



Oral Statement of the Ethylene Oxide/Ethylene Glycols Panel of American Chemistry Council Regarding Charge Questions To the EPA Science Advisory Board for Presentation on the Teleconference for the Review of the Draft IRIS Cancer Risk Assessment for Ethylene Oxide

December 8, 2006

Hello, my name is Dr. William Snellings of the Dow Chemical Company and today I am representing the Ethylene Oxide/Ethylene Glycols Panel of the American Chemistry Council. The Panel is comprised of the major producers and users of ethylene oxide in the United States. The Panel appreciates the opportunity to address the SAB as it prepares to extensively review and evaluate EPA's draft IRIS cancer risk assessment for EO. Our comments today will focus on the charge questions to the SAB and will briefly highlight our concerns with the draft cancer risk assessment. The Panel's written comments on the charge questions were submitted on December 1, 2006, and we encourage the SAB to include the Panel's recommended additions to the charge questions.

The EO/EG Panel continues to conduct an extensive review of the draft assessment and today, the Panel submitted written comments detailing our concerns on the draft cancer risk assessment for EO. We also plan to provide oral comments during the January 18-19, 2007, meeting of the SAB.

As an IRIS risk assessment, the draft cancer assessment is subject to the highest level of peer review under the Information Quality Act (IQA) and the Panel encourages the SAB to conduct this detailed review in a manner consistent with this high peer review standard. The Panel is deeply concerned with the draft cancer assessment, and our major concerns with the draft include:

- 1. The assessment fails to use all of the epidemiology data that should be included in an IRIS cancer assessment;**
- 2. Flaws in the statistical analysis and other incorrect procedures result in an extreme over prediction of risk;**
- 3. Certain policy decisions have been implemented in this assessment which should receive vigorous scrutiny by the SAB; and**
- 4. EPA's risk estimates do not pass simple reality tests.**

As a result of these flaws, which are described in significant detail in the Panel's written comments, the draft cancer assessment is not scientifically defensible, fails to meet the standards set forth under the IQA and EPA's cancer guidelines, and therefore, should be returned to NCEA to be rewritten to address these concerns.

As previously submitted, the Panel reviewed the charge questions related to carcinogenic hazard, risk estimation and uncertainty. The Panel strongly encourages the SAB to conduct a detailed review of the technical issues identified in these questions and to

thoroughly review comments submitted by the Panel and others on the draft cancer risk assessment prior to the January review meeting.

In addition to the charge questions posed to the SAB, the Panel submits the following questions that should also be posed to the SAB:

- 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?**
- 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?**

The Panel looks forward to the January 18-19, 2007 SAB meeting to review the draft cancer risk assessment. Thank you.