

Chemical Manufacturers Association
Record of Meeting
VINYL CHLORIDE RESEARCH COORDINATORS

September 20, 1979

CMA Offices, Room 404

Washington, D. C.

*Copies to
ChW
JFH
for your info.*

MEMBERS PRESENT:

R. T. Torkelson, Chairman	Dow Chemical Company
T. J. Benya	Ethyl Corporation
Z. G. Bell, Jr.	PPG Industries
W. D. Harris	Uniroyal, Inc.
M. N. Johnson	The BFGoodrich Company
R. N. Wheeler	Union Carbide Corporation
J. T. Seawell	CMA Staff

CHEMICALS
RESEARCH

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ATCL _____
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PRESENT BY INVITATION:

V. L. Kirkland	Shell Chemical Company
G. K. Hatfield	Diamond Shamrock

MEMBERS ABSENT:

C. D. Kary	Shell Chemical Company
W. M. Smith	Air Products & Chemicals, Inc.

1.0 Approval of Record of Last Meeting

The Record of the March 21, 1979 meeting was approved as recorded.

2.0 Update on Research Publications

Dr. T. R. Torkelson reviewed published research material that merited the attention of the Research Coordinators. The Project Administrator is to delay mailing of the Record of Meeting until copies are available of at least the title pages of the eleven literature citations made by the Panel Chairman. These title pages are to accompany the Record of Meeting.

14, 16, 19

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2.1 "Mortality and Cancer Morbidity in Workers in the Swedish PVC-Processing Industry"

As a result of the thoughtful efforts of Dr. W. M. Smith and his European associate, a copy of the full titles of the eighteen literature references cited in the above mentioned study (see Item 2.1 above) will be mailed with the title pages of research literature discussed.

3.0 Memorandum of Understanding Between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA)

On June 12, 1979 and June 22, 1979 the Administrators of the EPA and FDA, respectively, signed a Memorandum of Understanding establishing an agreement between the EPA and FDA with regard to the control of direct and indirect additives to and substances in drinking water.

EPA will contract for monitoring of existing water supplies to determine use patterns and the contribution of trace contaminants to drinking water from:

- A. Bulk chemicals
- B. Generic classes of paints and coatings
- C. Pipes and equipment

With respect to the indirect additives, that is, substances derived from items B and C above, EPA plans to identify the trace contaminants involved and then evaluate the related health risk and make appropriate recommendations for future use.

4.0 Central Institute Voor Voedingsonderzoek (CIVO)

The Chairman expressed the opinion that CIVO is proceeding with additional studies however this has not been confirmed recently by any of our European contacts.

5.0 German Epidemiological Study

Dr. Stafford of Imperial Chemical Industries, Ltd. (ICI) reported to Dr. Torkelson that those researchers conducting the German study were convinced of gross error in their computer program. Dr. Stafford will continue to follow the progress of the German study.

6.0 The "Final" Report on Maltoni's Studies on Vinyl Chloride

During a recent visit to Dow Chemical, Dr. Maltoni expressed the opinion that the final report on vinyl chloride would be

published "late this year". Presumably this final report will cover all of his studies on vinyl chloride.

7.0 Medical College, University of Louisville

Dr. Tamburro reported to Dr. Torkelson that no special studies are being conducted at the University of Louisville on brain tumors and, at this point in time, he did not anticipate that any would be initiated.

8.0 Status Report on Research Sponsored at Industrial Bio-Test Laboratories (IBT)

On July 20, 1979 the Project Administrator sent to CMA's General Council a letter-report summarizing the findings of the Vinyl Chloride Audit Task Group to date. The letter-report concluded that after a large expenditure of time and money by the members of the Vinyl Chloride Audit Task Group, little or nothing of salvagable value has evolved and it must be concluded that the study has gross, irreparable deficiencies. The letter-report concluded with the comment that little can evolve from audits of other equally important records and research materials, since inadequate pathologic studies and/or observations and insufficient numbers of tissues preclude scientifically valid conclusions on tumor incidence and dose-response relationships.

On September 11, 1979, Mr. Edmund B. Frost, CMA Vice President and General Council transmitted the above mentioned letter report to Mr. Fred R. Curren, Corporate Council Industrial Bio-Test Laboratories, Inc.

It was VOTED:

That if no response is received from IBT's General Council by October 30, 1979, that CMA's General Council would be requested to send an appropriate reminder to IBT's General Council.

9.0 Consideration of Possible Further Action by the Vinyl Chloride Audit Task Group (VC/ATG)

It was VOTED:

That the VC/ATG conduct no additional retrospective auditing nor expend further effort on summarizing audit data at this time.

One negative vote was cast by Dr. Z. G. Bell. He specifically requested that his negative vote be recorded. Dr. Bell voiced

the strong opinion that the VC/ATG should prepare a fully documented final report that should give careful attention to the chronology of the IBT research programs since unexplained "gaps" in the progress of various phases of the program could result in undue and unjustified criticism of the Panel and its coordination of this research effort.

10.0 Update of Tumor Incidences in Texas City, Texas Plant

Mr. R. N. Wheeler submitted a brief update on the Texas City tumor incidences and concluded his presentation with the opinion that it will be at least a year before anything definitive appears possible. Emphasis may be shifting to a study of the entire area. At this point in time there is no evidence that indicates vinyl chloride induces the formation of glioblastomas. Mr. Wheeler called attention to the fact that the same kind of study (a joint Carbide, OSHA, and NIOSH investigation) is just beginning at South Charleston, West Virginia plant.

11.0 Dr. Stafford's Report to Dr. Torkelson on a Chemical Epidemiological Study on 818 PVC Workers

Via telephone from England, Dr. Stafford reported that ICI had received a report from a chemical and epidemiological study on 818 PVC workers. Dr. Torkelson summarized Dr. Stafford's verbal report as follows and indicated that all of the items were subject to confirmation:

- 1) There was a small but statistically significant decrease in lung function. It was understood that FVC was decreased. Dr. Stafford reported that the decrease was considered to be the equivalent of 20 cigarettes per day.
- 2) While ICI was not certain of its significance, one of three radiologists saw small, round, smooth opacities in over 50 persons. The other two radiologists did not observe them. These may have been associated with men evidencing decreased lung function and with the highest exposure to dust.
- 3) One man with pulmonary fibrosis was discovered during x-ray studies. There was no excess lung cancer.
- 4) ICI did not have a good fix on TWA exposures. Available respirable dust samples had ranged from 0.15 to 2.8 mg/m³.
- 5) Dr. Stafford expects health authorities in England to set a new dust standard of 5 mg/m³ total dust and 2.5 mg/m³ for respirable dust.

- 6) ICI met with their employees on September 20, 1979 and did not receive any significant reaction. ICI officials were to meet with other PVC producers on September 21, 1979. The British government and the union already had the rough draft of the report. Dr. Stafford said that the report would be made available when written in final form and suggested a meeting in November, 1979 between U. S. and European manufacturers to discuss animal studies (which British Petroleum is advocating) as well as epidemiological studies. The epidemiology would investigate the effect of PVC dust as well as possible interaction of age, smoking, and other factors.

Dr. Torkelson informed Dr. Stafford that the Panel was, of course, interested in cooperating and that the Research Coordinators were considering PVC dust as one part of the extended Equitable Environmental Health study. Dr. Torkelson concluded by saying that the Research Coordinators were not in favor of animal studies at this time.

12.0 Consideration of Five-Year Update of Equitable Environmental Health (EEH) Epidemiological Study

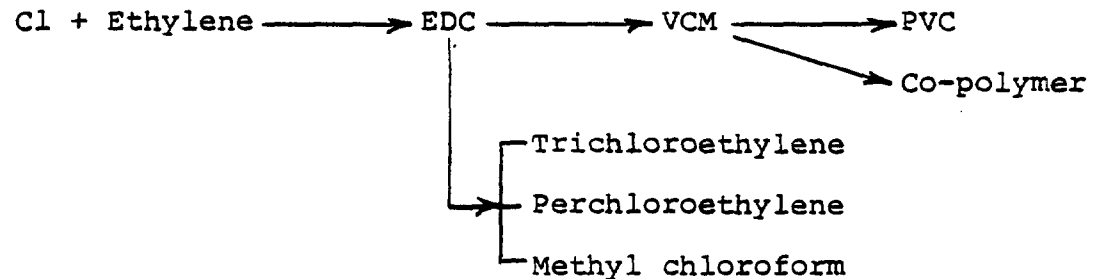
Dr. Torkelson reviewed discussions with and letters from Mr. Richard Davis of Environmental Health Associates (EHA). EHA has repeatedly emphasized that it does not know what is in the records being archived, and whether or not all of the original raw data are available. As a result, EHA cannot prepare a complete proposal without an on-site study of all the material archived at EEH.

Consideration of the epidemiological update included the following factors that are to be called to the attention of EHA and that are to be specifically included in the proposal by EHA:

- 12.1 The investigator is to identify the companies and their respective plants that were included in the original study. Thirty-one companies could have been involved, but at this point in time, we have no knowledge of those that were included and those omitted, and for what reasons.
- 12.2 The participating companies will be requested to identify whether they made emulsion or dispersion resins.
- 12.3 The participating companies will be asked to define and/or identify the degree of dust exposure in the emulsion plants only. This exposure is to be classified as "high" or "low".

12.4 The hypothetical question was raised, "Is there something we can learn by knowing more about the effects of ethylene dichloride (EDC) since it is estimated that ninety-five percent of those workers exposed to PVC (monomer) are exposed synchronously to EDC?" The opinion was expressed that VC monomer plants should be investigated to gain an insight into the possible effect(s) of EDC.

12.5 The following schematic was presented to assist in consideration of items 12.3 and 12.4:



12.6 The EHA proposal should reflect a case control study of brain tumors. The question was asked "Are we looking at any kind of brain tumors or just specific types"? Wherever possible the investigator must look at "the why" of brain tumors.

The case control study should consider the twelve present cases and provisions in the update should be made for additional studies later.

EHA will be requested to consider all of the above mentioned factors in their pending proposal.

It was VOTED by the Research Coordinators to recommend support of EHA during the preparation of a feasibility study on the material being archived at EEH and during the preparation of a formal proposal which will ultimately form the basis of all bid requests.

13.0 Consideration of Informal Proposal Submitted to Dr. Benya by the University of Tennessee Center for the Health Sciences

The Materials Science Toxicology Laboratory of the University of Tennessee Center for Health Sciences submitted an informal research proposal for studying pulmonary effects of PVC dust. Discussions of this proposal led to the following opinions:

- 1) Much more will be learned by means of the epidemiological study of people than from animal experimentation.

- 2) Should consideration be given to inter-inflation, inter-tracheal introduction of dust?
- 3) There is merit in conducting a study on ultra-pure PVC provided exposure occurs in a suitable inhalation chamber.
- 4) At this point in time, the consensus of opinion was that animal studies do not appear to be the research approach of choice.

14.0 Update on CPSC/Edgewood Arsenal "Single Hit" Study

At Dr. Torkelson's request, Dr. J. Norris is analyzing the CPSC report issued to date. While Dr. Norris' studies are not complete at this time, it appears as though autolysis could be as high at 10.5%, as far as a general average is concerned, and as high as 21% in some specific test groups. It appears as though there could be 19% autolysis in the controls.

It was the consensus of the Vinyl Chloride Research Coordinators that we should not accept poor science and certainly every effort should be made to preclude publishing of data based on poor scientific procedures. This preliminary discussion led to possible approaches to include:

- 1) Is the Freedom of Information Act the way to go?
- 2) If data are refused under the Freedom of Information Act, then do we proceed with a third party retrospective audit.
- 3) It appears that the adenomas might well have been the result of a virus.
- 4) Preliminary information indicates there are three and one half file cabinets full of data on this study.
- 5) Random checks should be made on a number of slides to determine the validity of reported pathology.

After considering these and many other factors, especially the inadvisability of proceeding at the onset with multiple requests under the Freedom of Information Act, it was VOTED:

To request, informally, documents under the following three categories:

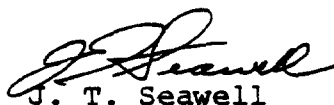
- I. The protocol and the amendments thereto

- II. Historical and concurrent control data, especially on incidences of pneumonia and adenomas
- III. All correspondence pertinent to publication, intended publication, or pending publication of research findings.

In addition to a CMA attorney requesting documents under all three of the above mentioned Categories, Mr. R. N. Wheeler will specifically request documents under Category I, Dr. G. K. Hatfield will request documents under Category II, and Dr. T. R. Torkelson will further request documents under Category III.

Depending upon the response received to the four requests mentioned above it was VOTED:

In the event that appropriate data is not forthcoming on the basis of informal requests, that the Research Coordinators recommend to the Panel that we proceed with procurement of data under Categories I, II, and III under the Freedom of Information Act.


J. T. Seawell
Project Administrator
Vinyl Chloride

JTS:jsj

Record Subject to Approval