

SHELL OIL COMPANY

VCM-MCA
REFERENCE

OG-C-005308

DATE FEBRUARY 26, 1974

TO (MEMORANDUM OF MEETING)

FROM MANAGER, INDUSTRIAL HYGIENE -
HEAD OFFICE

FEB 27 1974

SUBJECT MCA MEETING ON VINYL CHLORIDE

MEDICAL DIRECTOR

On February 19 and 20, the MCA Technical Task Group on Vinyl Chloride met. The meetings on the 19th were of the Work Practices Task Force and of the Research Coordinators. The full group met on February 20.

Work Practices Task Force

The group attempted to write a recommended work practice for control of vinyl chloride monomer exposure in polyvinyl chloride operations. We were quite explicit that this meant the resin activities only and was not applicable to monomer production activities. The rationale behind this was that a second work practices document for monomer would subsequently be written. The two documents would be compatible. However, it was considered important to assure that in the presentations to NIOSH and OSHA that there were essential differences between monomer and polymer operations. A draft was completed of a work practices document, and a small subcommittee comprising of Z. G. Bell of PPG Industries, R. N. Wheeler of Union Carbide, Mayo Smith of Air Products, and myself was formed to redo the draft in an acceptable format. The subcommittee met for three hours on February 20. A copy of that draft has been sent to Mr. Reynolds; one copy is appended to the original of this memorandum. Highlights of the draft include a proposal for exemption of resins which contain less than 0.1% free vinyl chloride monomer. The committee also decided not to recommend a threshold level for VCM. This is based on the definition of a threshold level which implies that it is a level below which no danger is assumed to exist. Rather, the committee adopted the concept of a "working level" which implies an interim version which is both related to current knowledge and technical feasibility. The working level also implies that it is a current target and that it will be changed as new information and methodologies become available. On this basis the work practices document contains a suggested working level of 50 ppm as the time-weighted average.

Research Coordinators

The Research Coordinators met on February 19, 1974. (The Work Practices Task Force adjourned so that the RCs could meet.) It was moved and seconded to recommend that Mayo Smith be added to the seven Research Coordinators. This was done on the basis that he represents industry on the NIOSH Ad Hoc Committee.

A number of the members present then detailed information on cases of cancer and other illnesses in their plants. Ben Zwicker of B. F. Goodrich Company identified two additional cases. These are the ones that had been reported in the Wall Street Journal on that day. One was a 1964 death in

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which the autopsy protocol had mentioned angiosarcoma, but the death certificate did not so state. This was a worker born in 1912 and who died at age 52. He had had 11 years experience in monomer manufacturing primarily with very little polymer experience, and according to Zwicker, almost no tank-cleaning activities. He subsequently had nine years of bagging and warehousing resins. The monomer process at the plant was the acetylene/hydrochloric acid process.

B. F. Goodrich has a sixth known case of a worker who is still alive. He had shown a slight elevation in one of the liver function tests in the SMA-12. The man's physician was suspicious, ordered a biopsy, and the angiosarcoma was confirmed. (In a subsequent discussion with Dr. Falk of CDC I learned that some 15 operators who had shown abnormal liver function tests on an SMA-12 repeat were given liver scans. This worker was the first scanned, showed a positive finding, and underwent a laparotomy. Dr. Falk stated that as of February 24, no other positive scans were found.) This worker had been with BFG for 13 years. He was born in 1928, was a polymer operator, and did clean reactors. He has had little exposure to vinylidene chloride.

R. N. Wheeler of Union Carbide then stated that UCC was notifying NIOSH that they had discovered a case of angiosarcoma of the liver in a worker in their South Charleston, West Virginia plant. This man had had surgery for gall stones, and an angiosarcoma was found during the process of the operation. The man died in 1968. He had had 18 years service with Carbide and did not clean reaction vessels but did work in solution polymers and dispersion resins operations. Wheeler also indicated that Carbide has completed the study of over 900 medical records in the South Charleston plant (which had started operations in 1935) and was still looking for cancer. Except for the one just cited, there were no other workers with either confirmed or suspicious angiosarcoma. Wheeler felt that this search of work records would also include employees who may have been exposed but were not picked up by the Tabershaw-Cooper epidemiologic study since they were not originally identified by the corporation as vinyl chloride workers.

Dr. David Duffield of ICI then reported on a death in one of their employees. The man, age 71, died in December 1972. He had worked on the autoclaves from 1946 to 1966 when he retired. Dr. Duffield does not know whether the man cleaned reactors but felt that it was likely. Diagnosis of the angiosarcoma was made at the postmortem examination in January 1973.

Dr. Rinehart of Ethyl indicated that in their Louisville bottle-manufacturing plant a worker died on December 28, 1973, and on the basis of the autopsy, cause of death was cancer of the gall bladder with metastases to the liver. The man was born in 1922 and had been employed at Ethyl for three years. Dr. Rinehart had no information as to other work history.

Mayo Smith reported that he had heard secondhand from Firestone people that there was a liver cancer death at that company, and he assumed it was at the Pottstown, Pennsylvania plant. As far as Air Reduction is concerned, Smith stated that in a review of their records, they have shown only two cancer deaths among their employees - one of cancer of the brain and one of the colon.

Zwicker then reported on the case that had been brought up by Mazzochi at the OSHA hearings, namely that of the eight-year old child who died of liver cancer. Both Drs. Maltoni and Duffield saw the autopsy slides at the National Cancer Institute the previous week. The cause of death was an embryonic hepatocellular carcinoma. The cause is not known nor were the pathologists able to say whether the etiology was transplacental or postnatal. The father did work in the PVC plant, but he has not shown any pathology.

Torkelson reported for Dow that they had found neither liver tumors nor cirrhosis in any of their vinyl workers, but they have had a slight, although statistically insignificant, excess of total cancer deaths.

Torkelson cited need for a vinyl workers cancer registry. He suggested perhaps revitalizing the AOL registry held at the University of Michigan. Dr. Harold Magnuson would be interested in reopening the registry on an expanded basis. The subcommittee then moved and recommended to the parent committee that a vinyl chloride pathology registry be established at the University of Michigan; further, that both NIOSH and organized labor be invited to cosponsor the registry.

Professor Maltoni then reported on the sputum work that he had done. He indicated that there was an early indication of a squamous metaplasia of bronchial epithelium showing up in the sputum of workers exposed to vinyl chloride. The cells were a type not seen in the general population, and their morphology is different. Maltoni has observed these in three different plants, and although the plants are widely separated geographically in Europe, he felt that the cells were the same. Having observed over 100,000 sputum samples in slightly over six years, Maltoni was of the impression that the incidence of these cells in the vinyl workers was greater than expected, and the morphology was rare. He was not able to state if there was a correlation with vinyl chloride exposure. He tends at this point to view this more as an irritation phenomenon similar to the metaplasias seen in individuals exposed to such items as cigarette smoke.

The coordinators then discussed the research proposals. I indicated our viewpoints, particularly with a modification and expansion of a metabolic study. This would include studies on the prophylactic value of feeding of sulfhydryl-containing amino acids, primarily cysteine and glutathione. Maltoni felt that this was a viable suggestion and thought that he could perform such a study in his laboratory. He was asked and promised to work up a project proposal and cost estimate.

When I questioned the real purpose of the teratology study, Torkelson claimed that the advantages were twofold - first, that it was a study that could be done quickly and neatly, and second, that it would allay fears of effects on offspring. With the case in Louisville of the eight-year old child, the advantage of doing such a study was enhanced.

Other possible studies were discussed and generally were tabled. A proposal on a mutagenicity study was delayed. It was felt that even though a claim has been made that vinyl chloride is an alkylating agent, the tests still were not of such sophistication to determine whether carcinogenesis could occur. The three-generation reproductive study is normally required for food additives, and the committee felt that this would be better deferred to the SPI. Proposals were also made for feeding studies on the monomer. I mentioned the possibility that Modesto might be able to do some of this work. Dr. Rinehart of Ethyl felt that SPI would be able to handle such studies and we would defer to them and reconsider at the next meeting. The prospective epidemiology study proposal was deferred to the Medical Task Force for advice. A question was brought up on studies on the inhalation of the polymer. Although NIOSH may already have agreed that the polymer, monomer-free, presents no hazard, OSHA may still be looking toward a pneumoconiosis study. It was suggested that MCA approach consultant laboratories to get a proposed protocol and cost determination on polymer dust studies.

One proposal was to give animals acute exposures and maintain them for a lifetime. This would be comparable to a tankcar rupture where workers would have high but short-period exposures. Professor Maltoni indicated that he had just started such a study in which he was exposing animals at levels of 6,000 and 10,000 ppm. It was agreed that we would table this proposal until the Maltoni data were made available.

BFG is now doing a study on skin absorption, and therefore, the Research Coordinators recommended tabling any action until the BFG data are available.

We discussed the forthcoming 11th International Cancer Congress. Maltoni felt that the list of speakers for the session on occupational cancers has already been set, but he will try to see if there is a possibility of getting other VCM data in, and if a message to the Congress based on the Tabershaw-Cooper report can also be inserted into the program. Maltoni said he would speak to the General Secretary of the Congress as to what could be done. Maltoni did state, however, that plans are now being made for a post-congress meeting of experts on vinyl chloride monomer, and they are making a worldwide screening of people as contributors. He felt that the Tabershaw-Cooper report would be better presented there. He also indicated that the WHO and the ILO would also be invited. I would suggest that we consider having an observer and/or participant at the post-congress activities.

Technical Task Group - February 20, 1974

At this meeting the Industrial Bio-Test people reviewed their study. We had already received a 90-day report. They also provided us with data, bringing the information up to date, i.e., five-month results. No soporific effects were seen on the animals. The cannibalism in the hamsters seems to have leveled off, although there was a dramatic increase on mortality in male mice at 50 ppm. The Bio-Test people were unable to explain whether the mortality was due to cannibalism or other factors, but they implied that it was not dose-related. They felt that the possible explanation of cannibalism in all of the species seems to be related to the lack of food. (The animals are denied food during the period of exposure.) The only other gross effects were in the body weights. Hamsters seemed to show a dose-related body weight decrease.

There was a bit of discussion on the implications of the loss of so many animals. The consensus of the Research Coordinators in a small Ad Hoc meeting during the coffee break was to discontinue the hamster exposures at the end of six months, retaining the animals for a lifetime. This would give a datum reference level for medium exposure as compared to the two species that would remain. I felt that since the hamster deaths had leveled off, exposure should continue with an evaluation being made of survivors on a month-to-month basis. In effect, if no more animals died via cannibalism, we should continue the exposure. On this I was outvoted. The recommendation was transmitted to the Bio-Test people.

Professor Maltoni repeated his testimony of February 15. He stated that he felt that the lesion in the animals was multifocal and that other changes, for example fibrosis, may not be good as possible indicators. He feels that there has been a confusion between cirrhosis of the liver and the fibrosis that may be associated with the angiosarcomas. According to Maltoni, cirrhosis should be seen as a degeneration of tissue, whereas the fibrosis is secondary to the cancer development. He insisted that in no way is fibrosis to be considered a precursor to angiosarcoma.

Maltoni was pessimistic about liver function tests as indicators of angiosarcoma and would like to see what research he could do further to determine predicted mechanisms. Two questions were asked of Professor Maltoni. He evaded direct answers. He was first asked, "Are you seeing any other, non-neoplastic injury at 50 ppm?" He delayed in answering and finally stated that he would like to review his data before replying. The implication here is that other effects might be occurring, but he is either waiting before publishing or is not certain. The second question is related to whether the onset of the tumor is dose-related. Maltoni's nonanswer was even more significant. He stated, "I would like to discuss this with the European partners before answering." Note that he had seen his first angiosarcoma at 40 weeks at a concentration of 2,500 ppm.

In the afternoon, the Technical Task Group heard the report of Tabershaw-Cooper & Associates. It was at this point that the small writing subcommittee retired to redo the work practices document. We shall have to wait either for R. B. Howard's notes or the minutes of the meeting for this activity.

Miscellany

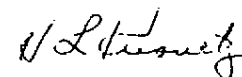
On February 19, Dr. Bell and I had lunch with Maltoni and Dr. Bartalini of Montedison. We were attempting to see what additional work Maltoni might be doing and what the possibilities might be for research by his laboratories. He is expanding the capacity of his laboratory, and by the end of April he expects to have the capability of exposing up to 15,000 animals by inhalation. He is committed for only one-half of this capacity and stated that he would welcome any increased participation. Particularly, we were interested in finding out whether he would be able to do any other tests on chlorinated hydrocarbons which can be screened for possible cancers. He is doing this now for Montedison; among his tests is work on ethylene dichloride and perchloroethylene. He also said that he is studying a non-chlorinated monomer but would not identify the material. Maltoni felt, and the Montedison representative agreed, that if any company, as an individual or through MCA, wanted to join in the research program for these chlorinated hydrocarbons as cosponsors, they would be most welcome. I would recommend that Shell pursue this further.

The work practices document contains a reference to analytic or sampling methods, but those sections have been left blank. Basically, it will require air monitoring by a method to be specified and then will state, "or any other method which shows equivalent accuracies on sensitivity and precision." Since Shell has a method for both sampling and analysis in the workers' breathing zone, we should consider the advantages and disadvantages of using the Shell method as the reference method.

We had a secondhand report from Mayo Smith who had heard from B. F. Goodrich the results of a discussion in Kentucky between the BFG people and Dr. Block of the Kentucky Department of Labor. According to this unconfirmed report, the Kentucky officials have set standards for the Louisville plant. These are: the plant will operate with a time-weighted average of 50 ppm, a ceiling value of 75 ppm, and will be subject to immediate shutdown at 200 ppm.

I was informed by Mr. N. Van Hendricks of the Exxon Corporation that he was present at a meeting in January of an occupational health research group at which Dr. Selikoff of Mt. Sinai stated that he was trying to start a study on the effects of shale oil. The Public Health Service had done such studies in the early 1950s in Rifle, Colorado. Dr. Donald J. Birmingham, now of Wayne State University, was Director of those studies. Selikoff would like

to go back and pick up the data of that time and look at both epidemiologic and animal studies on apparently skin effects and cancers. Van Hendricks wrote a detailed memo on this to James Hammond, Manager of Industrial Hygiene for Exxon. I am attempting to get a copy of this memo.



H. L. Kusnetz

Attachment

cc - Messrs. R. L. Brunner

B. W. Dunbar

~~This Copy For~~ R. E. Joyner, M.D.

R. L. Maycock

R. F. Nelson

R. J. Reynolds

A. L. Smith