



interscan corporation

PO Box 2496
Chatsworth, CA 91313-2496
1 800 458-6153
Fax (818) 341-0642
www.gasdetection.com

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Office of Environmental Information (OEI) Docket
Mail code: 2822T
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460-0001

Attention: Docket ID Number EPA-HQ-ORD 2006-0756

Re: Evaluation of the Carcinogenicity of Ethylene Oxide

Dear Sir or Madam:

Interscan Corporation is pleased to submit the following comments on the U.S. Environmental Protection Agency's (EPA) Office of Research and Development's September 22, 2006, draft cancer risk assessment on ethylene oxide (EO or EtO) (Draft Risk Assessment).¹

First of all, Interscan fully supports the comments of the Ethylene Oxide/Ethylene Glycols Panel of the American Chemistry Council, submitted under separate cover regarding the Draft Risk Assessment. We urge EPA to adopt these comments.

Interscan is a manufacturer of toxic gas detection instrumentation and related software. One of the gases we monitor is ethylene oxide, and we have become the leading supplier of monitoring systems for this gas in health care environments. While we have significant issues with the methodology used by the Agency to arrive at its present conclusions, we will confine ourselves to discussing analytical problems that would ensue should such low levels of EtO become mandated.

Simply stated, no technology is currently available that even comes close to having the sensitivity required to meet the demands of the Draft Risk Assessment. Present

¹ 71 Fed. Reg. 55470 (Sept. 22, 2006)

workplace EtO regulations stipulate an 8-hour time-weighted average (TWA) concentration of 1 ppm, with a short-term exposure limit of 5 ppm.

Best practices in occupational health monitoring provide for an instrument that operates accurately in the concentration range of one-tenth to 10 times the TWA. Not surprisingly, all good EtO systems operate in this range. As such, the practical limit for ACCURATE measurement is somewhere around 0.1 ppm.

Supposing that we were to abandon all best practices and operate at the minimum detectable level of the most sensitive instrument. That would bring us to 0.01 ppm.

Turning to non-continuous grab sampling methods, which are more appropriate to regulatory agencies and consultants, rather than hospital end-users, NIOSH method 3702 for EtO, using portable gas chromatography, and tested for the range 0.1 to 700 ppm, carries an accuracy of ± 17 percent. Supposedly, this method is intended for the range 0.001 to 1000 ppm.

Inasmuch as the minimum detectability given by most suppliers of photoionization detectors (as used with the GC) is 0.01 ppm EtO, it is doubtful that method 3702 can really go ten times lower than this. Indeed, the supporting paper for this method² (written by its developer) only documented the method down to 0.1 ppm.

Moreover, the Reagents section of this method effectively begs the question of accuracy, when it requires “Uncontaminated air for preparation of standards and purging samplers.” How is one to ensure that the air is “uncontaminated,” if this most sensitive method, assuming the write-up is credible, goes down to 0.001 ppm? What, then, is the standard for this uncontaminated air (also called zero air), and what analytical method is used to certify it?

To ask this question is to answer it.

Historically, the Agency has been far more concerned with source (or emission) measurements, and these are in ranges orders of magnitude higher—and generally are far easier to accomplish—than ambient air measurements. Unfortunately, it is NOT appropriate to draw analogies between source and ambient measurements, yet it seems to be the case here.

Ambient air measurements, especially to achieve the levels implied by the Draft Risk Assessment, will present insurmountable obstacles with respect to

- Basic sensitivity
- Accuracy
- Calibration

² Burroughs G. E., and Busch, K. A., "Field Validation of Direct-Reading Instrumental Methods for the Sampling and Analysis of Environmental Contaminants," unpublished NIOSH report (1985)

At this writing, the only technology that would even have the potential to measure EtO at the levels required involves the use of nanomechanical cantilever resonators. However, the incredible sensitivity of this method is severely hampered by its lack of specificity, and a practical application for EtO is not on the horizon, and may never become available.

Thus, we are forced to conclude that the Draft Risk Assessment overstates the carcinogenicity of EtO, and understates the difficulties inherent with measuring the compound at the very levels it would mandate.

InterScan Corporation appreciates the opportunity of submitting these comments. For further information, please contact the undersigned. [Direct phone (703) 796-6063]

Very truly yours,
INTERSCAN CORPORATION

A handwritten signature in black ink, appearing to read "M. Shaw", with a long horizontal flourish extending to the right.

Michael D. Shaw
Executive Vice President