

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.

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