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Monsanto

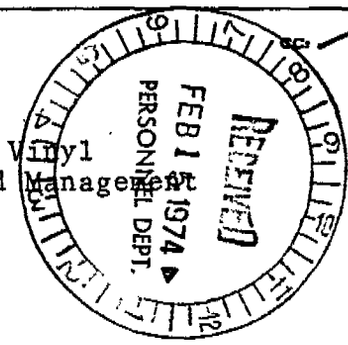
FROM R. L. Bourget

DATE February 14, 1974

SUBJECT NIOSH/CDC Briefing on Vinyl Chloride for Labor and Management Representatives

REFERENCE

TO H. J. Corbett



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On February 12, 1974, a NIOSH/CDC briefing on VCM was held at the Sheraton-Hopkins Hotel in Cleveland, Ohio. The meeting began at 10:00 a.m. and was structured in two phases: the first, a review of the problem and the second, a summary of NIOSH/CDC actions and proposals. A copy of the agenda is attached. In overview, NIOSH/CDC, under the direction of Dr. Marcus Key did a thoroughly professional job in handling the subject matter and appears to be working toward a rational solution that will serve as a model for future incidents. There is no question, however, that NIOSH/CDC considers this an extremely serious situation to the point of displacing other current NIOSH effort, and I have no doubt some rather tough industry standards, particularly as they relate to work practices, will be recommended by NIOSH to OSHA for implementation. In an attempt to avoid editorializing, I will follow my notes directly in dictating some of the key points developed during the meeting.

Since the meeting started at 10:00 a.m. and I arrived at 10:40, I missed Vernon Roses' Manufacturing and Industrial Hygiene discussion and picked up only the end of Dr. Henry Falk's Medical Findings and Pathology comments. For the time being, I will skip over these two subjects and start in with Dr. William Lloyd's discussion on Epidemiology.

Epidemiology - Dr. William Lloyd

Angiosarcoma is very rare/problems with classification supported by various literature researches, history of reported cases of angiosarcoma (I noted some but not all of the information) is as follows:

Angiosarcoma	Primary Liver Cancers	Total Cancers
16	1623	--
2	120	--
2	133	16528

From this and additional similar data they have estimated that the U.S. incidents of angiosarcoma is on the order of 20-30 deaths/year. In addition, the average age of the involved people at Goodrich is stated to be 46-47, whereas the general population involved in above data is in the 50's.

Toxicology - Dr. Donald Lassiter

VCM, relatively non-hazardous, 20-30% concentration required for lethal effect. They have gotten a list of 50 other chemicals used in the Goodrich facility and are presently conducting literature studies on these materials. He cited several studies which have explored the effect of VCM on animals and in some cases humans. I will list briefly the nature of these studies:

Rabbits	200 ppm	7-hour, 5 day exposure noted liver damage
Rats	500 ppm	liver/kidney problems
Rats		greater than 3% exposure bone tumors noted
Human volunteers	50/250/500 ppm	7-1/2 hour, 5 day exposur no noted problems
Humans	4000 ppm	Intoxication noted

Toxicology - Dr. Donald Lassiter (Cont'd.)

Referenced Tabashaw Cooper study, expect results in 18 months. Referenced a NIOSH/ICI plus other companies study--preliminary info from this study suggest definite cause and effect relationship. Results to be presented February 15 at Washington hearing.

The formal morning session ended at 11:30 and the meeting was opened for questions by Dr. Key.

Q - unidentified - In the Goodrich cases, what were the basic materials these people were exposed to?

A - Dr. Johnson-Goodrich - VCM common to all but also exposed to other materials in varying degrees.

Q - Dr. Yager, Harvard School of Public Health - What other VCM impurities are you planning to investigate? I have a personal interest in vinylidene chloride.

A - NIOSH - These aspects of the problem are being investigated.

Q - Union Rep - Has environment of Goodrich plant been characterized?

A - NIOSH - Not yet. Goodrich having difficulty getting results. They claim a layering effect and tendency of VCM not to disperse in air. Therefore, sample results are questionable. This is one reason behind request for breathing zone samples.

Q - Union Rep-Rubber Workers - Why isn't NIOSH going to monitor clinical and medical aspects instead of only environmental aspects?

A - NIOSH - Some people are getting ahead of the program. We will discuss that this afternoon.

Q - Union Rep. - Where do men eat?

A - NIOSH - In the Goodrich facility they have an isolated section of the building where people smoke and eat. Even this will not be acceptable under our proposals.

Q - unidentified - Much of the information suggests equal concern for PVC and VCM, are you concerned with VCM in PVC, or what?

A - NIOSH, Dr. Key - This is the advantage of work practice control approach. We can proceed without knowing the specific toxin. Admittedly, VCM is most suspect--supported by liver studies. Problem at hand, concentrate on horizontal which means other similar plants but also develop the vertical which means other operations handling VCM or PVC products.

Q - Union Rep.-Rubber Workers - What has been the concern of workers in the plant?

A - NIOSH - About 420 employees at the Goodrich facility have been exposed to VCM. Communications have been in small groups with plant management and the plant physician. NIOSH was accompanied by Union representative on walk through Goodrich plant. Workers concerned but no undue fright. Felt company and NIOSH were concerned. In addition to VCM, there has been a high degree of vinylidene at this site. Last two workers who died were in the vinylidene copolymer operation for two years. There are four separate buildings, one where vinylidene copolymer is produced.

Q - unidentified - Is status of situation one of imminent danger?

A - NIOSH, Dr. Key - Cancer is the most serious occupational hazard. NIOSH will recommend to OSHA appropriate standards but remember that it is OSHA who is responsible for instituting and implementing these standards.

Q - unidentified - Because of the latency period required for development of cancer, we must know not only what is happening now, but what happened 10 years ago. For example, VCM previously was produced using an arsenic based catalyst. Arsenic is known to cause this kind of problem. Will this be investigated?

A - No notes.

Q - unidentified - Reactor cleaning-500-1000 ppm of VCM has been found under wall scale, Is this hazardous?

A - NIOSH - This will be discussed this afternoon.

Q - unidentified - What is known about the B.F. Goodrich process? Is it unique? What are the differences from other industry processes?

A - NIOSH - We have visited the Louisville, Kentucky suspension plant and the New Jersey bulk process plant so far, and we plan to cover all the various processes.

Q - Jane Brodie, N.Y. Times - I have two questions, first, are your recommendations to B.F. Goodrich being made industry-wide and two, according to Scientific Community Debate on LTL, there is no acceptable level for carcinogens. Therefore, shouldn't the standard be zero?

A - NIOSH, Dr. Key - Recommendations sent to B.F. Goodrich and MCA for distribution to other plants. They are interim recommendations for the time being. We expect a new issue to be broader. In answer to your second question, we are trying to avoid recommending a specific lower limit. The approach will be as I mentioned before, via work practic standards. Our specified

environmental level will not be for toxicant LTL but only as a way for improved work practice standards. There is no data available that we know of which suggests a safe level for carcinogen. This is extremely difficult in proving but studies are under way.

Q - unidentified - What is the NIOSH opinions as to whether more cases will come?

A - NIOSH, Dr. Key - This is difficult to answer obviously, but we would expect cases to be limited to the polymerization process.

At this point there was a one-hour break for lunch. Meeting reconvened at 1:00 p.m. Dr. Key mentioned that comments by individuals or companies can be sent by mail to the key speakers on subject matter presented. Actions and proposals by NIOSH/CDC were the subject matter for the afternoon session.

AFTERNOON SESSION

Industrial Hygiene - Mr. Vernon Rose

Interim standards have been issued to B.F. Goodrich and MCA but these are only recommended temporary standards and they are not complete. The requirements for a complete health standard are as follows:

1. Labels
2. Symptoms and emergency treatment
3. Conditions and precautions for safe use

Where appropriate

4. Protective equipment and control
5. Monitoring
6. Medical exams

Industrial Hygiene - Mr. Vernon Rose (Cont'd.)

The next action step will be a meeting tonight after this session ends, with a committee made up of labor and industry to develop a complete health standard for recommendation to OSHA.

Epidemiology - Dr. William S. Lainhart

Major health problem-VCM. Identified four groups for study:

1. VCM production
2. VCM conversion to PVC
3. PVC conversion to other products/forms
4. Consumer PVC use

Our first priority will be in the second group. Main NIOSH program elements:

A. DFSCI/OHSB
   1. Tabershaw-Cooper study
   2. Government sponsored Epidemiology study
   3. Extent and use of vinyl chloride and polyvinyl chloride

B. OHSB
   1. Potential occupational exposures to vinyl chloride and polyvinyl chloride and other chemicals, 50-60 identified by Goodrich.

C. Office of the Director
   1. Uses of vinyl chloride and polyvinyl chloride in consumer products.
   2. Coordination with National Cancer Institute

D. Communicable Disease Center
   1. National surveillance program on angiosarcoma.

Dr. Joseph Wagoner, Director of DFSCI

NIOSH meeting held February 7 to develop field protocol. Propose to document incidents of angiosarcoma in industry and document other toxic effects. Five criteria developed for selection of sites.

1. ≥15 years - vinyl chloride polymerization operation
2. Sizable work force
3. PVC but no vinylidene chloride operation
4. Located in States willing to cooperate in providing data.
5. Inhouse medical program

Based on these criteria, the plants tentatively selected are clustered in Ohio, Kentucky and Pennsylvania. The second major area will be the development of protocol for industry hygiene investigations and the PVC and copolymer processing operations, including compounding, calendering and extrusion. Searching for how far down the line monomer will be available.

Dr. Clark Heath - Medical

A national angiosarcoma search, using death certificates as the basic source will be initiated. A first step will also be to convene a panel of liver experts to recommend a medical screening test.

Dr. Fairchild, Associate Director of NIOSH, Cincinnati-Experimental Toxicology

Literature search under way, much foreign literature on subject matter exists, particularly in Russian and German. Continuing animal experiments and following MCA sponsored toxic research studies. Looking for opinions-Cancer Institute, etc.

This presentation concluded the afternoon session of actions and proposals by NIOSH and a question period followed.

Q - Dr. Selencoff, Mt. Sinai Hospital - (1) Will your study encompass other carcinogens and other effects of this carcinogen such as respiratory, etc? You said a lot, I don't think you can do everything you have said unless you get more funds and people. Otherwise, you cannot keep promises. (2) What are your plans? (3) Will previous employees who have left plants be studied?

A - NIOSH-Dr. Key -

1. Yes, but the primary focus will be on the pertinent subject at hand.
2. We have applied for 40 new positions in 1975.
3. Yes.

Q - AFL/CIO Rep. - To do all this you will obviously need to drop some activity, will you not?

A - NIOSH-Dr. Key - Unfortunately that is correct. Some will need to be slowed down to devote the required attention to this high priority project.

Q - Industry Rep. - What was the background on the people at the Goodrich facility?

A - NIOSH-Dr. Falk - We interviewed the families of the deceased and in no case did we find any signs of hepatitis, no drug addiction or any other toxins, and in only one case was there even a question of an alcohol related problem.

Q - Union Rep. - Will process design and engineering control be a required part of your standards?

A - NIOSH-Mr. Rose - Yes, we expect ultimately that these will be incorporated into the study. As an example, we will look at opening reactor manholes and design changes that might be appropriate. Initially, however, we are specifying people protection because of the rapid response that can be achieved.

Dr. Key then attempted to present some concluding remarks as follows: NIOSH was alerted to the problem three weeks ago. We have a strong desire to handle the problem professionally and correctly, and if this approach works, it will serve as a model for other situations. More emphasis must be placed on testing new materials, cancer must be treated as one of our most serious problems. Our toxic substance list now numbers 11,000 -2-3000 have reference to cancer with human data on only 100 of these. There are many viewpoints we can take, one would be to enact the Dewey et al ruling, which suggests that toxic cancer producing agents be banned totally from all use. The other extreme is obviously no control at all. We don't expect this

situation will result in either extreme but something in between, and most probably an HEW ruling will issue. We are hopeful that angiosarcoma will remain a small occupational outbreak and do not expect a consumer problem. My reasons are threefold:

1. It is a very rare tumor.
2. Hopefully other plants are open construction rather than closed, as in the case of the Goodrich facility.
3. There is very little VCM in consumer products in use.

At this point in the meeting, or maybe just before Dr. Key had finished his concluding remarks, Dr. Epstein, NTA fame, presented a blistering retort on the inadequacy of the NIOSH approach. Dr. Epstein was of the opinion that it was only by pure chance that we had convened here today, because of this very rare and freak cancer. He mentioned that if it were a respiratory cancer or almost any other cancer that the cause and effect would not stand out so clearly and it would have gone unnoticed as he suspects many have done. He chastized NIOSH for not doing a more thorough job in preventing crises rather than reacting to them.

Other comments which may be of some interest:

---Dr. Selencoff of the Mt. Sinai Hospital, asbestos fame, undoubtedly was critical of NIOSH for the scope of their study. He wanted all toxins, all cancers to be included.

---Mr. Samuelson, representative of the AFL/CIO, requested that NIOSH not rely totally on industry (MCA data). He was assured by Dr. Key that that would not be the case.

---An unidentified NIOSH representative, in answer to Dr. Selencoff's request for a broader scope study, suggested many chemicals high on the list and read a few. I was surprised to hear AN as the third or fourth material mentioned.

At some point during the meeting I also picked up the following:

1. In addition to the four BFG deaths, four additional cases of liver tumors have been identified.
2. Mt. Sinai has offered to do free medical testing on anyone exposed to VCM in U.S. (picked up indirectly and not confirmed).

I hope that these notes present a fair rundown on the proceedings that took place. They attempt to focus on the content but in doing so, omit much of the "color" of the session. I would be happy to provide that separately upon request!!

RLB

R. L. Bourget

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NIOSH/CDC BRIEFING ON VINYL CHLORIDE FOR

LABOR AND MANAGEMENT REPRESENTATIVES

February 12, 1974

Cleveland, Ohio

I. Introduction: Dr. Marcus M. Key, Director
National Institute for Occupational Safety and Health

II. Review of the Problem

A. Manufacturing and Industrial Hygiene--Mr. Vernon E. Rose

B. Medical Findings and Pathology--Dr. Henry Falk

C. Epidemiology--Dr. J. William Lloyd

D. Toxicology--Dr. Donald V. Lassiter

III. NIOSH/CDC Actions and Proposals

A. Industrial Hygiene--Mr. Vernon E. Rose

B. Epidemiology--Dr. William S. Lainhart, Dr. Joseph K. Wagoner, and Dr. J. William Lloyd

C. Medical--Dr. Clark Heath and Dr. Henry Falk

D. Toxicology--Dr. Edward J. Fairchild

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