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December 3, 2001

The Honorable Christine Todd Whitman
Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Comments on HPV Test Plan and Robust Summaries for Methanol

Dear Administrator Whitman:

The following comments on the American Methanol Institute Testing Group's test plan for methanol are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than nine million Americans.

The American Methanol Institute Testing Group's test plan and robust summaries represent a comprehensive review of available information on the compound. The consortium has identified studies that satisfy all SIDS endpoints and has appropriately concluded that no further testing is necessary under the HPV program. Additionally, we commend the consortium's discussion of human clinical data and species differences in response to exposure to methanol—analyses that have been glaringly absent from other HPV test plans.

Methanol is a simple alcohol, and its physical, chemical, and toxicological properties are well understood. A wealth of existing epidemiological and toxicological data provides more than adequate information to understand the potential health implications of methanol exposure. Information on the extensive natural, food additive-related, and industrial human exposure to methanol permits the evaluation of the potential reproductive effects of methanol on human populations. Further, the fundamental biochemical basis of methanol metabolism and toxicity—in which methanol toxicity is related to the rate of formate metabolism—is well understood and can provide additional data on the toxicity of this ubiquitous compound. Since health and safety data on methanol have been gathered in numerous animal species, including humans, it is clear that no animals should be subjected to toxicity testing of this well-characterized compound.

Finally, abundant information on the reproductive and developmental toxicity of methanol to rats and nonhuman primates is available in the National Institute of Environmental Health Science's National Toxicology Program's (NTP) Center for the Evaluation of Risks to Human Reproduction's (CERHR) draft report on methanol released on July 16, 2001. The report can be viewed at http://cerhr.niehs.nih.gov/news/methanol_report.PDF. This report was further discussed at an expert panel meeting from October 15 to 17, 2001, in Alexandria, Virginia.

Thank you for your attention to these comments. I can be reached at 202-686-2210, ext. 302, or via e-mail at <ncardello@pcrm.org>. Correspondence should be sent to my attention at PCRM, 5100 Wisconsin Ave., N.W., Suite 400, Washington, DC 20016.

Sincerely,

Nicole Cardello, M.H.S.
Staff Scientist

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