

February 8, 2010

Dr. Ruth Lunn Director RoC Center National Institutes of Environmental Health Sciences P.O. Box 12233 K2-14 Research Triangle Park, NC 27709

RE: Comments on the Recommendation from the Expert Panel Report on Formaldehyde

Dear Dr. Lunn:

The Personal Care Products Council¹ appreciates the opportunity to submit comments on the recommendation and justification from the Expert Panel on the listing status of formaldehyde in the 12th Report on Carcinogens (RoC). We disagree the Expert Panel's conclusion, and believe that the current listing of formaldehyde (gas) in the RoC as "*reasonably anticipated to be a human carcinogen*" should not be changed.

The human exposure section of the panel report is misleading. This section does not make it clear that formaldehyde is a normal product of metabolism of living beings including humans. Formaldehyde is not only ubiquitous in the environment, it is ubiquitous in our own bodies. This section fails to distinguish between normal background levels and elevated exposure levels that sometimes occur in occupational settings. Products containing formaldehyde can be used without significantly increasing the background levels of formaldehyde. For example, outside air was found to be the greatest contributor to formaldehyde levels measured in nail salons where formaldehyde-containing nail products were used². Because formaldehyde is poorly absorbed from the skin³, use of products containing low levels of formaldehyde (less than 0.2%) on the skin would not significantly increase endogenous levels of formaldehyde.

We are especially concerned with the panel's inclusion of myeloid leukemia among the cancers

³See p.296 of the Formaldehyde: RoC Background Document

¹Based in Washington, D.C., the Personal Care Products Council is the trade association representing the cosmetic and personal care products industry in the United States and globally. Founded in 1894, CTFA has a membership of nearly 600 companies including manufacturers, distributors, and suppliers for the vast majority of finished personal care products marketed in the United States.

²McNary JE, Jackson EM. 2007. Inhalation exposure to formaldehyde and toluene in the same occupational and consumer setting. *Inhalation Toxicology* 19: 573-576.

used to reach the "*known to be a human carcinogen*" conclusion. This appears to disregard much of what is known regarding the mechanism of action of formaldehyde, e.g., Dr. Melvin Andersen's comments on the background document⁴. In their report, the expert panel states that "it is not implausible that formaldehyde can cause tumors at distal sites." The mechanistic evidence to support a conclusion of "*known to be a human carcinogen*" should be greater than "not implausible".

As indicated in the comments of the Formaldehyde Council, Inc., research is ongoing to address the issue of formaldehyde mechanism of action and distant site toxicity. For example, a rat inhalation study by Kun and Swenberg (submitted for publication) demonstrates that exogenous formaldehyde does not get past the nasal epithelium. This ongoing research on formaldehyde should be reviewed before the current RoC listing for formaldehyde is changed.

Sincerely,

[Redacted]

John E. Bailey, Ph.D. Executive Vice President - Science

⁴found at http://ntp.niehs.nih.gov/NTP/RoC/twelfth/2009/November/Public_Comments/Andersen2009101 6.pdf