

AP2111 -

V



TECHNICAL PAPERS

Regional Technical Conference

RECEIVED

JUN 10 1975

R. FLEMING, V. F.

VCM

THE PROCESSORS' PERSPECTIVE

PALISADES SECTION
VINYL PLASTICS DIVISION

OCTOBER 31 — NOVEMBER 1, 1974

AMERICANA HOTEL

7th Avenue and 52nd Street, New York City

SOCIETY
OF
PLASTICS
ENGINEERS, INC.

AP00054674

WHAT IS THE VINYL CHLORIDE MONOMER (VCM) PROBLEM?

Richard Fleming
Group Vice President - Chemicals
Air Products and Chemicals, Inc.

At the time I accepted this assignment to speak to you today, it was known that the permanent OSHA standard regarding exposure to vinyl chloride would issue on or about October 5. None of us in the industry imagined at that time, however, that, after nine months of gestation, OSHA would give birth to such a child! Under the circumstances, I find my job this morning incredibly more difficult, and perhaps it will be far less satisfying to you than I had hoped it could be. I hope you will understand, therefore, when I say that, while I am perfectly prepared to stand behind what I say here today as my personal understanding and belief, you should not view what I say as an industry position, an SPI position, or even an Air Products position. I speak to you, then, as an individual, i.e., what you see is what you get!

As visualized, this meeting was aimed at trying to help the PVC fabricator and processor to understand and to cope with some of the ramifications of a wholly new regulatory structure now affecting his business. My desire to contribute what I could in this regard is the reason I am here today, but, since many monomer and PVC producers are now involved in legal proceedings against OSHA and the Department of Labor about the new standard, and my company is one of those, you will appreciate that my comfort index on this platform is very low.

Your program says that I will attempt to do three things:

- (1) Present an up-to-date overview of the VCM problem, particularly as it relates to concerns of fabricators and processors for worker protection.
- (2) Discuss various key issues leading to the development of the OSHA standard published October 4.
- (3) Discuss polymer producers responsibility to workers and customers.

My remarks will most certainly address these issues in various ways, but I will follow a somewhat different general outline, in order to more clearly tell a coherent story, as follows:

- (1) The background leading to the necessity for a standard.
- (2) Comment regarding the standard itself and its potential impact on producers. What monomer and polymer producers are doing relative to the standard.
- (3) Some comments on what the standard requires of fabricators and processors - and courses of action they must now take.
- (4) I will also offer some thoughts on the procedures by which such regulations are generated in this country and the as yet incomplete regulatory matrix that will affect us all.

Background

I assume each of you has read most of the material appearing in the public press about the events leading to the now issued regulation. I do not intend to review these again in detail. But I do wish to indicate to you some things about these developments that I feel sure you haven't read in the mass media.

You have read that the first researcher to induce cancer in laboratory animals with vinyl chloride was an Italian, Dr. P. L. Viola. What you may not know is that Dr. Viola was and is a plant physician for Solvay & CIE, a Belgian company producing PVC. Dr. Viola did his work in the Italian plant laboratories of Solvay at the specific request of company management and at company expense. The study was aimed at learning more about the causes of acro-osteolysis (AOL), a disease involving deterioration of the bones at the tips of the fingers found in workers who cleaned PVC reactors. Although Viola exposed his animals at 30,000 ppm of vinyl chloride for four hours per day, five days per week, for one year, he could not produce acro-osteolysis, but he did find malignant tumors in his test animals. At company expense and with company approval, Dr. Viola reported on his work orally in Tokyo in 1969 and again in Houston in May, 1970, at the tenth International Cancer Congress. The written record of the Houston meeting was published in 1971.

Since his experiments were not designed for cancer studies, the VCM used had high amounts of unknown impurities; the dosages were so very high and the result was so surprising in view of all of the earlier research done with VCM, it was necessary to repeat Dr. Viola's work to confirm it. In his written report, Dr. Viola states, "No implications to human pathology can be extrapolated from the experimental model reported in this paper."

In Europe, four chemical companies, producers of VCM and/or PVC, banded together to sponsor new work to check Dr. Viola in the best available cancer research facilities. They hired an eminent Italian cancer research team and facility headed by Professor Cesare Maltoni at the University of Bologna. A specific understanding was reached with Professor Maltoni that the results of his work would be published after he was satisfied it had been properly analyzed and interpreted. He expected that to occur at the 1974 International Cancer Congress, then several years away.

In the U.S.A., the American VCM and PVC producers were also concerned. Through their trade association, the Manufacturing Chemists' Association, Inc., they brought Dr. Viola to this country to more fully explain his research. It was then decided that further research was needed, on laboratory animals, and on the human experience of their workers. After considerable searching, Industrial Bio-Test Laboratories, a Division of Nalco Chemical Company, was hired for animal studies and Tabershaw/Cooper Associates, Inc., was hired for epidemiological studies related to VCM-PVC workers mortality and cancer incidence. A liaison was later arranged between the American and European companies to share the results of the research each group was sponsoring. By mid-1973, it was known that cancers were being encountered among Professor Maltoni's test animals, and this was duly reported by MCA to NIOSH.

In January, 1974, the B. F. Goodrich Company announced the NIOSH and officials of the Occupational Safety and Health Office of the

AP00054676

State of Kentucky has been notified of the company's investigation of liver cancer deaths of several employees at their Louisville, Kentucky plant. These were confirmed cases of angiosarcoma of the liver. This was the first report of cancer in human beings potentially related to exposure to vinyl chloride.

That is a very summary description of the early events, and it leaves out a great deal. It does permit some conclusions, however, that, though obvious, have received virtually no notice from the host of industry critics in labor, government, social activists groups, and the mass media. Here are some:

- (1) The work of Dr. Viola was done at the initiative and expense of industry in an attempt to better understand employee health hazards. When cancers were found in his laboratory animals, Dr. Viola published his results extensively with the full approval of his company.
- (2) Although the reports of Dr. Viola's work were available to all, only industry undertook to follow it up. Industry in both Europe and the U.S. did this independently, on their own initiative, with their own money. So far as I know, neither the unions, the various government agencies, nor the currently vocal critics of industry did anything at all. In all of the testimony in Washington in June, only the industry presented information arising from laboratory experiments or worker health studies on this problem which were initiated before the January announcements of Goodrich.

Following the Goodrich announcement, there has been a plurality of investigations, studies, and pronouncements, all presumably aimed at a better understanding of the problem, its depth and scope, and how to deal with its various ramifications. Unfortunately, our society has not performed well in this period. What might have been a cooperative scientific, medical, and technological approach to the serious problem of protecting employee health has been turned into an emotional, name-calling adversary confrontation, largely by people who have little to contribute to the factual background against which carefully reasoned judgments must be made.

This situation is not peculiar to the vinyl chloride problem. Rather, it is a tiresome repetition of the same non-productive churning that has characterized many social issues generally and ecologically and toxicologically related matters in particular in our country for some time now. We cannot solve this problem today, but I cannot avoid noting it, and deploring it.

This period culminated in the public hearings conducted by the Department of Labor in Washington in late June and early July. In a record running to over 4,000 pages of testimony, the basic issues regarding the elements of a health standard for vinyl chloride were debated. Presumably on the basis of this record, OSHA was to promulgate a permanent standard legislating appropriate work place practices for the VCM-PVC industry.

The Basic Issues

The Occupational Safety and Health Act of 1970 states that OSHA, in regulating toxic materials "shall set the standard which most adequately assures, to the extent feasible, on the basis of the best

available evidence that no employee will suffer material impairment of his health or functional capacity even if such employee has regular exposure for the period of his working life".

In an opinion on a case involving Industrial Union Department, AFL-CIO v. Hodgson^{1/}, regarding an asbestos regulation, a three judge panel from the U. S. Court of Appeals for the District of Columbia Circuit commented on this as follows: "Congress does not appear to have intended to protect employees by putting their employers out of business - either by requiring protective devices unavailable under existing technology or by making financial viability generally impossible.".

Thus, any OSHA regulation must achieve an appropriated balance of satisfactory worker health protection and technologically and economically feasible means for assuring this. Herein are the basic issues the final regulation must resolve.

Unfortunately, the state of our knowledge does not permit the definition of an incontrovertible level of VCM exposure which is surely safe. For this reason, OSHA published a proposed regulation suggesting that, since a certainly safe level could not be defined, exposure should be held below detectable levels by a method accurate to 1 ppm $\pm 50\%$. Literally interpreted, this might mean acceptable exposure to levels of 1.5 ppm.

Our industry objected to these levels on three grounds:

- (1) Such low levels were not necessary to assure worker health.
- (2) There is no known technology to permit reducing concentrations in VCM and PVC plants to such levels.
- (3) If the VCM-PVC producers were forced to shut down by such a regulation, the economic impact would involve loss of as many as 2.2 million jobs in the U.S.A. and of about \$90 billion in GNP.

Most industry people, testifying at the June hearings, also argued that it was neither necessary nor desirable to apply a common regulation to VCM and PVC plants and to fabricators and processors of PVC. Based on its own assessments of the health issue, including all of the animal testing data and the human experience information, the industry proposed, through The Society of The Plastics Industry, Inc., a regulation involving a phased reduction, over a three year period, that would reduce permissible average exposure levels to 5 ppm in VCM plants and 10 ppm in PVC plants in the third year. (This compared to a previous regulation of 500 ppm.) Although technology was not in hand to assure these levels, it was felt by industry that they could be achieved with a maximum effort if the necessary time were allowed. SPI proposed initial TWA (time weighted average) exposures of 25 ppm with a ceiling level of 40 ppm to be effective October 5, 1974.

^{1/} Industrial Union Department, AFL-CIO v. Hodgson, _____ F. 2d at 1 OSHC 1631, No. 72-1713 (D.C. Cir., April 15, 1974)

In addition to the industry position presented by SPI, most of the individual producing companies in VCM and PVC presented testimony themselves. All were unanimous in their statements that promulgation and enforcement of the proposed OSHA standard as written would force the shut down of most, if not all, of the VCM-PVC producers.

Officials of the large chemical and rubber unions, consultants employed by them and activists groups testified in favor of the proposed standard, asserting that it could be achieved relatively quickly and asserting that industry was more interested in profits than the health of its workers.

Following the completion of the hearings and preparatory to issuing a final standard, OSHA hired Foster D. Snell, Inc., to prepare a report as to the technological and economic feasibility of various potential regulatory levels. This report was received and made a part of the record.

Its principal conclusions are as follows:

- (1) "Achieving 'No Detectable' (0-1) levels of VCM principally through engineering means is judged not feasible with present technology both in VCM and PVC sectors."
- (2) "The costs of compliance increase rapidly with decreasing VCM target levels and represent significant engineering uncertainty or infeasibility beyond 10 ppm ceiling and 2-5 ppm TWA for the VCM industry and 15-25 ppm ceiling and 10-15 ppm TWA for the PVC industry."
- (3) "Area monitoring, particularly in PVC plants is recommended to OSHA as a compliance requirement regardless of the target level selected by OSHA."
- (4) "It is recommended that OSHA establish phased requirements for reaching VCM target levels to allow the collection of additional VCM monitoring data to fully assess the efficiency of the corrective steps subject to review in the light of current medical findings and as they become available."

Like almost everything the industry said, these conclusions of OSHA's own consultant were largely ignored in the promulgation of the final standard.

The Standard Itself

On October 4, the new permanent standard was published. While the standard, plus its intended justification, ran nearly nine full pages in "The Federal Register", some of its more important provisions may be summarized as follows:

- (1) The standard applies to the manufacture, reaction, packaging, repackaging, storage, handling or use of vinyl chloride or polyvinyl chloride, but does not apply to handling or use of fabricated products made of PVC. Thus, it does apply to fabricators and processors of PVC.

- (2) Effective January 1, 1975, the standard calls for a maximum permissible limit of 1 ppm of VCM averaged over an eight-hour working day, with a ceiling of 5 ppm as measured over any period not exceeding fifteen minutes.
- (3) Requires establishment of regulated areas wherever vinyl chloride concentrations in the air are in excess of the permissible limits, i.e., 1 ppm.
- (4) Respirators will be required for all employees exposed in excess of the limits, except that until January 1, 1976, the use of respirators will be discretionary for employees whose exposure does not exceed 25 ppm measured over any fifteen minute period.
- (5) A so-called "action level" of 0.5 ppm was established. Where monitoring shows that employees are not exposed in excess of the "action level", the employer is effectively exempted from some provisions of the standard.
- (6) An initial monitoring program must be undertaken to determine which employees are exposed in excess of the "action level". Those employees whose exposures are above the "action level" but do not exceed the standard - that is, levels between 0.5 ppm and 1 ppm - must be monitored at least quarterly. Employees whose exposures exceed the permissible levels must be monitored monthly.
- (7) A substantial medical surveillance program is required for all employees exposed above the "action level".
- (8) There are provisions for warning signs, posters and labels which must carry the legend, "Cancer-Suspect Agent". This includes all packages of PVC.

If this listing of provisions leads you to feel that the standard is a precise and clear document which may be readily interpreted as to its intent and requirements, you have certainly not read the standard. There are many things in the standard I do not understand. Requests for clarification have been answered in ways that make me feel the authors of it do not understand it much better than I do. Certainly no written clarifications have been obtainable. What is worse, as you probably know, these standards will be followed by a "Field Enforcement Manual", which is a guide or directive to the OSHA inspector on how he should interpret the standard. This document is not prepared as yet, as far as I know. However, it is only a guide and experience with other standards indicates that there may be significant regional and personal interpretations within OSHA itself.

Implications for VCM-PVC Plants

In the preamble to the regulation appearing in "The Federal Register", OSHA makes the following statement: "We agree that the PVC and VC establishments will not be able to attain a 1 ppm TWA for all job classifications in the near future. We do believe, however, that they will, in time, be able to attain levels of 1 ppm TWA for most job classifications most of the time. It is apparent that reaching such levels may require new technology and work practices."

Thus it is clear that OSHA has knowingly promulgated a regulation it knows cannot be met by current technology. The answer to this, they say, is to put our workers in respirators one hundred percent of the time that they are within normal plant operating areas, effective January 1, 1975. The only exception to this is that, if an individual employee refuses to wear a mask, he may operate without it during 1975 at concentrations below 25 ppm. At levels above this, wearing of a mask is mandatory. Since the discretion is the employee's only, the company must be prepared to insure a maximum eight hour 1 ppm TWA by January 1, 1975.

Furthermore, OSHA states its belief that in time we, the producers, can attain 1 ppm TWA for most jobs, most of the time. Such performance, however, does not meet the requirements of the regulation and its apparent interpretation. There are, for example requirements in the standard that call for special precautions, such as the continuous wearing of a respirator, "where a release of vinyl chloride... might be expected as a consequence of the operation or because of an accident in the operation which would result in an employee exposure in excess of the permissible exposure limit". Under these circumstances, when can a man working in a plant handling vinyl chloride as such remove his mask?

There are a few other complications in attempting to comply, still speaking only of respirators and masks. Here are a few:

- (1) All respirators to be used must be approved by NIOSH. Thus far, only the respiratory equipment for use above 3600 ppm has been approved by NIOSH. This is essentially a self-contained breathing apparatus.
- (2) Cannister type respirators are permissible, according to the standard, for concentrations up to 25 ppm and are the only protective devices suitable for mobile jobs. Thus far, NIOSH has not approved any cannister or cartridge mask for this use and appears to be in controversy with OSHA as to whether such masks are, in fact, approvable.
- (3) Air supplied masks may be used, according to the standard, but they must be equipped with portable auxiliary air supplies. No mask of this type has yet been approved by NIOSH for vinyl chloride and it is doubtful that models currently available commercially will meet all applicable OSHA requirements.
- (4) Until specific approval requirements are known and the proper masks designed, they obviously cannot be ordered. Once they can be put into production, it now appears that a period estimated to be at least six months will be needed to meet the VCM-PVC industry demand.
- (5) Not every person is physically capable of safely using such respirators. Persons with less than normal pulmonary function cannot breathe properly in many such masks. The industry does not know now many of our current operating and maintenance people can safely use them for breathing purposes. We must set up appropriate criteria, test all affected people, remove those who cannot appropriately function, hire and train their replacements while continuing to operate our plants, or perhaps shut them down while we do this.

Even if the mask problem were solved tomorrow, there is a significant problem in equipping all affected areas with the assured clean air supply systems that permit their use, and the refill capability for the portable supplemental air cylinders. Time estimates to accomplish this are discouragingly long.

Once these problems are resolved, we do not know how to assure safe operation of VCM-PVC plants with people in masks one hundred percent of the time. Lots of testimony was given about this in the June hearings.

Here are some typical comments offered in those hearings:

Dr. Hyatt, Leader of the Respirator Research and Development Section at the Los Alamos Scientific Laboratory until July, 1973, and acting as OSHA's consultant at the VCM hearings with regard to respirator matters, stated, in answer to a question by the government's attorney, that, and I quote:

"At best, any of these devices (referring to respirators) are an instrument of torture."

Dr. Hyatt also pointed out that respirator masks are designed for the "average size" face and at least five percent of the population could not wear this size.

Much more serious consequences which could result from the use of respirators were summarized by Dr. Joseph F. Tomashefski, Head of the Pulmonary Disease Department of the Cleveland Clinic, as follows, and again I quote from the testimony:

"It must be recognized that (respirators) have undesirable features and hazards, the major of which are increased resistance to breathing, decreased efficiency or function, poor fit, leakage, false security, allergic reaction, irritation from perspiration and other particulate deposition, rebreathing deadspace ventilation, poor vision, fogging of the eyepieces, speech, psychological, and contamination problems."

Dr. Tomashefski also stated that people suffering from pulmonary diseases cannot use respirators. In the normal male population above thirty-five years of age, the incidence of such diseases is thirty-two percent.

In his concluding remarks, Dr. Tomashefski stated:

"It is my professional opinion that the use of respirators for full-time protection in vinyl chloride or polyvinyl chloride production facilities is unsafe and infeasible."

As a result of this unworkable situation, almost all VCM-PVC producers either have brought suit themselves, as my company has, or they have joined with others to seek judicial review. The various actions are being transferred to the U. S. Court of Appeals for the Second District of New York, and an expedited hearing schedule is being sought. If the expedited schedule can be arranged, it is hoped that the case will be heard before the end of the year. It now appears that this may be arranged with initial presentations scheduled about December 24. Clearly a decision before January 1,

1975, is not possible. Consequently, another possible legal course is for the industry to seek a stay, or a delay, of the effective date of the regulation until a final decision is rendered by the Court. Such a stay may be obtained from OSHA and, if they decline, an appeal to the Court for a stay may be made. In order to be granted a stay by the Court, a showing of irreparable harm by imposition of the regulation on January 1 must be made. The eventual decision by the Court will either confirm OSHA's standard or will find that OSHA did not act in accordance with the law and remand the standard back to OSHA for further consideration. The Court cannot prepare a revised standard.

What will happen in VCM and PVC plants if this regulation is permitted to stand? Every firm wants to provide a safe employment environment for its people. If it is finally decided that safety requires operating under the OSHA standard as written, there are tremendous pressures on the industry to cause it to try to operate rather than to shut down immediately. There is the job security of thousands of employees in VCM-PVC and perhaps of hundreds of thousands in the fabricating and other industries. There are the billions of dollars invested in the plants involved in both parts of the industry. There are the fabricating and processing firms whose economic structure and viability depend heavily on a continuing material supply, the suppliers who serve the entire VCM-PVC fabrication chain and the end users who need a continuing supply of end products, many of them not replaceable without very serious dislocations. For all of these reasons, most VCM-PVC operations may be expected to make every effort to comply. I cannot project what will come of these efforts or how long they will be continued. This will surely vary with the individual firm.

It is abundantly clear that, if any producer can comply, the costs for VC and PVC under this regulation will go up dramatically and production volumes will decline sharply. Although many of the provisions of the regulation apply to fabricators, the most important implications of all for you lie in your suppliers' ability to continue production. This ability is very much in doubt.

Why Fabricators Are Covered

All of you realize that people who handle PVC resins must carefully determine their posture with regard to this regulation. This is because the vinyl chloride charged to the PVC reactor is not completely polymerized when the batch is terminated. If it were, the polymer properties obtained with currently known technology would be completely unsuitable. Some of this unreacted vinyl chloride remains in the polymer through the recovery, drying, and packaging steps and then slowly evolves from the finished polymer. Before there was thought to be a health hazard involved in vinyl chloride exposure, this was of no practical consequence. Resins typically contained as much as 0.2% of VCM or more as shipped: this is 2,000 ppm. Depending upon the quantity present and the rate of VCM evolution, every large container of PVC has the potential of becoming a regulated area. Thus, a truck van or rail car loaded with bags of resin, a warehouse, an operating area can be affected. Appropriate ventilation can help, but to maintain levels below one part per million at all times requires careful attention to detail in even such areas.

Thus, storage areas for bagged PVC must be monitored and controlled or they may become regulated areas with all that that implies under the standard. The implications of this for the PVC distribution system can be disturbing.

It is this free monomer in the polymer that affects the PVC processor in relation to the regulation. Realizing this, every polymer producer has been giving thought to how such monomer in the finished polymers might be avoided, reduced, or immobilized. Different types of resins naturally carry less than do others, but all carry some. No technology as yet exists to eliminate this problem and implementation of techniques to mitigate may involve changes in resin characteristics as well as the procurement of capital equipment with long lead times.

Impact on Fabricators and Processors

Because fabricators and processors are covered by the standard, each of you should be fully aware of the responsibilities this imposes upon you. These are essentially the same as those imposed on VCM-PVC operations. Here is a partial list of requirements looked at in terms of fabricating operations which may be of some use. SPI has prepared an interpretation for you that is more complete.

- (1) Each establishment must be monitored and measured in order to determine whether any employee is exposed in excess of 0.5 parts per million of VCM - the so-called "action level"
- (2) If any employee is exposed over the action level, monitoring data must give information as to whether the employee is exposed over the permissible exposure limit, which is 1 ppm TWA over eight hours and never over 5 ppm over any fifteen minute period.
- (3) The respirator requirements discussed earlier apply if exposure is over permissible limits.
- (4) If levels in excess of permissible exposure limits are found, these will be classified "regulated areas, limited to authorized persons only" and a daily roster be kept of all entering these regulated areas. Entrances to such areas must be clearly labeled.
- (5) If employees are exposed above the permissible exposure limit, work practice control must be instituted immediately and engineering plans formulated and activated to reduce exposures to at or below the permissible level, i.e., 1 ppm.
- (6) If exposures above the "action level" are found, a program for determining the exposure of every employee must be established and the program repeated quarterly until exposure at or below action level is shown in two consecutive monitoring determinations not less than five working days apart.
- (7) Medical surveillance must be set up for employees exposed above the action level.

- (8) All containers of PVC, blends, or compounds intended for processing must be labeled as required (with reference to VCM content).
- (9) All employees engaged in PVC fabrication or processing operations shall be subject to a training program relating to the hazards of VCM and precautions for its safe use.

There are other requirements in the standard not mentioned in this list. Since there is a wide diversity among fabricators, you must carefully assess your own situation and act accordingly.

In general, if they act prudently, I believe most fabricators can operate most of their plants at below 1 ppm. Considerable testimony has been presented to this effect based on actual plant monitoring. Whether such plants can expect to operate below the action level on eight hour TWA, I do not know, since I have not seen enough data of this type. Spots to watch and monitor carefully are the places where incoming resin is unloaded and stored, packages are first opened, and the resin is first melted. These are the areas where accumulation of released vinyl chloride can most likely occur. Careful control of operating procedures and suitable ventilation at these locations with outside exhausting should control most situations below permissible levels. Fabricators using compounds will ordinarily have much smaller problems with released VCM than those handling resins which have not yet been through a melting process. Much of the rest of this meeting program is, as you know, directed toward helping you to formulate your specific programs.

Why Such A Standard?

OSHA indeed is assigned a difficult task. There is grave uncertainty as to how to define a safe working environment, or what can be practically achieved in creating such an environment by an industry not designed to cope with a newly recognized hazard. OSHA is under heavy political pressure and influence and they know that, in our adversary system, they are likely to be attacked by one side or the other, no matter what they decide, as irrational as that may seem. Yet it is their responsibility, under the law, to balance these factors and to promulgate safe, but practical and achievable work standards. In this instance, it seems clear that OSHA did not appropriately meet that responsibility.

The prime consideration must clearly be the provision of a safe working environment. The fundamental data relating to what constitutes a safe working environment are the laboratory animal data and what can be gleaned from the substantial human experience with VCM. Without getting into all of the details, the following conclusions would seem supportable in the minds of most medical observers, I believe:

- (1) Vinyl chloride is a proven carcinogen to certain laboratory animals. There is a dose-response relationship.
- (2) Enormous differences in susceptibility are the rule among animal species.
- (3) Even more striking are the differences found between strains of the same species.

(4) Animal dose data are NOT translatable to man.

If these things are so, then the human data that can be obtained must be given very heavy weight. What can be said here?

(1) VCM is a human carcinogen at high levels of exposure.

(2) That there is a "safe" dose or dose below which no effect can be demonstrated is strongly suggested by the fact that after a period of intense search, there has been no significant increase in the number of cases uncovered. The implication is that these very few cases might well be a reflection of a very low incidence even at the high doses to which individuals were exposed in the past.

(3) If this is true, a survey of a population of workers exposed in the past to lower levels (50-200 ppm?) might be expected to show no ill effects. This would form the basis for realistic and effective setting of limits.

Considerable data along these lines were presented to OSHA and more is becoming available. Much more needs to be done to accumulate and properly evaluate this experience.

Vinyl chloride became a bulk material in commerce over forty years ago. In that time, as a result of a whole host of practices now recognized as hazardous, large numbers of persons were exposed to massive amounts of vinyl chloride by current day standards. Of these persons, those exposed at the highest level over long periods of time have shown what is quite probably an unusual incidence of a very low incidence disease, angiosarcoma of the liver. That is a clear cause for corrective action to prevent high level long term exposure.

Workers in fabrication operations are known to have been exposed to much lower levels of VCM than monomer or polymer plant workers. Therefore, the health history of your workers is very important. NIOSH lists two American workers located in fabrication plants as angiosarcoma victims. One worked on a wire coating machine on which PVC was run an unknown proportion of the time he worked. The other was an accountant. At my specific request at the Washington hearings, the report of an evaluation of these cases was submitted for the written record by NIOSH. The evaluation report by Dr. L. B. Thomas, Chief, Laboratory of Pathology, National Cancer Institute, and Drs. Popper and Lingeman was completed after the hearings. Here is that evaluation report:

With regard to the wire coating worker:

"In brief, we are not completely certain that this is an angiosarcoma of the liver or even a primary sarcoma of the liver. It is not like any other tumors we have seen in the livers of VC-PVC workers."

In spite of this report, this case is continued on the list of vinyl chloride related angiosarcoma cases relates to vinyl chloride exposure compiled and published by NIOSH. This does not seem reasonable. In fact, in a recent EPA report presenting an analysis of related cases prepared by CDC, the source for NIOSH as well, this particular case is dropped.

AP00054686

The other case reported among fabricator workers by NIOSH is that of an accountant who is variously reported to "sometimes" or "frequently" have entered a manufacturing building separately located from his office at a calendered film operation. In this case, the report from the three pathologists is excerpted as follows:

"We cannot be certain, one way or the other, about this case. One histologic feature...is dissimilar to angiosarcomas seen in most VC-PVC cases. However, several other histological features are similar... In summary..., we cannot exclude this as a so-called VC-PVC type case."

It would thus seem that this case must be considered questionable at this time as to its diagnostic relationship to other occupationally exposed cases. Since virtually nothing is known of this man's exposure to vinyl chloride in fact, relating it to vinyl chloride is somewhat conjectural.

These reports demonstrate something else about angiosarcoma of the liver. That is, that it is very difficult to diagnose. It requires an autopsy, the preparation of slides, and the very careful study of a highly skilled pathologist. These facts might lead us to wonder just how much is known about the real incidence of this disease in the general population. It is believed that not more than thirty percent of all deaths are autopsied in this country. Furthermore, it is a truism that causes of death noted on death certificates are notoriously unspecific and untrustworthy, but this is the usual source of such mortality incidence information. Therefore, it is far from clear what incidence of angiosarcoma should be expected among workers generally. Clearly there seems to be an excess at the Louisville plant and perhaps one other. Beyond that, the question as to the excess among PVC workers seems much less clear.

NIOSH currently lists only one other case of angiosarcoma among fabrication workers. This is a case in Scotland which is still being studied by U.K. officials and physicians. We do not have enough information to relate this angiosarcoma case to occupational exposure.

The importance of knowledge of the health history of fabrication workers is probably more than evident to you. Here is a very much larger population that has had long term exposure to relatively low levels of vinyl chloride. If there is no excess incidence of angiosarcoma or other potentially VCM related disease among these people, strong inferences as to safe levels may be possible. Epidemiological analysis of the health experience of workers in PVC fabrication must be done. Unfortunately, actual measurements of historical exposures are not available any more here than in VCM-PVC plants. Reasonable estimates should be possible, however, based on careful simulation of past practice.

Other Government Agencies

If our concerns with the regulatory process were limited to our problems with the OSHA standard, perhaps I could terminate this discussion with some, "We shall overcome!" statement. Unfortunately, this is not the case, since a number of other government agencies must still be heard from. EPA, FDA, DOT, and others must also

consider what they deem to be appropriate action on their part. Close coordination of these organizations to assure a coherent, consistent, and concurrent set of regulations does not seem to now be a fact. There may even be some differences of opinion among these agencies as to where the jurisdiction of one ends and the other begins.

As one example of additional regulations, EPA has announced their intention to prepare an air quality standard relating to vinyl chloride. This would be preceded by a performance standard requiring seventy-five percent reduction in VCM emissions from polymer plants and ninety percent from monomer plants, estimated to increase resin costs by four percent or about one cent per pound. Perhaps Mr. Schweitzer, who follows later in this program, will comment on the basis for this estimate, which seems to be missing from the EPA Task Force Report or any other potential source I have been able to find.

EPA expects to have to decide on acceptable levels of VCM in the ambient air. The unrealistically low determination as to what is safe in a working environment made by OSHA must have its impact on EPA thinking as well. It is hoped, however, that the EPA and other concerned agencies will overcome this influence and exercise sound judgment in their own deliberations. Surely the EPA timetable for doing this is more realistic provided the needed work is done.

Conclusions -- Not Yet Ascertainable

You will recall that my assignment today was to discuss "What is the vinyl chloride problem?". What I have said is that there are many problems, each with many parameters. Since facts are limited, viewpoints may be expected to be relatively unlimited and they are. I have given you some personal ones. Luckily my assignment did not require me to give you all the answers. You know I'm not capable of that. I am hopeful that some of the most critical ones will be available soon.

There is one unmistakable conclusion I can offer you now however. That is -- unless prompt relief from the new OSHA standard is obtained there will be severe dislocations within the PVC industry which will have a substantial economic impact on our society.

###

Mr. Fleming's edited remarks to questions -

Q: *If a plant is to be closed down due to violation of the new ruling, what, if any, hope do the workers have to keep the plant open for a reasonable time until foreseeable safety measures can be implemented? And 2, are any programs being started now to medically examine plant workers to make sure no other cancer cases arise?*

A: The first one is rather easy. Do the workers have a vote on whether the plant shuts down? No, they do not. They have no discretion about such a decision. If the plant cannot operate under the standard, the employer is subject to significant penalties and there is no ability on the part of the employees to affect that. I guess the only people who can affect it are OSHA. Now there are provisions in the standard for the granting by OSHA of waivers under certain of the requirements. Whether OSHA, in its wisdom, would be prepared to grant such waivers and what the conditions are, I do not know. Now, with regard to

the question as to whether any programs are being started now to medically examine plant workers to make sure no other cancer cases exist, I can tell you that these medical programs have been underway now for quite a long period of time within the monomer and polymer industries. I can't speak for the fabricating industry. I think in fabricating plants it varies quite a bit. I do know of many such programs within fabricating operations but I can't speak for the fabricating industry as a whole. As far as the monomer and polymer workers are concerned, I can assure you that very, very extensive and detailed research has been undertaken and medical programs have been carried out. A number of companies at the Washington hearings in June reported results of medical surveys taken of their work forces and so that work is very well along. That's why the listing of cases already found is a fairly comprehensive one, insofar as American VCM-PVC workers are concerned. There is a problem in going back to people who worked in such plants years ago and are no longer in the employ of the companies. Not all of those people have been tracked down as yet.

Q: *Thousands of people die of cancer every year, cancer in many forms. Have any studies been done to determine the occupations of these people and is there any relation...correlation between occupational chemical exposure and cancer found other than for plastics (VCM) angio-sarcoma.*

A: Studies of this type really can only be done by government, since the information comes in from so many different types of sources. But, yes, there is quite a bit of work that is done of this type by government. I myself, am not capable of telling you the details of any of that work, but I think we can look to the Center for Disease Control and the National Cancer Institute and organizations of that general type who are expected to study matters like this. Now in terms of studies of occupational causation of cancer, there had been a good deal of attention given to that subject. Some of it has many of the characteristics of what has happened in vinyl chloride, in the sense of an early revelation of some very incomplete information followed by a public outcry and battle of words and so on. This has occurred with regard to asbestos, and you've heard of the "black lung" disease controversy. These are then followed up by work to study the human experience more carefully. So there's a tremendous amount of work being done and the problem is to bring out of all that work, real information that bears on a specific problem that permits rational decision making. And that's very difficult to do.

Q: *How many known cases of angio-sarcoma of the liver are there specifically not related to VCM exposure?*

A: Well, I tried to comment on that question in my paper...we don't know. An estimate that was widely reported in the press was a statement, I believe originally attributed to NIOSH, that there are about 25 or so known cases of angio-sarcoma of the liver in the general population of the United States each year. That's a very small number. When you dig into the basis for that number, as I tried to indicate in my talk, it's very, very questionable whether we really have a valid number. I think, as a matter of fact, that it's generally conceded that there is no good information on this point. Yet, it is one of the things that we really must know, because we need to compare incidence in any working group with what would normally be expected in a non-exposed population. Unfortunately, we really don't know what would normally be expected.