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CHEMICAL MANUFACTURERS ASSOCIATION
July 24, 1992

CAP
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Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460



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: DCN

Attention: Section 8(e) Coordinator (CAP Agreement)

Dear Sirs:

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88920003787: DCN

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U.S. GOVERNMENT PRINTING OFFICE

We wish to comment on a recent notification provided under Section 8(e) of TSCA pursuant to the Compliance Audit Program (CAP).

In a June 24, 1992 submittal, a company reported findings from National Toxicology Program (NTP) 13-week drinking water studies on 2-butoxyethanol (CAS #111-76-2). The "preliminary data tables" purportedly indicated a statistically significant decrease in epididymal sperm density in male rats exposed at the 3,000, 4500, and 6000 ppm dose levels, and a decrease in female uterine weights at the 3,000 and 6,000 ppm dose levels.

We wish to point out that the two NTP data tables (pp. ix and xii) attached to the submission, which summarize the findings of concern, are labeled, "13-Week Subchronic Study of 2-Ethoxyethanol [CAS #111-80-5] in Male/Female F344/N Rats", not 2-butoxyethanol. The 2-butoxyethanol tables summarizing findings in the rat study are limited to hematology/clinical chemistry/bone marrow 90-day sample collection data. Given the confusion, it is very uncertain if the NTP abstract submitted by the company correctly summarizes the 2-butoxyethanol study's findings. This situation illustrates the problems that can arise when unaudited data are subject to TSCA 8(e) notification.

CMA urges EPA to disregard the TSCA 8(e) notification until NTP issues a complete quality assurance audited report of the study. We understand that the draft report on the 13-week rat studies will be made available later this year, and that the studies currently are scheduled for review by the NTP Board of Scientific Counselors in December 1992.

Sincerely,

Carol R. Stack, Ph.D.
Manager
Glycol Ethers Panel

cc: William Eastin, Ph.D., National Toxicology Program