

SHELL OIL COMPANY

PRIVATE AND CONFIDENTIAL

TO FILES

DATE JULY 17, 1973

FROM MANAGER, INDUSTRIAL HYGIENE -
HEAD OFFICESUBJECT NOTES ON THE MEETING OF THE
VCM COMMITTEE

On July 10 the Steering Committee met. Present were Dr. M. Johnson of B. F. Goodrich, Dr. K. D. Johnson of Manufacturing Chemists Association, Dr. T. Torkelson of Dow Chemical, Mr. W. D. Harris of Uniroyal, Dr. W. Rinehart of Ethyl Corporation, and Dr. Z. Bell and Mr. L. Sargert from PPG. Mr. R. N. Wheeler of Union Carbide and Dr. R. J. Reynolds of Shell joined us later.

Dr. Torkelson had just spoken to the Bio-Test people. As of July 10 they had still not exposed any animals. Subsequently, it was determined that they would start the exposure by July 16. Dr. Maltoni has invited a Bio-Test pathologist to Italy to review slides to assure that those groups would be examining slides the same way. At this time, however, Bio-Test has not indicated who their pathologist is.

There was a long discussion on the shortcomings of the Bio-Test setup as we had seen it in our visit to Decatur, Illinois. The concensus of the group was we should follow Bio-Test very closely and make sure that they tighten their procedures, but that there was just no one to whom else the group could turn.

Dr. Torkelson suggested that each of the member companies have a statement to the media on the position being taken with VCM ready for distribution, if necessary, immediately after the NIOSH meetings. I feel it is important at this time to bring Mr. Dunphy into the picture.

As far as the discussion with NIOSH is concerned, we suggested that the MCA group's role would be only to acknowledge Maltoni's data and that we want to confirm his findings. We would also point out that Maltoni had done his work only with rats, whereas the MCA protocol calls for mice and hamsters as well. We would also tell NIOSH of the five action items that we have proposed, but these would be in very general terms without leaving any written information. The five items are that the several companies have planned plant atmospheric studies, that they will exchange analytic techniques, that they will be working at a TLV of 200 and will be moving toward some lower TLV, that they will be following up the animal studies with epidemiology studies, and they would welcome the participation of NIOSH.

I then asked that the group going to NIOSH formulate a series of statements as to what it is they want NIOSH to do after the meeting. We

301133

agreed that the approach should be that they would prefer NIOSH take no precipitous action now. Since NIOSH has announced that it will not be ready for a vinyl chloride criteria document for at least two years, our research should be ready about that time for input. We should recommend no shift in priority; further, we would keep NIOSH apprised. I further suggested that our people get off the topic of animal work as quickly as possible and shift into the epidemiology study and that they leave copies of both protocols with the NIOSH people. I also further suggested that perhaps they even request NIOSH assistance such as with social security, or if very low levels are to be examined, that NIOSH or some other agency of the Federal government, for example, the Food and Drug Administration, Pine Bluff, Arkansas facility, do those types of studies.

Dr. Torkelson then brought up some question that were raised by the SPI. They are concerned about the liquor bottle ban and have also requested that MCA sponsor feeding studies. The main problem is that since VCM is a gas, feeding studies would be quite difficult. It is also dangerous to try to make an estimate going from an inhaled concentration to a dietary dose, although this can be done as a mathematical exercise. What one must guard against here is the fact that if we attempt to define any dietary dose at which cancers may or may not occur, we may run into Delaney type of strictures. Reynolds mentioned that the Europeans are ready to do a feeding study. Some of the questions that might be asked are does vinyl chloride stay in the diet, does it react with the food, and if so, to what forms does it react.

We decided at that if there was going to be any approach on the feeding study, perhaps the first step would be to do a short study on the feasibility of being able to maintain a stable dose in the diet or water. Dr. Reinhart suggested that Carnegie-Mellon University has a metabolite screening technique which they are using in a study for API now and suggested they might be approached for such a study for MCA.

Dr. Torkelson mentioned that the metabolic pathway of VCM appears to be a -SH reaction in cysteine and that Dow is doing a study of metabolites. However, Dow is not about to divulge any details at this point.

The larger meeting on July 11 was merely a repeat and expansion of the suggestions made at the Steering Committee meeting. Dr. Rowe indicated the Europeans also have an interest in oral work, primarily on extractants. He indicated that Dr. Garlanda is doing work on VCM in oil, alcohol, and water. He finds that residues in aqueous systems are less than 0.2 ppm and less than 0.3 ppm in oil. These are lower levels than have been found by the FDA in alcohol in the bottle study.

301134

There was further discussion on the meeting with NIOSH. It was not apparent at this time whether either Dr. Key or Mr. Baier would be there. The concensus of the group was that it was important that either one or both be there. Mr. Best then made several attempts to contact Dr. Key later in the afternoon. He was successful and got a promise that Dr. Key would arrive. Subsequently, we found out that the other people with whom the group would be meeting are Drs. Christensen, Jacobson, Lassiter, and Mitchell. Jacobson and Christensen are old-timers and likely to be highly receptive to the presentation, particularly by Dr. Rowe. Lassiter is a young man with fairly recent Ph.D., who is feeling his new position and has been rather brusque. There may be some difficulty from him. I do not know Dr. Mitchell.

With regard to the status of the epidemiology studies, no company has yet been visited by Tabershaw-Cooper Associates. Mr. C. D. (Pete) Yaffe is the project officer. The contract was signed June 18, and the first report is due in mid-August.

With regard to Bio-Test, the visiting committee will go back within two weeks after the exposures start. It may be that we will encourage them to use this current group of 2,400 animals for a shake-down period and then insist that they use fresh animals, particularly if there seemed to be any problems or questions on the part of the technical committee as to the validity of the study.

With regard to the feeding studies, the proposal is for Dr. Kenneth Johnson to write to a number of laboratories to see if any interested group wants to try to look at chronic dietary problems starting with a feasibility study of stability in the diet. Dr. Johnson pointed out that any moneys for feeding or metabolism studies cannot come out of the funds already earmarked for the animal study and that the request will have to go back to management. A feasibility study might be on the order of \$10-25,000, whereas a full-blown feeding study in two species might run as high as \$125,000. There were no estimates made at this point on costs for the metabolic study.



H. L. Kusnetz

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cc - Messrs. B. W. Dunbar
R. E. Joyner, M.D.
R. L. Maycock
R. J. Reynolds

301135