



CHEMICALS
RESEARCH

MAR 24 1980

CHEMICAL MANUFACTURERS ASSOCIATION

March 20, 1980

To: Vinyl Chloride Project Panel

*Copy to JT Hall
CL Whitaker
W.D. Brubaker
Virginia Moore*

FK	_____
OCK	_____
ADL	_____
DJR	_____
CMS	_____
WRB	_____
ATCL	_____
LM	_____

Gentlemen:

Enclosed is a copy of a communication to Mr. Frank D. Kover that serves as a letter of transmittal for the report from Experimental Pathology Laboratories, Inc. (EPL) entitled "Vinyl Chloride Pathology Report". Please note the last paragraph of the letter and the fact that CMA has not attempted to evaluate the report as a Section 8(e) TSCA report because CMA does not have a reporting obligation under Section 8(e).

Also enclosed is a record of the Panel meeting held on March 18, 1980.

A copy of the EPL report is being sent to all Panel members who were unable to attend the March 18 meeting.

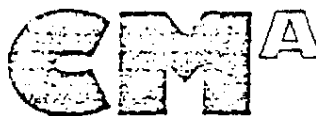
Sincerely,

J. T. Seawell
Project Administrator
Vinyl Chloride

JTS:db

Enclosures

CCR 000011321



BY MESSENGER

CHEMICAL MANUFACTURERS ASSOCIATION

March 19, 1980

Mr. Frank D. Kover - TS 792
Chief
Chemical Hazards Identification
Branch
Assessment Division
Environmental Protection Agency
401 M Street, S.W.
611 East Tower
Washington, D.C. 20460

Dear Mr. Kover:

On January 14, 1977, Mr. Albert Clark forwarded to Mr. Robert McGaughy of EPA, on behalf of the Manufacturing Chemists Association (now the Chemical Manufacturers Association), a copy of the protocol and the 23-month status summary for the Association-sponsored research on vinyl chloride at Industrial Bio-Test Laboratories (IBT). Mr. Clark stated in that letter that the final report was expected to be submitted soon, and when available, would be forwarded to the Agency.

As you know, all testing undertaken at IBT has come under a cloud. In particular, serious flaws were discovered in the vinyl chloride study, and no final report of the IBT study was ever issued. The Association undertook to determine whether the vinyl chloride study could be validated through an audit of the pathology by Experimental Pathology Laboratories (conducted by Dr. William Busey). Dr. Busey subsequently submitted a report of his audit to the Association on January 9, 1979. It was reviewed by an Association task force and, because it was part of a larger audit (including a review of compliance of IBT with good laboratory practices), was not further distributed at that time. Unfortunately, because of the interim change in the management of the Association and the extraordinary increase in the scientific work of the Association caused by the Toxic Substances Control Act and related environmental legislation, we failed to send it to the Agency as a follow-up to Mr. Clark's letter of January 14, 1977.

CCR 000011322

Mr. Kover
March 19, 1980
Page Two

Recently, the Association has established a task force to oversee and coordinate all scientific testing projects. In the course of reviewing existing projects, this group discovered that we had not made Dr. Busey's audit report on the vinyl chloride study available to the Agency. Accordingly, I am enclosing a copy of the audit report as a follow-up to Mr. Clark's letter of January 14, 1977.

As shown in the interim report sent to the Agency in January, 1977, three suspect brain tumors were noted in male rats at the high dose level. These brain tumors, plus one at the lower dose level, were confirmed by pathology subsequently conducted by IBT and then by Dr. Busey. Unfortunately, not all of the brain specimens were retained by IBT and not all retained specimens were examined. The Association has therefore concluded to determine whether additional information can be obtained from whatever brain specimens remain at IBT from this highly-flawed study by conducting histopathological examination of all remaining brain tissues. We have not identified any other findings that would appear to warrant further attempts to salvage other information from this study.

We apologize for failing to follow-up on Mr. Clark's earlier letter, and wish to assure you that we will, in the future, keep you apprised of any additional relevant information as it becomes available to us.

While CMA does not itself have a Section 8(e) reporting obligation, and while it appears that this information would not be reportable under Section 8(e) in any event, pursuant to our earlier commitment we are submitting it to the Agency.

Sincerely yours,

Hasmukh Shah

Hasmukh C. Shah, Ph.D.
Director, Special Projects

cc: (with enclosure)
Mr. Robert McGaughy
Office of Research &
Development
Environmental Protection Agency

CCR 000011323

Chemical Manufacturers Association

Record of Meeting

VINYL CHLORIDE PROJECT PANEL

March 18, 1980

Washington Hilton Hotel

Washington, D. C.

MEMBERS PRESENT:

W. M. Smith	Air Products & Chemicals, Inc.
H. W. Blakeslee	CertainTeed Products
T. R. Torkelson	Dow Chemical Company
T. J. Benya	Ethyl Corporation
R. Park	Firestone Plastics Co.
M. N. Johnson	BFGoodrich Company
Z. G. Bell	PPG Industries, Inc.
R. N. Wheeler	Union Carbide Corporation
J. T. Seawell	CMA Staff

PRESENT BY INVITATION:

C. R. Hopper	Gulf Oil Chemicals Co.
J. P. Murphy	Stauffer Chemical Co.
R. M. Walter	Firestone Plastics Co.
H. Shaw	CMA Staff
R. W. Hill	Diamond Shamrock
G. K. Hatfield	Diamond Shamrock
J. Hanson	Dow Chemical Co.
D. F. Zoll	CMA Staff
E. Frost	CMA Staff
W. Busey	Experimental Pathology Labs., Inc.
W. F. Carroll	Firestone Plastics Co.
R. T. Gottesman	Tenneco Chemicals, Inc.

MEMBERS ABSENT:

J. T. Carter	BP Chemicals, Ltd.
W. Bittenbender	Borden Chemical
F. Kennedy	Continental Oil Co.
R. W. McBurney	Diamond Shamrock

CCR 000011324

J. Lynch
R. W. Laundrie
J. Gabbett
C. A. Johnson
R. B. Judge
P. Cohen
R. L. Gibson
R. J. Abramowitz
G. Roush
A. G. Wheeler
S. K. Law
R. L. O'Connell
R. Brookman
V. L. Kirkland
J. Stauffer
P. M. Reed
W. D. Harris

Exxon Chemical Co.
General Tire & Rubber Co.
Georgia-Pacific Corp.
Goodyear Tire & Rubber
W. R. Grace & Company
Great American Chemical Co.
Gulf Oil Chemicals Co.
Hooker Chemicals & Plastics Corp.
Monsanto Company
ICI Americas, Inc.
Keysor-Century Corp.
Olin Corporation
Pantasote Company
Shell Chemical Co.
Stauffer Chemical Co.
Tenneco Chemicals, Inc.
Uniroyal, Inc.

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- 1.0 Edmund Frost, Esq., summarized the purpose of the meeting and briefly described the history of the Panel's research project with Industrial BIO-Test and an audit of the study by the Experimental Pathology Laboratory (EPL).
 - 2.0 Following a discussion of EPL's January 9, 1979 "Vinyl Chloride Pathology Report" a motion was made, duly seconded and passed to submit the Report forthwith to the U. S. Environmental Protection Agency.
 - 3.0 Following a discussion of the research project conducted by Industrial BIO-Test, a motion was made, duly seconded and passed to immediately conduct further pathologic analysis of all remaining brain tissue salvageable from the study.

- 4.0 Following discussion of CMA's efforts to terminate the Industrial BIO-Test contract and to seek reimbursement of funds, it was the consensus of the Panel that no additional efforts were required at this time and that the CMA Legal Department would handle the remaining aspects of the matter.



J. T. Seawell
Project Administrator
Vinyl Chloride

JTS:md

Record Subject to Approval

March 20, 1980

CCR 000011326

EPL

EXPERIMENTAL PATHOLOGY LABORATORIES, INC.

Note to J. J. Hall
C. L. Whetstone
W. D. Broddle
Virginia Moore

This report was included in my
earlier mailing to you.

F. Kennedy

VINYL CHLORIDE PATHOLOGY REPORT

Submitted to
Manufacturing Chemists Association
Washington, D.C. 20009

January 9, 1979

CCR 000011327

Vinyl chloride: Talked to Dr. Schwetz
of Dow, 1/29/80 of reproduct effects:

- 1) Reproduction: VC, 500-2500ppm, had no effect on implantation, ~~reception~~ or teratogenic parameters in mice, rat, or monkeys.
- 2) Dow's position on employee or ~~the~~ ^{lay} public living near VC plants: no health effects at ≤ 1 ppm.
- 3) Report by Dr. Infante on fetal wastage etc in women married to VC workers: has been discounted by federal agency (CDC).

The planned system would be more efficient, the official explained, and would allow better use of agency personnel by allowing them to set aside quickly those notices which present little concern.

At one time, EPA treated all notices the same throughout the review period. The agency, however, quickly learned that such an approach would not work once the volume of notices being submitted increased. It then established the 40-day preliminary screening and discovered that one of every six or seven notices needs a more detailed review, the EPA official told Chemical Regulation Reporter March 17.

While the new review system would establish a "slow track" and a "fast track" for different new chemicals, the EPA official stressed that the agency still will review every new chemical.

A new chemical cannot be dismissed on the basis of its chemical structure alone, he said. Even though its structure may be similar to an existing chemical or the substance may be part of a group of chemicals considered to be innocuous, the agency cannot dismiss the chemical without considering its application and exposure, he noted.

Even structurally related chemicals may vary in fat solubility, in ability to be broken down by light, or in other characteristics which alter their potential for creating hazards, he said.

Continuing Lack of Data

The agency is trying to find more ways to get data on individual notices. The EPA official noted that after many months of receiving notices, the amount and quality of data received on new chemicals has improved very little.

There are two troubling trends, he said. The first, one which the agency has complained about on numerous occasions, is the lack of test data on new substances. Many of the notices contain no test data and almost none have presented any subchronic or chronic studies, he noted.

Industry is not keeping promises it made to submit information on new chemicals, he said. Some of the submitters, many of them large firms with long-term experience in the chemical industry, have refused to provide use information, he said.

He complained that some of the firms which promised a cooperative effort in submitting PMN information now are refusing to supply basic information.

Industry is shirking responsibility for testing new chemicals, he said, adding that he sees no evidence of a trend indicating industry intends to assume such a responsibility.

Exemption Requests

The second problem facing the agency in the review of the notices is an industry trend to submit a test marketing exemption (TME) request with the premanufacture notice.

Since the TME must be approved or disapproved within 45 days, the agency is forced to perform the review more quickly, he explained.

The trend could lead to instances where the agency lacks evidence at 45 days to disapprove the TME but decides later in the PMN review period to take some regulatory action on the new substance, he noted. If the trend continues, the agency will have to uncouple the two reviews, he said.

In recent weeks EPA has taken several actions to reinforce its position that PMNs and TMEs should include adequate information and test data.

Such efforts include the rejection of some submissions as inadequate. Another is increasing interest in using significant new use rules to require future reporting for substances which complete review without any regulatory action being taken.

Vinyl Chloride

ALCOHOL INCREASES CANCER EFFECTS. UNIVERSITY RESEARCHER TELLS CONFERENCE

Alcohol drinkers may have increased susceptibility to the carcinogenic effects of vinyl chloride vapors, a Government-sponsored conference was told March 20.

Martha Radike, of the University of Cincinnati, reported the results of a study in which laboratory rats were given water containing 5 percent ethanol and were exposed to vinyl chloride.

The animals that received alcohol had a much higher incidence of vinyl-chloride-induced malignant tumors than the rats exposed to vinyl chloride alone, she said.

The test animals were exposed to a concentration of 600 part per million vinyl chloride vapor, four hours each day, five days a week for one year.

Control groups exposed to vinyl chloride alone and to alcohol alone had elevated tumor rates in comparison with a control group not exposed to either substance, Radike reported.

The tumors in the alcohol-only group tended to be benign, rather than malignant, she said.

Radike compared the level of alcohol given to the test animals to a moderate drinking level, similar to a six-pack of beer or a few glasses of wine.

She said the experiment was suggested by the fact that ethanol and vinyl chloride are known to share a step in the metabolic pathway.

Radike suggested that epidemiological studies should be carried out on human populations exposed to vinyl chloride to determine whether chronic alcohol use is related to cancer incidence.

The two-day conference on vinyl chloride toxicity was sponsored by the National Institute of Environmental Health and Safety, the National Institute for Occupational Safety and Health, and the Occupational Safety and Health Administration.

The conferees heard reports from 37 researchers, including Caesar Maltoni of the Institute of Oncology and Tumor Center in Bologna, Italy.

Inhalation Studies

Maltoni reported the results of extensive inhalation studies in rodents at various dose levels ranging from one to 30,000 ppm.

In long-term studies, test rats developed increased incidences of cancer at levels as low as 10 ppm, Maltoni said.

The OSHA standard for worker exposure to vinyl chloride sets a maximum limit of one ppm, averaged over an eight-hour period.

Maltoni's experiments involved exposure of test animals for four hours a day, five days a week, for varying periods.

He reported that the test animals exposed to vinyl chloride suffered a variety of tumors, including cancer of the liver, lung, kidney, stomach, skin, brain, mammarys, and Zymbal's gland.

May Affect Fetus

Maltoni also reported a study suggesting that exposure of a pregnant animal to vinyl chloride can increase the incidence of cancer in her offspring.

He described experiments in which female rats were exposed during pregnancy to vinyl chloride vapors at concentrations of 6,000 and 10,000 ppm.

The offspring of the exposed rats later developed a higher incidence of liver cancer than the offspring of unexposed control rats, Maltoni said.