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INTER-OFFICE MEMO **TENNECO CHEMICALS, INC.**

TO G. I. Rozand AT DATE November 16, 1972  
 FROM A. C. Siegel AT COPY TO Dr. M. Rosen  
 P. R. Scarito  
 SUBJECT VINYL CHLORIDE TECHNICAL TASK GROUP MEETING

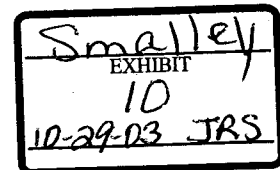
On November 14, 1972, a meeting was held in the Washington, D.C., offices of the Manufacturing Chemists Association (MCA) to discuss the proposed agreement between the European and American producers for sharing research data on the possible carcinogenic effects of vinyl chloride.

George Best, Technical Director for the MCA, gave a brief opening statement of the circumstances leading to the meeting and introduced Mr. D. M. Elliot of Imperial Chemical Industries Limited, who was representing the European manufacturers of vinyl chloride.

After Mr. Elliot re-emphasized the need for maintaining the confidentiality of any information he may disclose, a discussion ensued regarding the secrecy agreement sent to the participating companies by the MCA. Dr. W. Mayo Smith, of Air Products, stated that they had considerable reservation about signing such an agreement and submitted a document prepared by his Legal Department. They reserved the right to exclude such items as public domain, prior knowledge, independent development, and requested a limitation of 5--10 years on any such agreement. Additionally, they required a release where legal proceedings may force disclosure, particularly where it involves any governmental agencies.

Another company representative also indicated that their Company had the same reservations, but were willing to submit a much simpler "best efforts" type of secrecy agreement without the involved language as presented by Dr. Smith. Mr. Elliot indicated that the legal duress within the U.S. was precisely what concerned the European companies. They did not want any preliminary or premature disclosure of information they developed before they were ready to publish the data. He indicated that they had already been embarrassed by Dr. Viola's presentation at Houston, which had not received prior approval from the Solvay Company.

Upon questioning of the minimum 10-year time limitation required by the European companies, Mr. Elliot indicated that Dr. A. Caputo, who was one of the co-authors of the paper presented by Dr. Viola, was preparing to publish an additional paper in Florence, Italy, in October of 1974; and, therefore, the European companies may be forced to publish information within that period. Once it became public domain, obviously anybody could use this data.



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A quick survey by George Best indicated that an estimated 60-70% of the companies represented were willing to sign the MCA proposed agreement immediately. Both the B. F. Goodrich and Dow representatives expressed disappointment that the other representatives were not empowered or were unwilling to do so. They both felt that this has been a problem which has caused the program to drag on and on indeterminately. One representative suggested that those companies who were unwilling or unable to sign, be asked to leave the conference.

As a compromise, it was agreed that everyone would impress upon their respective managements their obligation to sign a secrecy agreement and submit it to the MCA within the next week to ten days. Additionally, the participants to the meeting were asked to refrain from taking any notes while the data was being presented by Mr. Elliot.

With this agreement, Dr. Walter Harris, Toxicologist for Uniroyal, reported upon his visit and his reception by Professor Maltoni of the Instituto Di Ancologiaia Bologano, Italy. Professor Maltoni is in charge of the research project for the European companies. As far as Dr. Harris could tell, nothing was hidden from him with regard to the test protocol or experimental facilities used in their research. However, no results whatsoever were revealed to him. He did, however, get the impression that there have been some disturbing information generated. He then went on to explain the use of the various cages, the method of exposure, the type of people involved, and so forth.

Mr. Elliot indicated he was not prepared to give a formal presentation and disclaimed any medical expertise stating that his involvement is for the financial responsibilities of the project rather than the protocol. He did, however, review the test protocol as per the attached.

None of the animals are to be sacrificed for the duration of the test period. Once they have died, however, at least four organs will be examined for evidence of cancer. These were the cercuminal gland located in the ear canal, the liver, kidney, and lungs. Listed below are the exposure levels, monomer type, and the approximate survival rate after 28 weeks.

<u>Exposure Level</u>	<u>Monomer Type</u>	<u>Range of Animals Per Group</u>	<u>Approx. No. Survived After 28 Weeks</u>
2,500	Vinyl Acetate	65 - 95	?
10,000	Vinyl Chloride	65 - 95	20 - 25
6,000	Vinyl Chloride	65 - 95	20 - 25
2,500	Vinyl Chloride	65 - 95	25 - 30
500	Vinyl Chloride	65 - 95	40
250	Vinyl Chloride	65 - 95	43
50	Vinyl Chloride	65 - 95	44
0	Vinyl Chloride	65 - 95	44

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Since no primary tumors were evident in the animals (rats) exposed to vinyl acetate, this phase of the program will probably be dropped. At least one primary tumor was evident for vinyl chloride exposure at levels of 250ppm and above. The greatest proportion of primary tumors (7 to 10) developed in the ceruminal gland located in the ear canal. The highest number of tumors were coincident with the highest level of exposure. The number of tumors declined as the exposure was reduced. Although at a reduced level, this was also true with regard to tumors found in the kidney. The only tumor to date that developed in the liver was at the 250ppm level. This was considered both significant and disturbing since there appears to be no previous history in this particular strain of rats for developing tumors in this organ. Tumors that developed in the lungs appear to be a secondary metastatic growth of the malignant tumors that originally developed in the other organs.

The program is now in its 74th week and is expected to run its full course of two years. This is also the normal life expectancy of the unexposed rats.

Mr. Elliot restated that he could not answer any involved medical questions with any authority and, therefore, encouraged the group to send knowledgeable representatives to thoroughly discuss the program with their European counterparts. He did indicate that the vinyl chloride monomer used for experimentation was a good, pure commercial grade and expressed doubts that the low level of impurities had any significance with regard to the results. There was no distinction between acetylene and ethylene derived monomers. It was the writer's opinion as well as that of the Borden and Uniroyal representatives that the additional testing of acetylene monomers was no longer necessary.

After much discussion involving the need to revise the current American Program including the reincorporation of an epidemiological study as originally proposed, it was the decision of the meeting members to immediately reconvene the original Ad Hoc Planning Group to develop the final program.

With regard to financial support of the Program and the member companies' budget problems, it was agreed to displace the current payment schedule by six months making the first 40% payment due by January 1, 1973.

At the conclusion of the meeting, a number of members expressed both their concern and disappointment with the degree of progress and the length of time it has taken to initiate any action. In view of the serious nature of our problem, it was hoped that any future company representatives would be empowered to commit their respective companies both legally and financially.

Attached is the European project protocol and the current financial commitments of the participating companies.

Based upon the initial European test results, we as a Company should give very serious thought toward developing programs such as: solvent cleaning

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reactors, increased ventilation of monomer areas, testing of reactor room atmospheres, etc., with a goal of Oppm exposure of operating personnel. )

I am forwarding additional copies of my report to you and Dr. Rosen for further distribution as you both deem necessary.

If any additional information is required, please advise.

*A.C. Siegel*

A. C. Siegel

ACS:pjd  
11/16/72

Attchs.

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Vinyl Chloride Monomer - European Project Protocol

Animal species: Sprague-Dawley rats of thoroughly documented pedigree especially with regard to cancer incidence in various tissues.

Dosages: 10,000, 6,000, 2,500, 500, 250, and 50ppm.  
65-95 animals per group.

*M Vac - 2500*

Time of exposure: 4 hours real time/day, 5 days per week for one year. Animals are observed until natural death. Professor Maltoni feels that one year is better than longer exposure since toxicity may kill animals before cancer develops especially at higher dosages.

Animal housing and handling: All animals of one group were in one chamber which had three levels with two cages of 10 or more animals each at the beginning of the experiment. Of the original 577 animals at the start of exposure, 275 have died of natural causes. There is a separate mixing device for each chamber. The VC air mixture is fed through a large pipe into each of the three levels of the chambers. A gas sample tube leads from each metering device to a central gas chromatograph. Periodic samples are also taken from the chambers to maintain the dosage very close to the desired levels. Records are complete and neat. Professor Maltoni is intimately acquainted with every phase of the work. Three Ph. D's work on this phase of the work. A standard balanced laboratory <sup>is</sup> *feed* supplied by a feed company according to his formula.

Observation and pathology:

Weighed every two weeks.

Observed individually several times daily.

Careful clinical examinations weekly.

On death complete autopsy. Those with tumors are x-rayed-whole body by a special technique which shows cancerous tissue. All organs examined carefully. Professor Maltoni personally reads all slides. Color photos are made of tumors.

European Project Sponsors:

Imperial Chemical Industries  
Solvay et Cie  
La Cellophane  
Montedison  
Rhône-Progil

Research Investigator in charge:

Professor Cesare Maltoni  
Istituto Di Oncologia  
Bologna, Italy

Prospective Research Project

Carcinogenic Potential of Vinyl Chloride Monomer

Contributors	Combined Production Capacity VCM & PVC million lb/yr	%	Proportionate share of \$165,000	Division of supplementary \$28,000 <sup>1</sup>	First & second payments...each 40% of share	Final payment... 20% of share
Air Products	160	1.9	\$ 3,135	\$	\$ 1,254	\$ 627
Allied Chemical	440	5.1	8,415		3,366	1,683
Borden Chemical	390 <sup>2</sup>	4.5	7,425	9,334	6,703.60	3,351.80
Conoco	830	9.7	16,005		6,402	3,201
Dow	1,200	14.0	23,100		9,240	4,620
Ethyl	450	5.3	8,745		3,498	1,749
Exxon	(150) <sup>3</sup>	1.8	2,970		1,188	594
Firestone	240	2.8	4,620		1,848	924
Goodrich	1,600	18.7	30,855		12,342	6,171
Monsanto	150	1.8	2,970		1,188	594
Olin	150	1.8	2,970		1,188	594
PPG	900	10.5	17,325		6,930	3,465
Shell	800	9.4	15,510		6,204	3,102
Stauffer	150	1.8	2,970		1,188	594
Tenneco	300	3.5	5,775	9,333	6,043.20	3,021.60
Union Carbide	350	4.1	6,765		2,706	1,353
UNIROYAL	285 <sup>2</sup>	3.3	5,445	9,333	5,911.20	2,955.60
	8,545	100.0	\$165,000	\$28,000	\$77,200	\$38,600

<sup>1</sup> For one additional exposure level with acetylene-derived monomer

<sup>2</sup> Includes Monochem capacity

<sup>3</sup> Non-producer; participation based on matching lowest capacity level among producer participants