



October 18, 2007

Via E-Mail

Suhair Shallal, Ph.D.
Designated Federal Officer
Science Advisory Board (1400F)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: SAB's Quality Review of the Draft Review Report on EPA's Draft Assessment, "Evaluation of the Carcinogenicity of Ethylene Oxide"

Dear Dr. Shallal:

As you know, on October 5, 2007, the chartered Science Advisory Board (SAB) conducted a quality review of the Draft Review Report on EPA's Draft Assessment, "Evaluation of the Carcinogenicity of Ethylene Oxide" (Draft Review Report). Dr. Jane Teta, presented comments for the SAB's consideration on behalf of the Ethylene Oxide/Ethylene Glycols Panel (Panel)¹ of the American Chemistry Council. The Panel would like to underscore and elaborate on a critical issue that Dr. Teta could only briefly discuss during her presentation due to time limitations.

The SAB Draft Review Report encourages the U.S. Environmental Protection Agency (EPA) to "broadly consider all of the epidemiological data in developing its final Assessment," and specifically references the Union Carbide (UCC) ethylene oxide (EtO) worker mortality study (Greenberg *et al.*, 1990; Teta *et al.*, 1993; and Teta *et al.*, 1999). Prompted by SAB's unequivocal recommendation, The Dow Chemical Company offered to provide EPA with an updated UCC epidemiologic study to incorporate into EPA's draft assessment. As noted by Dr. Teta during her October 5, 2007, remarks, "[t]he vital status follow up is now complete for a total of 64 years (1940-2003). Average follow up for study subjects is about 42 years. Importantly nearly two-thirds of the approximate 2,000 UCC EtO workers were first assigned to

¹ The EO members of the Panel are: 3M, ARC/Balchem Corporation; BASF Corporation; Bayer MaterialScience LLC; Celanese Chemicals, on behalf of itself and Old World Industries; Croda, Inc., The Dow Chemical Company; Eastman Chemical Company; Equistar Chemicals LP; Honeywell; Huntsman; Sasol North America, Inc.; Shell Chemical LP; and Sunoco, Inc.



an EtO using or producing department prior to 1960, many in the 1940s and earlier, when exposures were at their highest intensities.”

Dr. Teta also indicated that she was “hopeful that . . . this updated study ultimately will be included in EPA’s revised assessment,” based on what appeared to be affirmative steps by EPA to include this study in its EtO assessment. Recent discussions between The Dow Chemical Company and EPA, however, indicate that EPA is noncommittal, if not demonstrably reluctant to comply with SAB’s unequivocal recommendation. Without this updated study, the EtO assessment will not reflect the best available science, a fundamental requirement of all EPA risk assessments. Thus, the Panel urges SAB to highlight and emphasize to the greatest extent possible its recommendation that EPA “consider all of the epidemiological data in developing its final Assessment.”

The Panel, along with SAB, fully acknowledges that this recommendation, along with SAB’s other recommendations, “will require significant effort.” But ensuring the scientific robustness of EPA’s evaluation of EtO’s carcinogenicity potential requires nothing less, particularly in light of its public health and economic significance.

The Panel appreciates the opportunity to make this follow-up submission. If you have any questions, please contact me at (703) 741-5613 or via e-mail at Kristy_Morrison@americanchemistry.com.

Sincerely yours,

Kristy L. Morrison
Manager
Ethylene Oxide/Ethylene Glycols Panel