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cc: R. N. Johnson
H. S. Wheeler

September 11, 1986

Express Mail

To: Members, Vinyl Chloride Special Programs Panel

From: Has Shah, Program Manager *H. Shah*
Gabrielle H. Williamson, Assistant General Counsel *G.H.W.*

Re: Informational Submission to EPA: Summary of Draft
Results of an Epidemiology Study of Vinyl Chloride
Workers

Enclosed for your information and review for possible individual company notification to EPA is a copy of the referenced submission CMA made today on behalf of the Panel. Pursuant to Has Shah's request for your reactions, ten Panel member companies indicated that CMA should file an FYI notice with EPA on this study, while two believed the results of the study were inconclusive and that a filing was, therefore, not warranted.

Has's earlier communication to you included only a request for your reaction on the emphysema finding. You will note that the enclosure also refers to the excess liver and biliary cancer shown in the study above the observed mortality from angiosarcoma of the liver, with a statement that it remains unclear whether vinyl chloride is related to this development. This statement was included in CMA's informational filing to EPA at the request of your Panel Chairman, Bill Gaffey of Monsanto, who also drafted this portion of the letter.

We also note that CMA's enclosed filing was sent only as an informational notice to EPA; it was not a Section 8(e) filing on behalf of the Panel, nor does it refer to Section 8(e) anywhere in its text. Given the general content of the notice, the timeliness of submission, etc., EPA may decide, as a practical matter, that CMA's informational notice provides the Agency with adequate data to avoid the need for additional FYI or Section 8(e) filings of the same information by Panel members. However, since the CMA FYI notice is not formally a Section 8(e) submission, EPA might determine that the companies which manufacture (including import), process, or distribute vinyl chloride in commerce remain technically liable for filing individual Section 8(e) notices if they believe that the information contained in the study reasonably supports the conclusion that "substantial risk" exists. We urge you to

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review EPA's Statement of Interpretation and Enforcement Policy, Notification of Substantial Risk, 43 Fed. Reg. 11110 (March 16, 1978) in making your individual company decisions on whether or not to file additional FYI or Section 8(e) notices concerning results of this study.

Please call either of us (Has Shah (202/887-1192); Gabrielle H. Williamson (202/887-1356)) if you have any questions or comments on this matter.



CHEMICAL MANUFACTURERS ASSOCIATION

GERALDINE V. COX, Ph.D.
Vice President
Technical Director

September 11, 1986

HAND-DELIVERY

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U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460

RE: For Your Information Submission: Summary of
Draft Results of an Epidemiology Study
of Vinyl Chloride Workers

DOCUMENT CONTROL OFFICE
1986 SEP 11 AM 2:02

Dear Sir/Madam:

The Chemical Manufacturers Association (CMA) has just learned of the draft results of an epidemiology study of vinyl chloride workers conducted by Environmental Health Associates. The study was sponsored by the Vinyl Chloride Program Panel ("the Panel") of CMA. The significant findings from this study are reported here for your information on behalf of the Panel. The member companies of the Panel are listed on Attachment I.

The current study is an update of an earlier mortality study of vinyl chloride workers. The draft report received by CMA on the current study shows an excess mortality from three causes not previously associated with vinyl chloride exposure.

The study showed an excess of liver and biliary cancer over and above the observed mortality from angiosarcoma of the liver. Without the known angiosarcomas, there were 22 observed deaths from liver and biliary cancer versus 6 expected. Because some of the deaths from liver and biliary cancer may, in fact, be undiagnosed deaths from angiosarcoma, it is not certain at this time that there is, in fact, a vinyl chloride related excess in these cancers.

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In addition, the study showed an excess mortality from emphysema, which includes bronchitis and chronic obstructive pulmonary disease. However, the dose-response relationship is not consistent with vinyl chloride as a causal agent. If it were, one would expect that the excess would become greater with increasing duration of exposure when, in fact, the opposite is observed in the study. Also, one would expect that the excess would be greatest in those hired at the youngest ages. Again, the reverse is true. Finally, one would expect that persons whose exposure began a long time ago would have more emphysema than those whose exposure began recently, which was also not observed in the study. Therefore, although the excess deaths due to emphysema appear to be real, their relationship to vinyl chloride is questionable.

A final report is expected from the contractor in four to six weeks and will be submitted to the Agency for its detailed review. Meanwhile, please call Dr. Has Shah, Program Manager, of my staff at 887-1192, if you have specific questions.

Sincerely yours,

Geraldine V. Cox

Geraldine V. Cox, Ph.D.
Vice President-Technical Director

cc: Vinyl Chloride Program Panel

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ATTACHMENT I

Participating Companies
of the
Chemical Manufacturers Association's
Vinyl Chloride Program Panel

Air Products and Chemicals, Inc.

BFGoodrich Company

Borden, Inc.

Certain Teed Corporation

Diamond Shamrock Chemicals Company

DiversiTech General

Dow Chemical USA

Ethyl Corporation

Exxon Chemical Company

The Goodyear Tire and Rubber Company

Gulf Oil Products Company

Monsanto Company

Occidental Chemical Corporation

PPG Industries, Inc.

Stauffer Chemical Company

Shell Oil Company

Union Carbide Corporation

Uniroyal Chemical Company

Vista Chemical Company