

May 9, 2006

**Formaldehyde Council, Inc., Perspective on  
Why the CIIT Model is Best Available Science for Evaluating  
Chronic Health Effects of Formaldehyde**

In 1999, researchers at the CIIT Centers for Health Research -- with input from the U.S. Environmental Protection Agency, Health Canada and peer reviewers -- published a thorough evaluation of potential cancer risk from formaldehyde.

The evaluation includes 20-plus years of research and integrates various toxicological, mechanistic and dosimetric data (CIIT 1999).<sup>1</sup> In 2004, CIIT refined and restated the assessment, using a detailed understanding about how formaldehyde causes cancer in animals to construct a biologically based model to describe these effects. Combined with data on the similarities and differences between animals and people, findings in animals can be extrapolated to humans with a high degree of accuracy.

Biologically based modeling minimizes the need for the unfounded assumptions and uncertainties inherent in regulatory approaches that currently are used for carcinogens (i.e., the so-called no-threshold model, which assumes -- based on no data whatsoever -- that cancer risk is linear to zero). The CIIT-developed model for formaldehyde-induced upper respiratory tract tumors predicts accurately the doses of formaldehyde required to produce tumors in animals and in people.

Thus, the CIIT model overcomes problems in the application of "standard" risk-assessment methods, which result in overly conservative and, therefore, scientifically questionable projections of potential risk. For example, it is simply incorrect to assume as a default that the cancer risk of formaldehyde is linear to zero when people are exposed continuously to formaldehyde as part of normal cellular metabolism and for which highly efficient enzyme systems have evolved to detoxify formaldehyde.<sup>2</sup>

In conducting a cancer risk assessment for a chemical, the risk-assessment process should consider -- as in the case of formaldehyde -- the fact that it is a normal component of metabolism.

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<sup>1</sup> The CIIT risk assessment represents the collective work of numerous experts as reflected in dozens of peer-reviewed papers. One key report published by the CIIT on the subject is entitled Formaldehyde: hazard characterization and dose-response assessment for carcinogenicity by route of inhalation.

<sup>2</sup> See the Formaldehyde Council, Inc., "Formaldehyde and Human Health" paper for an explanation.

The most recent application of the CIIT model combines animal data with human respiratory tract cancer from smokers (formaldehyde is one component of cigarette smoke), nonsmokers and a mixed population of nonsmokers and smokers to predict the likelihood of cancer occurring in people at various levels of formaldehyde exposure.

When the animal data were used in one way, the model predicted no additional risks of respiratory tract cancer up to about one part per million (ppm) of formaldehyde in all three cases. When the animal data were used in an even more conservative way, the estimate of additional cancer risk was up to 1,000 times lower than estimates based on models currently used to extrapolate animal data to humans.

Even when elevated breathing rates due to different levels of physical activity were put into the model (which could increase uptake of formaldehyde), this situation did not make large differences in predicted additional risks. Assuming 80 years of continuous exposure to formaldehyde at 100 parts per billion (0.1 ppm), the CIIT model predicts an increased risk of developing cancer of 2.7 in 100,000,000 (one hundred million) for nonsmokers, which is well below the one-in-a-million risk level typically used by regulators to establish an acceptable exposure level.

The CIIT model has been accepted and used by several national and international standards-setting bodies<sup>3</sup> and is widely respected. These organizations draw heavily on the CIIT approach and agree that formaldehyde is not likely to be carcinogenic to people at low doses.

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<sup>3</sup> National Academy of Sciences, World Health Organization, Australia Department of Health and Aging, Environment Canada and Health Canada, Germany's MAK Commission, and Organization for Economic Cooperation and Development. For details, contact the Formaldehyde Council, Inc., or visit [www.formaldehyde.org](http://www.formaldehyde.org).