November 12, 1964

Dr. J. Newman
33880 Lake Road
Avon Lake, Ohio

CONFIDENTIAL

Dear Doctor Newman:

We have recently observed several cases of hand disabilities in one of our plants, the cause of which is as yet unknown. We would like to determine as quietly as possible whether similar disabilities might exist in the Avon Lake Plant, and for this reason I would like to have you casually examine our employees' hands as a part of any other medical service you provide to them.

Specifically, the disability that we have seen is characterized by soreness of the tips of the fingers. Roentgenography of the hand has demonstrated bone changes, particularly bone resorption, in the distal phalangeal joints. In some cases this is quite marked. Blanching of the skin from decreased temperature is prevalent. Several of the cases exhibit fibrous rope-like dermatological changes of the hands. The disability has been described by several consultants as Raynaud's Phenomenon. In one instance it was called Scleroderma. The presenting symptoms do not clearly fit the classical description of either of these diseases.

I would like you to make careful observations of the hands of our employees as you see them for any reason. If you observe any soreness in the tips or any symptoms similar to those that I have described, will you please make a careful notation of the job assignment of the individual as well as his work history with the Company. As yet, we have no firm opinion that the disabilities we have seen are occupational in origin. We are investigating this matter and hope to eventually resolve this question. A logical avenue of investigation is to obtain as much information as we can about our own employees.

I would appreciate your proceeding with this problem as rapidly as possible, but doing it incidentally to other examinations of our personnel. We do not wish to have this discussed at all, and I request that you maintain this information in confidence. Will you please advise me by January 1, the approximate number of hands that you have seen and of any positive findings.

Sincerely yours,

Rex H. Wilson, M.D.

RHW/js

cc: O.F. Beckmeyer
A. Vittone
W.W. Baughman

2638?001
BFG50759

St. Louis - General Offices

January 6, 1966

B. F. Goodrich Chemical--
PVC Health Problem

F. E. Reese
L. W. Sessions
B. L. Williams
C. L. Knowles
J. M. Chamberlin

Mr. Proc Avon
PAVON

Confidential

This will record some of the comments made to me by Harry Warner, Corporate Vice President of B. F. Goodrich and ex President of B. F. Goodrich Chemical, in the Cleveland airport mid-December concerning their health problem involving PVC.

In addition to merely confirming the seriousness with which Goodrich management considers their health problem with PVC, Mr. Warner stated that not only had they observed the severe dermatitis problem now showing more serious effect in some employees' hands, including some drawing and fixation of the joints of the hands, but that they are also concerned that some effect can be detected to employees who have never been involved specifically with the cleaning of the interior of their polymerization reactors, but who have merely worked in the area of vinyl polymerization. In fact, Mr. Warner stated that this phenomena was first noticed, as far as he can remember, when he was a plant manager several years ago.

He reported that recently they had taken some X-rays which is the means of detection of the bone structure of employees' hands. Apparently an M.D., expert in this field from Brussels, when observing the X-rays stated categorically that the damage to the bone tips to him indicated that these people had been working around PVC. This doctor, and I don't have his name, has had similar experience in Europe with Solvay, and stated that he was about to publish an article covering this phenomenon. Goodrich was concerned enough about the response to such a published article that Mr. Warner attempted to have one of their representatives, who was in Europe, stop by and try to discourage or to influence the wording of such an article to be sure that it didn't condemn PVC in general. He was unsuccessful in catching their representative but their man from Hague has been in Brussels and talked to this Solvay doctor. Perhaps jointly, for consultation as well as to discourage or edit the publication, Goodrich is sending a team of either two or three men to Brussels next week to be with this doctor.

011-1966-00003926

RSV 0009169

Vinyl Chloride
Digital Process Instruments, Litigation Support
(504) 522-1910

As Mr. Warner described it, the bone endings appear to have experienced some of the same symptoms similar to the astronauts with an apparent loss of calcium from the ends of the bones. The fact that this has been noticed with employees who have not been involved with kettle cleaning may explain the lack of action you have been getting from Goodrich on our kettle cleaning license.

I expressed concern in the general area and assured Mr. Warner that with Monsanto Europe's headquarters being in Brussels, if they were unsuccessful or if assistance from us in this area would be helpful, we would be happy to cooperate with Goodrich in trying to be sure that the Solvay doctor publication is not condemning to PVC per se.

Mr. Warner also suggested that if we had not done so, we might wish to have a random group of employees who have been exposed to PVC manufacture for some time X-rayed to detect whether or not there appeared to be any bone damage. I am sure Messrs. Reese, Chamberlin, et al, will want to consider whether or not this should be done from a safety-union relationship, et al, standpoint.

J. V. Waggoner

/je

1/6/66.1 VCT2 RSV 9169 - 9170
011-1966-00003927
Page Number 002 Acro 1;Rail 3
Baggett, McCall & Burgess

RSV 0009170

St. Louis

January 7, 1966

PVC EXPOSURE

J. M. Chamberlin - JCHAM
S. L. Hunter - SHUNT
W. E. Nessell - SPRINGFIELD
G. W. Ingle - SPRINGFIELD
F. E. Reese - FREES
J. V. Waggoner - JWAGG
P. H. Avon - PAVON

FILE

Mr. A. G. Erdmen
SPRINGFIELD

Dr. William Nessell, Springfield Plant, and I attended a meeting at B. F. Goodrich in Akron yesterday. Those attending for Goodrich were:

Dr. Rex Wilson, Medical Director
Mr. William McCormick, Manager Industrial Hygiene & Toxicology
Mr. M. Miller, Vice President of Personnel

The purpose of the discussion was for Goodrich to relate to us their experience with the workers in their various vinyl chloride polymerizing plants.

In brief, Goodrich has 22 people who have either symptoms of painful hands and/or absorption of the bone in the distal parts of the fingers to a greater or lesser degree. While approximately 6 or 7 of these have developed symptoms and have come into the dispensary, the others have been found as a result of an X-ray program which has seen 800 workers in Goodrich's polyvinyl chloride plants having their hands X-rayed. Another 1200 are scheduled within the next two months for such X-rays.

These cases have occurred as follows:

Avon	8
Henry	2
Welland & Niagara Falls	4
Louisville	8

All but one were cleaners of the poly kettles. This exception was a chemist. Goodrich has paid compensation on some of the cases, and 5 of them are being represented by a lawyer. The first case was discovered about 18 months ago.

There is at present no clue as to the cause. No one knows whether monomer is indicted but Goodrich is eventually going to X-ray workers in these installations also. No one knows whether this is local absorption, inhalation, exposure to plasticizers, or what. Goodrich has explained this same situation to Union Carbide and that company's response was much like ours. "We don't think we have any cases but we will look."

What Monsanto should do is X-ray the people who are presently working in the PVC polymerization room at Springfield. I am sure Dr. Nessell can prepare these people with an adequate story so that no problem will exist. Depending upon what happens following this X-raying, we will have to see what our next step is.

RSV 0009171

I am to keep in contact with Goodrich. At present their Hector Wilson is on his way to Brussels to see if he can stop a publication of a paper by a Solvay doctor who allegedly had at least two cases occur in a Solvay plant which exhibited the same bone destruction that occurred in the Goodrich cases.

While this is not completely hush hush, I think discretion should be used to prevent any undue talking, and the name of Goodrich should be kept in the background.

R. Emmet Kelly, M. D.

REK/ln

MEETING PVC RESIN PRODUCERS
AT
CLEVELAND ENGINEERING SOCIETY
UNDER THE SPONSORSHIP OF
MCA AND B. F. GOODRICH CHEMICAL COMPANY

OCTOBER 6, 1966

Attendees: (See attachment)

Mr. F. H. Carman - MCA

1. MCA normally sets up functional rather than product-oriented committees. This group is an exception and required authorization by Board of Directors.

2. All policy statements, press releases, etc. must be handled by MCA. The committee on Occupational Health may issue no statements of its own accord.

3. Meetings other than this one are not recognized by MCA.

Dr. Rex Wilson & Mr. William McCormick - B. F. Goodrich Company

Several years ago one of the plants noted a case of an employee having soreness of finger tips. Further examination showed bone damage in the fingers.

They have since X-rayed all personnel in PVC plants. This showed one percent of all people examined had some damage; six percent of PVC pot cleaners were affected. Personnel in the Cleveland Office and one Rubber Plant were examined without finding any similar damage. Currently, they have identified thirty cases—two not connected with PVC. Two cases showed external ulceration; four showed scleroderma.

Affected personnel were assigned to other work. On repeated examination most showed improvement with some new bone tissue formed. Improvement was not uniform throughout the group.

Communication with some U. S. companies and foreign companies showed one foreign company had a number of similar cases which they thought was related to vinyl chloride intoxication.

011-1966-00003968

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Vinyl Chloride
Digital Process Innovations, Litigation Support
(504) 522-1950

B. F. Goodrich has used consultants and medical school research facilities to study disease. Various theories are as follows:

1. May be a change in collagen tissue resulting in failure to hold calcium.

2. May be polymerization of VC in body (not too likely).

3. May be a systemic disease as opposed to a purely localized disease (fingers).

B. F. Goodrich's program, based on findings, is as follows:

1. All new employees are given hand X-ray examinations.

2. PVC pot cleaners will be required to wear gloves (PVC coated). Other type gloves are being studied for permeability.

3. Plant personnel are being X-rayed every six months.

4. Employee information:

   Plant physician has told those affected of the disease. They are considered Compensation cases. They are given copies of examination findings for transmission to their own doctors. Other personnel have been told there is a medical problem and the cause is not known. People are aware it is in the PVC pot cleaning area. No lost-time injuries have resulted from disease yet. One case involved sympathectomy to make hands warm.

5. Personnel affected by the disease are transferred to other work. There is no complaint from unions or people and no reluctance to clean PVC pots.

6. Further studies are planned though this is complicated by the fact that no animal exhibits Raynaud's phenomena. Collagen tissue studies will be made. They are worried about possible long-term effect on body tissue, especially if it proves to be systemic.

B. F. Goodrich is sharing its knowledge with all PVC manufacturers. They hope all will use discretion in making the problem public. Any new findings should be communicated to the MCA Occupational Health Committee or to Dr. Rex Wilson of B. F. Goodrich Company. They would read any X-rays supplied them without charge. They particularly want to avoid exposés like Silent Spring and Unsafe at Any Speed.

011-1966-00003970

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(504) 522-1950

B.F.GOODRICH CHEMICAL COMPANY
Inter-Organization Correspondence

To: W.E. McCormick — Date: March 24, 1969

Location: Akron — From: L.B. Crider

Subject: Some New Information on the Relative Toxicity of Vinyl Chloride Monomer

CONFIDENTIAL

Our continuing search of the literature for information concerning the toxicity of vinyl chloride monomer has revealed that a considerable amount of work has been done in Europe that we were not aware of. A summary of this work was presented at a Symposium on Aerosols in England in 1961 and subsequently published in Aerosol Age (April, 1964 p. 44). In this work a comparison was made of the relative toxicity of vinyl chloride monomer with other commonly used aerosol propellants. In general, VCl monomer was found to be less toxic than Freon 11, Freon 12, and Freon 114.

These conclusions were based on animal tests at Battelle Institute in Frankfort. These tests included 100 day exposures of mice, rats and guineapigs at concentrations of 0.5, 1.5 and 5.0% VCl by volume. Including the controls, 120 animals of each type (in groups of 10) were exposed 2 hours daily for 100 days. These tests showed the following results;

1. No deviations from normal conditions appeared up to 1.5% by volume of VCl monomer. Inhalation of 5% by volume of VCl at first increased the mobility of the animals. With repeated exposures, however, this did not occur.

2. Growth function was not influenced at all.

3. The blood patterns of all animals was normal.

4. The autopsy of all test animals showed no morphological changes.

Another series of tests were also carried out at Battelle using vinyl chloride monomer as a propellant in a shellac-based hairspray. Three groups of white mice were sprayed 30 seconds daily for 5 weeks. The animals were closely observed and dissected after the tests. Again, the autopsies showed no morphological changes.

Another study at Battelle was to investigate the amount of toxic gases produced from the burning of halogenated hydrocarbons. The thermal decomposition of vinyl chloride, Freon 11, Freon 12 and Freon 114 was carried out in the presences of O_2 at temperatures between 100-1000°C. The amounts of carbon monoxide, phosgene and HCl produced at 1000°C. were measured:

	CO	$COCl_2$	HCl
1g Vinyl Chloride ⟶	39.5mg +	0.11mg	+102mg
1g Propellant 11 ⟶	1.5mg +	7.00mg	+94mg
1g Propellant 12 ⟶	1.5mg +	2.40mg	+79mg
1g Propellant 114 ⟶	0.8mg +	12.00mg	+59mg

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EXHIBIT
22
Creech

The propellants tested were only partially decomposed by the method used. The results do show, however, that the amount of phosgene produced from VCl monomer is much lower than the other propellants. With complete burning of 100 grams of VCl gas in a flame at 1000°C in a room having a capacity of 50 M^3 the concentration of phosgene would be 0.05 ppm, well below the ppm MAC. Vinyl chloride monomer is the only halogenated propellant that passes this test where the combustion products are below the MAC for carbonyl halide.

The relatively low toxicity of VCl monomer as shown by the work at Battelle in Europe has certainly had some influence on it wide acceptance as an aerosal propellant. About 20 M#'s/yr of VCl monomer is now being used in aerosol products. BFG sales for end use in aerosol propellants amounts to 1.5 M #'s/year.

The people in the cosmetics trade have been concerned about the possible toxicity of these propellants. Some calculations have been made to show the concentration of propellant in a typical small hair dressers room. When VCl monomer is used as the propellant in a hairspray and the operator treats 20 customers in an 8 hour period the average concentration of VCl monomer is 250 ppm by volume. In some cases where the duration of spraying is long (3 minutes) the concentration may be as high as 1400 ppm. All of this suggests that beauty operators may be exposed to concentrations of VCl monomer equal to or greater than the level in our polys.

I feel that the work at Battelle is most significant with respect to our over all concern about the toxicity of VCl monomer and its possible implication in causing decalcification of bone tissue. They had a total of 360 test animals exposed for 100 days to monomer levels much higher than any of our testing at Kettering. I have asked Bob Meyer to contact the appropriate people at Battelle in Frankfort to obtain the complete details of their study.

Now to a slightly different subject. I have talked to the people in monomer sales about the use of trace inhibitors in VCl monomer. Two of our monomer customers, Hooker and Pansasote, are now using inhibitors. Hooker is using 2 ppm of phenol in their bulk polymerization process. In their aqueous systems they use the same level of hydroquinone. Pansasote is using 25 ppm of phenol as an inhibitor in their monomer. It might be worthwhile to check with Dr. Dinman to see if these two companies were included in the MCA survey and if they showed lower incidence of the hand problem.

If you would like more details on the use of VCl monomer in aerosol propellant or the use of trace inhibitors in VCl monomer I would suggest that you contact Jim Wolff or Bill Schloenbach in our monomer sales group in Cleveland.

L.B. Crider

cc: O.F. Beckmeyer
J.E. Jansen
C.H. Lufter
J.L. Nelson - E.W. Harrington
F.L. Ramp
Dr. R.H Wilson
R.D. Scott
R.J. Wolf
B.M.G. Zwicker
Technical Council
File (2)

BFG40157

dmr

MCA MANUFACTURING CHEMISTS ASSOCIATION
1825 CONNECTICUT AVENUE, N. W. • WASHINGTON, D. C. 20009 • (202) 483-6126

Report of

Meeting - May 6, 1969
PVC Resin Producers Representatives
University of Michigan Epidemiologic Study
Washington, D. C.

This meeting under the auspices of the Association's Occupational Health Committee was held at the University Club. A list of representatives from sponsoring companies and the University of Michigan Institute of Industrial Health is attached.

Committee Chairman, Dr. C. U. Dernehl opened the meeting with a brief outline of the project program to date, the general objectives, a short discussion of the complexity of the problem, and interpretation of the findings. He then presented recommendations of the Occupation Health Committee (OHC) which had considered the report in a meeting April 30.

The Committee recommended the following changes in the "recommendations" which appear on page 104 of the report supplied to all producer representatives:

(a) RECOMMENDATION 1

Eliminate the last sentence "Where it is necessary for workers to enter the reactor tanks, sufficient ventilation should be provided to reduce the vinyl chloride concentration below 50 ppm." Insert in its place "Where it is necessary for workers to enter the reactor tanks adequate ventilation should be provided. Inasmuch as the etiologic agent of the disease is unknown, a level of vinyl chloride below 50 ppm should be used as an index of adequate ventilation."

(b) RECOMMENDATION 3

Change word "continued" to "supported"

UCC
002602

MEMORANDUM

November 20, 1972

CONFIDENTIAL

RECEIVED
NOV 20 1972
LEGAL DEPT.

MEMO TO: Mr. J. C. Fedoruk
Mr. A. P. McGuire

FROM: W. A. Knapp

There was considerable confusion at this meeting as to agreement to retain confidentiality of the data. When Dr. Harris arrived in Italy, it was discovered that Mr. Best's (MCA) agreement with Mr. Lindsell (ICI, Director of European Monomer Group) was not satisfactory. Consequently, Dr. Harris was shown the equipment and given only the test protocol, not the results. The protocol is attached.

At our meeting, a few wanted limitations placed on confidentiality (particularly as it may relate to disclosure requirements in Food Additive petitions) but most thought disclosure restrictions a detail, difficulties concerning which were very unlikely to occur. After rather weak reassurances, Mr. Don M. Elliot (ICI) decided that he would take it upon himself to disclose what he knew. He requested that no notes be taken (which request was honored) so that summary of results attached may be subject to some inaccuracies but is generally correct. Further, with respect to confidentiality of data, it is reported that a Dr. Caputo at the Univ. of Florence (a cohort of Dr. Viola?) will present a continuation of Dr. Viola's results at a meeting in 1974 which will thereby reduce confidentiality of results. Apparently, Dr. Viola's presentation at Houston about 2 years ago was made without Solvay's permission that Europeans are very sensitive about disclosure conditions.

The major disclosure is that substantial numbers of tumors were formed at 10,000 ppm and single tumors at concentrations as low as 500 and 250 ppm. It is to be noted that exposures were for one year and are now completed except where replacements were made for early deaths. How many such replacements were necessary was not clear. The fact is exposures have been completed and animals are now being retained awaiting death from whatever cause. One thing not clear in the protocol is whether food and water for the

Mr. J. C. Fedoruk
Mr. A. P. McGuire

animals remained in the cage during the exposure period; the animals were apparently not removed from exposure chambers between exposures. It is the feeling of the writer that absorption on fur and subsequent licking plus solution of gas in water or in fat component of food can be the greatest source of intake and must be monitored if results are to be meaningful. Many questions with respect to protocol and results could not be answered.

To the most knowledgeable people, the results were sufficiently disconcerting to prompt immediate reconsideration of the U.S. Industry Program. Accordingly, the Task Force was to meet directly following our session. Among things to be reconsidered are metabolism studies and the epidemiology deleted from first program because of cost.

Recipients of this memorandum are reminded that by agreement with the European Group, we will exert every reasonable effort to retain contents in strict confidence within company personnel. To this end, it is requested that disclosure not be made beyond recipients of this memorandum without prior notice to the writer. Only this will reasonably retain the strict confidentiality required.

W. A. Knapp

WAK:md

cc: Mr. W. S. Ferguson
Mr. H. L. Noble
Mr. S. R. Stevinson

ASI 000013836

A. Vittone, Jr. January 9, 1973

PROPOSED MCA EPIDEMIOLOGICAL STUDY

I have contacted the addressees on this subject after having sent the attached memo. The responses have been affirmative with the following provisos:

(1) A high percentage of industry participation.

(2) Appropriate design of the study (steering committee responsibility after MCA receives proposals).

(3) Reasonable total cost and fair BFG share cost.

(4) Avoid triggering problems with our employees by pinpointing the reason for the study - George Pow suggested that they avoid interviews if possible, and if not, make it "general health" and logical - maybe an extension of the hand problem studies.

I have prepared a suggested reply to George Best which I have cleared with Bill McCormick.

BMGZ:kcd

B. M. G. Zwicker

cc: W. E. McCormick

BFG37629

ACGIH1;V 2

vcm+/c

ALLIED CHEMICAL CORPORATI

MEMORANDUM

March 1, 1973

MEMO TO: Mr. W. S. Ferguson

FROM: W. A. Knapp

SUBJECT: Vinyl Chloride Monomer (VCM)

Pursuant to your request, the following is a brief summary of status of industry supported MCA studies and of propellant use of VCM.

With respect to MCA study, a delegation headed by Dr. Torkleson (Dow) visited the European toxicology project at Milan and reported satisfaction with work but a question concerning exposure of food and bedding to the toxicant, a practice not practiced in inhalation studies here. To resolve this question, the MCA study will include one group of animals (highest inhalation level only) with food and bedding similarly exposed. Present MCA study to be conducted by Industrial Biotest now includes 12 month inhalation to 5000, 500 and 50 ppm with three species (mice, rats and hamsters). Some 2400+ animals will be used.

Four epidemiological consultants were invited to the February 20 meeting to explore possibilities and costs in this area. They were Tabershaw, Harvard, a Nebraska firm represented by Dr. John Keller and U. of Mich. represented by Dr. Ralph Smith. The most recent results of Italian study were not disclosed to the consultants, the concern of the industry being based on the original Viola article and the expectation that Dr. Viola will have further results at a symposium to be held in the fall of 1974. There is also the possibility that TLV for vinyl chloride may be further lowered based on the Torkleson et al work of 1961 (Am. Ind. Hyg. Assoc. J. 22, 354-61 (1961).

The epidemiologists were requested to submit programs by March 9 and an MCA meeting arranged shortly thereafter, possibly on March 13.

Concerning use of VCM as aerosol propellant, it was opinion of those present (Research Coordinators) at the January 30 meeting that serious consideration should be given to withdrawal from this market since value of market was limited and potential for liability great. The TLV is now reduced to 200 ppm and there is a probability that this will be reduced further. It is not reasonable to recommend propellants with low TLV's. The writer believes that a decision to suspend sale should be executed by personal visits to substantial fillers (or marketers) using this propellant.

At present, SCD purchases aerosol grade VCM from Dow on a swap arrangement and from Ethyl Corperation. ICD product is not suitable for aerosol use due to very low concentrations (ppm) of butadiene and/or butenes which polymerize.

W. A. Knapp

WAK:md

cc: Mr. E. W. Callahan

Manufacturing Chemists Association

Minutes of Meeting

VINYL CHLORIDE RESEARCH COORDINATORS

MCA Conference Room Washington, D. C.

May 21, 1973

MEMBERS PRESENT:

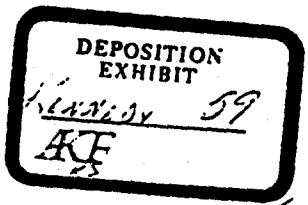
T. R. Torkelson, CHAIRMAN	The Dow Chemical Company
T. R. Aalto for Marvin Rosen	Tenneco Chemicals, Inc.
Z. G. Bell, Jr.	PPG Industries, Inc.
F. J. Doyle for A. B. Lindquist	Stauffer Chemical Company
M. N. Johnson, M. D.	The B. F. Goodrich Company
Flynt Kennedy	Continental Oil Company
W. A. Knapp	Allied Chemical Corporation
R. W. McBurney, M. D.	Diamond Shamrock Corporation
W. W. Madden	Firestone Plastics Company
R. L. Maycock	Shell Chemical Company
W. E. Rinehart	Ethyl Corporation
W. M. Smith	Air Products & Chemicals, Inc.
R. N. Wheeler	Union Carbide Corporation

OBSERVERS PRESENT:

C. H. Dernehl, M. D.	Union Carbide Corporation
D. P. Duffield, M. D.	ICI, Mond Division
W. S. Ferguson	Allied Chemical Corporation
D. A. Rausch	The Dow Chemical Company
B. M. G. Zwicker	B. F. Goodrich Chemical Company

MCA STAFF PRESENT:

B. M. Barackman	MCA
A. C. Clark	MCA
K. D. Johnson	MCA



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CONFIDENTIAL

The meeting was called to develop recommendations of the Task Group with regard to a proposed presentation of data to the National Institute for Occupational Safety and Health and a discussion with them of occupational health hazards associated with vinyl chloride.

The initial discussion centered around such a conference, and the timing therefor. Tacit approval of such a concept had been assumed from the lack of unfavorable response to the MCA letter of March 26, 1973, and this judgment was confirmed by telephone discussions with major producers. Final action of the management contacts regarding the presentation is not contemplated until they have received and studied the recommendations of the Technical Task Group on Vinyl Chloride Research.

A significant element for consideration by the Task Group was the development of an alternate presentation in the event that the release of European data cannot be negotiated with reasonable dispatch. All present agreed that, if at all possible, such release be secured before the proposed NIOSH conference, so that this information can be included.

Staff counsel briefed the Task Group on thier responsibilities and obligations under the confidentiality agreements now operative between MCA and the sponsors of the present project on the one hand, and the European group on the other. In brief, his admonishments were to the effect that absent permission from the European group, we should not volunteer reference to the European project or substantive data derived therefrom, but that, in response to direct inquiry, we could not deny awareness of the project and knowledge concerning certain preliminary results.

The scope of the proposed conference was discussed at length. The Task Group proposed to present published industry production and use data in terms of quantities involved, without a breakdown by percentages of the various uses, and without attempting to account for minor uses or losses. Attention is to be focused on monomer production and the manufacture of polymers, and on the occupational health hazards associated with these operations. It was judged that possible consumer safety and

VVC 000006756

related potential hazards would not be pertinent to a presentation to NIOSH which is concerned with employee health matters.

The proposed discussion outline distributed with the meeting notice next received the attention of the Task Group. A revised outline; amended to reflect the technical recommendations of the Task Group, was subsequently edited by your Chairman and distributed under separate cover.

Respectfully submitted,

Kenneth D. Johnson, Ph.D.
Secretary

KDJ:mb
July 6, 1973
Minutes Subject to Approval

C O N F I D E N T I A L

C O N F I D E N T I A L

Notes on Meeting
between representatives of
MCA Technical Task Group on Vinyl Chloride Research
and
National Institute for Occupational Safety and Health (NIOSH)
Rockville, Maryland July 17, 1973

Participants

For MCA:

Dr. W. E. Rinehart
(Ethyl Corporation)

Dr. V. K. Rowe
(The Dow Chemical Company)

Mr. R. N. Wheeler
(Union Carbide Corporation)

Mr. George E. Best
(MCA Staff)

As liaison representative from
the European Group project
sponsors:

Dr. David P. Duffield
(Imperial Chemical Industries)

For NIOSH:

Dr. Marcus M. Key, Director

Dr. Keith Jacobson

Mr. Richard B. James

Dr. Donald Lassiter

Dr. Frank Mitchell

Advance arrangements for this meeting were made by Mr. Best with Mr. Edward J. Baier, NIOSH Deputy Director, details having been handled for him by Dr. Herbert Christensen, an associate of Dr. Charles H. Powell, NIOSH Assistant Director for Research and Standards Development. Its purpose was to inform NIOSH as an agency of the U. S. Government regarding the program concerning the toxicology of vinyl chloride being administered by MCA on behalf of a group of companies with interest in that chemical.

At the outset it was noted with regret that Dr. Tiziano Garlanda, Montedison (Italy), had been unable to share in representing the European Group project as planned.

Speaking from pencil notes, Dr. Rowe outlined the background for the investigative program, beginning with an indication of the magnitude of the vinyl chloride and polyvinyl chloride industries. He proceeded to refer to a number of scientific papers, including the entry on vinyl chloride in "Documentation of the Threshold Limit Values" (American Conference of Governmental Industrial Hygienists, Third Edition, 1971, pp. 277-8). In this background review, he highlighted MCA's role in administering a scientific study of acroosteolysis in certain polyvinyl chloride workers in the late 1960's, and in arranging for a consultation meeting in May 1971 with Dr. Luigi Viola (Regina Elena Institute for Cancer Research, Rome, Italy) on his inhalation studies with rats, in which he reported occurrence of tumors after exposure at 30,000 ppm vinyl chloride vapor.

Dr. Rowe stated that initiation of MCA's program had been held up to take advantage of information from a program sponsored by a group of European companies started somewhat earlier, commenting on MCA's appreciation for the liaison becoming established which made possible such an exchange.

Dr. Duffield began by stating that a post-examination of the histologic specimens from Dr. Viola's work had led to the firm conclusion that none of the observed lung tumors were primary tumors, but occurred as a secondary effect from malignancies in other parts of the animal body. He indicated there were other questionable factors, such as the handling of the test animals, etc. (He reminded that the purpose of Dr. Viola's research was to develop an "animal model" for acroosteolysis, which appears not to have been accomplished.)

Dr. Duffield stated the European Group program was directed both to epidemiology and to animal testing. He reported that an exhaustive examination of ICI employees, for

example, had revealed no indication of hazard from worker exposure to vinyl chloride, and that so far there was no reason to suspect any threat to human health.

Nevertheless, Dr. Viola's observed findings stimulated an ainmal testing program with rats which has produced some tumors, but Dr. Duffield pointed out the program is still in progress and no firm conclusions yet drawn. He said publication of the results is planned for late 1974. He mentioned that the European companies involved intend discussing this work with their respective governments, but this has been done so far only in part.

Dr. Rowe then continued with an explanation of the particulars of MCA's program, distributing copies of the two protocols, i.e., animal inhalation research being conducted by Industrial BIO-TEST Laboratories, Inc., and epidemiological survey just getting under way by Tabershaw-Cooper Associates, Inc. He invited comments and suggestions from NIOSH.

With regard to animal testing, Dr. Jacobson inquired about the strain of rats selected, at the same time saying it was more a matter of curiosity than any question relating to significance of results. Considerable discussion ensued about various rat strains and problems associated with test animals supply.

Dr. Lassiter was pleased to note the inclusion of the food, water, and bedding exposure comparison animal group. Responding to his queries, Dr. Duffield (1) identified the European study exposure range to be 50 to 10,000 ppm, but with repetition of the 30,000 ppm level being added, (2) gave 250 ppm as the lowest level at which tumors have been observed, and (3) stated that no tumors have been seen in either the blank or vinyl acetate control groups.

Dr. Jacobson asked whether vinyl chloride might have an alkylating effect, and this possibility was discussed from various angles.

Regarding the epidemiological survey, Drs. Mitchell and Jacobson emphasized the great importance of having as much documentation of exposure levels as possible. Dr. Lassiter pointed out the desirability of separating smokers from non-smokers, but realized this would likely be impossible in the presently planned approach which would rely solely on personnel records.

Dr. Key suggested further discussion with Dr. H. E. Stokinger in his capacity as chairman of the Threshold Limit Value Committee of the American Conference of Governmental Industrial Hygienists. (Initial contact for this purpose has been made.)

Responding to a question from Dr. Key, Mr. James indicated that vinyl chloride is among those due for fairly early consideration in the program of criteria documents development, perhaps due about midway in the current fiscal year (beginning July 1). It appeared, then, that preliminary indications from the MCA epidemiological survey, at least, would become available in time to be taken into account.

Dr. Jacobson mentioned having been puzzled by a recent phone inquiry about inability to purchase vinyl chloride for use as an aerosol propellant. Speaking as a representative of his company, Dr. Rowe stated they are no longer selling it for this purpose, and Dr. Rinehart indicated likewise. Mr. Wheeler said it has been used in this way only in relatively small quantities in paint and lacquer spray cans, with the likelihood that such application will be discontinued altogether by the end of the year.

Dr. Key characterized the meeting as being highly useful, and he and his associates expressed much appreciation for the initiative on the part of MCA and the industry which brought it about.

He said NIOSH would be interested in receiving interim reports of progress as the program goes forward, and

C O N F I D E N T I A L

was assured this would be arranged.

Papers left with Dr. Key and the members of his staff who took part were:

(1) Brief summary of vinyl chloride and polyvinyl chloride industry (single sheet)

(2) Referenced ACGIH reference (single sheet)

(3) MCA Chemical Safety Data Sheet SD-56 -- Vinyl Chloride (Revised 1972) (18-page booklet)

(4) Condensed protocols for MCA inhalation and epidemiological studies, corrected as of July 13, 1973 (8 sheets)

(5) MCA news release on these studies (2 sheets)

George E. Best

GEB:tp

July 19, 1973

UNION CARBIDE

INTERNAL CORRESPONDENCE

Exhibit B

CHEMICALS AND PLASTICS • SOUTH CHARLESTON PLANT P. O. BOX 8004, SOUTH CHARLESTON, W. VA. 25303

cmcl Mr. J. L. Carvajal, 514
cc Dr. Carl U. Dernehl, NYO-4
cc Mr. G. J. Hanks, 511
Dr. Kenneth S. Lane, NYO-4
Dr. A. B. Steele, NYO-28
to Dr. N. L. Zutty, NYO-32

Date July 19, 1973

CONFIDENTIAL

Originating Dept.

Answering letter date

Subject Vinyl Chloride Research
MCA Report to NIOSH

The Manufacturing Chemists Association selected the following persons to make a technical presentation to the National Institute of Safety and Health on the status of the vinyl chloride known health hazards and the current research program:

1. Dr. V. K. Rowe, Dow Chemical Company
2. Dr. W. E. Rinehart, Ethyl Corporation
3. Mr. R. N. Wheeler, Jr., Union Carbide Corporation
4. Mr. George E. Best, Manufacturing Chemists Association

Dr. David Duffield, Imperial Chemical Industries, was designated by the four European vinyl chloride resin producers to discuss European work.

The MCA group met with the Vinyl Chloride Industry Technical Representatives on July 11, 1973 to discuss the presentation, the objectives of the presentation, and limitations on the representatives. The presentation was to be oral with only copies of the study protocols and generally-known data provided for distribution. The objectives were to apprise NIOSH of vinyl chloride studies in progress and to avoid over-reaction by the Department of Labor and NIOSH should data become available from this or other sources.

Industry technical representatives were advised to consider statements to the press or to their employees should the data become generally known.

The MCA group, along with Dr. D. P. Duffield, met at MCA headquarters on July [redacted] and the morning of July 17 to prepare and review the presentation. Dr. V. K. Rowe was selected as spokesman for the group. Doctor Duffield was to present the European data. Mr. Bruce M. Barackman, an MCA attorney, provided advice on legal questions.

[redacted]

[redacted]

The presentation was made at 1:00 P.M. on July 17, 1973 at NIOSH headquarters in Rockville, Maryland. Representing NIOSH were Dr. M. Key, Director of NIOSH. Dr. N. Mitchell, Dr. Donald Lassiter, Dr. Keith Jacobson, and Mr. Richard James.

An outline of the presentation is as follows:

1. Inductory remarks and purpose of visit.

2. A review of the size of the industry in the U.S. and the world (this was presented via handout).

3. A review of the history of vinyl chloride toxicology (handouts of the vinyl chloride data from the ACGIH and the MCA technical data sheet were distributed).

4. A review of MCA and U.S. industry participation in the study of vinyl chloride hazards:

   a) The MCA study of acroosteolysis epidemiology.

   b) The MCA Occupational Health Committee's meeting with Dr. Viola following the publishing of his work.

   c) The planning of vinyl chloride research by the MCA Industry Technical Group on Vinyl Chloride.

5. Dr. Duffield discussed work done or underway in Europe on vinyl chloride monomer studies.

   a) I.C.I. did epidemiology study of all VC and PVC workers exposed between 1962 and 1972 without indication of hazard.

   b) I.C.I. did epidemiology study of all VC workers exposed between 1946 and 1971 without indication of hazard.

   c) The four European companies - I.C.I., Montedison, Rhône-Progil, and Solvay - sponsored the rat inhalation study now underway in Italy, with concentrations ranging from 50 to 10,000 ppm.

5. d) The European group plans to do a feeding study and short-term inhalation studies on rats.

6. (Dr. V. K. Rowe resumed) The protocols of the inhalation study and the epidemiology study were reviewed. (Handouts of the study protocols and the MCA press releases were presented.)

7. Concluding remarks, asking for comments and cooperation. Study results will be made available to NIOSH when complete.

Comments and Questions

Doctor Key: This is a fascinating presentation; we appreciate it. Too bad OSHA procedures are not more flexible. The existing tracking system makes work difficult, and we can't get caught up. We should be able to use representatives of industry, labor, and academic in some kind of seminar for preparing Criteria Documents.

Doctor Lassiter: Concerned about identifying exposure data on retrospective studies. Did not like Viola's work because animals died, were discarded, and replaced by new animals.

Doctor Jacobson: Is vinyl chloride an alkylating agent? Are foods affected?

Doctor Jacobson: What is the situation regarding the use of vinyl chloride as a propellant? Thought use was larger and was an industrial use. (He was informed that VC was used in pressurized spray cans of paint. VC represented about 25% of the propellant mix. The use is being discouraged by economics as well as hazard, and should be completely terminated by the end of the year.)

Unknown - possibly Doctor Lassiter to Doctor Duffield

What is the lowest VC concentration that you have found tumors? (Doctor Duffield stated that study was incomplete, but one tumor had been found at 250 ppm.)

Doctor Key: Mr. Herbert Stockinger should be consulted on the study protocols. MCA should contact him for a future discussion. I did not realize PVC was such a large industry.

The MCA group and Doctor Duffield were invited to Doctor Key's office for further discussion of future industry aid with Dr. Herbert Christianson and Mr. Edward Baier, Assistant Director. Items discussed were:

1. NIOSH had a computer printout of 1100 possible or actual carcinogens.

2. Doctor Rowe discussed problems of the OSHA Carcinogen Advisory Committee. He called it a "snake pit", and hinted that the responsible members might all quit soon.

3. Doctor Rowe proposed that carcinogens be put in four or five classifications, depending on the known hazard.

4. MCA's facilities will be utilized to contact known producers of various materials requiring Criteria Documents.

5. Mr. Edward Baier proposed that an independent agent, such as a college professor, collect industry data on various materials and publish it so NIOSH can use the data. NIOSH is limited to generally known or published data.

6. Doctor Rowe met with Doctor Key in a separate office for approximately thirty minutes, at Doctor Key's request. Doctor Rowe commented that this private discussion of the carcinogen problem was worth the whole effort. He did not elaborate.

The consensus of the MCA group and Doctor Duffield was that the presentation was extremely well received and that the chances of precipitous action by NIOSH on vinyl chloride were materially lessened. NIOSH did not appear to want to alienate a cooperative industry or they did not want to know too much unpublished data.

These notes are subject to the human frailties and errors that always occur, and are intended to show the procedure and flavor of the presentation. Needless to say, any breach of the presentation's informal confidentiality could be extremely costly to industry.

Copies of Criteria Documents on Chromic Acid and Toluene Diisocyanate were received and forwarded to Doctor Lane; these are the first published.

Very truly yours,

R. N. Wheeler, Jr.

RNWJr/ra

(2 Enclosures to Dr. K. S. Lane)