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Chemical Manufacturers Association

Record of Meeting

CHEMICALS
RESEARCH

MAY 28 1980

VINYL CHLORIDE PROJECT PANEL, RESEARCH COORDINATORS

AND AUDIT TASK GROUP

May 14, 1980

Washington Hilton Hotel
10:00 a.m.

Washington, D.C.
Jackson Room

FK _____
CCM _____
ALL _____
DUR _____
CMS _____
WRBe _____
ATCL _____
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MEMBERS PRESENT

A. G. Wheeler
H. W. Blakeslee
F. Kennedy
T. R. Torkelson
T. J. Benya
R. Park
M. N. Johnson
Z. G. Bell, Jr.
V. L. Kirkland
J. P. Murphy
R. N. Wheeler
R. K. Hinderer
G. K. Hatfield
W. A. Bittenbender
D. M. Serrone (for R. W. McBurney)

ICI Americas, Inc.
Certain-Teed Corporation
Continental Oil Company
Dow Chemical U.S.A.
Ethyl Corporation
Firestone Plastics Company
BFGoodrich Company
PPG Industries, Inc.
Shell Oil Company
Stauffer Chemical Company
Union Carbide Corporation
BFGoodrich Company
Diamond Shamrock Corporation
Borden Chemical
Diamond Shamrock Corporation

J. T. Seawell
H. C. Shah
C. R. Stack
E. B. Frost

CMA Staff
CMA Staff
CMA Staff
CMA Legal Department

MEMBERS ABSENT

W. M. Smith
R. W. Laundrie
P. Cohen
R. J. Abramowitz
R. Brookman
W. D. Harris
C. P. Wen
J. T. Carter
J. Lynch
J. Gabbett
C. A. Johnson
R. B. Judge
S. K. Law
G. Roush, Jr.
P. M. Reed

Air Products and Chemicals, Inc.
General Tire and Rubber Company
Great American Chemical Corporation
Hooker Chemicals and Plastics
Pantasote, Inc.
UNIROYAL, Inc.
Gulf Oil Chemicals, Inc.
BP Chemicals, Ltd.
Exxon Chemical Company
Georgia-Pacific Corporation
Goodyear Tire and Rubber Company
W. R. Grace and Company
Keysor-Century Corporation
Monsanto Company
Tenneco Chemicals, Inc.

PRESENT BY INVITATION

Dr. Carroll
W. M. Busey

Firestone Plastics Company
Experimental Pathology Labs, Inc.

The meeting was called to order by the Panel Chairman, Dr. Ted Torkelson, at 10:05 a.m.

1.0 Review of Dr. Busey's Pathology Report

Copies of Dr. William Busey's histopathology report on all remaining brain tissues from mice, hamsters, and rats exposed to vinyl chloride in the flawed Industrial Bio-Test (IBT) research project were distributed to those present. Dr. Busey made an oral presentation of his findings to the group.

No gross or microscopic alterations were seen in any of the brains examined from the mice and hamsters, however, the number of brains available for examination represented a small percentage (3 - 14%) of the groups exposed at any given dose level. The yield of rat brains was slightly better but did not exceed 23% for any one exposure group.

Histopathological examination of the rat brains revealed olfactory neuroblastomas in seven animals (five males and two females) exposed to vinyl chloride at the highest dose level. This type of tumor is the same as that diagnosed by Maltoni as a "neuroblastoma" and is characterized histologically by pseudo-rosette formation and a high incidence of mitotic figures. In addition, a single glioblastoma multiforme was detected in one male rat exposed at 200 ppm, and a single astrocytoma was found in the brain of a female rat exposed to the same concentration.

Dr. Busey concluded that a causal relationship existed between vinyl chloride exposure and the development of olfactory neuroblastomas, as these tumors rarely occur spontaneously in the rat. No significance could be attached to the single occurrences of the other tumor types found.

2.0 Review of Dr. West's IBT Audit Report

Dr. Bob West's report was distributed to the group and his observations on the IBT study were discussed. Dr. West's audit focused on the recording and monitoring of exposure concentrations, body weight data, mortality logs, hand written observations and correspondence. The report indicated that the study was conducted using poor laboratory techniques. Perhaps the most disturbing finding was substantial

evidence of animal replacement well into the course of the research. Dr. West concluded that the results could only be viewed in qualitative terms and no quantitative analysis of the data is possible.

3.0 Panel Action on Audit Reports

- 3.1 A motion was made to accept Dr. Busey's report as written. The motion was passed unanimously.
- 3.2 A motion was made to accept Dr. West's report with the words "confidential and privileged" removed from each page. The motion passed unanimously.
- 3.3 The Panel moved and agreed to send the reports to:
 - A) Mr. Frank Kover, Chief, Chemical Hazards Identification Branch, EPA, with a cover letter saying that this is the additional material referred to in our letter of March 19. The research is a confirmation of Maltoni's findings and does not merit further study; the Panel will direct its resources at other work. CMA will be negotiating a settlement with IBT along the same lines as that being pursued for trichloroethylene.
 - B) Six Federal Agencies: EPA(Office of Douglas Costle), FDA, NCI, NIOSH, OSHA, and CPSC. This package will include the 23-month status report summary prepared by IBT and Dr. Busey's earlier pathology audit (submitted to CMA January 9, 1979), as well as the two most recent reports of Drs. Busey and West. The cover letter will contain similar information as that stated in A above.

Dr. Zeb Bell, Dr. Ted Torkelson, and CMA staff will prepare the cover letters. Panel approval of the letters is not needed.
- 3.4 Appreciation of the Panel was expressed to both Drs. Busey and West for the expeditious and thorough manner in which they conducted their work. A \$500 cost overrun on Dr. West's contract was unanimously approved.
- 4.0 The Panel was reminded that CMA has no TSCA 8(e) reporting obligation however, submission of the two audit reports to Mr. Kover will, in all likelihood, place them in the 8(e) office and files of EPA.
- 5.0 The Busey and West reports will be sent to IBT and a meeting arranged in the near future. CMA will ask for cost reimbursement of the entire contract.

6.0 Mr. Edward Frost, the CMA General Counsel, related the case pending in Louisiana against Union Carbide in which a cancer patient exposed to acrylonitrile is claiming that he would not have exposed himself to this chemical if he had known of the carcinogenic properties of vinyl chloride. Acrylonitrile and vinyl chloride share a common broad-based chemical structure. The accusation is being made that CMA suppressed vinyl chloride information in the early 1970's. Liskow and Lewis are handling the case for Union Carbide; CMA has no defense funds at present. Mr. Frost will write letters to Counsels of participating companies to make some financial arrangements.

7.0 Epidemiology Study - Environmental Health Associates (EHA)

A copy of Mr. Joe Seawell's letter to Mr. Richard Davis of EHA was distributed to those present. The letter outlined Panel action on a proposal received from EHA on January 15. In order to expedite preparatory work and plans for the evaluation of the current data base, a five-year update of the cohort, and a brain case control study, it was suggested that a meeting be arranged at EHA. Those participating would include CMA staff, EHA staff, Project Panel representatives, and individuals involved with the original study done by Equitable Environmental Health. A motion was made to this effect and passed unanimously.

8.0 Dr. Torkelson spoke briefly on the possible reason for OSHA's concern over vinyl chloride at this time. It was speculated that rule-making on polyvinyl chloride is possible. Dr. Stack mentioned that the two University of Louisville annual reports were submitted to OSHA in response to their request (Federal Register, December '79) for information on vinyl chloride and polyvinyl chloride. The reports were also sent to five other Federal agencies at this time.

The meeting was adjourned at 12:00 noon.

5/21/80

Carol R. Stack, Ph.D.
Project Administrator
Vinyl Chloride



CRS:md
Enclosures: Revised final reports
from Drs. Busey and West

Record Subject to Approval
May 21, 1980