

MCA

MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D. C. 20009 (202) 483-6126

April 17, 1974

To: TECHNICAL TASK GROUP ON VINYL CHLORIDE RESEARCH

Subject: Report on Conference with Industrial BIO-  
TEST Laboratories, April 15, 1974

Gentlemen:

As a result of the telephoned information received by MCA from Industrial BIO-TEST personnel last week, a conference at the Northbrook, Illinois offices of IBT was set up at which an oral status report on the chronic inhalation studies with vinyl chloride was presented to MCA, industry and federal agency representatives.

Those in attendance, and their affiliations, are shown below:

|                     |                                          |
|---------------------|------------------------------------------|
| Z. G. Bell, Jr.     | PPG Industries, Inc.                     |
| A. S. Cummin        | Borden, Inc.                             |
| E. J. Fairchild     | NIOSH                                    |
| J. W. Goode         | Industrial BIO-TEST Laboratories         |
| D. E. Gordon        | Industrial BIO-TEST Laboratories         |
| W. D. Harris        | UNIROYAL, Inc.                           |
| M. N. Johnson, M.D. | The B. F. Goodrich Company               |
| Flynt Kennedy       | Continental Oil Company                  |
| M. L. Keplinger     | Industrial BIO-TEST Laboratories         |
| R. J. Kociba        | The Dow Chemical Company                 |
| H. L. Kusnetz       | Shell Oil Company                        |
| D. V. Lassiter      | OSHA                                     |
| W. E. Rinehart      | Ethyl Corporation                        |
| W. M. Smith         | Air Products & Chemicals, Inc.           |
| J. F. Stara         | U. S. Environmental Protection<br>Agency |
| T. R. Torkelson     | The Dow Chemical Company                 |
| R. N. Wheeler       | Union Carbide Corporation                |
| B. M. G. Zwicker    | B. F. Goodrich Chemical Company          |
| R. F. Blewitt       | MCA                                      |
| A. C. Clark         | MCA                                      |
| K. D. Johnson       | MCA                                      |

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Dr. Goode first presented the mortality data and gross observations, and then Dr. Gordon described the pathology observed in the mice. The data, as presented, are shown in the attached tables. There are apparent discrepancies between the total mortality data and the detailed listing of recent deaths. These will be resolved. No test-related pathology has yet been noted in any animals other than mice.

Dr. Fairchild, of NIOSH, reported that Dr. David Rall, of HEW, had appointed a committee to coordinate departmental toxicology and related programs, and that under this committee there has been named a subcommittee to develop a "white paper" on guidelines for research to determine "socially acceptable" levels of risk. A report from this subcommittee, which will cover both philosophical and statistical considerations, is expected in the next few weeks.

Dr. Stara expressed the view that the vinyl chloride problem presented industry with a unique opportunity to seek to demonstrate a "no effect level" of a human carcinogen with a sensitive animal model of well-documented validity.

Dr. Lassiter expressed a guarded judgment that the mouse data reported by IBT would not lead OSHA to modify the emergency temporary standard, but that it might well cause OSHA to accelerate the rule-making process for the development of a permanent standard.

Dr. Lassiter also reported briefly on the retrospective morbidity and mortality studies being conducted by NIOSH/CDC at nine or ten locations (six companies) around the country. No epidemiological data were presented.

In an afternoon session of the Research Coordinators, it was agreed that the exposure of the mice in the present project should be terminated at nine months, but that exposures of both rats and hamsters should proceed for the initially-planned twelve months.

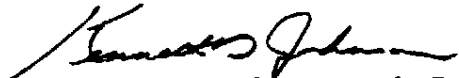
It was further moved, seconded and carried that the chairman appoint a group to begin investigating the cost and availability of facilities of new experiments to be conducted at lower levels of exposure, with larger groups of animals. He was asked specifically to seek to encourage the National Center for Toxicological Research, at Pine

Bluff, Arkansas, to offer to undertake such a program. Details of the test protocol are to be left open until after the Rall committee makes its report available.

The Research Coordinators asked MCA to call a meeting of the Technical Task Group on Vinyl Chloride Research as soon as the report of Tabershaw-Cooper Associates on their epidemiological study reaches them.

A copy of the MCA news release reporting the Industrial BIO-TEST mouse data has been sent to you in this morning's mail.

Sincerely,



Kenneth D. Johnson, Ph.D.  
Secretary  
Technical Task Group on  
Vinyl Chloride Research

KDJ:mb

Tables Attached

cc : Mr. A. W. Barnes  
D. P. Duffield, M.D.  
Dr. Tiziano Garlanda  
Vinyl Chloride Management Contacts



TABLE 1

Mouse Mortality Data

| DATE              | GROUP           |          |           |          |            |          |             |          |
|-------------------|-----------------|----------|-----------|----------|------------|----------|-------------|----------|
|                   | <u>Controls</u> |          | <u>TI</u> |          | <u>TII</u> |          | <u>TIII</u> |          |
|                   | <u>F</u>        | <u>M</u> | <u>F</u>  | <u>M</u> | <u>F</u>   | <u>M</u> | <u>F</u>    | <u>M</u> |
| February 10, 1974 | 2               | 8        | 6         | 26       | 2          | 4        | 7           | 8        |
| April 12, 1974    | 5               | 11       | 9         | 31       | 13         | 7        | 13          | 18       |

*Industrial BIO-TEST Laboratories, Inc.*

1810 FRONTAGE ROAD

NORTHBROOK, ILLINOIS 60062

TABLE II

Summary of Tumors in Vinyl Chloride Exposed Mice

IBT Number 663-03222-MCA

| <u>Group, Animal No., Sex</u> | <u>Histopathologic Findings</u>     |              |                                                       | <u>Date of Death</u> |
|-------------------------------|-------------------------------------|--------------|-------------------------------------------------------|----------------------|
|                               | <u>Lung</u>                         | <u>Liver</u> | <u>Skin</u>                                           |                      |
| T-I                           |                                     |              |                                                       |                      |
| 1023 Male                     | AA (s)*                             | HS (s)**     | ***                                                   |                      |
| 1110 Female                   | AA (s), Metastatic<br>Skin Tumor    |              | EC (para-aural)                                       | 3-20-74              |
| 1119 Female                   |                                     | HS (s)       |                                                       | 3-24-74              |
| 1200 Female                   | Metastatic Skin<br>Tumor            |              | EC & MC+ (Femoral<br>region)                          | 3-30-74              |
| T-II                          |                                     |              |                                                       |                      |
| 1347 Female                   | Metastatic Skin<br>Tumor            |              | EC (Abdomen)                                          | 3-5-74               |
| 1309 Female                   |                                     | HS (s)       |                                                       | 3-18-74              |
| 1889 Male                     | AA (s)                              | HS           |                                                       | 3-25-74              |
| 1382 Female                   |                                     | HS (s)       |                                                       | 4-2-74               |
| 1350 Female                   | AA (s)                              | HS (s)       |                                                       | 4-5-74               |
| 1299 Female                   | AA (s)                              |              | EC & MC (Inguinal<br>Region)                          | 4-9-74               |
| T-III                         |                                     |              |                                                       |                      |
| 1538 Female                   | AA (s)                              | HS (s)       |                                                       | 3-6-74               |
| 1532 Female                   | AA (s)                              |              | LS⊕                                                   | 3-7-74               |
| 1562 Female                   | AA (s)                              | HS (s)       |                                                       | 3-8-74               |
| 1598 Female                   | AA (s)                              | HS (s)       |                                                       |                      |
| 1405 Male                     | AA (s)                              | HS (s)       |                                                       | 2-25-74              |
| 1494 Male                     | AA (s)                              | HS (s)       |                                                       | 3-22-74              |
| 1574 Female                   | AA (s)                              | HS (s)       |                                                       | 3-22-74              |
| 1531 Female                   |                                     | HS (s)       | EC & MC (Femoral<br>region)                           | 3-23-74              |
| 1588 Female                   |                                     | HS (s)       |                                                       | 3-25-74              |
| 1593 Female                   | AA (s)                              | HS (s)       |                                                       | 3-30-74              |
| 1505 Female                   | AA (s)                              | HS (s)       |                                                       | 4-3-74               |
| 1565 Female                   | AA (s)                              | HS (s)       |                                                       | 4-3-74               |
| 1409 Male                     | AA (s)                              | HS (s)       |                                                       | 4-5-74               |
| 1543 Female                   | AA (s)                              | HS (s)       |                                                       | 4-5-74               |
| 1544 Female                   | AA (S)                              | HS           |                                                       | 4-5-74               |
| 1546 Female                   | AA (s)                              | HS (s)       | MC (Axillary<br>region)                               | 4-5-74               |
| 1535 Female                   | AA (s)                              | HS (s)       |                                                       | 4-7-74               |
| 1432 Male                     | AA (s)                              |              |                                                       | 4-8-74               |
| 1477 Female                   | AA (s)<br>Metastatic Skin<br>Tumor? | HS (s)       | EC (Para-Aural)<br>MC (Abdomen)<br>EC (Pelvic region) | 4-9-74               |

TABLE III

*Industrial BIO-TEST Laboratories, Inc.*

1810 FRONTAGE ROAD  
NORTHBROOK, ILLINOIS 60062

Summary of Mortality & Tumor Data Among Vinyl Chloride Mice  
IBT Number 663-03222 (MCA)

| Group | No. Mortalities with Neoplasms | Location of Tumors |            |                        |
|-------|--------------------------------|--------------------|------------|------------------------|
|       |                                | Lung               | Liver      | Skin Metastasis → Lung |
| T-I   | 4 (1 Male, 3 Females)          | 2(50%)             | 2(50%)     | 2(50%) 2               |
| T-II  | 6 (1 Male, 5 Females)          | 3(50%)             | 4(66.7%)   | 2(33%) 1               |
| T-III | 19 (4 Males, 15 Females)       | 17(89.5%)          | 17(89.5 %) | 3(15.8%)               |

Key to Symbols

- \* Alveologenic Adenoma of Lung (AA)
- \*\* Hemangiosarcoma of Liver (HS)
- \*\*\* Epidermoid Carcinoma of Skin (EC)
- + Mammary Carcinoma of Skin (MC)
- ⊕ Lymphosarcoma of Thymus
- (s) Multiple tumors of indicated type

