

SHELL OIL COMPANY

TO FILES

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FROM MANAGER, INDUSTRIAL HYGIENE -
HEAD OFFICESUBJECT REPORT OF MEETINGS ON
VINYL CHLORIDE:

1. NEW YORK ACADEMY OF SCIENCES
2. AMERICAN INDUSTRIAL HYGIENE
CONFERENCE
3. MCA RESEARCH COORDINATORS

1. New York Academy of Sciences

The meeting was held at the Delmonico Hotel in New York City on May 10-11, 1974. Organizers of the conference were Irving J. Selikoff, M.D. of the Mount Sinai School of Medicine of City College of New York, and E. Cuyler Hammond, Sc.D., of the American Cancer Society. A copy of the program is attached. The list of participants is appended to the original of this report. This report is made on the basis of a review of each paper listed in the program. An overall impression will be given at the end.

In his introductory remarks, Dr. Selikoff indicated that there would be no attribution of results to any paper presented but that there would be a transcript of the meeting. The fact that this was not adhered to, witness the newspaper articles of Saturday, May 11, Sunday, May 12, and subsequent publicity, belied the assurances given by Dr. Selikoff.

In the first paper, Dr. Veltman stated that in April, 1972 he reported acroosteolysis in 13 PVC workers in a plant in Germany. He considered the disease as a systemic neurosis. He saw circulatory and liver changes, and felt that the term, acroosteolysis, was no longer adequate. He calls the condition "vinyl chloride disease". Veltman cited 70 patients out of 120 workers with an average of 7.7 years of exposure (range six months to 21.75 years) in such activities as pot cleaning and centrifuge cleaning. Of the skin changes, some occurred after only one year of exposure, but these regressed with cessation of exposure. Veltman also reported thrombocytopenia and suggested this as a clinical test for possible vinyl chloride disease. This appeared both with and without splenomegaly. Veltman did not indicate exposure levels, but from his description of processes and conditions in the plant, one would guess that the concentrations must have been in the thousands of ppm.

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Dr. Lange described results in PVC processing. From a description of his work, it appeared that he was talking about PVC fabrication. It was Dr. Lange's remarks that were the subject of the major newspaper articles on fabrication workers. He described 50 workers with an average of five years experience (range 1-1/2 to 30 years). Of his workers, seven showed thrombocytopenia, seven showed an elevated BSP, 15 showed a reticulocytosis, one had a lucopenia, and splenomegaly was observed in several. Lange states that the above five changes define PVC disease.

Lange then gave two case histories of angiosarcoma among PVC autoclave workers who had no history of AOL, Reynaud's syndrome, or scleroderma. One was a 38-year old PVC autoclave cleaner with 12 years' experience. Nodes were seen on the surface of the liver, and upon autopsy, an hemangiosarcoma was found. The second worker, a 39-year-old PVC autoclave cleaner, had had 11 years experience in PVC, plus two years in the machine shop. In the original examination, liver enlargement was found. A laparotomy showed a fist-sized tumor of the liver with nodes in both lobes. There was no primary tumor seen in the peritoneal cavity. The case was diagnosed as an angiosarcoma of the liver. The patient died in 1971. Exposure levels were not given, but again from Lange's description, the levels must have been in the thousands of ppm.

Dr. Suci of Rumania gave one of the less believable papers. He described alleged VCM concentrations ranging from 2,298 to 146 mg/M³ over a 10-year period. (This corresponds to levels of 765 ppm to 50 ppm.) Suci reported workers' symptoms including singing, laughing, giddiness, somnolence, followed by complete narcosis. According to Suci, workers would fall asleep on the job at the night shift, and at home they would collapse into 14 hours of dreamless sleep. He found also a 21.5% reduction in sexual potency among his workers at these concentrations. Suci also stated that these concentrations were at levels sufficient to catch fire spontaneously. Since the lower explosive limit of vinyl chloride is in excess of 30,000 ppm, the Suci data must be assumed to be either off by a factor of 1,000 (possibly he meant mg/liter) or his work should be discounted completely. Suci also claimed an allergic manifestation of the skin and respiratory tract occurs when a sensitized worker merely passes through the area, and he claims to have observed one case collangiohepatocarcinoma.

Dr. Creech reported on the studies in the B. F. Goodrich Plant. The cases of angiosarcoma all were from the PVC plant. Creech felt that the diseases had to be related, at least qualitatively, to exposure. Goodrich utilizes the SMA-12 for initial liver function screening. If one test is elevated, the SMA is repeated; and if it is still elevated, then special liver function tests are run. If two tests in the SMA-12 show a possible elevated liver function, then the special battery is

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immediately instituted. The special tests include CEA (carcinoembryonic antigen) and ICD (isocitrate dehydrogenase). Biopsies of the first two of the vinyl workers were done by laparotomy. Others were done through the hepatic vein. Creech indicated that to date there were 17 special cases, 16 of whom have already been biopsied. One man has refused, although they think he will subsequently allow himself to undergo the procedure.

Creech also indicated that there was no one test that appeared to be significant for diagnosis of vinyl chloride, but he noted that on electrophoresis, factor 4 of the LDH fractionation is up in 66% of the affected workers compared to an elevated level of 0.02% in hospital patients. In black workers, CPK were elevated in 75% compared with a 12% elevation in white workers. Creech feels that the SMA-12 and the special liver function batteries without a liver scan are not sufficient, although the scan itself will not always indicate fibrosis.

Sakabe from Japan described acroosteolysis in vinyl chloride plants in Japan. VC/PVC activities started in 1949. In 1954, Reynaud's syndrome was noted, and the first AOL case occurred in 1972.

Dr. Lilis then reported on the studies the Mount Sinai group did in March, 1974 at the Goodyear plant in Niagara Falls. They looked at 267 workers in the polymer plant and 87 former workers. Fifty percent of the workers were under 40 years of age. Lilis emphasized that there were no exposure data, but she guessed that they were high enough to cause unconsciousness in 14 workers. (This alone would indicate exposures in the thousands of ppm.) She indicated that skin manifestation and Reynaud's syndrome seemed to correlate with years of exposure (10% at +20 years). Skin changes were noted in 23 workers or 6.4%, and joint pain in the fingers in 8% of the workers. They are now looking at X-rays of hands and feet and are beginning to find AOL-type changes. Hypertension and urine were not abnormal in the workers, but the liver was enlarged slightly in 15% of the workers. An elevated alkaline phosphatase was found in 16% of the workers, otherwise they were low. Alkaline phosphatase was not correlated in her studies with ethanol intake, but the clinical manifestations did appear to be correlated with an elevated alkaline phosphatase situation. In her summary she felt that the abnormalities were related to duration of exposure. There was no information given on controls, either in the plant or in the area. (Note how Dr. Lilis' reports of slight liver enlargement compares with the Mount Sinai/Selikoff newspaper stories of severe liver disease.)

In the discussion session which followed, Dr. Berk gave a case history and felt that the real problem was getting a test of effects on the liver. He suggested a bile-acid clearance test. Berk claimed that the principle lesion was fibrosis leading to diminished hepatofunction.

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Dr. Miller discussed the respiratory tests done at Goodyear. He noted airway obstructive findings that were elevated with both age and smoking. He pointed, however, that in the Goodyear workers only 16, or 5%, had restrictive disease.

A third-year medical student at the University of Kentucky (Wyeth) participated in the studies of the B. F. Goodrich workers. He found no significant differences in cholesterol studies except differences in albumin levels between PVC and other workers. As far as cholesterol changes with age, they appeared to be less elevated in PVC workers than in other workers.

A Dr. Snyder of Hoffman-LaRoche Corporation did the CEA analysis of the workers that had been reported upon by Dr. Lillis. He noted elevated CEAs, but no positive conclusions could be made. All data were preliminary. He noted that there were other pathology besides cancer which gave an elevated CEA. He cautioned against taking Lillis' results too seriously.

In paper No. 6, Dr. Marsteller reported examining 50 workers. He found gastro-intestinal bleeding in four out of the 50. Ten workers had esophageal varices. Enlarged liver was found in 31, and enlarged spleens in 16. He showed many slides and referred to one case with a suspicious angiosarcoma. In this man, however, there were only 2-1/2 years of known exposure. Marsteller's data were not very conclusive.

Dr. Hans Popper presented the next paper. He showed many slides of lesions and indicated that he was not sure that the mechanism of the lesion was known, but he felt it might be due to the specific activation of some cell, possibly sinusoidal cells. He stated that vinyl chloride workers have shown similar lesions to those exposed to arsenic, thorotrast, and those with hypervitaminosis A.

In the discussion which followed, Gedigk from Bonn University said that he was able to classify four histologic groups of 51 cases of liver damage allegedly due to vinyl chloride. His slide was unreadable, but three of the classifications included degeneration, fibrosis, and a proliferation of sinusoidal cells. According to Gedigk, the degenerative changes were reversible and appeared to be dose dependent. He claimed his cases were identical with arsenic poisoning.

Dr. Gehring of Dow spoke next on the metabolism of vinyl chloride. He postulated a reaction between vinyl chloride, cysteine, and glutathione. He has also investigated possible alkylating activity from the vinyl chloride. In his in vitro tests, he bubbled vinyl chloride through cysteine and glutathione and saw no reaction. However, this lack of reaction did not apply to in vivo studies. Gehring postulates the formation of beta-chloroethanol leading to sulfhydryl (SH) depression. When he examined urine of rats exposed to 5,000 ppm, he found formation of beta-hydroxy ethyl cysteine and monochloroacetic acid in the excreted urine. No monochloroacetic acid was found in animals

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exposed to 50 ppm. At concentrations > 220 ppm, dose response appeared to be a zero order relationship, that is, no correlation between dose and change in sulfhydryl level. However, at concentrations < 120 ppm, sulfhydryl depression appeared to be a first order reaction.

Gehring is now using C^{14} gaseous vinyl chloride at 50 ppm and one hour exposure, thus giving a mean dose of 0.5 mg/kg in the one hour. Within the first 15 hours he sees the bulk of metabolites in the urine. This is equivalent to 58-71% of his total dose. Ten to 13% appear in the feces, and another 10-13% appear in expired air as carbon dioxide. He sees no changes in his animals between 30 and 75 hours, but even after 75 hours, he sees a 6-8% retention of C^{14} VCM with 1-2% being in the liver.

In the discussion, Oster indicated he tested for vinyl chloride binding to serum albumin using fluorescent antibody techniques. He did not elaborate on the techniques. More important, he noted also that the monomer may be in existence as trapped free-radical chains in the polymer. Oster was concerned with PVC dust in plants having monomer and free radicals attached. One would expect a proliferation of free radicals to be compatible with an alkylating activity.

Jaeger, continuing the discussion, noted that vinyl chloride prevented serum transaminase injury which occurred with vinylidene chloride (1,1 dichloroethylene) exposure. His studies were four-hour exposures in fasted rats.

David Wegman of Massachusetts Department of Labor also spoke at the discussion following Gehring's paper. He examined 37 PVC process workers, where, he claimed, no exposure to vinyl chloride was possible. (The workers were in a calendar press operation making plastic place mats.) He found work exposure ranged from six months to 21 years, with the workers' ages between 18 and 62 years. He found large numbers of abnormalities in the blood chemistries; 20% had elevated alkaline phosphatase, 60% abnormal LDH, 30% abnormal SGOT, 10% abnormal SPGT, and 35% with abnormal platelet counts. X-rays showed three workers with evidence of fine nodular changes, four with abnormal FEVs, and three with abnormal FVCs.

In opening the afternoon session, Dr. Lloyd of NIOSH indicated that they were now aware of 18 confirmed cases, and pointed out that Union Carbide in South Charleston, West Virginia had just announced a second phase.

Dr. Heath of CDC reported on the B. F. Goodrich, Kentucky, angiosarcoma data. He showed an observed to expected ratio of 400 to 1 in these cases. Normally, Dr. Heath noted, one would expect 0.0014 cases of angiosarcoma per 100,000 population per year. Thirteen cases in

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20,000 workers have been seen over a 10-year period. Dr. Heath indicated that the presenting signs and symptoms were varied and nonspecific, although abdominal masses appeared in four out of seven workers. Liver function abnormalities were present in all, but there was no pattern with the exception that the SGOT was abnormal in seven out of the seven cases.

Epidemiology studies showed that approximately 270 out of 1,200 workers in PVC work were looked at at B. F. Goodrich. Exposures ranged from 12-28 years with a median of 17.9 years from the first introduction to vinyl chloride work until diagnosis. Heath indicated that the data suggested dose response relationship. In all cases the workers started as "helpers". This meant that they would be assigned the dirtiest jobs, including that of vessel cleaning. The duration of workers as helpers correlated with time to diagnosis. Heath was able to give no assurances however on any indication of evaluating a latency period from exposure to tumor development as contrasted with liver disease.

The next paper was the Tabershaw-Cooper report presented by Dr. Gaffey. Since this is available within Shell, no further comments will be made.

Dr. Wagoner of NIOSH repeated the criteria for looking at plants in the NIOSH study. These will be PVC plants. Phone surveys started in February of 1974. Six polymer facilities located in Ohio, Pennsylvania, West Virginia, and Massachusetts have been chosen for detailed study. The industrial hygiene walk-throughs at all six were completed on March 19, 1974. Samples taken to date were found to be as high as 1,000 ppm at the face of the manway to the vessel. Wagoner also reported levels as high as 340 ppm of vinyl chloride in bags of polyvinyl chloride. (When Marshall LaMier of NIOSH reviewed the findings on Wednesday, May 15, the 340 ppm figure was shown to be an outlier, with most figures being <10 ppm and many <2 ppm. Dr. Wagoner's presentation of the 340 number, therefore, was to say the least, somewhat misleading.) Wagoner also indicated that the records were very poor.

Nicholson of Mount Sinai then reported on mortality experience in the cohort of 257 Goodyear workers. They were picked for having been in PVC polymer operations for at least five years. Exposures started in 1946-47. These workers have been observed from their 10th anniversary of work until April 1974. To date, 255 out of the 257 have been traced; 151 were production workers, 60 were maintenance, 26 were shipping, and 18 from the laboratory. New workers would be given jobs as baggers, but they were also given reactor cleaning operations. Nicholson said there were no data on levels, only that he knows that the levels were under 30,000 ppm. (Apparently, because the plant did not catch fire.) He has no data on others in plants. He assumed that the VCM concentrations in the area were "extremely high". The reactors would be vented into the reactor building, with 20 reactors in the building itself. He estimated.

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therefore, that exposures in the plant would range from 1,000-10,000 ppm. Twenty-four deaths were seen in plant population of 257, with an expected 19; and nine cancers were observed, with an expected 3.9. These cancers were not, however, all angiosarcomas.

In the discussion, Mancuso felt that vinyl chloride was an indicator index chemical and presented the same refrain that he did at the hearings in Washington on February 15. Dr. Newhouse gave some U.K. data, but this was essentially a rehash of the information already supplied by ICI and BP.

Dr. Holmberg described two cases of possible angiosarcomas in Sweden. One company in Sweden has two plants. One, started in 1965, produces 60,000 tons per year and has about 625 workers. Before 1968 there were no levels measured, but dizziness and unconsciousness were frequently seen. In 1968 a second plant was opened and measurements were made. Holmberg claims that levels of 18-20 ppm existed near the reactors, and 5 ppm where the resin is dried.

His first case was in a male PVC operator, 43 years old, with 18 years of experience throughout the period 1951-1970. The patient exhibited splenomegaly and high alkaline phosphatase. The second case was a male, age 61, whose work experience spanned 1945-1977. This worker supposedly was involved exclusively in VCM synthesis for a period of 23 years. The original diagnosis was hepatocarcinoma, but according to Holmberg, a reexamination of the specimens now suggests angiosarcoma. If this is true, it would be the first and only case of an exclusive vinyl chloride monomer exposure leading to an angiosarcoma.

Dr. Wagoner of NIOSH then returned in the discussion and pointed out that they were beginning to look at cosmetologists. This is the fourth leading occupational group with lymphomas, and three studies have shown bladder cancers in these operators.

Dr. Thomas then reviewed the data from 14 cases of known angiosarcoma, 13 in the U.S. and one in the U.K. He found the same sinusoidal cell pattern, as described by Drs. Popper and Gedigk, in 11 of 13 cases. Three out of the 13 showed anaplastic patterns in their cells. Thomas showed a series of slides on histopathology.

The paper by Dr. Volkheimer was related to PVC microparticles. He described a condition known as cytopempsis which occurs with particles less than 1 nanometer in diameter. After feeding PVC particles to animals, they were found subsequently in the bile and urine and in the milk of lactating animals. Volkheimer claims these particles were also found in the cerebrospinal fluid of dogs. Using potato starch as an indicator particle, Volkheimer noted that it takes four minutes for the starch to appear in the blood after ingestion, with a peak at 10 minutes.

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Dr. Maltoni followed and brought his information up to date. No reprints of his material were available, and his slides were almost unreadable. He stated that he was now starting exposures at 25, 10, and 5 ppm, and further stated that he learned a few weeks ago that at 50 ppm cancers developed. It was not clear, and we could not elicit this in the questioning, whether this was from his own studies or from the Bio-Test data. His results showed in his first, original group, that after 135 weeks he found one nephroblastoma and one angiosarcoma of the liver at 50 ppm. This will be the first time that this lesion was seen in a rat at that level. However, Maltoni indicated that he considered this as a spontaneous tumor since this was such a tremendously long period as compared to the normal rat lifetime.

In his inhalation experiments at 200, 150, and 100 ppm, four hours daily, five days a week, he has found no tumor after 41 weeks. In his experiment exposing rats to 20,000 ppm (his attempt to redo the Viola experiments), at the end of 41 weeks he has found 12 tumors of the Zymbal gland but no other tumors. His experiment BT-3 is a repeat of his initial experiment using Sprague-Dawley rats exposed four hours a day, five days a week for four months. He is now into 66 weeks of the experiment and has found no angiosarcomas in any of his animals. The tumors in this group compare with those that he has shown in his experiment BT-1 where he exposed animals at the same concentrations but for a full year. In the BT-3 experiment, he shows fewer of these other tumors at the same length of time as BT-1.

In the high level, teratogenesis experiment at 10,000 and 6,000 ppm, he has found one subcutaneous angiosarcoma after 24 weeks in a male offspring and a similar one after 22 weeks in a female.

In Sprague-Dawley rats, Maltoni shows that among males there are strain and species differences. After 31 weeks exposing mice at 50 ppm, he shows no lung tumors and no angiosarcomas at that level, but he does see tumors of other types at other sites. In higher concentrations, he finds pulmonary adenomas and mammary carcinomas. In the hamster, after 28 weeks, he has found three lymphomas, one melanoma, and three other tumors.

The scheduling of Industrial Bio-Test for a presentation was included in the program without the knowledge or permission of the Industrial Bio-Test people. Therefore, they did not appear. However, Dr. Torkelson of Dow presented a summary of the Bio-Test data. The information is appended to this report.

In the discussion period, Dr. Bingham of the University of Cincinnati emphasized the need to know the latent time necessary for tumors to develop, and she suggested serial sacrifices. She added absolutely nothing new. Dr. Van Duuren said he felt that vinyl chloride

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has to be activated to a proximal compound to cause a cancer, and he suggested that it might be the epoxide. He tried to relate this by showing how the carcinogenic properties of chloroethylene oxide are related to chloromethyl methyl ether and bischloromethyl ether, both known carcinogens. Van Duuren then indicated that if, in fact, the epoxide structure was responsible, epichlorohydrin should be looked at more closely.

During the discussion period Dr. Maltoni was asked about the relation between fibrosis and angiosarcoma, and he indicated that with high exposure the angiosarcomas occur without fibrosis. At low exposures they come with fibrosis, and he was careful to distinguish that the angiosarcoma did not come from fibrosis.

During the questioning, Burt Contine of the Health Research Group, a Nader affiliate, tried to put Maltoni on the spot as to when he told American industry of his findings. Apparently, this question had come up in a press conference earlier. Contine was trying to make the case that both American industry and governmental officials knew early that angiosarcomas had occurred in Maltoni's experimental animals and were hiding this from the public. Maltoni would not be led into this trap. Maltoni replied that the experimental work would have to precede epidemiologic work and that there was no action taken that would have adversely affected American workers based on knowledge or lack of knowledge of his data. It was Contine who tried to ask the same type of question of Mr. Reynolds during Shell's testimony before OSHA on February 15.

In the next paper, V. K. Rowe of Dow reviewed the methods of analysis for vinyl chloride, including gas chromatography, flame ionization spectrometry, combustion conductivity, and infrared analysis. He indicated that sensitivity in each of these methods could be well below 1 ppm, and with gas chromatography it could get down to approximately 1 ppb. He warned that with activated carbon specificity varies and that each batch must be checked. Rowe then brought up the suggestion that breath analysis might be a good tool but that this needs workmen's cooperation. Rowe then reviewed the Dow program and illustrated the computer treatment of time-weighted averages calculated on the basis of time in area with the areas being measured by remote sequential sampling equipment. Eighteen points are utilized in the Dow process.

In the oldest of the Dow monomer plants, the average now is 2 ppm with peak values at 40-45 ppm. In 1970 all time-weighted averages were less than 10 ppm except in the lab which had some higher values. In Dow's second oldest plant (opened in 1958), by 1973 overall TWAs were at 5 ppm. The highest levels were 10-15 ppm in the laboratory. In Dow's newest monomer plant, TWAs ranged from 1 to 10.4 ppm. In the polymer

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plant in 1973, all values but one were under 25 ppm, most in the range of 1-5 ppm. In one area, however, levels did reach as high as 100-150 ppm, and there Dow uses respiratory protection. In pumping reactors, Rowe indicated that levels ranged from 1-34 ppm, and in loading operations from 8-31 ppm. Rowe expected short-term excursions, even as high as 1,000 to 2,000 ppm; and so in 1974 Dow was concentrating on the hot spot reactions.

Rowe also made an announcement of the formal additions to the MCA study. These will be described under the results of the meeting of the MCA Research Coordinators which was held at 7:00 a.m. on May 11.

Levinson of the IFCGW Union, rather than acting the part of impartial chairman, was highly partisan. He indicated that the need was not only to minimize exposure but to exclude all exposure. He insisted that all studies be joint studies with labor representatives having the right to indicate which laboratories are to do the studies, to set the experimental protocols, and participate in the analysis of the results. He also indicated further this was only part of his union's interest to assure that labor sat on the boards of directors of all major companies.

Schweitzer of the EPA listed the actions taken by that organization. He indicated that all pesticide sprays were suspended and recalled; all outdoor spraying was banned. EPA is proceeding against vinyl chloride, not only under the Clean Air Act, but under the Water Pollution Control Act as well. Schweitzer was concerned that there was a 6% loss in the PVC process with an annual estimate of vinyl chloride of 200MM lbs./year and of polyvinyl chloride, 50MM lbs./year. The paper by Schweitzer was then later distributed, and a copy is appended to this report.

In the discussion period that followed, Dr. Corn of the University of Pittsburgh described engineering methods which he had used in the past to design down below 500 ppm. He indicated, however, that it was not possible for an engineer to design to assure the achievement of a standard. He also indicated that by the time one got around to designing to the very low levels, dollars and feasibility of implementation of such designs must become a major consideration.

Dr. Ken Brickbord of EPA gave some preliminary results on the measurement of vinyl chloride from aerosol sprays. One to two minute samples were taken in Tedlar bags. He showed the decrease in measurable vinyl chloride going from 13.06 ppm after two minutes to 0.1 ppm in 360 minutes. Brickbord then went through a series of convoluted calculations on home exposures. For example, he showed that a typical mother who sprays her hair in a small closed bathroom may end up with the equivalent of 16 ppm time-weighted average. The

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numbers by Brickbord were highly theoretical with many assumptions. He did, however, present them as data to be strongly considered. I have requested from Brickbord a copy of his paper and will make that available as soon as it arrives.

Dr. C. A. Johnson of the Goodyear Company described the program in the polymer plant. They are using essentially the program recommended by NIOSH and Mount Sinai. For new employees, their studies include a history (family and occupational) physical examinations, X-ray of the hands, pulmonary function, and laboratory tests. New employees, however, will not be hand X-rayed. For present workers, they will use the Mount Sinai examinations as the baseline. Dr. Johnson said there is a new French procedure, using an infrared technique for determining bone changes in hand which they are hoping to substitute for X-ray. He had no further details on this.

Perkel of the Textile Workers Union wanted the Federal government to do the medical examinations. He does not trust employer-paid or related physicians. Further, he wants employers to establish registries of workers exposed to vinyl chloride.

Tony Mazzochi of the Oil, Chemical and Atomic Workers Union was very clear about his intention that the resolution of the vinyl chloride problem will be political and economic, not scientific. He said Goodyear was a good example of not having to work together. He stated that only out of adverse relationships can knowledge grow, and therefore, he indicated it was not in the union's best interest to cooperate but rather to take an adverse position. With regard to the distorted information presented by some of the German papers the previous day and by the EPA, Mazzochi indicated that distorted information was better than no information at all. This was the first scientific meeting I had ever been at which the speaker was roundly booed.

Cuyler Hammond indicated he had no new data to report, but he was concerned with co-factors at work which might increase the risk of effect. He realizes that large numbers of people are needed. Hammond did indicate the zero risk is foolish, and therefore, he said, there is a need to study the low-exposure groups. He wants to study large cohorts of polymer fabricators who might have had monomer exposure.

Dr. Schneiderman of the National Institutes of Health pointed out that the extrapolation problem was difficult from mouse to mouse much less from mouse to man. He noted that the doses indicated by the various speakers were relatively high levels; he was concerned with the low dose levels. He then proceeded to question the proposed MCA levels of exposure and size of animal groups. At this point Schneiderman managed to violate his own dicta. For example, he extrapolated, based on the Maltoni data, that we would expect only one cancer in 10,000.

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mice, and therefore, he felt it was useless to run any experiments with groups of 1,000 mice. But Schneiderman managed to use data on rats without any correction, for conclusions on mice.

Schneiderman further indicated that according to U.S. figures, all cancers reduced the general life span in the total population by about two years. However, an average cancer victim has his life span shortened some 12-15 years. The average work life span was reduced about six or seven years, and therefore, according to Schneiderman, one year's cancer in the population was equivalent to an \$18 billion cost. He gave no indication as to how he arrived at the figures. Schneiderman pointed out that one needs to look at the estimates of exposure - risk criteria for general populations and to find guarantee levels at which no cases will occur. He made no comments as to the feasibility of guaranteeing that no cancers would ever occur.

My overall impression of this meeting was that it was a stacked meeting made for political rather than for scientific purposes. The inclusion of the foreign papers, particularly such as the Rumanian and German papers without any data whatsoever as far as exposure was concerned, made these contributions worthless. The EPA contortion figures and conjecture was grist for the newspaper mills but added nothing scientifically. Selikoff managed to have the press and T.V. coverage at the right time. For example, at the opening of the session, the kleig lights were on with T.V. present. After Selikoff made his opening remarks and was duly recorded on video tape, he then graciously turned towards the audience, suggested that the lights may be bothering them, and at that point asked the T.V. crews to leave.

A similar incident occurred shortly after the presentation of the Tabershaw-Cooper report. Dr. Harry Heimann, a colleague of Dr. Selikoff's at Mount Sinai, set up a press conference between Tabershaw, Gaffey, and the media representatives. They were called out of the meeting. I watched Dr. Wegman, who was one of the participants and a rather strong anti-industry partisan, note their departure from the hall. Once they were gone and unable to answer questions, Wegman stood up and started to attack the statistical approach used in the Tabershaw-Cooper report.

Mazzochi's remarks I think were also typical as were the attempts by the Nader group to ascribe dark and evil motives to industry representatives. The only hard experimental data presented at the meeting happened to have been two sets of animal studies conducted with industry support. These are the Maltoni and Industrial Bio-Test data. It is from these two sets of information that standards are being proposed. It is interesting to note, however, that there was no credit given to industry for attacking the vinyl chloride problem and making the first inroads.

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2. American Industrial Hygiene Conference

The contrast between the New York meeting and the vinyl chloride session on Wednesday, May 15, at the annual meeting of the American Industrial Hygiene Conference was quite great. The meeting was set up as a special session of the Conference which was sponsored both by the American Industrial Hygiene Association and the American Conference of Governmental Industrial Hygienists. The session was chaired by Edward Baier, Deputy Director of NIOSH. An estimated 600-800 people were in attendance. Media coverage included the AP, UPI, Business Week, BNA, and the Miami Herald. Representatives of labor, management and government were listed for the panel.

Mr. Baier announced that he received a telegram from Mr. Louis Beliczky of the United Rubber Workers International Union, stating that he would be unable to appear. Each time, apparently, the unions have been invited to appear at the scientific sessions, they have managed to withdraw.

Mr. V. K. Rowe of the Dow Chemical Company was the first speaker. He reviewed the background of VCM toxicology studies and went over in detail the more recent involvement of industry and the MCA. He showed the same Industrial Bio-Test results that were shown at the New York Academy meeting. Rowe also stated the industry had had some knowledge of the Maltoni results in the Fall of 1972.

Following Rowe, R. N. Wheeler of Union Carbide and Mayo Smith of Air Products reviewed the technology of VCM and PVC manufacture.

Dr. Zeb Bell of PPG followed Wheeler and Smith. He referred to the proposed standard and cited what could be done to control exposure. Bell placed the burden on the employee, citing the need for education and motivation.

Marshall E. LaNier of NIOSH next reviewed that organization's role of measuring VCM and PVC operations. Most of the very sparse data were taken or based on samples taken from bags and containers of resin. LaNier's data showed low levels, mostly under 1 ppm, with a single outlier at 340 ppm. As noted earlier, this is the one number that Wagoner of NIOSH highlighted and implied that it was typical of VCM content in PVC resin.

Pier DeCoufle of NIOSH reviewed some of the epidemiology of angiosarcoma. He indicated there were 13 known U.S. cases, plus two in Sweden, one in the U.K., one in Norway, and one in West Germany. The median age in the U.S. was 48 years with a range of 36-61 years. The range from first exposure to polyvinyl chloride until death was 12-29 years, with a mean of 20 years. In none of the angiosarcoma cases was

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acroosteolysis a factor. DeCoufle then reviewed some of the NIOSH studies and indicated that long-term mortality studies of PVC workers were being done at the Pottstown plant of Firestone and at several Ohio plants. He noted, too, Dr. Falk's work for CDC who is now looking at all angiosarcomas listed on death certificates in the U.S. in 1970.

Floyd Van Atta of OSHA reviewed the proposed 6(b) permanent standard. He called it "essentially a 1 ppm limit". Van Atta spent most of his time, however, reviewing the mechanics of promulgating a standard, rather than the substance of the standard itself.

Ray McClure of OSHA's compliance unit then indicated how that group would approach both the temporary emergency and permanent standards. They intend to use both grab sampling flasks and charcoal tubes. All samples will go to NIOSH labs in Salt Lake City for analysis. They are hoping to get a 24-hour turnaround and feel that there will be no loss of vinyl chloride from the sampling equipment in that period, including the shipping. McClure indicated that a program directive is now in preparation and that vinyl chloride inspections have a very high priority among the compliance staff.

Later in questions on the samples, McClure and the NIOSH people were asked what knowledge does either NIOSH or OSHA have on shipping and subsequent analysis. The questioner indicated that he doubted whether hard data were available as to the retention of material. McClure tried to indicate that they felt that there will be no losses but had no data. At this point, Dr. Elliot Harris of NIOSH's Cincinnati laboratories indicated that there was a limit to sampling on charcoal tubes. For example, at 50 ppm, the maximum 3-1/2 liters could be sampled at a maximum rate of 50 cc per minute. At higher rates, vinyl chloride would desorb from the charcoal. High levels of vinyl chloride would also normally desorb from the charcoal in shipping and would be lost. He had other problems in desorption, including the fact that vinyl chloride monomer would be lost from the carbon disulfide which is normally used to strip the tubes and that there would be a need to work quickly and in the cold. Harris' comments only led to reinforce the conclusion that NIOSH still was not fully capable of doing analyses on samples shipped long distances. Harris also pointed out that different charcoals have different efficiencies.

Dr. W. C. Cooper reviewed the Tabershaw-Cooper studies. He called the report presented at the New York Academy meeting preliminary. He also felt that the results of the Tabershaw-Cooper studies have been misinterpreted and misquoted.

During the question/answer period, one question was asked as to what level might be in polymer film. LaNier of NIOSH said that they had done only meat wrapper studies and found no VCM. However, they have

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not looked at other films. Mayo Smith of Air Products guessed that levels might be less than 1 ppm.

Dr. Phil Polakoff, a NIOSH medical officer, noted that resins seem to have an adverse respiratory effect and warned others to watch for aerosols. He also wants other plastics to use the same protocols and care as indicated for vinyl chloride. Polakoff indicated that NIOSH might be interested looking subsequently at polystyrene, polyethylene, and other commercial polymers.

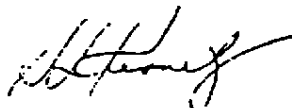
In a final question on levels available from spray coating, Wheeler stated that he expected no free vinyl chloride available from solution polymers, but LaNier indicated that although NIOSH had not done any sampling, one firm has reported levels up to 900 ppm of VCM in spray coating operations.

3. MCA Research Coordinators.

During the New York Academy meeting, a meeting of the Vinyl Chloride Research Coordinators was held. The MCA has already prepared a report of that meeting, although there was one error in the MCA report. Dr. Joyner was not the guest from Shell, rather Dr. M. B. Slomka attended. The questions resolved by the Coordinators were that we would not recommend going to ceiling value testing. We agreed that exposures to experimental animals should be made at 0, 1, 5, 15, and 25 ppm if costs are not in excess of 10% of the previously committed funds. In this particular case, 1,000 animals per level would be exposed, and food would be left in the chamber. There was some discussion on an acute accident level simulating a tankcar rupture, and a proposal was made to run a two-hour exposure at 10,000 ppm using 500 male and 500 female animals.

A committee is being set up to start studies on ethylene dichloride. Dow is now running studies on 1,1,1 trichloroethane and have just started studies on vinylidene chloride and perchloroethylene. These exposures are at two dose levels, seven hours per day. They are using 96 rats of each sex at each level and for each compound with food omitted from the plants.

Regarding the NIOSH proposals for studies in the vinyl chloride-PVC industry, a question arose as to whether a contractor could legally come in and do studies acting as an agent for the Federal Agency. It was indicated further that Bendix, Tabershaw-Cooper Associates, and Stewart-Todd Associates will be among the expected bidders.


H. L. Kusnetz

Attachments

cc - (Distribution attached)

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cc - Messrs. R. E. Joyner, M.D.
R. F. Nelson
R. J. Reynolds
M. B. Slomka, Ph.D.

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