



SHARON H. KNEISS  
VICE PRESIDENT  
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Via E-mail

Ruth M. Lunn, Ph.D.  
Director, Report on Carcinogens Group  
NIEHS  
P.O. Box 12233  
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Research Triangle Park, NC 27709

Re: Comments on Notice Announcing the Availability of the Draft  
Background Document for Styrene; 73 Fed. Reg. 29139 (May 20,  
2008)

Dear Dr. Lunn:

The Ethylbenzene Panel and the Plastics Division of the American Chemistry Council (ACC) are submitting these comments in response to the above-referenced notice dated May 20, 2008, announcing the availability of the National Toxicology Program's (NTP) Report on Carcinogens Draft Background Document for Styrene. This Draft Document will be peer-reviewed by an expert panel to be convened July 21-22, 2008. ACC offers these comments for consideration by the expert panel in its deliberations on the listing status for styrene in the 12<sup>th</sup> Report on Carcinogens (RoC). Since these comments emanate from two groups within the ACC addressing distinct aspects of this report, we request your consideration in having two witnesses at the hearing.

For all of the reasons discussed in these comments, ACC believes the Draft Document should be revised to consider fully the hypothesized alternative mode of action (MOA) for mice lung tumors, as well as the evidence supporting the alternative MOA, and that the NTP Draft Document should be revised to conclude that these mouse-specific tumors provide insufficient evidence to support listing of styrene in the forthcoming RoC. Importantly, NTP's listing criteria anticipates substances, such as styrene, "for which there is evidence of carcinogenicity in laboratory animals, but there are compelling data indicating that the agent act through mechanisms which do not operate in humans and would therefore not reasonably be anticipated to cause cancer in humans."

Apart from the compelling scientific merit of including meaningful consideration of the alternative MOA for mice lung tumors, ACC believes that the Draft Document must include this information to be consistent with Section 515(a) of the Treasury and General



Government Appropriations Act for Fiscal Year 2001 (commonly referred to as the Information Quality Act (IQA)) and the U.S. Department of Health and Human Services (HHS), National Institutes of Health (NIH) Guidelines implementing the Office of Management and Budget's (OMB) IQA Guidelines. These authorities require the use and reliance upon "the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer reviewed studies when available." Moreover, the IQA requires that NTP use "data collected by accepted methods or best available methods" and be comprehensive, informative, and understandable.

ACC appreciates this opportunity to comment on the Draft Document for styrene. If you have any questions, please contact Sarah McLallen, the Ethylbenzene Panel Manager, at (703) 741-5607 or via e-mail at [Sarah\\_McLallen@americanchemistry.com](mailto:Sarah_McLallen@americanchemistry.com) or Steve Russell Managing Director, Plastics Division at 703-741-5178 or at [Steven\\_russell@americanchemistry.com](mailto:Steven_russell@americanchemistry.com).

Sincerely yours,

A solid black rectangular box redacting the signature of Sharon H. Kneiss.

Sharon H. Kneiss  
Vice President, Products Divisions

Attachment