

August 27, 2004

Ms. Dorothy Shimer
Staff Air Pollution Specialist
Research Division
California Air Resources Board
P.O. Box 2815
Sacramento, California 95612

Dear Ms. Shimer:

These comments are submitted on behalf of the California Wood Industry Coalition (the "Coalition"), a broad-based group representing industries and companies that manufacture wood adhesives, wood panel products and items such as furniture and cabinets made from them.¹ Many of the products are manufactured with urea-formaldehyde ("UF") resins. We appreciate the opportunity to comment on the June 2004 Draft Report to the California Legislature on Indoor Air Pollution in California (the "Report").

The Coalition has been an active participant with California Air Resources Board ("ARB") officials from the Air Quality Measures Branch of the Stationery Source Division in discussing the development of an Air Toxic Control Measure ("ATCM") for formaldehyde in pressed wood products. These cooperative efforts have included plant tours, extended briefings on the technological and

¹ A list of the Coalition members is attached as Exhibit A.

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operational aspects of resin and panel production, explanations of the economic impacts of regulation particularly in light of the huge influx of imported furniture. These officials have been extremely complimentary of the industries' efforts during the proceeding and in their stewardship efforts to reduce formaldehyde emissions over the years.

The task given to the ARB by the Keeley Bill was daunting. The indoor air issue is tremendously complicated. The Coalition is extremely concerned, however, that the draft Report does not present a balanced view of the available information and scientific literature in many areas, particularly with respect to formaldehyde. Data that is the most critical of the substance is trumpeted while references to equally or more prestigious studies, governmental pronouncements and guidelines that are less critical of formaldehyde are omitted. Specific examples are noted in the following comments, although the approach is pervasive.

I. No Consideration is Given to Feasibility

The "Keeley Bill" -- A.B. 1173 -- which authorized the Report contained several directions to the ARB regarding its contents. The legislation requires an analysis of indoor emissions, exposures, and potential health effects. It also

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mandates that options for mitigation be presented in light of **the feasibility and public health effects of implementing each option.** A.B. 1173, Section 2, amending Section (b)(3) of Section 39330 of the Health and Safety Code.

Although there is some passing discussion of options for mitigation of emissions from pressed wood products in the Report, there is absolutely no discussion of the feasibility of the recommendations or the health impact of such mitigation measures. For instance, the report notes that composite woods products designed for outdoor use are made with phenol-formaldehyde ("PF") resin and recommends that such products are preferred alternatives to UF-made products.² Yet, there is absolutely no discussion of the feasibility of this product substitution suggestion. While it is true that phenol-formaldehyde panels emit less formaldehyde, it is also true that the production equipment and technology to use that resin system is substantially different from what is used by the industry. With the exception of only a handful of hardboard plants utilizing PF resins, primarily for exterior siding and trim products, there is only one small producer of P-F particleboard in the country. The overwhelming majority of existing plants cannot simply change resins without substantial equipment changes and retrofitting. Moreover, some end use applications such as hardwood plywood

² Report at 50. See also page 118 – "...alternative building materials that emit little of no formaldehyde

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cannot use PF resins because of resin "bleed-through" or discoloration which makes such products unusable by furniture, cabinet and other downstream users. There is similarly no discussion of the costs of such different approaches – a concept that is inherent to feasibility. There is also no discussion of what health benefits might realistically be expected with any of the suggested mitigation features.

The report also notes that low formaldehyde-emitting products could be used safely, but infers that PF products are being recommended. This is in marked contrast to the recent Indoor Air Quality Guideline issued by ARB this month,³ which urges consumers using UF-based products to look for the Composite Panel Association ("CPA") and Hardwood Plywood and Veneer Association ("HPVA") certification marks when making purchases, because of their formaldehyde emission restrictions. These programs are mentioned as current mitigation techniques in the Report, but no similar endorsement or recommendation is made.⁴

are generally available and can be used in place of a building material that emits formaldehyde."

³ We are also confused as to why ARB would issue this Guideline as a final document during the pendency of a public comment period on the 1173 Report, which addresses many of the same issues.

⁴ Report at 106.

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The Report is totally silent on the public health effects that its mitigation strategies would garner. We believe that there would be no benefits from the product substitution suggested in the Report.

II The Health Effects Discussion Does Not Include Critical New Information

It has long been known that some species of laboratory animals exposed to extraordinarily high, life-time doses of formaldehyde have contracted nasal tumors. However, the extrapolation of the animal data to human exposures at very low doses has always been acknowledged to be very uncertain and controversial.

The report definitively estimates 230 excess cancers from exposure to indoor pollutants and 62 from formaldehyde exposure. We respectfully suggest that this is a misuse of the risk assessment methodology and does not take into account or mention very important new information that indicates that there is no risk at normal exposure levels.⁵

⁵ The International Agency for Cancer Research ("IARC") recently upgraded its classification of formaldehyde to a "known human carcinogen," a fact that the industry immediately brought to ARB's attention. The Formaldehyde Council has also presented a number of papers and analyses of this decision. The fact that a substance is classified in a particular category does not impact the risk assessment which is used to determine the relative level of risk at given exposures. Evaluations prior to the IARC reclassification were developed with the assumption of carcinogenicity in the laboratory animals and a cross-species evaluation.

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The specific risk numbers are derived from the 1994 OEHHA Comparative Risk Project ("CRP Report") which evaluated a large number of substances based on risk assessments done by federal and state regulators. The CRP Report repeatedly references certain caveats and conditions, including the following:

The Human Health Committee decided that consistent application of standards assumptions and methods would provide the best basis for comparing risks across topic areas, with the important caveat that resulting risk estimates should not be interpreted as predictions of actual disease incidence.⁶

(Emphasis added).

The underlying principle that these statistical constructs should not be used as point estimates of risks is reiterated in all of the EPA risk assessments of formaldehyde and other compounds. There are numerous reasons for this caution. First, the numbers are derived from complex computer models in which default assumptions are inserted in the absence of known scientific information. These assumptions are purposely conservative with safety factors on virtually every input. In the aggregate, these safety factors, create orders of magnitude of impact. Second, results in the Comparative Risk Project are not average or most likely estimates ("MLE") generated by the models, but rather "upper bound" confidence limits ("UCL") – a statistical construct which states that there is a

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95% probability that the actual risk will not be higher. The more uncertain the inputs, the wider the disparity in the MLE term and the UCL term. For instance, in the case of the 1987 EPA risk assessment for formaldehyde, there was a difference of approximately five orders of magnitude between the MLE and UCL expressions.

We also submit that the 1173 Report should reflect the major new discoveries that have been made on formaldehyde cancer risk assessment since the last OEHHA report in 1992. The CIIT Research Center has developed a major new work, FORMALDEHYDE: Hazard Characterization and Dose-Response Assessment for Carcinogenicity by the Route of Inhalation. This state of the art, peer-reviewed study was developed over many years with the cooperation and guidance of EPA and Health Canada personnel. It shows a dramatically lower risk than had previously been assumed.

The new CIIT risk assessment has several new features, primarily based on the insertion of scientifically determined inputs, replacing the conservative “default assumptions.” For instance, the new CIIT risk assessment uses sophisticated computational fluid dynamics to determine the air patterns in the respiratory tracts of different species in order to predict the regional

⁶ CRP Report at 104.

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formaldehyde dose. A two-stage clonal growth model was used that incorporated data on the rate of cell division and on the number of cells at risk in different regions of the respiratory tracts of rats and humans. The exposure models were also much more sophisticated, incorporating lifetime information and age differences in the computations.

There is no mention of the CIIT work in the discussion or bibliography of the Draft 1173 Report. The CIIT risk assessment was submitted to ARB two years ago with the request that the California risk assessment be reopened.⁷ Although OEHHA has recommended that it not take the time to reevaluate its risk assessment and the SRP has similarly recommended a delay of any new evaluation, the fact remains that respected governmental bodies around the world have endorsed the new work. It deserves inclusion in the Report even if ARB does not endorse its conclusions.

The CIIT risk assessment has been adopted by the U.S. EPA in recent Maximum Achievable Control Technology ("MACT") standards for

⁷ The Petition was submitted to ARB on April 11, 2002 by the Formaldehyde Epidemiology, Toxicology and Environmental Group, Inc. (the predecessor to the Formaldehyde Council, Inc.) and supplemented by letter dated April 23, 2004. These documents have been submitted for the staff's review..

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particleboard and Composite Wood Products,⁸ Metal Can⁹ and Stationery Combustion Turbines.¹⁰ It has been espoused by Health Canada,¹¹ German authorities¹² and health officials in the European Community.¹³ It is a weighty and profound study worthy of recognition as a reputable, highly-regarded and widely-accepted methodology.

The EPA also has done important work, showing lower risks that are not included or mentioned in the Report. At least three previous formaldehyde risk assessments have been conducted by EPA. A 1987 version, which is still the basis of information in EPA's Integrated Risk Information System, showed an upper bound risk at 0.1 ppm exposure of 1.6×10^{-3} , although the maximum likelihood estimate ("MLE") was much lower -- 5×10^{-7} . This work was in large measure based on certain "default assumptions" which again were used in the absence of definitive inputs on various aspects of the carcinogenic mechanism of formaldehyde.

⁸ 69 FR 45943, *et seq.*, July 30, 2004.

⁹ 68 FR 64431, *et seq.*, November 13, 2003

¹⁰ 69 FR 10511 *et seq.*, March 5, 2004.

¹¹ Environment Canada and Health Canada, Priority Substances List Assessment Report: Formaldehyde Feb. 2001.

¹² German MAK Commission, Formaldehyde (undated)

¹³ Organization for Economic Cooperation and Development (OECD), SIDS Initial Assessment Profile, (March 2002)

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Additional work (much of it by CIIT) on the delivered dose to the tissues at risk, cell proliferation, and cross-species comparisons resulted in revised assessments by EPA scientists in 1990 and 1991, showing a 56-fold reduction in indicated risk from the 1987 risk assessment. Although the latter two were never formally adopted by the Agency, the 1991 work was published in a peer-reviewed journal.¹⁴ The California formaldehyde risk assessment from the early 1990's was based on some, but not all, of the principles reflected in the 1990 and 1991 EPA work.

The following is a comparison of the indicated unit risks at 0.1 ppm in the 1987 EPA Risk Assessment, the 1991 EPA work, the 1992 CARB study and the most recent CIIT work:

¹⁴ Hernandez, O., Rhomber, L., Hogan, K., Siegel-Scott, C., Lai, D., Grindstaff, G., Henry, M., and Cotruvo, J. (1994) Risk assessment of formaldehyde. *J. Hazard. Mat.* 39, 161-172.

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<u>Risk Assessment</u>	<u>Risk Estimates -- Upper Bound (MLE)</u>
U.S. EPA 1987	1.6×10^{-3} (5×10^{-7})
U.S. EPA 1991	
Rat-based DPX Dosimetry	2.8×10^{-4} (3.1×10^{-5})
Monkey-based DPX Dosimetry	3.3×10^{-5} (4.2×10^{-7})
CARB 1992 Study	4.0×10^{-3} (7.0×10^{-4})
CIIT 1999 Clonal Growth Model	
Workplace	
Smokers	1.0×10^{-7}
Nonsmokers	4.1×10^{-9}
Environmental	
Smokers	6.7×10^{-7}
Nonsmokers	2.7×10^{-8}

The “environmental” exposures in the CIIT study assumed constant exposure at 0.1 ppm (100ppb) for 80 years. Constant occupational exposures at 0.1 ppm for 40 years were coupled with background for non-working hours of 0.004 ppm for the workplace evaluation.

This work too should be included in the Report as a counterpoint to the extraordinarily divergent OEHHA numbers.

III The Non-Cancer Reference Levels are Inappropriately Low

The chronic REL of 2.4 ppb that is being used for formaldehyde in California – below the level of the outdoor ambient -- is extraordinarily, and we believe inappropriately, low. It preordains the conclusions. The acute REL of 76 ppb

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has the same difficulty. Much work has been done in terms of non-cancer endpoints. An excellent recap of the available studies prepared by Dr. Joel Bender is attached as an Exhibit to these comments.¹⁵ This paper critically evaluates the studies that formed the basis of the ASTDR Toxicological Profile for formaldehyde, the same profile which we understand was used to develop the California RELs. The Bender paper notes the inherent inadequacy of using human studies alone to develop reference levels for formaldehyde. He noted that some individuals begin to sense irritation at about 0.5 ppm (500 ppb) with 5-20% reporting eye irritation at 0.5 -1.0 ppm. The unreliability of human responses in chamber tests, with significant responses often being reported with placebos was also catalogued. This paper provides an excellent overview of the scientific papers in the area. This paper and the significant studies reported in it should be included in the description and bibliography regarding noncancer effects and RELs.

IV. The References to Asthma Exacerbation are Contradicted in the Report

The Report repeatedly states without qualification that formaldehyde can exacerbate asthma. This is contrary to a 2000 report by the National Academy

¹⁵ Bender, The use of noncancer endpoints as a basis for establishing a reference concentration for formaldehyde, Reg. Tox. and Pharm. 35, 23-31 (2002).

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Institute of Medicine which found that there was only limited or suggestive evidence of an association between formaldehyde and worsening of asthma.¹⁶ This conclusion is reported on page 29 of the Report. The statement about asthma exacerbation is also contrary to the review of this subject by the California Science Review Panel at its June and July, 2001, meetings. An outline of the substantial authority refuting this assertion will be submitted by the Formaldehyde Council. That submission also points out the weaknesses and limitations of the Delfino study which is given such prominence in the Report.

V. The Listed Levels of Concern Do Not Mention the Views of Other Reputable Bodies

We are aware that OEHHA has set extraordinarily low reference levels for formaldehyde – levels that are at odds with almost every other governmental pronouncement on the subject. The chronic REL of 2.4 ppb is below the ambient level in almost all urban and rural areas and indeed, even in excess of some levels reported by the World Health Organization in ocean sites. Readings in the eastern Indian ocean region were reported between $<1 - 14 \mu\text{g}/\text{m}^3$ ($<0.82 - 11.5$ ppb). Readings in the central Pacific were reported between $0.1 - 0.8 \mu\text{g}/\text{m}^3$

¹⁶ National Academy of Sciences, Institute of Medicine, Clearing the Air: Asthma and Indoor Air Exposures (2000).

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(0.08 - .64 ppb).¹⁷The 8-hour REL is 27 ppb with the acute REL at 78 ppb.

Levels at the lower end of these ranges can not even be readily measured.

We respectfully request that ARB report the guidelines of other reputable bodies who have determined levels far different than those set by OEHHA. For instance, the Consumer Product Safety Commission,¹⁸ the U.S. EPA¹⁹ and Health Canada have all identified 0.1 ppm as a "level of concern." The World Health Organization has used 0.08 ppm as its benchmark.²⁰ The average ambient levels reported in the Appendix to the Report .037 ppm for manufactured homes, 0.014 ppm for conventional homes (with even the 90th percentile in one study being only 0.037 ppm) are well within almost all international guidelines except for California's unusually low numbers. The numbers also reflect major reductions from historic levels.

VI. The Progress of the Industry in Reducing Emissions Has Been Dramatic

The wood products industry has made great progress in reducing emissions over the years. Although the Report acknowledges this in some respects, the Report should be corrected in some very important ways.

¹⁷ World Health Organization, Environmental Health Criteria 89 – Formaldehyde (1989), p.39.

¹⁸ U.S. Consumer Product Safety Commission, "An Update on Formaldehyde," (1997 ed.), p.3.

¹⁹ U.S. Environmental Protection Agency, "Sources of Indoor Air Pollution – Formaldehyde," on the web at www.epa.gov/iaq/fomalde.html.

²⁰ World Health Organization (WHO), 2000, Air Quality Guidelines, Chapter 5.8, Geneva, Switzerland

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The ARB has calculated that emissions since the 1980's from pressed wood products generally have come down by 49%. We believe that overall reductions are much greater; a conclusion bolstered by an analysis of particleboard reductions. The claim that particleboard emissions are, on average, 92% of the levels in the early 1980's (i.e. an 8% reduction)²¹ is not an accurate representation. The CPA estimates that reductions over this period have been in the range of 80% or more. The average cabinet grade particleboard ASTM 1333 large chamber test results obtained pursuant to CPA's certification program for 2003 were at 0.18 ppm.(underlayment and manufactured home decking averages were 0.15 ppm)²² This constitutes an 80% reduction from the average 1.0 to 1.4 ppm test results recorded in 1980 when the test results were first compiled. In fact, CARB's independent findings note an 80% emissions reduction by the industry in their August 4th presentation to industry, which discussed and summarized their research into composite panels.

The reliance on studies from the 1980's to characterize ambient levels, even with mathematical adjustments for emission reductions are not reflective of the tremendous progress that has been made.

²¹ Report at Page III-1.

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We are also very wary of the extraordinarily high numbers that are included for composite panel emissions ranges in the Report. For example, on page 50 there is a comment that "raw board" has emission rates in the range of 8.6 to 1,580 $\mu\text{g}/\text{m}^2/\text{hr}$, citing a report prepared by Battelle for the state. Products meeting the ANSI standards would have average ASTM 1333 test results at an emission rate in the range of 250 to 450 $\mu\text{g}/\text{m}^2/\text{hr}$. These products would typically be treated after production with laminates that would reduce emission rates from 70% to 95+%. The real world emission rate would be on the lower end of the range cited in the Battelle report, 7-140 $\mu\text{g}/\text{m}^2/\text{hr}$. The only particleboard products used in a "raw board" form are underlayment and manufactured home decking products.²³ As cited above, these products have lower ANSI emission standards and their average initial emission rates would be in the range of 200 $\mu\text{g}/\text{m}^2/\text{hr}$ as measured the ASTM 1333 test. Formaldehyde emission levels typically diminish or "decay" over time, sometimes quite rapidly. With a high loading of composite panel based products in the home, including particleboard underlayment, hardwood plywood paneling, kitchen cabinets and doors, measurements dropped

²² The large chamber tests samples at specified loading and testing conditions. Although the results are reported in parts per million, the reported numbers bear no relation to ambient levels that might be experienced in the living environment.

²³ ARB has acknowledged in the context of the ATCM proceeding that materials used in the construction of manufactured homes are exempt from state regulation because of the preemptive features of the HUD regulations in this area.

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from 0.07 PPM to 0.04 PPM in 30 days.²⁴ The high end of the emission ranges cited appears to reflect totally uncharacteristic materials or testing anomalies. There are other pages in the report that have similarly unusual and uncharacteristic higher ranges. The bar graph on page 52 is inappropriate. It shows ambient levels in both conventional and manufactured housing in excess of 200 parts per billion. We believe these are much, much higher than levels currently found, even on the high end of the ranges. Structures and furnishings made with CPA and HPVA certified wood products would result in even lower levels. The low formaldehyde level average cited in the Draft Report in real world homes (e.g. 17 ppb in conventional homes) no doubt reflect the lower emission levels of current UF bonded products and that fact should be specifically recognized in the final report.

We also note on page 50 a theme that appears throughout the report, namely that coverings, laminations and some finishes contribute to the success in reducing formaldehyde levels in homes. However, no attempt has been made in the report to show the existing data that demonstrates the significance of emission reductions which would counter the recommendations made in the report.

²⁴ Koontz, et al., Residential Indoor Air Formaldehyde Testing Program: Pilot Study, Final Report.

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This is an important point that merits accentuation.

VII. Conclusion

The Coalition realizes that formaldehyde has been a focus of the ARB for several years and we fully expected a full discussion of the compound in this Report. We also recognize that California statutes require the ATCM proceeding that is currently underway due to the fact that the compound has been listed as a Toxic Air Contaminant. We are very disappointed, however, in the treatment of formaldehyde in the Report and hope CARB does not miss this opportunity to comment on current science. The ARB officials evaluating a new ATCM for pressed wood products, after almost three years of study of the industry, have informally indicated that they do not currently contemplate a requirement to substitute away from the use of UF resins. The Draft Report is seriously divergent from this view and the final report should include this conclusion.

The Coalition is concerned that major favorable studies regarding formaldehyde, higher "levels of concern" recommendations from other regulatory and advisory bodies and other information which would have presented a more balanced and comprehensive evaluation of formaldehyde did not find their way into the Report. We respectfully request that these references be inserted into the final report and the bibliography.

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We appreciate the opportunity to comment on the Report.

Very truly yours,

Brock R. Landry

Attachment: Non-Cancer Endpoints Article by Joel Bender

Exhibit A: California Wood Industry Coalition Members:

American Forest & Paper Association
American Furniture Manufacturers Association
APA – The Engineered Wood Association
Association of Woodworking and Furniture Suppliers
Composite Panel Association
Formaldehyde Council, Inc.
Hardwood Plywood & Veneer Association
Kitchen Cabinet Manufacturers Association