

May 9, 2006

**Formaldehyde Council, Inc., Perspective on the
International Agency for Research on Cancer's Formaldehyde Classification**

In June 2004, the International Agency for Research on Cancer (IARC) – part of the World Health Organization – classified formaldehyde as “carcinogenic to humans” (Group 1). IARC based its decision, which the Formaldehyde Council, Inc. (FCI), considers questionable, primarily on findings from a National Cancer Institute (NCI) study of workers indicating that formaldehyde causes nasopharyngeal cancer (NPC) in humans. NPC is a very rare form of cancer that occurs where the rear of the nasal cavity meets the throat.

This study involved more than 25,000 workers at 10 plants where occupational exposure to formaldehyde occurred. Of 10 total cases of NPC, six came from one of the 10 plants and the other four cases were distributed randomly over the other nine plants. This situation is not the expected pattern from an occupational carcinogen, but rather suggests causes other than formaldehyde exposure at the single plant where most of the cases were observed. In fact, a separate study in 2002 of this one plant found no credible association with formaldehyde, and the authors suggested some other factor(s) must have been involved¹.

It is important to understand that IARC judges the scientific evidence based exclusively on the potential hazard posed by a particular chemical, not the expected risk. Risk assessment considers exposure level and dose in combination with hazard. IARC classifications do not cover exposure and dose.

In addition, IARC concluded that two recent studies provided “strong but not sufficient evidence for a causal association between leukemia and occupational exposure to formaldehyde.” One of these studies also was from NCI and was a companion to the NCI study that reported NPC. However, IARC’s conclusion about leukemia was tempered since “they could not identify a mechanism for leukaemia [British spelling] induction.” This IARC statement represented an important cautionary note since subsequent to IARC’s skepticism, a number of peer-reviewed critical evaluations have concluded that, based on a substantial body of information about chemical-induced leukemia, it is biologically implausible that formaldehyde would be capable of causing this disease.

(more)

¹Pharyngeal cancer mortality among chemical plant workers exposed to formaldehyde by G. M. Marsh et al., *Toxicology & Industrial Health*, 2002, 18(6):257-68.

Shortly after the NCI studies were published in 2003 and 2004 in the peer-reviewed *Journal of the National Cancer Institute*, the FCI commissioned independent reviews by biostatisticians Gary Marsh, Ph.D., and Ada Youk, Ph.D., of the University of Pittsburgh. Their reviews -- one on NPC and the other on leukemia – were based on a reanalysis of the original NCI data. One of these reviews was published in 2004 and the other in 2005 in the peer-reviewed *Journal of Regulatory Toxicology and Pharmacology*²; they indicated that NCI's findings pertaining to both NPC and leukemia were highly questionable.

Because studies of the type published by NCI are complicated, there can be legitimate grounds for differences of opinion on how the data are interpreted. However, in addition to the reviews by Marsh and Youk, a number of published letters to the editors of peer-reviewed journals have offered criticisms consistent with the Marsh-Youk findings.

Even though the NCI studies were published only in 2003 and 2004, the federal institute already has agreed to do an update, adding an additional eight years of already-available data that will increase the “strength” or accuracy of the study. This update should help determine if the relationships are stronger or weaker regarding occupational exposure to formaldehyde and increased risk of cancer. And IARC will have these and other findings in hand the next time it updates its formaldehyde carcinogen classification, which probably will occur in 2009.

In the meantime, it is worthwhile to bear in mind that no government regulatory agencies have classified formaldehyde as a known human carcinogen. The EPA, which currently classifies formaldehyde as a probable carcinogen, plans to await results from the NCI update before proceeding with a review of formaldehyde's cancer classification under the Integrated Risk Information System (IRIS) program.

Because of regulations and the combined efforts of science and the industries that make and use formaldehyde, the levels emitted into indoor air from wood products that contain formaldehyde have decreased dramatically over the past 30 years and now approach normal ambient background levels.

Based on what we know today about formaldehyde toxicity, consumers and workers are protected when formaldehyde is handled and used properly under current government regulations.

###

² Reevaluation of mortality risks from leukemia in the formaldehyde cohort study of the National Cancer Institute, *Regulatory Toxicology and Pharmacology* 40 (2004) 113-124, and Reevaluation of mortality risks from nasopharyngeal cancer in the formaldehyde cohort study of the National Cancer Institute, *Regulatory Toxicology and Pharmacology* 42 (2005) 275-283.