

PPG

Inter-Office Correspondence

TO: T. G. Brown
Lake Charles

DATE: March 2, 1988

FROM: J. A. Barter/
Z. G. Bell

LOC: 36 West

SUBJECT: EPA Withdrawal of
Proposed Test Rule on
Vinylidene Chloride

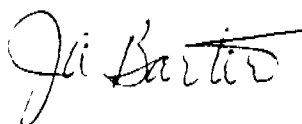
On August 12, 1986, the Office of Toxic Substances of U.S. EPA issued a notice (51 FR 28840-28846) of a Proposed Test Rule for 1,1-Dichloroethylene (Vinylidene Chloride) which would have required the manufacturers (PPG and Dow) to conduct additional toxicology studies at a total cost of approximately \$1,200,000. The basis of this proposed rule was concern by EPA's Office of Air Quality Planning and Standards that some data suggest that 1,1-DCE may be an oncogen and that inhalation of 1,1-DCE by populations living near manufacturing and processing plants may present unreasonable risk of oncogenicity.

Working through the CMA Vinylidene Chloride Panel, we argued that the weight of scientific evidence (18 long term studies had been conducted) did not suggest oncogenicity and that EPA had sufficient information to reach a decision that there was no unreasonable risk. Additionally, we obtained information on emissions of 1,1-DCE from both manufacturers and processors which established that emissions were considerably reduced from the data EPA was using to form their judgement.

The attached letter from EPA documents that the Air Office has withdrawn their proposal for additional testing and, therefore, we will not be required to conduct these studies. As indicated in the letter, the decision is based, in part, on the data showing reduced emissions. We are presently awaiting the finalization of the decision by the Test Rules Development Branch which should be announced by a Federal Register Notice.

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This case provides a concrete example of the value of doing a good job. Special thanks are due to those at Lake Charles who provided us the data in a timely fashion and to all there who have been involved in the decisions and implementations that resulted in significant reductions in Vinylidene Chloride emissions over the years. These efforts actually helped shape the course of events on this issue and saved the manufacturers from a requirement to conduct studies which would have provided no new information useful in safeguarding the public by regulating 1,1-DCE.



J. A. Barter



Z. G. Bell

cc: J. Cafaro
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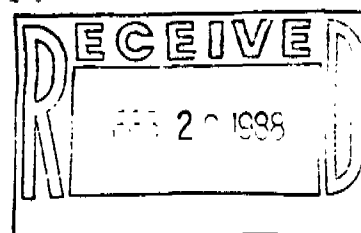
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Air Quality Planning and Standards
Research Triangle Park, North Carolina 27711

18 FEB 1988

Dr. Robert R. Romano
Associate Director, Special Programs
Chemical Manufacturers Association
2501 M Street, N. W.
Washington, D. C. 20037



Dear Dr. Romano:

This is in response to your letter of January 7, 1988, concerning testing for 1,1-Dichloroethylene under the Toxic Substances Control Act, Section 4. The Office of Air Quality Planning and Standards has concluded that testing of 1,1-Dichloroethylene is not warranted at this time based, in part, on the emissions data submitted by the Chemical Manufacturers Association. Although we have not confirmed these emission estimates, they indicate a 75 percent reduction in ambient air emissions since the proposal of the test rule in August 1986. In addition, the industry has publicly accepted the cancer potency estimate based on the single positive bioassay. Using the current emission estimates and the cancer potency estimate, the annual cancer incidence would be reduced significantly from previous estimates. Given the magnitude of the cancer incidence values based both on the unverified industry data as well as the original estimates of the Agency it is unlikely that we would initiate Federal regulatory development efforts on 1,1-dichloroethylene. As a result, we have withdrawn our proposal for the testing of 1,1-dichloroethylene. Should additional information become available in the future, we will reevaluate the need at that time.

We continue to support the efforts of the industry to reduce emissions of 1,1-dichloroethylene and we appreciate your efforts to keep us informed of the progress in this area.

Sincerely,

Nancy B. Pata, D.V.M.
Project Officer
Pollutant Assessment Branch
Emission Standards Division

cc: C. Glasco
R. Northrup
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G. Timm

For Distribution by CMA
SPECIAL PROGRAMS DIVISION

From Romano
Ref. No. 21240/88
Date UDC Pata

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**ENVIRONMENTAL PROTECTION
AGENCY****40 CFR Part 799****(OPTS-42082 (FRL-3031-2))****Toxic Substances, 1,1-
Dichloroethylene; Proposed Test Rule****AGENCY:** Environmental Protection
Agency (EPA).**ACTION:** Proposed rule.

SUMMARY: EPA is proposing that manufacturers and processors of 1,1-dichloroethylene (CAS No. 75-35-4) be required, under section 4 of the Toxic Substances Control Act (TSCA), to conduct distribution, excretion and metabolism (DEM) studies and a two-year inhalation oncogenicity bioassay in mice. The Agency proposes to delay the initiation of the oncogenicity testing until after the DEM data have been completed and evaluated.

DATES: Submit written comments on or before October 14, 1986. If persons request an opportunity to submit oral comment by September 28, 1986, EPA will hold a public meeting on this rule in Washington, DC. For further information on arranging to speak at the meeting see Unit VIII of this preamble.

ADDRESS: Submit written comments, identified by the document control number (OPTS-42082), in triplicate to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT:
Edward A. Klein, Director, TSCA
Assistance Office (TS-799), Office of
Toxic Substances, Rm. E-543, 401 M St.,
SW., Washington, DC 20460. Toll free:
(800-424-9085). In Washington, DC: