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January 7, 2011

Ms. Katherine Chalfant
Acting Director, Quality Staff
U.S. Environmental Protection Agency
Washington, D.C. 20460

Dear Ms. Chalfant:

Thank you for your latest status update on our July 9th, 2010, Information Quality Guidelines Request for Correction regarding the IRIS Toxicological Review of Methanol. The Methanol Institute is somewhat puzzled by this response as this current letter anticipates providing a final response within 90 days, which is just what a previous letter from then-Director Reggie Cheatham, dated October 5, 2010, had indicated.

Let us provide again here the essence of our July 9th, 2010, request:

"EPA's draft toxicological review of methanol, and all other documents and assessments related to the methanol study conducted by the Ramazzini Institute, should be removed from the IRIS database and other EPA public dissemination sources immediately. Unless and until a full and independent pathology review and a quality review of the pathology data and specimens has been conducted to determine the true findings of the Ramazzini Institute's methanol study, the National Toxicology Program's Report demonstrates that EPA cannot rely on the reported findings of this study as data that meet EPA's Guidelines for influential scientific information for any purpose. Because EPA's draft toxicological review of methanol relies so heavily upon the Ramazzini Institute's methanol study, EPA cannot continue to distribute it to the public through its website or otherwise without violating the IQA. The continued dissemination of these defective data contravenes the standards of objectivity and utility outlined in both the OMB and EPA Guidelines, and poses continued harm to the Methanol Industry and its members.

The Methanol Institute respectfully requests that this request for correction be granted and the corrections implemented accordingly. We ask that this be done quickly so as to remove the risk of immediate harm to the public and the methanol industry. This action does not prejudge EPA's decisions regarding the Ramazzini study of methanol at the end of EPA's own review process, but assures that in the meantime the public is not misinformed about methanol and the basis for determining whether or not it has potential health effects."

Our request was simple and straightforward, and called for ***immediate*** action by the Agency. On June 15th, 2010, the EPA acknowledged in a press release that there were significant questions as to the credibility of the research by the Ramazzini Foundation, leading the Agency to take the highly unusual action of placing the methanol IRIS assessment (and three others) on hold. Since this research was the basis for the proposed cancer classification in the draft methanol toxicological assessment, the proposed classification itself has been rendered questionable. Therefore, the further dissemination of the draft

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methanol assessment on the Agency's web site is providing the public with information of questionable quality and jeopardizing the reputation of an entire industry. The simple fix is to remove the draft assessment document from the Agency's web site until the situation has been clarified with regards to the Ramazzini Foundation data.

We see no reason why the review of the draft response to the Methanol Institute should take an additional 90 days to complete. The National Toxicology Program's Report clearly demonstrates that the EPA cannot rely on the reported findings of the Ramazzini Foundation study. The result is that, for the past six months, the public has been provided with defective data that clearly fails the EPA's own influential scientific information guidelines.

Further, while the publicly-available NTP report gave a summary of that Agency's review of the methanol slides, it did not contain many of the essential quantitative details. For that reason we asked NTP for the data sheets from that review (via Freedom of Information Act (FOIA) requests). NTP has now released the data sheets from that NTP review to the Methanol Institute, and we have had Dr. George Cruzan of Toxworks analyze them. Enclosed is the report that Dr. Cruzan prepared for us.

The new data from NTP are quite revealing as they further accentuate the diverging opinions between U.S. government pathologists and those at the Ramazzini Foundation regarding the potential impact of exposure to methanol. The information provided by the NTP also makes it clear that the Ramazzini Foundation data are not scientifically reliable.

(1) NTP pathologists disagree with Ramazzini pathologists on most lymphomas and ear cancers; and

(2) The NTP analysis of the Ramazzini Foundation slides does not support a conclusion of cancers from methanol exposure.

We reiterate our request that the EPA's draft toxicological review of methanol, and all other documents and assessments related to the methanol study conducted by the Ramazzini Institute be removed from the IRIS database and other EPA public dissemination sources ***immediately***, until the EPA has resolved its analysis of the Ramazzini research from the NTP findings or a full and independent pathology review and a quality review of the pathology data and specimens has been conducted to determine the true findings of the Ramazzini Institute's methanol study.

We would like to meet with you at your earliest convenience to discuss our request in the context of this new data now available on the NTP visit to the Ramazzini Foundation laboratory in Italy.

Sincerely,

Gregory Dolan
Executive Director
Americas/Europe

CC: Malcolm Jackson, Assistant Administrator and CIO
Margaret Schneider, Principal Deputy Assistant Administrator

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