NEW STUDY CHALLENGES FORMALDEHYDE CANCER FINDINGS
Data Challenges EPA Analysis of Health Risk

WASHINGTON (May 2, 2017) – A newly published reanalysis of raw data from a study widely used by chemical assessment agencies to set hazard assessments for formaldehyde shows no link between formaldehyde exposure and leukemia. The peer-reviewed paper was just published online in the *Journal of Critical Reviews in Toxicology*.

Kenneth A. Mundt, Ph.D., the lead author of the reanalysis and Health Science Global Practice Network Leader and Director of Applied Epidemiology for Ramboll Environ, has led several studies that analyze the health risks from formaldehyde exposure. “The weight of scientific evidence does not support a causal association between formaldehyde and leukemia,” he said.

The original paper, published in January 2010 by Luoping Zhang and 33 co-authors in *Cancer Epidemiology, Biomarkers & Prevention*, compared the presence of reported chromosomal abnormalities in a small group of Chinese workers occupationally exposed to formaldehyde to the presence of these abnormalities in unexposed workers. The researchers suggested that the observed differences might indicate a mechanism linking formaldehyde exposure to leukemia.

In their paper, Mundt and his co-authors analyzed raw data from the Zhang study, including previously unavailable data on individual workers’ exposure to formaldehyde. Those data were recently released by the National Cancer Institute, part of the U.S. National Institutes of Health, which co-funded the original study. They also reviewed several other new publications on the health effects of formaldehyde, including studies showing that formaldehyde cannot reach the bone marrow where leukemia-causing effects are generally recognized to occur. The authors concluded: “Taken as a whole, the epidemiological evidence from the most recent analyses and follow-up of available cohorts provides little if any evidence of a causal association between formaldehyde exposure and AML (acute myelogenous leukemia).”

Since its publication in 2010, the conclusions of the Zhang study have been used by several health assessment organizations to inappropriately conclude that formaldehyde causes leukemia. For example, in its 2012 monograph on formaldehyde, the International Agency for Research on Cancer (IARC) determined “that the epidemiologic evidence shows that occupational exposure to formaldehyde causes leukemia.” In addition, the U.S. Environmental Protection Agency relied heavily on the Zhang study in its 2010 draft assessment of formaldehyde health risks under its Integrated Risk Information System (IRIS), a draft assessment that was heavily criticized by a 2011 National Academy of Sciences (NAS) peer review report.
“The findings in this reanalysis are important because they call into question the validity of all these recent formaldehyde assessments,” said Kimberly White, Ph.D., Senior Director of the American Chemistry Council Formaldehyde Panel. “The original paper failed to meet its own data quality standards and the scientific standard of reproducibility. Relying on it consequently led to unsubstantiated regulatory decisions and unwarranted outcomes. The EPA and other agencies evaluating chemical risk from exposures must consider the entire weight of evidence on formaldehyde when setting exposure limits.”

To learn more, view this fact sheet or visit americanchemistry.com/formaldehyde.

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