

**Summary of American Chemistry Council
Comments to Science Advisory Board
Concerning EPA's Draft Cancer
Assessment on Ethylene Oxide**

**Dr. William Snellings
The Dow Chemical Company**

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Summary of Presentations by Dick Albertini, Jane Teta, Chris Kirman

Since

- EO is not a potent mutagen
- EO is not a potent animal carcinogen
- EO is not a potent human carcinogen
- EO is produced naturally in the human body at levels approximately 2 to 3 orders of magnitude greater than the de minimis level

How can the proposed EPA de minimis value for EO be ranked among the most potent carcinogens?

If the proposed IRIS de minimis value (0.6 ppt) seems inappropriately low, **then the risk assessment methodology EPA used may be incorrect.**

Reality Check

Why didn't NIOSH find more of an association between EO exposure and cancer, when for 33 years, EO workplace exposure limits were equal to or greater than 50 ppm?

ACGIH TLV (8 hr TWA)

- 100 ppm for 10 years (1946 to 1956)
- 50 ppm for 23 years (1957 to 1980)

ACGIH STEL

- 75 ppm for 4 years (1976-1980)

Summary of Presentations by **Bob Sielken and Jane Teta**

Scientific deficiencies and unjustifiable conservative procedures used by EPA in its EO Cancer Assessment are significant issues that the SAB needs to address.

Based on Current Draft Assessment, ACC Believes Most of the Charge Questions Should Be Answered “NO” When the Following Is Considered

- Should EPA’s dose-response model be accepted when it was based on summary statistics instead of available actual individual data? **NO**
- Did EPA rely on the full and most complete data set available for the time period established by EPA in its review? **NO**
- Should EPA rely entirely on males in the NIOSH cohort study when this study consisted of more women than men and there is no mechanistic justification for treating males and females differently with respect to lymphohematopoietic cancers? **NO**
- Should EPA rely on the lower bound of the point of departure when using human data? **NO**
- Should EPA use background incidence rates with mortality-based relative rates? **NO**
- Should EPA use 85-year lifetime in the excess risk calculations when it is known that this new period (70 to 85 years) heavily impacts the dose-response model and it has not been reviewed by SAB? **NO**
- Should large age adjustment factors be added when there are published studies that show this significant change is not justified? **NO**

Thus, ACC strongly urges SAB to request that EPA substantially revise the document so that the answer to each Charge Question in the future will be a “YES.”

Conclusion

Based solely on the scientific deficiencies in the Draft EO Cancer Assessment, ACC feels that the SAB has several reasons to advise EPA that this risk assessment should be substantially revised.