



December 1, 2006

VIA EMAIL

Dr. Sue Shallal
Designated Federal Officer
Science Advisory Board (1400F)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

RE: Science Advisory Board Review of the Draft Assessment - "Evaluation of the Carcinogenicity of Ethylene Oxide"

Dear Dr. Shallal:

The Ethylene Oxide/Ethylene Glycols Panel (Panel) of the American Chemistry Council submits the following comments on the draft charge for the Science Advisory Board (SAB) review of the ethylene oxide (EO) carcinogenicity assessment. The Panel is comprised of the major producers and users of ethylene oxide in the US. We appreciate the opportunity to address the charge questions proposed for the SAB's upcoming January review of the draft IRIS cancer risk assessment for EO. The Panel is continuing its review of the draft EO cancer risk assessment and intends to submit its initial comments on the assessment on December 8, 2006.

The Panel reviewed the charge questions related to carcinogenic hazard, risk estimation and uncertainty. In general, the Panel believes the questions are appropriate for the SAB review and the questions cover most of the significant technical issues that should be included in this review. In addition to the charge questions posed to the SAB, the Panel believes a number of important issues should be considered by the SAB and submits the following questions with the request that they be included in this review:

1. Is the unit risk factor calculated in this assessment reasonably consistent with the mutagenic potency of EO and with regard to the relative risks that can be derived from the body of epidemiology studies? Is it realistic given endogenous levels of EO that are produced naturally in humans?



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2. Has EPA presented its conclusions about the carcinogenic risk from EO exposure in a public health context that is both understandable and useful to decision makers? Specifically, has EPA adequately described the distribution of risk estimates, including lower, central and upper bound risk estimates?
3. How well has EPA characterized the carcinogenicity of EO in light of the requirements specified in the EPA Publications, “*Information Quality Guidelines, EPA’s Risk Characterization Handbook*” and “*EPA’s Guidelines for Carcinogenic Risk Assessment*”? Have potential risk assessment policy changes such as the use of (1) 85 year lifetime excess cancer risk instead of 70 years; (2) background incidence rates of cancer with mortality-based relative risk estimates; and (3) the lower bound on the point of departure when using human data been adequately reviewed by the SAB?
4. How justified are EPA’s statistical modeling and analyses decisions, particularly in its epidemiology-based dose-response modeling using only summary surrogate statistics from a publication? Should available data on individual study subjects be used in the analyses?

Please contact me regarding any questions concerning these comments. I can be reached at (703) 741-5613 or at william_gulledge@americanchemistry.com.

Sincerely yours,

William Gulledge

William P. Gulledge
Manager, EO/EG Panel