment of formaldehyde does not even mention the work upon which USEPA, Health Canada, WHO and Australia rely for their risk assessments of formaldehyde.

CARB should carefully evaluate the proposal to reduce exposure to formaldehyde in light of the tenuous public health benefits represented by the estimated reduction in cancer cases in California. If reducing exposure to formaldehyde will not result in any meaningful reduction in cancer risk in California, the proposed action must be questioned. Given the fact that over 100,000 Californians are expected to die from cancer annually, it is especially important to focus the State's resources on strategies that will result in real reduction in cancer and improvement in public health.

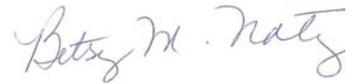
⁶ 35 cancer cases prevented per million people over a 70-year lifetime x 35 million people divided by 70 years = 18 cancer cases prevented per year

⁷ National Emission Standards for Hazardous Air Pollutants: Plywood and Composite Wood Products; List of Hazardous Air Pollutants, Lesser Quantity Designations, Source Category List. 71 Fed. Reg. 8348-49 (Feb. 16, 2006).

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The Formaldehyde Council and its members would be happy to discuss this matter or provide additional analysis if it would assist the Air Resources Board.

Sincerely,

A handwritten signature in cursive script that reads "Betsy M. Natz". The signature is written in black ink and is positioned above the typed name.

Betsy M. Natz
Executive Director